

## **FULL PROTOCOL TITLE**

Mindfulness-Based Blood Pressure Reduction (MB-BP) Study

### **Study Chairman or Principal Investigator:**

Eric B. Loucks, PhD

Assistant Professor, Department of Epidemiology

Brown University School of Public Health

### **Supported by:**

**The National Center for Complementary and Integrative Health**

1UH2AT009145-01

## A NOTE TO READERS:

v.2019.01.11

This document is to serve as a supporting information file to the PLOS ONE manuscript titled, *Mindfulness-Based Blood Pressure Reduction (MB-BP): Stage 1 Single-Arm Clinical Trial*. The study protocol that is found with the following pages contains the complete and detailed plan (in its original language as it was submitted) for the conduct and analysis of the trial that the ethics committee (i.e., Brown University Institutional Review Board (IRB)) approved before the trial began.

The original protocol that was submitted to the Brown IRB on December 5, 2014 was a pilot study and precursor to the MB-BP Stage 1 Single Arm Clinical Trial funded by the NCCIH. In September 2015, the study PI (Loucks) was awarded a five year NIH UH2/UH3 grant (1 UH2 AT009145-01 entitled “Mindfulness Influences on Self-Regulation: Mental and Physical Health Implications”). With this funding, the pilot study approved by the Brown IRB was amended to match the proposed single arm trial approved by NCCIH. Data from the NIH-funded study are presented in this paper. Data from the pilot study are not, as primary outcomes were different between studies.

The Brown IRB reviews and approves modifications to study protocols through the use of stand-alone modification submission forms. That being said, the IRB approved study protocol for *Mindfulness-Based Blood Pressure Reduction (MB-BP): Stage 1 Single-Arm Clinical Trial* is the conglomeration of the original submission along with all approved modification submissions included in this report.

To assist in navigating, please use the hyperlinked table found on the proceeding pages.

Additional questions can be directed to the study investigator: [Eric Loucks@brown.edu](mailto:Eric_Loucks@brown.edu).

## Mindfulness-Based Blood Pressure Reduction (MB-BP) Study: Brown University

### IRB Submission History and Summary of Protocol Amendments

For additional detail on protocol revisions and/or for a copy of the full IRB amendment submissions, with Study PI Signature, contact the Senior Project Coordinator, [Frances\\_Saadeh@brown.edu](mailto:Frances_Saadeh@brown.edu) or study PI, [Eric\\_Loucks@brown.edu](mailto:Eric_Loucks@brown.edu).

IRB Submission #	Submitted	Approved	Stage	Summary of Submission / Protocol Revisions
Original Submission	12/5/14	3/12/15	Pilot	The project was submitted to the Brown IRB in December 2014. The IRB requested three iterations of revisions to the submission prior to granting approval. These revisions were submitted: 1/5/15, 2/10/15, and 2/19/15.
Amendment #1	4/8/15	7/1/15	Pilot	This amendment dated 6/17/15, (originally submitted 4/8/15) includes changing the survey software to Qualtrics, updating the phone screening questionnaire, clarifying the study safety plan, modifying the consent form, adding questionnaires to the baseline survey, and modifying recruitment procedures.
Amendment #2	7/15/15	8/6/15	Pilot	This amendment dated 7/15/15 (revised and re-submitted on 8/5/15) included: The addition of a new participant population (NEFS sub-set) and new recruitment procedures for that population, revisions to the In-person Screening Assessments 1 and 2, revisions to wording of the phone screening questionnaire, addition of a place for staff to note contact information on the safety plan document, adding a version footer to the consent document.
Amendment #3	9/1/15	9/3/15	Stage 1	This amendment dated 9/1/15 included the addition of a funding source (grant #1 UH2 AT009145-01, grant title: Mindfulness Influences on Self-Regulation: Mental and Physical Health Implications), a change in scope of work and related study activities secondary data analyses involving concurrent studies, additional measures and study procedures, and revised informed consent document.
Amendment #4	11/11/15	1/7/16	Stage 1	This amendment (dated: 11/11/2015) requests approval to (a) add compensation, (b) add a NIH safety monitoring plan, (c) update the names and content of the phone screen and assessments, (d) add a 1-year follow-up visit, and (e) update the consent document to incorporate these changes.
Amendment #5	2/26/16	2/26/16	Stage 1	This amendment (dated: 2/26/16) requests approval to allow participants, who are not able to come to the study site in person, the option to participate by online video conferencing.
Amendment #6	4/11/16	5/9/16	Stage 1	This amendment (dated: 4/11/2016) requests approval to (a) change the study title; (b) revise the NCCIH Safety Monitoring Protocol; (c) separate the Baseline and Follow-up Assessments into two visits; (d) change the data collection mode to Qualtrics for Daily Practice Forms and Class questionnaires; (e) revise study recruitment material and use online advertising; (f) revise the in-class worksheets and assessments; and (g) revise the MB-BP Questionnaire, In-Person Assessment, Home Assessment, and Measurement of Mindfulness Practices.

IRB Submission #	Submitted	Approved	Stage	Summary of Submission / Protocol Revisions
Amendment #7	8/9/16	9/13/16	Stage 1	Approval of the amendment (memo dated August 9, 2016) includes the addition of 2 new questions to the Home Baseline Assessment.
Amendment #8	5/15/17	6/12/17	Stage 2a	This amendment (dated 5/15/2017) requests approval to (a) begin Stage 2a (previously called Stage 1b) to conduct the Randomized Controlled Trial with enhanced usual care. Stage 2a comes with changes to the study flow, incentives, screening and eligibility, consent document, phone screener, in-person screener, baseline in-person assessment, baseline-online home assessment, safety protocol, and study recruitment material.
Amendment #9	8/26/17	10/13/17	Stage 2a	This amendment (dated: 8/28/2017) requests approval to (a) add an Infographic Card, (b) add a Recruitment Card, (c) conduct a direct mailing at a partnering provider office, (d) add NIH Administrative Supplement funding to award #004754-001 "Mindfulness Influences on Self-Regulation: Mental and Physical Health Implications," IP #17101586, and (e) update the consent document with Certificate of Confidentiality language.
Amendment #10	11/6/17	1/25/18	Stage 2a and additional follow up for Stage 1	This amendment (dated: 11/6/2017) requests approval to (a) modify the approved focus group discussion questions into a one-on-one qualitative phone interview, (b) re-contact Stage 1 participants for a 2-year in-person assessment, (c) rearrange compensation amounts, (d) add recruitment for and data sharing from the UMass Medical School fMRI study, (e) add the "UMass Medical School fMRI Study Recruitment Talking Points," (f) add a consent addendum for enrolled participants to complete the phone interview, and (g) revise the approved consent to reflect the appropriate changes.
Amendment #11	5/8/18	6/13/18	Stage 2a	This amendment (dated: 5/8/2018) requests approval to (a) drop the 12 month and two year follow-ups for Stage 2a participants only; (b) reduce the number of home blood pressure readings and drop the mandatory introduction session that is part of the course; (c) assist collaborators at UMass Medical School with the initial screening and scheduling processes for their fMRI study; (d) conduct the 9-week mindfulness intervention off site in safe, community-based locations; (e) recruit from the partnership at Lifespan Emergency Department; (f) conduct qualitative interviews with low SES population to explore perceptions of and openness to mindfulness-based interventions; and (g) update consent forms with new format. Also includes approval of revised phone screener (SCR-P, v.3.0 – 5/10/2018)
Amendment #12	8/7/18	10/15/18	Stage 2a	Requested the following: 1) permission to conduct abbreviated 1 year follow-up assessment with the intervention arm of the study; 2) request to use a general release form to video-record mindfulness classes; 3) video-recording; 4) removal of the actigraph device; 5) additional questions for the 6 month follow-up assessment for control participants; 6) updated consent document (v.3.1 – 10/11/18); and 7) consent addendum for already enrolled participants.



**BROWN UNIVERSITY  
INSTITUTIONAL REVIEW BOARD  
HUMAN RESEARCH PROTOCOL**

Protocol Title: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Funding Source (if no external funding for the project, enter "University"): \_\_\_\_\_

- (1) Attach to this form the information required for a complete protocol, as outlined on the IRB Form #1 Instructions and Information pages. In addition, please review the document "What Makes a Complete Protocol" (an appendix to the 'Brown University Policies and Procedures for the Protection of Human Participants in Research') at <http://research.brown.edu/about-brown-research/policies/irb-policies-procedures-protection-human-participants-research>.
- (2) Select the appropriate type (and category number) of review. (See the following pages for a description of the exempt and expedited categories. If no exempt or expedited categories completely describe the proposed research, select 'Full Board'. ) ☐ Exempt # ☐ Expedited # ☒ Full Board
- (3) **Principal Investigator Conflict of Interest Statement:**  
(1) Have you filed the annual Assurance of Compliance form and, if necessary, a disclosure as required by the University's Conflict of Interest Policy for Officers of Instruction and Research (<http://research.brown.edu/about-brown-research/policies/conflict-of-interest-statement>)? ☒ YES ☐ NO  
(2) Do you have a significant financial interest that is related to this research protocol? ☐ YES ☒ NO

Principal Investigator certifies to the following: (1) The rights and welfare of the participants are adequately protected. (2) The risks to an individual are outweighed by the potential benefits to him/her or by the importance of the knowledge to be gained. (3) This protocol is accurate and complete; and if the project scope or design is later changed, the PI will resubmit for review. (4) All research personnel, including the PI, has been, or will be, adequately educated in human research protections prior to beginning work on the project. (5) Where a financial conflict exists, the PI has disclosed all relevant information regarding Conflict of Interest according to University policy.

Principal Investigator signature: \_\_\_\_\_ Date: 12/5/2014

(Advisor's signature is required for all graduate/medical student projects.)

Advisor certifies to the following: Advisor has read the protocol and approves of the project.

Advisor's signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print name: \_\_\_\_\_

Undergraduate student investigator signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print name: \_\_\_\_\_ (optional signature)

**For IRB Use Only**

FULL BOARD PROTOCOLS - Institutional Review Board Members: If approving the proposed project, please certify to the best of your knowledge to the following: (1) IRB Member is familiar with the above described proposed research. (2) The rights and welfare of the research participants will be adequately safeguarded by the procedures described. (3) The potential benefits justify the risks involved. (4) IRB Member has no vested interest in the project.

IRB Member Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of the Authorized Official of the IRB: \_\_\_\_\_ Date: \_\_\_\_\_

## Protocol Checklist and Submission Procedures

### Protocol Checklist

All protocols for IRB review (full board, expedited, or exempt) must be submitted in the following format. Protocols that do not follow this required format will be returned to the investigator without IRB review.

- #1   X   IRB Form # 1 (fully signed)
  - #2   X   Required protocol components (pages must be numbered) (see “What Makes a Complete Protocol” for a more detailed description)
  - #3   X   Consent forms, including assent forms (if applicable) (pages must be numbered)
  - #4   X   Interview instruments/questionnaires (if applicable) (pages must be numbered)
  - #5   X   Recruitment documents (such as advertisements, flyers, cards) (if applicable)
  - #6  N/A  Letters of commitment/approval from collaborating organizations (see “What Makes a Complete Protocol” for a more detailed description) (if applicable)
  - #7  N/A  Copies of other IRB approvals (if applicable)
  - #8  N/A  Checklist Form for Research Involving the Use of Prisoners as Study Participants (if applicable)
  - #9  N/A  Complete application for outside funding/support (pages must be numbered)
- ~~~~~

### Protocol Submission Procedures

**Full Board Protocols:** Submit the original and 11 copies of the complete protocol (as identified above) to the Research Protections Office, Box 1986 in sufficient time to meet the agenda deadline (see [http://research.brown.edu/rschadmin/hrpo\\_meetingdates.php](http://research.brown.edu/rschadmin/hrpo_meetingdates.php) for upcoming IRB meeting dates and protocol deadlines).

**Exempt or Expedited Protocols:** There is no specified deadline for submissions of Exempt or Expedited Protocols. Review time varies depending upon the project. The average review time is approximately 4 weeks. Please submit the complete (as identified above) original protocol to the Research Protections Office (RPO), Box 1986, with sufficient time to allow for review and revisions, if necessary.

{Note that the IRB (not the investigator) makes the final determination of whether a protocol is full board, expedited, or exempt. Thus, full board review may be necessary even if you suggest expedited or exempt review in your protocol.}

# **MINDFULNESS-BASED HYPERTENSION THERAPY PILOT STUDY**

## **IRB APPLICATION**

**December 5<sup>th</sup>, 2014**

Eric B. Loucks, PhD  
Assistant Professor  
Department of Epidemiology  
Brown University School of Public Health  
121 South Main St., Box G-S121  
Providence, RI, 02912  
Phone: 401-863-6283  
Email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu)

**Section A:**  
**Lay-Person Summary of Proposed Project**

# 1 Specific Aims

1. To formally develop a Mindfulness-Based Hypertension Therapy (MBHT) intervention tailored to the needs for hypertensive patients, utilizing a multi-disciplinary team of experts and patients, and incorporating a Delphi-like technique to adapt protocols of a standardized mindfulness-based intervention developed at UMass Medical School for patients with prehypertension or hypertension.
2. To determine the optimal dose of the intervention developed in aim 1. We will estimate the feasibility, acceptability and safety of two different doses of the MBHT intervention in 60 patients (30 per dose arm) randomly assigned to a “low” or “high” dose of MBHT.
3. To finalize the protocol of the MBHT intervention and design of the future RCT. We will use the results of our developmental work (aim 1) and of the dosing study (aim 2) to make the final adjustments to the protocol of the intervention that will be tested for efficacy in our future RCT, incorporating the expertise of our interdisciplinary panel to optimize the design of the future RCT.

## 2 Significance and Innovation

The World Health Organization reported that suboptimal BP is responsible for over half of cardiovascular disease mortality world-wide.<sup>1,2</sup> Furthermore, of those with hypertension, more than half have uncontrolled BP.<sup>3,4</sup> This is despite widespread knowledge of hypertension risk factors and treatments including diet, obesity, physical activity, medication adherence and excessive alcohol consumption.<sup>5,6</sup> Mindfulness interventions appear to improve self-regulation, self-care, and the ability to not respond to cravings for hypertension risk factors such as high caloric palatable foods and sedentary activities (and resulting obesity).<sup>7-11</sup> In fact, a 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.”<sup>12</sup> Evidence-based mindfulness interventions including Mindfulness-Based Stress Reduction (MBSR) may have some effects, where a recent meta-analysis and systematic review of 4 randomized controlled trials (RCTs) demonstrated significant effects, but evidence of heterogeneity in effect sizes.<sup>13</sup> The methodologically highest quality studies had the smallest effect sizes. MBSR has been customized to a number of disease processes, such as recurrent depression, smoking and substance use addiction with resulting increases in effect sizes compared to general mindfulness-based interventions that do not take the disease process of interest into consideration.<sup>10,14,15</sup> The same may be true for hypertension, however this has not yet been studied.

Until methodologically rigorous studies to evaluate customized mindfulness-based interventions for hypertension are performed, we will not know if the observed preliminary effects of mindfulness-based interventions on BP could have much greater effect with a tailored approach. Consequently, we propose to conduct a stage I behavioral therapy intervention study to provide the most rigorous evaluation to date on whether MBSR customized to prehypertensive and hypertensive patients provides clinically relevant reductions in BP.

## 3 Approach

### 3.1 Initial Development of High and Low-Dose MBHT (Aim 1)

We will assemble a team of experts in cardiology (e.g. Dudley, Wu, Shimbo), family medicine (e.g. Eaton), physical activity (e.g. Williams, Davidson), diet (e.g. McCaffery), medication adherence (e.g. Kronish), mindfulness interventions (e.g. Britton, Salmoirago-Blotcher, Brewer), and patients with prehypertension or hypertension. With this team, we use an iterative, Delphi-like technique to adapt protocols of a standardized mindfulness-based intervention developed at UMass Medical School, called MBSR, for patients with prehypertension or hypertension, to the unique safety and treatment needs of this population. Adaptions may include, for example, types of specific mindfulness exercises, sequence in which they are introduced, and relative emphasis on hypertension education vs. mindfulness practice components.

### 3.2 Study Population (Aim 2)

Participants will be recruited through cardiology and family practices via established relationships with physicians at Rhode Island Hospital (e.g. Sam Dudley, MD), Memorial Hospital of Rhode Island (e.g. Charles

Eaton, MD), Providence VA Medical Center (e.g. Hank Wu, MD), amongst others. Furthermore, advertisements will be posted throughout Rhode Island inviting participants with pre-hypertension or hypertension to enroll. For Aim 2, we anticipate n=60 participants with equal proportions of males and females, and stratified across prehypertension/hypertension categories, including (1) pre-hypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. This will allow for early indications of potential differential effects of MBHT by gender and prehypertension/hypertension status.

*Inclusion Criterion:* Hypertension/prehypertension ( $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure or taking antihypertensive medication).

*Exclusion Criteria:* Exclusion criteria follow standard guidelines:<sup>16</sup> current regular meditation practice (>once/week); current substance abuse, suicidal ideation or eating disorder; history of bipolar or psychotic disorders or self-injurious behaviors.

### 3.3 MBHT Intervention Groups

*High Dose:* MBHT is based on the standardized MBSR intervention described elsewhere,<sup>17-20</sup> and will likely consist of nine 2.5-hour weekly group sessions and an 8-hour one-day session, led by Dr. Loucks. Dr. Loucks is an expert in cardiovascular physiology, cardiovascular epidemiology, and social epidemiology. He completed MBSR instructor training at UMass Medical School, and has 16 years of mindfulness meditation experience, including teaching and mentoring community members, as well as a recent publication record investigating associations of mindfulness with cardiovascular health.<sup>11,21,22</sup> The unique areas of MBHT are expected to be education on hypertension risk factors, hypertension health effects, and specific mindfulness modules focused on awareness of diet, physical activity, medication adherence, alcohol consumption, stress, and social support for behavior change. A preliminary manual has been created based on the standardized MBSR manual developed at UMass Medical School, and will be further developed through the Delphi-like approach described above, and sequentially revised based on participant feedback and preliminary findings.<sup>19,20</sup> MBHT sessions contain instruction and practice in mindfulness meditation, and conversations about stress and coping. Students learn a range of mindfulness skills including body scan exercises, meditation and yoga. Homework consists of practicing skills for  $\geq 45$  min/day, 6 days/week. Booster sessions will be offered (likely 2.5-hour sessions every 2 months).

*Low Dose:* Low Dose MBHT will be based on the High Dose intervention above, but instead prioritizing practices to fit within nine 1-hour weekly groups sessions. Through the aforementioned Delphi-like approach, the most salient parts of the high dose intervention described above will be offered in low dose MBHT.

### 3.4 Measures of Compliance

*Participant Adherence:* Data on treatment protocol adherence will be collected weekly by research staff.

*MBHT Instructor Competency and Treatment Fidelity:* Treatment fidelity strategies will be performed in accordance with recommendations of the NIH Behavior Change consortium.<sup>23</sup>

### 3.5 Blinding

All study staff, including those performing health assessments and contacting participants to schedule follow-up assessments, will be blinded to treatment allocation with the exception of the MBHT instructor (Loucks) and data manager (who performs randomization).

### 3.6 Equipoise

This study will be designed to disrupt clinical equipoise, defined as “no consensus within the expert clinical community about the comparative merits of the alternative [trial arms] to be tested.”<sup>24</sup>

### 3.7 Assessments

We will follow study procedures similar to those performed during previous epidemiologic studies by our group. In-person screenings will take place at the Brown University Center for Population Health and Clinical Epidemiology, described in Sections 2.7.1 and 2.7.2 at baseline, completion of the 9-week MBHT course and at 3- and 6-months post-intervention. Major assessment variables are shown in **Table 1**. Qualitative interviews (likely focus groups) will evaluate participants' experiences such as usefulness of specific modules, duration of sessions, time burden, and overall intervention effectiveness.

### 3.7.1 Primary Outcomes

**Clinic BP Assessment:** Clinic-assessed systolic and diastolic BP remains the standard of care for monitoring hypertension treatment.<sup>3,5,6,25,26</sup> Baseline clinic BP will be determined at two in-person screening visits  $\geq 1$  week apart, completed according to American Heart Association guidelines,<sup>25</sup> followed by in-person assessments at all follow-up periods. BP will be assessed using a calibrated Omron HEM907XL Intellisense automated BP monitor with established validity.<sup>27</sup>

### 3.7.2 Potential Mediators

*Examples of mediators to be assessed include:* (1) **Body Mass Index:** height and weight directly assessed using standard epidemiologic methods. (2) **Physical activity:** MET minutes per week, assessed using actigraphy, which enables the quantification of physical activity.<sup>28-32</sup> (3) **Diet:** diet assessed utilizing Dietary Approaches to Stop Hypertension (DASH) eating pattern score,<sup>33</sup> measured via diet history food frequency questionnaire.<sup>34</sup> (4) **Perceived stress:** measured using Perceived Stress Scale.<sup>35</sup> (5) **Antihypertensive Medication Adherence:** measured continuously using electronic medication bottle caps (GlowCaps).

### 3.7.3 Potential Effect Modifiers

We propose to evaluate 2 potentially important effect modifiers: (1) gender, (2) prehypertension/hypertension category.

## 3.8 Intervention Allocation

Stratified randomization will be used.<sup>36,37</sup> Variables used to create strata include gender (male vs. female), race/ethnicity (white vs. non-white), and prehypertension/ hypertension status (pre-hypertension, controlled hypertension, uncontrolled hypertension). Simple random sampling will occur within each strata.

## 3.9 Data Analysis

Qualitative analyses will evaluate participant experiences such as usefulness of specific modules, duration of sessions, time burden, and overall intervention effectiveness. Quantitative analyses will incorporate generalized linear models (GLM) with properly chosen link functions, performed using generalized estimating equations (GEE) with robust standard error estimators.<sup>38,39</sup> We will test effects of high vs. low dose MBHT on clinic-assessed systolic and diastolic BP. Following “intention-to-treat” principles, analyses will be conducted on all participants randomized to high vs. low dose, regardless of intervention completion. To test whether effects of MBHT on BP may be effect modified by variables described in Section 2.7.3 we will add product terms between MBHT and each potential effect modifier to models described above. Formal statistical significance tests of product terms will be performed. Analyses are considered statistically underpowered, but will provide effect size estimates and statistical variances for NIH grant applications to support studies with larger sample sizes.

**Table 1.** Examples of variables proposed to be assessed during MBHT study

Variables	Obtained During Study			
	Baseline	8 w	3 m	6 m
Race/ethnicity	✓			
Gender	✓			
Adverse childhood experiences	✓			
Socioeconomic status	✓	✓	✓	✓
Depressive symptomatology	✓	✓	✓	✓
Anxiety	✓	✓	✓	✓
Perceived stress	✓	✓	✓	✓
Self efficacy	✓	✓	✓	✓
Mindfulness	✓	✓	✓	✓
Blood pressure	✓	✓		✓
Smoking	✓	✓	✓	✓
Diet	✓	✓	✓	✓
Physical activity	✓	✓	✓	✓
Alcohol consumption	✓	✓	✓	✓
Body mass index	✓	✓		✓
Sleep quantity and quality	✓	✓	✓	✓
Social support	✓	✓	✓	✓
Loneliness	✓	✓	✓	✓
Medication use and adherence	✓	✓	✓	✓

m, months; w, weeks

## References

1. Mendis S, Puska P, Norrving B. *Global atlas on cardiovascular disease prevention and control*. Geneva: World Health Organization;2011.
2. Hoyert DL, Xu J. Deaths: Preliminary Data for 2011. *National Vital Statistics Reports*. 2012;61(6):1-65.
3. Chobanian AV, Bakris GL, Black HR, et al. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Hypertension*. Dec 2003;42(6):1206-1252.
4. United States Centers for Disease Control and Prevention. Getting blood pressure under control. *CDC Vital signs*. 2012;September.
5. James PA, Oparil S, Carter BL, et al. 2014 evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. Feb 5 2014;311(5):507-520.
6. Weber MA, Schiffrin EL, White W, et al. Clinical practice guidelines for the management of hypertension in the community: A statement by the American Society of Hypertension and the International Society of Hypertension. *J Hypertens*. 2014;32(1):3-15.
7. Epstein RM. Mindful practice. *JAMA*. Sep 1 1999;282(9):833-839.
8. Sedlmeier P, Eberth J, Schwarz M, et al. The psychological effects of meditation: a meta-analysis. *Psychol Bull*. Nov 2012;138(6):1139-1171.
9. Lutz A, Slagter HA, Dunne JD, Davidson RJ. Cognitive-emotional interactions - Attention regulation and monitoring in meditation. *Trends Cogn Sci*. Apr 2008;12(4):163-169.
10. Brewer JA, Mallik S, Babuscio TA, et al. Mindfulness training for smoking cessation: results from a randomized controlled trial. *Drug Alc Depend*. 2011;119(1-2):72-80.
11. Loucks EB, Britton WB, Howe CJ, Eaton CB, Buka SL. Positive associations of dispositional mindfulness with cardiovascular health: The New England Family Study. *Int J Behav Med*. 2014: DOI 10.1007/s12529-12014-19448-12529.
12. Institute of Medicine. *Initial National Priorities for Comparative Effectiveness Research*. Washington, D.C. 2009.
13. Abbott RA, Whear R, Rodgers LR, et al. Effectiveness of mindfulness-based stress reduction and mindfulness based cognitive therapy in vascular disease: A systematic review and meta-analysis of randomised controlled trials. *J Psychosom Res*. May 2014;76(5):341-351.
14. Goyal M, Singh S, Sibinga EM, et al. Meditation programs for psychological stress and well-being: A systematic review and meta-analysis. *JAMA Intern Med*. Mar 1 2014;174(3):357-368.
15. Bowen S, Witkiewitz K, Clifasefi SL, et al. Relative Efficacy of Mindfulness-Based Relapse Prevention, Standard Relapse Prevention, and Treatment as Usual for Substance Use Disorders: A Randomized Clinical Trial. *JAMA Psychiatr*. Mar 19 2014.
16. Santorelli SF, Kabat-Zinn J. *MBSR Curriculum Guide and Supporting Materials. Mindfulness Based Stress Reduction Professional Training*. Worcester, MA: University of Massachusetts Center for Mindfulness; 2003.
17. Kabat-Zinn J. An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results. *Gen Hosp Psychiatry*. Apr 1982;4(1):33-47.
18. Kabat-Zinn J, Massion AO, Kristeller J, et al. Effectiveness of a meditation-based stress reduction program in the treatment of anxiety disorders. *Am J Psychiatry*. Jul 1992;149(7):936-943.
19. Santorelli S, Bonus K, McCallum C, et al. Mindfulness-Based Stress Reduction: Guidelines and Standards of Practice. *Integrative Medicine Mindfulness Program at University of Wisconsin- Madison and the Center for Mindfulness, University of Massachusetts*. 2004.
20. MacCoon DG, Imel ZE, Rosenkranz MA, et al. The validation of an active control intervention for Mindfulness Based Stress Reduction (MBSR). *Behav Res Ther*. Jan 2012;50(1):3-12.
21. Loucks EB. Meditation intervention reviews: selecting ideal control groups for meditation interventions. *JAMA Intern Med*. Jul 2014;174(7):1194-1195.
22. Loucks EB, Britton WB, Howe CJ, et al. Associations of dispositional mindfulness with obesity and central adiposity: The New England Family Study. Under Review.
23. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol*. Sep 2004;23(5):443-451.



24. Freedman B. Equipoise and the ethics of clinical research. *N Engl J Med*. Jul 16 1987;317(3):141-145.
25. Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. *Circulation*. Feb 8 2005;111(5):697-716.
26. Williams B, Lindholm LH, Sever P. Systolic pressure is all that matters. *Lancet*. Jun 28 2008;371(9631):2219-2221.
27. El Assaad MA, Topouchian JA, Darne BM, Asmar RG. Validation of the Omron HEM-907 device for blood pressure measurement. *Blood Press Monit*. Aug 2002;7(4):237-241.
28. Chen KY, Acra SA, Majchrzak K, et al. Predicting energy expenditure of physical activity using hip- and wrist-worn accelerometers. *Diabet Technol Therapeut*. 2003;5(6):1023-1033.
29. Crouter SE, Clowers KG, Bassett DR, Jr. A novel method for using accelerometer data to predict energy expenditure. *J Appl Physiol (1985)*. Apr 2006;100(4):1324-1331.
30. Troiano RP. Translating accelerometer counts into energy expenditure: advancing the quest. *J Appl Physiol (1985)*. Apr 2006;100(4):1107-1108.
31. Esliger DW, Tremblay MS. Technical reliability assessment of three accelerometer models in a mechanical setup. *Med Sci Sports Exerc*. Dec 2006;38(12):2173-2181.
32. Heil DP. Predicting activity energy expenditure using the Actical activity monitor. *Res Quart Exercise Sport*. Mar 2006;77(1):64-80.
33. Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics--2012 update: a report from the American Heart Association. *Circulation*. Jan 3 2012;125(1):e2-e220.
34. Subar AF, Thompson FE, Kipnis V, et al. Comparative validation of the Block, Willett, and National Cancer Institute food frequency questionnaires: The Eating at America's Table Study. *Am J Epidemiol*. Dec 15 2001;154(12):1089-1099.
35. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. Dec 1983;24(4):385-396.
36. Kernan WN, Viscoli CM, Makuch RW, Brass LM, Horwitz RI. Stratified randomization for clinical trials. *J Clin Epidemiol*. 1999;52(1):19-26.
37. Friedman LM, Furberg CD, DeMets DL. *Fundamentals of Clinical Trials*. New York, NY: Springer; 2010.
38. Liang K-Y, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika*. 1986;73(1):13-22.
39. Zeger SL, Liang K-Y. Longitudinal data analysis for discrete and continuous outcomes. *Biometrics*. 1986;42:121-130.

## **Section B:**

### **Application for Funding**

**An Application for the Brown internal Richard B. Salomon Faculty Research Award has been made.**

**An NIH R34 is planned to be submitted in March, 2015.**

## **Section C: Specific Aims and Methodology**

# 1 Significance and Innovation

The World Health Organization reported that suboptimal BP is responsible for over half of cardiovascular disease mortality world-wide.<sup>1,2</sup> Furthermore, of those with hypertension, more than half have uncontrolled BP.<sup>3,4</sup> This is despite widespread knowledge of hypertension risk factors and treatments including diet, obesity, physical activity, medication adherence and excessive alcohol consumption.<sup>5,6</sup> Mindfulness interventions appear to improve self-regulation, self-care, and the ability to not respond to cravings for hypertension risk factors such as high caloric palatable foods and sedentary activities (and resulting obesity).<sup>7-11</sup> *In fact, a 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.”*<sup>12</sup> Evidence-based mindfulness interventions including Mindfulness-Based Stress Reduction (MBSR) may have some effects, where a recent meta-analysis and systematic review of 4 randomized controlled trials (RCTs) demonstrated significant effects, but evidence of heterogeneity in effect sizes.<sup>13</sup> The methodologically highest quality studies had the smallest effect sizes. MBSR has been customized to a number of disease processes, such as recurrent depression, smoking and substance use addiction with resulting increases in effect sizes compared to general mindfulness-based interventions that do not take the disease process of interest into consideration.<sup>10,14,15</sup> *The same may be true for hypertension, however this has not yet been studied.*

*Until methodologically rigorous studies to evaluate customized mindfulness-based interventions for hypertension are performed, we will not know if the observed preliminary effects of mindfulness-based interventions on BP could have much greater effect with a tailored approach.* Consequently, we propose to conduct a stage I behavioral therapy intervention study to provide the most rigorous evaluation to date on whether MBSR customized to prehypertensive and hypertensive patients provides clinically relevant reductions in BP. These preliminary findings will set the stage for NIH applications, including R34 and R01 applications.

## 2 Specific Aims

- 1 To formally develop a Mindfulness-Based Hypertension Therapy (MBHT) intervention tailored to the needs for hypertensive patients, utilizing a multi-disciplinary team of experts and patients, and incorporating a Delphi-like technique to adapt protocols of a standardized mindfulness-based intervention developed at UMass Medical School for patients with prehypertension or hypertension.
- 2 To determine the optimal dose of the intervention developed in aim 1. We will estimate the feasibility, acceptability and safety of two different doses of the MBHT intervention in 60 patients (30 per dose arm) randomly assigned to a “low” or “high” dose of MBHT.
- 3 To finalize the protocol of the MBHT intervention and design of the future RCT. We will use the results of our developmental work (aim 1) and of the dosing study (aim 2) to make the final adjustments to the protocol of the intervention that will be tested for efficacy in our future RCT, incorporating the expertise of our interdisciplinary panel to optimize the design of the future RCT.

## 4 Approach

### 4.1 Initial Development of High and Low-Dose MBHT (Aim 1)

We will assemble a team of experts in cardiology (e.g. Dudley, Wu, Shimbo), family medicine (e.g. Eaton), physical activity (e.g. Williams, Davidson), diet (e.g. McCaffery), medication adherence (e.g. Kronish), mindfulness interventions (e.g. Britton, Salmoirago-Blotcher, Brewer), and patients with prehypertension or hypertension. With this team, we use an iterative, Delphi-like technique to adapt protocols of a standardized mindfulness-based intervention developed at UMass Medical School, called MBSR, for patients with prehypertension or hypertension, to the unique safety and treatment needs of this population. Adaptions may include, for example, types of specific mindfulness exercises, sequence in which they are introduced, and relative emphasis on hypertension education vs. mindfulness practice components.

## 4.2 Study Population (Aim 2)

Participants will be recruited through cardiology and family practices via established relationships with physicians at Rhode Island Hospital (e.g. Sam Dudley, MD), Memorial Hospital of Rhode Island (e.g. Charles Eaton, MD), Providence VA Medical Center (e.g. Hank Wu, MD), amongst others. Furthermore, advertisements will be posted throughout Rhode Island inviting participants with pre-hypertension or hypertension to enroll. For Aim 2, we anticipate n=60 participants with equal proportions of males and females, and stratified across prehypertension/hypertension categories, including (1) pre-hypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. This will allow for early indications of potential differential effects of MBHT by gender and prehypertension/hypertension status.

*Inclusion Criterion:* Hypertension/prehypertension ( $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure or taking antihypertensive medication). All genders and racial/ethnic groups are eligible to be included.

*Exclusion Criteria:* Exclusion criteria follow standard guidelines and recommendations:<sup>1</sup> (a) current regular meditation practice (>once/week); (b) serious medical illness precluding regular class attendance; (c) current substance abuse, suicidal ideation or eating disorder, (d) history of bipolar or psychotic disorders or self-injurious behaviors. These participants are excluded because they may disrupt group participation, require additional or specialized treatment, or are already participating in practices similar to the intervention.

## 4.3 Confidentiality of Data

The clinical data will be de-identified but linked. Private information such as name, date of birth, and address for recontacting will be kept in a password protected, encrypted database on a different disk than the clinical data. Only the principal investigator for the purposes of patient safety or monitoring by the NIH, data safety monitoring boards or HIPPA compliance officer approved agents will be given access to identifiable personal information.

Data which contains person-identifiers is considered highly sensitive. Such data is, by policy, only stored within the VMScluster at the Brown University Center for Population Health and Clinical Epidemiology. Access is controlled by the VMS ACL mechanism, allowing read-only access to a small group of specific users and read-write access to an even smaller group. Internet access (e.g., via a Web server) is disallowed for such storage areas. Windows security controls are superseded by VMS controls, although Windows access is permitted since some data is acquired on Windows-specific media (e.g., CD-ROM). All uses of privileged necessary to grant/revoke access to any data, as well as any other security-relevant event data, is continuously logged and analyzed in the context of both the VMScluster and the Windows Domain. Network access is tightly controlled to allow anonymous access only to a small amount of read-only data; all “risky protocols” are disallowed from Internet access. For any given study with person-identifying information, such data is stripped before the data is made accessible to staff not authorized to access such identifiers. In those cases where the data is longitudinal, a non-reversible encryption of the person ID is made in order to provide a unique person ID not traceable to the underlying person. The specific algorithm used for any given set of data is stored in the same fashion and given the same security as the data itself. To make data use simpler, hierarchical “trees” of directories are given consistent access controls tied to a unique identifier, which is then granted to staff authorized to use such data. Programming staff authorized to make individual-level data available to staff not authorized to access the person-identifying components routinely copy the “encrypted” versions from the more-secured tree to a less-secured tree. Security controls are thus relatively automatic, based on the propagation of rights based on the location of a file within the file system and the identity of the user attempting to access it.

## 4.4 MBHT Intervention Groups

*High Dose:* MBHT is based on the standardized MBSR intervention described elsewhere,<sup>17-20</sup> and will likely consist of nine 2.5-hour weekly group sessions and an 8-hour one-day session, led by Dr. Loucks. Dr. Loucks is an expert in cardiovascular physiology, cardiovascular epidemiology, and social epidemiology. He completed MBSR instructor training at UMass Medical School, and has 16 years of

mindfulness meditation experience, including teaching and mentoring community members, as well as a recent publication record investigating associations of mindfulness with cardiovascular health.<sup>11,21,22</sup> The unique areas of MBHT are expected to be education on hypertension risk factors, hypertension health effects, and specific mindfulness modules focused on awareness of diet, physical activity, medication adherence, alcohol consumption, stress, and social support for behavior change. A preliminary manual has been created based on the standardized MBSR manual developed at UMass Medical School, and will be further developed through the Delphi-like approach described above, and sequentially revised based on participant feedback and preliminary findings.<sup>19,20</sup> MBHT sessions contain instruction and practice in mindfulness meditation, and conversations about stress and coping. Students learn a range of mindfulness skills including body scan exercises, meditation and yoga. Homework consists of practicing skills for  $\geq 45$  min/day, 6 days/week. Booster sessions will be offered (likely 2.5-hour sessions every 2 months).

**Low Dose:** Low Dose MBHT will be based on the High Dose intervention above, but instead prioritizing practices to fit within nine 1-hour weekly groups sessions. Through the aforementioned Delphi-like approach, the most salient parts of the high dose intervention described above will be offered in low dose MBHT.

## 4.5 Measures of Compliance

**Participant Adherence:** Data on treatment protocol adherence will be collected weekly by research staff.

**MBHT Instructor Competency and Treatment Fidelity:** Treatment fidelity strategies will be performed in accordance with recommendations of the NIH Behavior Change consortium.<sup>23</sup>

## 4.6 Blinding

All study staff, including those performing health assessments and contacting participants to schedule follow-up assessments, will be blinded to treatment allocation with the exception of the MBHT instructor (Loucks) and data manager (who performs randomization).

## 4.7 Equipoise

This study will be designed to disrupt clinical equipoise, defined as “no consensus within the expert clinical community about the comparative merits of the alternative [trial arms] to be tested.”<sup>24</sup>

## 4.8 Assessments

We will follow study procedures similar to those performed during previous epidemiologic studies by our group. In-person screenings will take place at the Brown University Center for Population Health and Clinical Epidemiology, described in Sections 2.7.1 and 2.7.2 at baseline, completion of the 9-week MBHT course and at 3- and 6-months post-intervention. Major assessment variables are shown in **Table 1**. Qualitative interviews (likely focus groups) will evaluate participants’ experiences such as usefulness of specific modules, duration of sessions, time burden, and overall intervention effectiveness.

### 4.8.1 Primary Outcomes

**Clinic BP Assessment:** Clinic-assessed systolic and diastolic BP remains the standard of care for monitoring hypertension treatment.<sup>3,5,6,25,26</sup> Baseline clinic BP will be

**Table 1.** Examples of variables proposed to be assessed during MBHT study

Variables	Obtained During Study			
	Baseline	8 w	3 m	6 m
Race/ethnicity	✓			
Gender	✓			
Adverse childhood experiences	✓			
Socioeconomic status	✓	✓	✓	✓
Depressive symptomatology	✓	✓	✓	✓
Anxiety	✓	✓	✓	✓
Perceived stress	✓	✓	✓	✓
Self efficacy	✓	✓	✓	✓
Mindfulness	✓	✓	✓	✓
Blood pressure	✓	✓		✓
Smoking	✓	✓	✓	✓
Diet	✓	✓	✓	✓
Physical activity	✓	✓	✓	✓
Alcohol consumption	✓	✓	✓	✓
Body mass index	✓	✓		✓
Sleep quantity and quality	✓	✓	✓	✓
Social support	✓	✓	✓	✓
Loneliness	✓	✓	✓	✓
Medication use and adherence	✓	✓	✓	✓

m, months; w, weeks

determined at two in-person screening visits  $\geq 1$  week apart, completed according to American Heart Association guidelines,<sup>25</sup> followed by in-person assessments at all follow-up periods. BP will be assessed using a calibrated Omron HEM907XL Intellisense automated BP monitor with established validity.<sup>27</sup>

#### **4.8.2 Potential Mediators**

*Examples of mediators to be assessed include: (1) Body Mass Index:* height and weight directly assessed using standard epidemiologic methods. *(2) Physical activity:* MET minutes per week, assessed using actigraphy, which enables the quantification of physical activity.<sup>28-32</sup> *(3) Diet:* diet assessed utilizing Dietary Approaches to Stop Hypertension (DASH) eating pattern score,<sup>33</sup> measured via diet history food frequency questionnaire.<sup>34</sup> *(4) Perceived stress:* measured using Perceived Stress Scale.<sup>35</sup> *(5) Antihypertensive Medication Adherence:* measured continuously using electronic medication bottle caps (GlowCaps).

#### **4.8.3 Potential Effect Modifiers**

We propose to evaluate 2 potentially important effect modifiers: (1) gender, (2) prehypertension/hypertension category.

### **4.9 Intervention Allocation**

Stratified randomization will be used.<sup>36,37</sup> Variables used to create strata include gender (male vs. female), race/ethnicity (white vs. non-white), and prehypertension/ hypertension status (pre-hypertension, controlled hypertension, uncontrolled hypertension). Simple random sampling will occur within each strata.

### **4.10 Data Analysis**

Qualitative analyses will evaluate participant experiences such as usefulness of specific modules, duration of sessions, time burden, and overall intervention effectiveness. Quantitative analyses will incorporate generalized linear models (GLM) with properly chosen link functions, performed using generalized estimating equations (GEE) with robust standard error estimators.<sup>38,39</sup> We will test effects of high vs. low dose MBHT on clinic-assessed systolic and diastolic BP. Following “intention-to-treat” principles, analyses will be conducted on all participants randomized to high vs. low dose, regardless of intervention completion. To test whether effects of MBHT on BP may be effect modified by variables described in Section 2.7.3 we will add product terms between MBHT and each potential effect modifier to models described above. Formal statistical significance tests of product terms will be performed. Analyses are considered statistically underpowered, but will provide effect size estimates and statistical variances for NIH grant applications to support studies with larger sample sizes.

## References

1. Mendis S, Puska P, Norrving B. *Global atlas on cardiovascular disease prevention and control*. Geneva: World Health Organization;2011.
2. Hoyert DL, Xu J. Deaths: Preliminary Data for 2011. *National Vital Statistics Reports*. 2012;61(6):1-65.
3. Chobanian AV, Bakris GL, Black HR, et al. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Hypertension*. Dec 2003;42(6):1206-1252.
4. United States Centers for Disease Control and Prevention. Getting blood pressure under control. *CDC Vital signs*. 2012;September.
5. James PA, Oparil S, Carter BL, et al. 2014 evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. Feb 5 2014;311(5):507-520.
6. Weber MA, Schiffrin EL, White W, et al. Clinical practice guidelines for the management of hypertension in the community: A statement by the American Society of Hypertension and the International Society of Hypertension. *J Hypertens*. 2014;32(1):3-15.
7. Epstein RM. Mindful practice. *JAMA*. Sep 1 1999;282(9):833-839.
8. Sedlmeier P, Eberth J, Schwarz M, et al. The psychological effects of meditation: a meta-analysis. *Psychol Bull*. Nov 2012;138(6):1139-1171.
9. Lutz A, Slagter HA, Dunne JD, Davidson RJ. Cognitive-emotional interactions - Attention regulation and monitoring in meditation. *Trends Cogn Sci*. Apr 2008;12(4):163-169.
10. Brewer JA, Mallik S, Babuscio TA, et al. Mindfulness training for smoking cessation: results from a randomized controlled trial. *Drug Alc Depend*. 2011;119(1-2):72-80.
11. Loucks EB, Britton WB, Howe CJ, Eaton CB, Buka SL. Positive associations of dispositional mindfulness with cardiovascular health: The New England Family Study. *Int J Behav Med*. 2014: DOI 10.1007/s12529-12014-19448-12529.
12. Institute of Medicine. *Initial National Priorities for Comparative Effectiveness Research*. Washington, D.C. 2009.
13. Abbott RA, Whear R, Rodgers LR, et al. Effectiveness of mindfulness-based stress reduction and mindfulness based cognitive therapy in vascular disease: A systematic review and meta-analysis of randomised controlled trials. *J Psychosom Res*. May 2014;76(5):341-351.
14. Goyal M, Singh S, Sibinga EM, et al. Meditation programs for psychological stress and well-being: A systematic review and meta-analysis. *JAMA Intern Med*. Mar 1 2014;174(3):357-368.
15. Bowen S, Witkiewitz K, Clifasefi SL, et al. Relative Efficacy of Mindfulness-Based Relapse Prevention, Standard Relapse Prevention, and Treatment as Usual for Substance Use Disorders: A Randomized Clinical Trial. *JAMA Psychiatr*. Mar 19 2014.
16. Santorelli SF, Kabat-Zinn J. *MBSR Curriculum Guide and Supporting Materials. Mindfulness Based Stress Reduction Professional Training*. Worcester, MA: University of Massachusetts Center for Mindfulness; 2003.
17. Kabat-Zinn J. An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results. *Gen Hosp Psychiatry*. Apr 1982;4(1):33-47.
18. Kabat-Zinn J, Massion AO, Kristeller J, et al. Effectiveness of a meditation-based stress reduction program in the treatment of anxiety disorders. *Am J Psychiatry*. Jul 1992;149(7):936-943.
19. Santorelli S, Bonus K, McCallum C, et al. Mindfulness-Based Stress Reduction: Guidelines and Standards of Practice. *Integrative Medicine Mindfulness Program at University of Wisconsin-Madison and the Center for Mindfulness, University of Massachusetts*. 2004.
20. MacCoon DG, Imel ZE, Rosenkranz MA, et al. The validation of an active control intervention for Mindfulness Based Stress Reduction (MBSR). *Behav Res Ther*. Jan 2012;50(1):3-12.
21. Loucks EB. Meditation intervention reviews: selecting ideal control groups for meditation interventions. *JAMA Intern Med*. Jul 2014;174(7):1194-1195.
22. Loucks EB, Britton WB, Howe CJ, et al. Associations of dispositional mindfulness with obesity and central adiposity: The New England Family Study. Under Review.



23. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol.* Sep 2004;23(5):443-451.
24. Freedman B. Equipoise and the ethics of clinical research. *N Engl J Med.* Jul 16 1987;317(3):141-145.
25. Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. *Circulation.* Feb 8 2005;111(5):697-716.
26. Williams B, Lindholm LH, Sever P. Systolic pressure is all that matters. *Lancet.* Jun 28 2008;371(9631):2219-2221.
27. El Assaad MA, Topouchian JA, Darne BM, Asmar RG. Validation of the Omron HEM-907 device for blood pressure measurement. *Blood Press Monit.* Aug 2002;7(4):237-241.
28. Chen KY, Acra SA, Majchrzak K, et al. Predicting energy expenditure of physical activity using hip- and wrist-worn accelerometers. *Diabet Technol Therapeut.* 2003;5(6):1023-1033.
29. Crouter SE, Clowers KG, Bassett DR, Jr. A novel method for using accelerometer data to predict energy expenditure. *J Appl Physiol (1985).* Apr 2006;100(4):1324-1331.
30. Troiano RP. Translating accelerometer counts into energy expenditure: advancing the quest. *J Appl Physiol (1985).* Apr 2006;100(4):1107-1108.
31. Esliger DW, Tremblay MS. Technical reliability assessment of three accelerometer models in a mechanical setup. *Med Sci Sports Exerc.* Dec 2006;38(12):2173-2181.
32. Heil DP. Predicting activity energy expenditure using the Actical activity monitor. *Res Quart Exercise Sport.* Mar 2006;77(1):64-80.
33. Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics--2012 update: a report from the American Heart Association. *Circulation.* Jan 3 2012;125(1):e2-e220.
34. Subar AF, Thompson FE, Kipnis V, et al. Comparative validation of the Block, Willett, and National Cancer Institute food frequency questionnaires: The Eating at America's Table Study. *Am J Epidemiol.* Dec 15 2001;154(12):1089-1099.
35. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav.* Dec 1983;24(4):385-396.
36. Kernan WN, Viscoli CM, Makuch RW, Brass LM, Horwitz RI. Stratified randomization for clinical trials. *J Clin Epidemiol.* 1999;52(1):19-26.
37. Friedman LM, Furberg CD, DeMets DL. *Fundamentals of Clinical Trials.* New York, NY: Springer; 2010.
38. Liang K-Y, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika.* 1986;73(1):13-22.
39. Zeger SL, Liang K-Y. Longitudinal data analysis for discrete and continuous outcomes. *Biometrics.* 1986;42:121-130.

**Section D:**  
**Possible Risks to Participants**

The following is a statement from NCCAM about the potential risks of meditation practice: “Meditation is considered to be safe for healthy people. There have been rare reports that meditation could cause or worsen symptoms in people who have certain psychiatric problems, but this question has not been fully researched. People with physical limitations may not be able to participate in certain meditative practices involving physical movement. Individuals with existing mental or physical health conditions should speak with their health care providers prior to starting a meditative practice and make their meditation instructor aware of their condition.”<sup>285</sup>

*Discomfort during meditation:* Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable emotions with increased attention to them. In order to minimize risk, instructors encourage participants to be aware of their discomfort and to set their own limitations. Participants are encouraged to alter their postures, including standing, sitting in chairs, lying down, as needed in order to be comfortable. In addition, the curriculum of the training program is specifically geared towards addressing such discomfort.

*Psychological distress:* Research subjects participating in this study may have feelings of loss of privacy from being contacted about participating in the study, and possible psychological distress caused by questions on the diagnostic interview that bring up painful memories or feelings. However, the resulting potential for injury to research subjects is judged to be minimal. We have already contacted and clinically evaluated thousands of participants from the New England Family using similar assessment procedures to this study, with good responses from the participants. With regard to psychological distress from taking part in the MBHT intervention, given that screening questions will exclude participants with substantial mental illness, and given the NCAAM statement above that “Meditation is considered to be safe for healthy people.”,<sup>285</sup> we expect that risk of psychological distress will be low. The risk of increased psychological distress from meditation will be clearly outlined in the consent form and participants will be encouraged to consult with both the course instructor and study staff in the case of any increased distress. One of the co-investigators (Dr. Britton) is a clinical psychologist. She will be available to advise on any psychological events that occur, and provide referrals for treatment if needed.

*Loss of confidentiality:* Likelihood: rare. Minimization: Confidentiality will be maintained by numerically coding all data, by disguising identifying information, and by keeping all data in locked file drawers. All information obtained from participants will be accessible only to research staff.

*Potential Benefits of the Proposed Research to Human Subjects and Others:* There may be no direct benefits from participating in this study. The potential benefits of participating in the proposed study include improved knowledge on stress reduction techniques and risk for hypertension. Each participant will also be contributing to an important study which will answer questions on whether mindfulness-based stress reduction may influence health.

## **Section E: Informed Consent**

Each potential participant will be fully informed about the nature of the study, its risks and benefits, and about his/her rights as a research subject. The person performing the consent will be either Dr. Loucks or a trained undergraduate trained research assistant. The participant will sign and receive a copy of the document stating that he/she has given his/her informed consent to participate before interviewing is begun. In every instance, project personnel will verbally review the content of the consent form before participants sign.

## **Agreement to Participate in a Research Study**

### ***Investigation of the effects of mindfulness meditation on blood pressure and well-being***

You are being asked to take part in a Brown University research study about the effects of mindfulness and hypertension education on blood pressure and risk factors for hypertension. This form will explain the purpose of the study, how the study will be carried out and what you will be expected to do. It will also explain the possible risks and possible benefits of being in the study. If any part of the following description is not clear to you, you are encouraged to contact the researcher to answer any questions before you decide whether to take part in the study. If you decide to participate, please fill out and sign the last page of this form.

#### **1a. Nature and Purpose of the Study**

The purpose of the study is to investigate the impact of mindfulness practices and health education on blood pressure. You have been selected for this study because you expressed interest and met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program. In order to assess the effects of these practices, you will be asked to complete some questionnaires, and a laboratory assessment before and after learning the mindfulness practices.

#### **1b. Explanation of Procedures**

If you agree to participate, you will be asked to consent to the following:

- 1) Participate in an interview in which you will be asked questions about past and present mental health, including depression and suicide.
- 2) Complete questionnaires about a wide range of topics, including your diet, physical activity, smoking, medication use, personality, emotions, attention and past experiences, including stressful or traumatic experiences. These questions will probe sensitive psychological areas, including physical, emotion and sexual abuse. These questionnaires may take up to 2 hours to complete. By completing the interviews and questionnaires, you are giving the researchers permission to use the information you have provided. You have the right not to answer any of the questions.
- 3) Directly assessed blood pressure, height, weight, waist circumference and hip circumference.
- 4) You will be asked to perform some cognitive tasks. One of these tasks may involve computer-based tests of attention or decision-making. Together these tests may take as long as 45 minutes.
- 5) You will be randomly assigned (like the flip of a coin) to enter one of two 9 week meditation programs.
- 6) You will participate in the 9-week meditation program, which consists of 9 weekly sessions of 1-2.5 hours each and may include one 6 hour weekend retreat. Daily homework assignments may take as long as one hour and consist of practicing mindfulness exercises with the aid of a guided audio CD and completing worksheets related to stress, thoughts, and common reactions to various types of events.

- 7) Class sessions will be audio taped so we can analyze the quality of the treatment you receive. The recordings will be transcribed so that we may analyze the text. The recordings will be identified by study number, will only be heard by study staff and will be destroyed after transcription.
- 8) You will be asked to complete a few short questionnaires each week during the 9 week condition and to notify the lab if you change your medication in any way.
- 9) After 9 weeks, you will be asked to complete a second packet of questionnaires and return to the laboratory to repeat the same procedures for a second day of testing.
- 10) Three months and six months after the end of the 9 week condition, you will be asked to return to the laboratory to repeat the same testing procedures.

#### Feedback:

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing % change (increase or decrease) on scales of attention, stress, mood, health behaviors and blood pressure across the study.

#### 2. Discomforts and Risks

The questionnaires are routine, standardized forms for epidemiologic research. Certain questions may be upsetting as they may probe sensitive psychological areas and inquire about upsetting or traumatic events, including physical, sexual or emotional abuse and/or current psychiatric symptoms. Since your participation is voluntary, you have the right to skip any questions that make you uncomfortable.

Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable feelings with increased attention to them.

#### 3. Benefits

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) gaining first-hand knowledge about the most current scientific methods in scientific research d) receiving information about your psychological and physical functioning.

#### 4. Alternative Therapies

A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

#### 5. Confidentiality

Your responses for this study will be kept confidential. All data that we collect will be linked to a study ID# instead of your name. All questionnaires in this study will be filled out through an online survey website (SurveyMonkey). All of these questionnaires will be linked solely to your study ID#, so that your identity is protected and your answers are confidential. Although these measures have been taken to protect your personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet.

While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then the PI, or a co-investigator (Willoughby Britton) who is a clinical psychologist, may contact the you

to discuss your responses and possible referral to another treatment provider. Questionnaire items that may warrant follow-up include endorsements of statements about hurting yourself or others, any high scores in depression, anxiety, aggressive behaviors, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires researchers to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a unique code number and initials. All study records and specimens will be stored in a secure storage area.

*Keeping study records:* The Principal Investigator for this study will keep your research records indefinitely for research purposes.

#### 6. Refusal/Withdrawal

Participation is voluntary, and you may decide to opt out or refuse any part of participation, including not answering certain questions. If you decide now to participate, you can change your mind later and quit the study. The decision to not participate or to withdraw from the study will not adversely affect current or future interactions with Brown University.

If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

#### 7. Contact Information

If you have questions about study procedures at any time you may contact the researchers: Dr. Eric B. Loucks, email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu), telephone (401) 863-6283. If you would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Brown University Research Protections Office, telephone number 1-866-309-2095 or 401-863-3050.



**CONSENT FORM:**  
**Please sign and return.**

Please read the following agreement and sign to consent to participating.

**I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY.**

\_\_\_\_\_  
**PRINT NAME**

\_\_\_\_\_  
**Signature of participant**

\_\_\_\_\_  
**Date**

**CONTACT INFORMATION**

**Name (print):** \_\_\_\_\_


**Permanent Address:** \_\_\_\_\_

**Email(s):** \_\_\_\_\_

**Telephone:** \_\_\_\_\_ **(cell)** \_\_\_\_\_ **(other)**


## **Section F: Recruiting Materials**

**Front of Advertisement Card:**



Brown University  
School of Public Health  
Department of Epidemiology

**RESEARCH STUDY:  
Mindfulness-Based Intervention for  
Blood Pressure Reduction**



**Free to qualified participants**

**Back of Advertisement Card:**

This is a 9-week program that includes mindfulness meditation, mindful movements, and education about risk factors for blood pressure. The study is testing whether combining these interventions lowers blood pressure. The program consists of nine weekly sessions that are 1 or 2.5 hours (depending on study arm), and an all-day weekend retreat.

Research participation includes interviews, questionnaires and measurements of blood pressure, height, weight, and waist circumference, before and after the meditation program.

Contact: For more information, or to see if you qualify, call the Brown Sociobiology Laboratory at 401-863-6283, or email [SBL@gmail.com](mailto:SBL@gmail.com). See website at [URL needs to be created].

**Sample Text of Recruitment Letter (placed on Dr. Loucks' letterhead):**

[Date]

Dear \_\_\_\_\_,

Your physician [name of physician] identified you as someone with prehypertension or hypertension who may be interested in participating in a new study at Brown University that is designed to evaluate effects of an intervention called Mindfulness-Based Hypertension Therapy (MBHT). MBHT combines mindfulness practices such as meditation and mindful movements with education about hypertension management and prevention. The aim of MBHT is to create a skill set and supportive environment to help to reduce blood pressure, and improve overall well-being. Your involvement in this study could help us better understand if MBHT is effective, and how it could be improved. The MBHT intervention will take place over 9 weeks, and would involve you attending a class once per week that would be between 1 and 2.5 hours, depending on which group you are assigned to. You may also be assigned to participate in a full day mindfulness retreat that would be about 7.5 hours duration. Also, health assessments would be performed before you start the intervention, and again immediately at the end of the 9-week intervention, as well as at 3 months and 6 months follow-up. The assessments would include measures such as blood pressure, height, weight, diet, physical activity, smoking, depression, stress, and medication use. These assessments will take 1-2 hours to complete.

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing your changes on scales of attention, stress, mood, health behaviors and blood pressure across the study.

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) gaining first-hand knowledge about the most current scientific methods in scientific research d) receiving information about your psychological and physical functioning.

If you are interested in participating in this study, please call 401-863-6283, or email [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu).

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Eric Loucks', is written over a light yellow rectangular background.

Eric B. Loucks, Ph.D.  
Assistant Professor

**Section G:**  
**Questionnaires and Focus Group Topics**

SCREENING QUESTIONNAIRE  
(PHONE-DELIVERED)

## MBHT PHONE SCREEN

**Date of Screen:** \_\_\_\_\_ **Interviewer:** \_\_\_\_\_

**Screening #:** \_\_\_\_\_ (month.date.year.hour.minute)

**Name:** \_\_\_\_\_

**Address:** \_\_\_\_\_

**Phone number(s):** \_\_\_\_\_

**Email address (or mailing if no email):** \_\_\_\_\_

**Notes from Interviewer:**

---

---

---

My name is \_\_\_\_\_. I am calling from the Epidemiology Department at the Brown University School of Public Health, because you expressed interest in participating in our mindfulness study. I want to do 10-15 minutes phone interview with you to determine if you are a good match for this particular study. Is now a good time to speak? [If yes, proceed. If no, ask for other times and note in Potential Subject Log].

There are a few things that I'd like to make clear before we start the interview. First of all, some of the questions will be very personal and sensitive. Are you in a private place to talk? Because this interview is of a personal nature, it is important that you understand that everything you say will be kept strictly confidential. No one outside of our project will ever be able to see your answers, and we will not keep your name in the same place as any of your answers. If you are not eligible after the phone screen, we will destroy your information. If you like, though, we can keep your information on file for future studies.

INCLUSION CRITERIA: Need YES to all			
			Comments
AGE	Age_____ Between 18 and 65?	YES NO	
FXN	Highest level of education?		
FXN	Current occupation?		
ENG	Can you read and write in English?	YES NO	
INTEREST	What interested you about this study? What kind of symptoms are you hoping to treat?	YES NO	
EXCLUSION CRITERIA: LIFETIME: must be NO			
			Comments
Bipolar depression MANIA	Has anyone ever told you that you have bipolar disorder or manic depression?	YES NO	
BPD	Has anyone ever used the word “Borderline” to describe you?	YES NO	
Psychosis	Have you ever had a hallucination or seen things that other people can’t see, or hear things other people can’t hear? Have you ever been diagnosed with schizophrenia or psychosis?	YES NO	
MANIA/ Antipsychotic MEDS	Have you ever taken any of the following medications? Lithium? Seroquel (quetiapine) Abilify (aripiprazole) Zyprexa (olanzapine) Clozaril (clozapine) Haldol/Haloperidol Geodon (ziprasidone) Risperdal (risperidone)	YES NO	
Self-harm	Have you ever deliberately cut or injured yourself? Have you ever had a suicide attempt? (Details/age)	YES NO	
Antisocial	Have you ever been arrested? Any Legal problems? Have you ever been in a fight?	YES NO	



EXCLUSION: CURRENT (check timeframe)			
		YES NO	Comments
PTSD	Would you say you have a trauma history? Physical sexual abuse, assault rape? Where are you with that now? Any problems with dissociation (memory loss)? Flashbacks?		Last month?
OCD	Any problems with obsessions or compulsions? Washing hands or checking the oven over and over? If yes, Has anyone diagnosed you with obsessive compulsive disorder?		Last month?
PANIC	Have you ever had a panic attack? (Sweating, heart palpitations, nausea, trouble breathing, fear of dying/choking/going crazy... Out of blue or triggered? Have you had one in the last month?		Last month?
ALCOHOL	How much alcohol do you currently drink? Any drug use? Ever abuse drug/alcohol? Time in recovery – min 1 year		Last year?
EATING DIS	How is your relationship with food? Ever have an eating disorder? Starving, Binge eating, or vomiting? Where are you with that now?		Last year?
MEDITATION	What is your experience with meditation? Rule out current regular practice (>1 week) Lifetime daily mindfulness meditation (see “what is meditation?)		
MISC	Any other psychological problem I haven’t mentioned? Social Anxiety? Ok in groups? Phobias?		
Time commitment	(After study explanation) This study is a significant time commitment, is this a good time for you?		
DECISION	PASS NO PASS QUERY		

PASS FORM: Initial appropriate boxes with dates		Date/initials
NO PASS	According to this test, it doesn't look like you are going to be a good fit for the study. There may be other studies you qualify for. Would you like me to keep your information to pass on to these studies? Otherwise, our copy of this information can be destroyed.	
QUERY	There are several items I will need to check with my supervisor about. We will get back in touch.	
PASS: Study description and requirements Time commitment	You qualify for the study. If you want to continue, the next phase would require an interview, a packet of questionnaires and evening visit to the laboratory before the 9 week meditation program. After the program, you would fill out the same questionnaires and do the lab visit again. The meditation program is either 1 or 2.5 hours once a week, usually in the evening, and requires up to an hour of practice every day. There also may be an all-day retreat on a Saturday part way through the course. Is this something that you would be able to make time for in your schedule?	YES    NO
SCHEDULE Available for current program?	It's important to attend all 9 sessions. The next program is: Availability: Mon 9:00-11:30, 4-6:30 pm Tues 9:00-11:30, 4-6:30 pm Wed 9:00-11:30, 4-6:30 pm Thurs 9:00-11:30, 4-6:30 pm  Other:	YES    NO

# QUESTIONNAIRES ANSWERED BY PARTICIPANTS AT BASELINE

## Questionnaire Table of Contents

Introductory Questions .....	8
Background Questions.....	10
Physical Activity.....	14
Food and Drinks (FD).....	16
Eating Practices (EP).....	21
Alcohol Consumption (AC).....	23
Smoking (SM) .....	24
Medications (ME).....	25
Self-Control .....	47
Sense of Control .....	48
CES-D Depression Inventory .....	50
Perceived Stress Scale .....	52
Mindfulness .....	53
Emotion Regulation.....	64
Beck Anxiety Inventory.....	66
Parent's Education.....	67
Your Childhood Experiences.....	69
Loneliness.....	74
Your Sleep .....	75

## **Introductory Questions**

IQ1. What is your main reason for participating in this study?

IQ2. What do you care about most?

IQ3. What gives you most pleasure in your life?

IQ4. What are your greatest worries?

**Please list three personal goals you have for taking this mindfulness program:**

**1.** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**2.** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**3.** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## **Background Questions**

B1. What is your age? \_\_\_\_\_ years old      ☐ I do not know      ☐ I prefer not to answer

B2. Are you Latino or Hispanic?

- ☐ No → **skip to B3**
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

B2a. Which of the following represents your family's country of origin? (**check all that apply**)

- |  |   |
|--|---|
| <input type="checkbox"/> Cuba          | <input type="checkbox"/> Dominican Republic     |
| <input type="checkbox"/> Mexico        | <input type="checkbox"/> Other Central American |
| <input type="checkbox"/> Puerto Rico   | <input type="checkbox"/> Other: _____           |
| <input type="checkbox"/> Spain         | <input type="checkbox"/> I do not know          |
| <input type="checkbox"/> South America | <input type="checkbox"/> I prefer not to answer |
| <input type="checkbox"/> Columbia      |   |

B3. If you were asked to put yourself into only one of these groups, in which one would you place yourself? (**select one only**):

- |   |   |
|---|---|
| <input type="checkbox"/> Asian                  | <input type="checkbox"/> Native American        |
| <input type="checkbox"/> Pacific Islander       | <input type="checkbox"/> Other : _____          |
| <input type="checkbox"/> African American/Black | <input type="checkbox"/> I do not know          |
| <input type="checkbox"/> Caucasian/White        | <input type="checkbox"/> I prefer not to answer |

B4. Which of the following best describes your current work situation? (**select one only**)

- |   |  |
|---|--|
| <input type="checkbox"/> Working full-time                          | <input type="checkbox"/> Keeping house or raising children full-time |
| <input type="checkbox"/> Working part-time                          | <input type="checkbox"/> Military                                    |
| <input type="checkbox"/> Retired                                    | <input type="checkbox"/> Full-time student                           |
| <input type="checkbox"/> Unemployed: Looking for work               | <input type="checkbox"/> Other: _____                                |
| <input type="checkbox"/> Unemployed: Not currently looking for work | <input type="checkbox"/> I do not know                               |
| <input type="checkbox"/> Unemployed due to disability               | <input type="checkbox"/> I prefer not to answer                      |

B9. What is the highest grade or level of regular school you have completed?

- ☐ Elementary School
- ☐ Junior High
- ☐ High School
- ☐ College
- ☐ Graduate School
- ☐ I do not know
- ☐ I prefer not to answer

B11. What is the highest degree you earned? (*select one only*)

- |   |  |
|---|--|
| <input type="checkbox"/> GED                                | <input type="checkbox"/> Professional (MD, JD, DDS, DVM, etc.)                                 |
| <input type="checkbox"/> High school diploma or equivalency | <input type="checkbox"/> Other: _____  |
| <input type="checkbox"/> Associate degree (Junior College)  | <input type="checkbox"/> None of the above (less than GED or less than high school graduation) |
| <input type="checkbox"/> Bachelor's degree                  | <input type="checkbox"/> I do not know   |
| <input type="checkbox"/> Master's degree                    | <input type="checkbox"/> I prefer not to answer  |
| <input type="checkbox"/> Doctorate (Phd, EdD, etc)          |  |

B12. Did you ever attend any other school like a technical, vocational, or trade school?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

B13. In total, about how many full-time years of education have you had, including 1<sup>st</sup> grade and all years of school after 1<sup>st</sup> grade?

\_\_\_\_\_ years

- ☐ I do not know
- ☐ I prefer not to answer



B14. Do you currently live alone?

- ☐ No
- ☐ Yes → ***skip to B15***
- ☐ I do not know
- ☐ I prefer not to answer

B14a. How many people are currently living in your household, including yourself?

\_\_\_\_\_ people    ☐ I do not know    ☐ I prefer not to answer

B14b. Of these people, how many are under 18?

\_\_\_\_\_ people    ☐ I do not know    ☐ I prefer not to answer  
***(if none, write 0)***

B14c. Of the adults in your household (including yourself), how many bring income into the household?

\_\_\_\_\_ people    ☐ I do not know    ☐ I prefer not to answer  
***(if none, write 0)***

B16. How much did YOU earn, before taxes and other deductions, during the past 12 months?  
***(Please include all income from your job(s), money from government programs, child support, interest and dividends, money from rental property, etc.)***

- |  |  |
|--|--|
| <input type="checkbox"/> Less than \$5,000         | <input type="checkbox"/> \$50,000 through \$74,999 |
| <input type="checkbox"/> \$5,000 through \$11,999  | <input type="checkbox"/> \$75,000 through \$99,999 |
| <input type="checkbox"/> \$12,000 through \$15,999 | <input type="checkbox"/> \$100,000 and greater     |
| <input type="checkbox"/> \$16,000 through \$24,999 | <input type="checkbox"/> I do not know             |
| <input type="checkbox"/> \$25,000 through \$34,999 | <input type="checkbox"/> I prefer not to answer    |
| <input type="checkbox"/> \$35,000 through \$49,999 |  |

B17. How much did your HOUSEHOLD earn, before taxes and other deductions, during the past 12 months? *(Please include all income from your job(s), your family member's job(s), money from government programs, child support, interest and dividends, money from rental property, etc.)*

- |  |  |
|--|--|
| <input type="checkbox"/> Less than \$5,000         | <input type="checkbox"/> \$50,000 through \$74,999 |
| <input type="checkbox"/> \$5,000 through \$11,999  | <input type="checkbox"/> \$75,000 through \$99,999 |
| <input type="checkbox"/> \$12,000 through \$15,999 | <input type="checkbox"/> \$100,000 and greater     |
| <input type="checkbox"/> \$16,000 through \$24,999 | <input type="checkbox"/> I do not know             |
| <input type="checkbox"/> \$25,000 through \$34,999 | <input type="checkbox"/> I prefer not to answer    |
| <input type="checkbox"/> \$35,000 through \$49,999 |  |

## **Physical Activity**

Physical activities are activities where you move and increase your heart rate above its resting rate, whether you do them for pleasure, work, or transportation. The following questions ask about the amount and intensity of physical activity you usually do. The intensity of the activity is related to *the amount of energy* you use doing these activities.

### **Examples of physical activity intensity levels:**

#### **Light activities**

Your heart beats slightly faster than normal

You can talk and sing



Light exercise



Light stretching



Light vacuuming  
or yard work

#### **Moderate activities**

Your heart beats faster than normal

You can talk but not sing



Brisk walking



Aerobics class



Strength training



Swim gently

#### **Vigorous activities**

Your heart rate increases a lot

You can't talk, or your talking is broken up by large breaths



Aerobics classes



Jogging, Running,  
or Power Walking



Singles tennis,  
Racquetball, Pickle ball

## How physically active are you?

	YES	NO
PA1. I rarely or never do any physical activities.		
PA2. I do some light and/or moderate physical activities, but not every week.		
PA3. I do some light physical activity every week.		
PA4. I do moderate physical activity every week but less than 5 days per week or less than 30 minutes on those days.		
PA5. I do vigorous physical activities every week, but less than 3 days per week or less than 20 minutes on those days.		
PA6. I do 30 minutes or more per day of moderate physical activities 5 or more days per week.		
PA7. I do 20 minutes or more per day of vigorous physical activities 3 or more days per week.		
PA8. I do activities to increase muscle strength, such as lifting weights or calisthenics, once a week or more.		
PA9. I do activities to improve flexibility, such as stretching or yoga, once a week or more.		

## **Food and Drinks (FD)**

The first set of questions ask about foods you usually eat or drink. For each food, please place an X in the box (e.g. ☒) for the answer that best matches how often you eat or drink it. Remember to count fruit or vegetables that were part of another dish, like a banana on cereal or vegetables in a stew. Also, please pay attention to the serving sizes. For example, one serving size of bread is one slice, so a sandwich would contain 2 servings of bread. Please include all foods you eat, both at home and away from home. Enclosed are pictures of common serving sizes to assist you in filling out your questionnaire.



**4-6 ounces**



**3 ounces**



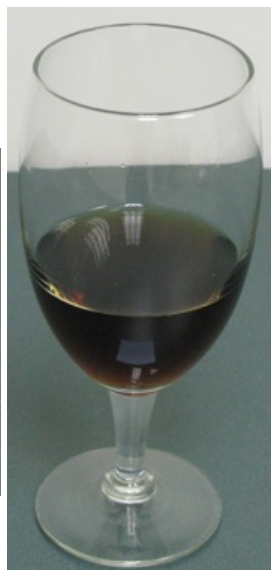
**1 teaspoon**



**1 tablespoon**



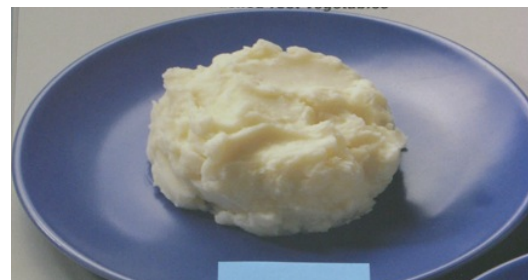
**8 ounces**



**Small glass**



**1 cup**



**1 cup**



**4 ounces**

### How Often You Eat or Drink This Item

	Never or less than 1 per month	1-3 per month	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	More than 5 per day	I don't know	I prefer not to answer
<b>FD1.</b> Skim/low fat milk (8 oz. glass)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD2.</b> Whole milk (8 oz. glass)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD3.</b> Ice cream (1 cup)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD4.</b> Yogurt (1 cup)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD5.</b> Cottage or ricotta cheese (1/2 cup)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD6.</b> Butter, added to food or bread (1 pat), exclude use in cooking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD7.</b> Fruit (not including fruit juice. A serving = 1 piece, or 1/2 grapefruit, or 1/2 cup berries)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD8.</b> 100% fruit juice, not including fruit drinks (small glass)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### How Often You Eat or Drink This Item

	Never or less than 1 per month	1-3 per month	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	More than 5 per day	I don't know	I prefer not to answer
<b>FD9.</b> Vegetables - raw and cooked (1/2 cup), including mixed dishes such as soups, casseroles and lasagna. Do not include potatoes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD10.</b> Eggs (do not include egg beaters) (1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD11.</b> Chicken or turkey (4-6 oz.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD12.</b> Processed meat (1 piece sausage, 1 slice salami, 2 pieces bacon)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD13.</b> Hot dog/ hamburger	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### How Often You Eat or Drink This Item

	Never or less than 1 per month	1-3 per month	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	More than 5 per day	I don't know	I prefer not to answer
<b>FD14.</b> Beef, pork, or lamb as a sandwich or mixed dish, e.g. stew, casserole, lasagna, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD15.</b> Beef, pork, or lamb as a main dish, e.g. steak, roast, ham, etc. (4-6 oz.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD16.</b> Fish (including canned tuna) (3-5 oz.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD17.</b> Shellfish such as shrimp, lobster, scallops and clams as a main dish	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD18.</b> White bread (including pita bread) (slice)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD19.</b> Dark bread (incl. whole wheat and rye) (slice)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD20.</b> Bakery items (cookies, brownies, doughnuts, cake) (1 piece or slice)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD21.</b> Nuts (small packet, 1 oz., 1 Tbs peanut butter)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD22.</b> Pasta (e.g. spaghetti, and macaroni and cheese; 1 cup cooked)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD23.</b> Potatoes, baked, boiled or mashed (do not include French fries/chips) (1 potato or 1 cup)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



### How Often You Eat or Drink This Item

	Never or less than 1 per month	1-3 per month	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	More than 5 per day	I don't know	I prefer not to answer
<b>FD24.</b> Regular soft drinks (including caffeine free, but NOT including diet colas) (consider the serving size as 1 glass, bottle or can)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>FD25.</b> Coffee (regular or decaf) (1 cup)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Eating Practices (EP)**

	Definitely True	Mostly True	Mostly False	Definitely False
1. I deliberately take small helpings to control my weight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I start to eat when I feel anxious.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Sometimes when I start eating, I just can't seem to stop.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. When I feel sad, I often eat too much.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I don't eat some foods because they make me fat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Being with someone who is eating, often makes me want to also eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. When I feel tense or "wound up", I often feel I need to eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I often get so hungry that my stomach feels like a bottomless pit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I'm always so hungry that it's hard for me to stop eating before finishing all of the food on my plate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. When I feel lonely, I console myself by eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I consciously hold back on how much I eat at meals to keep from gaining weight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating even if I've just finished a meal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I'm always hungry enough to eat at any time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. If I feel nervous, I try to calm down by eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. When I see something that looks very delicious, I often get so hungry that I have to eat right away.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. When I feel depressed, I want to eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Seldom	Usually	Almost Always
17. How often do you avoid 'stocking up' on tempting foods?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Unlikely	A little likely	Somewhat likely	Very likely
18. How likely are you to make an effort to eat less than you want?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Rarely	Sometimes	At least once a week
19. Do you go on eating binges even though you're not hungry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Only at mealtimes	Sometimes between meals	Often between meals	Almost always
20. How often do you feel hungry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	1	2	3	4	5	6	7	8
21. On a scale from 1 to 8, where 1 means no restraint in eating and 8 means total restraint, what number would you give yourself? Mark the number that best applies to you:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Alcohol Consumption (AC)**

A drink of alcohol is defined as 1 can or bottle of beer, 1 glass of wine, 1 can or bottle of wine cooler, 1 cocktail, or 1 shot of liquor.

AC1. During the past 30 days, how many days per week or per month did you have at least 1 drink of any alcoholic beverage? [if none, **STOP**]

---

AC2. On the days when you drank, about how many drinks did you drink on average?

---

AC3. **Men:** Considering all types of alcoholic beverages, how many times during the past 30 days did you have 5 or more drinks on an occasion?

**Women:** Considering all types of alcoholic beverages, how many times during the past 30 days did you have 4 or more drinks on an occasion?

---

## **Smoking (SM)**

SM1. Have you smoked at least 100 cigarettes in your entire life?

- ☐ Yes
- ☐ No
- ☐ Don't know
- ☐ Prefer not to answer

SM2. Did you ever become a daily smoker (that is, smoke every day or nearly every day for two months or longer)?

- ☐ Yes
- ☐ No → *skip to SM6*
- ☐ Don't know
- ☐ Prefer not to answer

SM3. How old were you when you last smoked daily?

Age \_\_\_\_\_ (in years)

- ☐ Don't know
- ☐ Prefer not to answer
- ☐ Still smoking daily

SM4. Do you smoke cigarettes now?

- ☐ Yes
- ☐ No → *skip to next section*
- ☐ Don't know
- ☐ Prefer not to answer

SM4a. How many cigarettes per day do you smoke? (One pack equals 20 cigarettes)

Number of cigarettes \_\_\_\_\_

- ☐ Don't know
- ☐ Prefer not to answer

## **Medications (ME)**

ME1. Do you take any prescription medications or over-the-counter drugs?

- ☐ No → *skip to end of survey*  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

What is the name of the first prescription medication or over-the-counter drug that you take?

ME2a. ☐ Label product name: \_\_\_\_\_

☐ Label generic name: \_\_\_\_\_

☐ Don't know ☐ Prefer not to answer

ME2b. What is the dosage form?

### Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

### Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

### Inhaled

- ☐ Inhaler or nebulizer

### Injected

- ☐ Injection

### Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

### Other:

- ☐ Don't know  
☐ Prefer not to answer

ME2c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME2d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME2d1. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ % ☐ \_\_\_\_\_ mg

- ☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME2e. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME2f. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME2g. ***Interviewer comments:***

ME2h. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → ***skip end of survey***  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME83a. ☐ Label product name:

- ☐ Label generic name: \_\_\_\_\_  
☐ Don't know ☐ Prefer not to answer

ME3b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME3c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME3d. What is the strength? (***Record strength of how it is actually taken, not how it is prescribed.***)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME3d1. Total dosage ***per day.*** (***Record strength of how it is actually taken, not how it is prescribed.***)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME3e. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME3f. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME3g. ***Interviewer comments:***

\_\_\_\_\_

ME3h. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → ***skip to end of survey***  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

- ME4a. ☐ Label product name: \_\_\_\_\_  
☐ Label generic name: \_\_\_\_\_  
☐ Don't know ☐ Prefer not to answer



ME4b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule
- ☐ Sublingual or orally-disintegrating tablet
- ☐ Liquid solution or suspension (drink, syrup)
- ☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know
- ☐ Prefer not to answer

ME4c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

- ☐ Don't know
- ☐ Prefer not to answer

ME4d. What is the strength? (***Record strength of how it is actually taken, not how it is prescribed.***)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME4d1. Total dosage **per day**. (***Record strength of how it is actually taken, not how it is prescribed.***)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME4e. Do you take it regularly or only as needed?

- ☐ Regularly
- ☐ Only as needed

- ☐ Don't know
- ☐ Prefer not to answer

ME4f. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks
- ☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years
- ☐ Don't know
- ☐ Prefer not to answer

ME4g. **Interviewer comments:**

---

ME4h. Do you take any other prescription medications or over-the-counter drugs?

☐ No → *skip to next section*

☐ Don't know

☐ Yes

☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME5a. ☐ Label product name:

---

☐ Label generic name: \_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME5b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME5c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

☐ \_\_\_\_\_ times per month

☐ Don't know

☐ Prefer not to answer

ME5d. What is the strength? (***Record strength of how it is actually taken, not how it is prescribed.***)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME5d1. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- |                                      |  |
|--------------------------------------|--|
| <input type="checkbox"/> _____ %     | <input type="checkbox"/> _____ I.U.              |
| <input type="checkbox"/> _____ mg    | <input type="checkbox"/> _____ Other unit: _____ |
| <input type="checkbox"/> _____ mcg   | <input type="checkbox"/> Don't know              |
| <input type="checkbox"/> _____ grams | <input type="checkbox"/> Prefer not to answer    |

ME5e. Do you take it regularly or only as needed?

- |   |   |
|---|---|
| <input type="checkbox"/> Regularly      | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Only as needed | <input type="checkbox"/> Prefer not to answer |

ME5f. For how long have you been taking it?

- |   |   |
|---|---|
| <input type="checkbox"/> For _____ days   | <input type="checkbox"/> For _____ years      |
| <input type="checkbox"/> For _____ weeks  | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> For _____ months | <input type="checkbox"/> Prefer not to answer |

ME5g. ***Interviewer comments:***

ME5h. Do you take any other prescription medications or over-the-counter drugs?

- |   |   |
|---|---|
| <input type="checkbox"/> No → <b><i>skip to end of survey</i></b> | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Yes                                      | <input type="checkbox"/> Prefer not to answer |

What is the name of the next prescription medication or over-the-counter drug that you take?

ME6a. ☐ Label product name:

☐ Label generic name: \_\_\_\_\_

- |                                     |   |
|-------------------------------------|---|
| <input type="checkbox"/> Don't know | <input type="checkbox"/> Prefer not to answer |
|-------------------------------------|---|

ME6b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule
- ☐ Sublingual or orally-disintegrating tablet
- ☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)

- ☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

ME6c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

- ☐ Don't know  
☐ Prefer not to answer

ME6d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME6d1. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME6e. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME6f. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME6g. *Interviewer comments:*

ME6h. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → *skip to next section*  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME7a. ☐ Label product name:

\_\_\_\_\_

☐ Label generic name: \_\_\_\_\_

- ☐ Don't know ☐ Prefer not to answer

ME7b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME7c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME7d. What is the strength? (***Record strength of how it is actually taken, not how it is prescribed.***)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME7d1. Total dosage **per day.** (***Record strength of how it is actually taken, not how it is prescribed.***)

- ☐ \_\_\_\_\_ % ☐ \_\_\_\_\_ mg

- ☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME7e. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME7f. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME7g. ***Interviewer comments:***

---

ME7h. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → ***skip to end of survey***  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME8a. ☐ Label product name:

---

☐ Label generic name: \_\_\_\_\_

- ☐ Don't know      ☐ Prefer not to answer

ME8b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Topical

Inhaled

☐ Inhaler or nebulizer

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Injected

☐ Injection

Other:

☐ Don't know

☐ Prefer not to answer

Suppository

ME8c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

☐ \_\_\_\_\_ times per month

☐ Don't know

☐ Prefer not to answer

ME8d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME8d1. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME8e. Do you take it regularly or only as needed?

☐ Regularly

☐ Only as needed

☐ Don't know

☐ Prefer not to answer

ME8f. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME8g. **Interviewer comments:**

---

ME8h. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → *skip to next section*  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME9a. ☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

- ☐ Don't know      ☐ Prefer not to answer

ME9b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME9c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME9d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME9d1. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg

- ☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams



☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

☐ Don't know  
☐ Prefer not to answer

ME9e. Do you take it regularly or only as needed?

☐ Regularly  
☐ Only as needed

☐ Don't know  
☐ Prefer not to answer

ME9f. For how long have you been taking it?

☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME9g. ***Interviewer comments:***

---

ME9h. Do you take any other prescription medications or over-the-counter drugs?

☐ No → ***skip to next section***  
☐ Yes

☐ Don't know  
☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME10a. ☐ Label product name: \_\_\_\_\_

☐ Label generic name: \_\_\_\_\_

☐ Don't know      ☐ Prefer not to answer

ME10b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Topical

☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME10c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME10d. What is the strength? (***Record strength of how it is actually taken, not how it is prescribed.***)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME10d1. Total dosage **per day**. (***Record strength of how it is actually taken, not how it is prescribed.***)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME10e. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME10f. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME10g. ***Interviewer comments:***

ME10h. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → ***skip to end of survey***  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME11a. ☐ Label product name: \_\_\_\_\_

☐ Label generic name: \_\_\_\_\_

☐ Don't know ☐ Prefer not to answer

ME11b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME11c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME11d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME11d1. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME11e. Do you take it regularly or only as needed?

☐ Regularly

☐ Only as needed

☐ Don't know

☐ Prefer not to answer

ME11f. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME11g. ***Interviewer comments:***

---

ME11h. Do you take any other prescription medications or over-the-counter drugs?

☐ No → ***skip to end of survey***

☐ Yes

☐ Don't know

☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME12a. ☐ Label product name: \_\_\_\_\_

☐ Label generic name: \_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME12b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME12c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME12d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME12d1. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME12e. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME12f. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME12g. *Interviewer comments:*

ME12h. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → *skip to end of survey*  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME13a. ☐ Label product name: \_\_\_\_\_

☐ Label generic name: \_\_\_\_\_

- ☐ Don't know      ☐ Prefer not to answer

ME13b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule
- ☐ Sublingual or orally-disintegrating tablet
- ☐ Liquid solution or suspension (drink, syrup)
- ☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know
- ☐ Prefer not to answer

ME13c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

- ☐ Don't know
- ☐ Prefer not to answer

ME13d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME13d1. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME13e. Do you take it regularly or only as needed?

- ☐ Regularly
- ☐ Only as needed

- ☐ Don't know
- ☐ Prefer not to answer

ME13f. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days

- ☐ For \_\_\_\_\_ weeks

- ☐ For \_\_\_\_\_ months  
☐ For \_\_\_\_\_ years

- ☐ Don't know  
☐ Prefer not to answer

ME13g. **Interviewer comments:**

---

ME13h. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to next section**  
☐ Yes
- ☐ Don't know  
☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME14a. ☐ Label product name: \_\_\_\_\_

☐ Label generic name: \_\_\_\_\_

- ☐ Don't know ☐ Prefer not to answer

ME14b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME14c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME14d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ % ☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ mg ☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

☐ Don't know  
☐ Prefer not to answer

ME14d1. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME14e. Do you take it regularly or only as needed?

☐ Regularly  
☐ Only as needed

☐ Don't know  
☐ Prefer not to answer

ME14f. For how long have you been taking it?

☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME14g. **Interviewer comments:**

ME14h. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of survey**  
☐ Yes

☐ Don't know  
☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME15a. ☐ Label product name: \_\_\_\_\_

☐ Label generic name: \_\_\_\_\_

☐ Don't know ☐ Prefer not to answer

ME15b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Topical



Inhaled

☐ Inhaler or nebulizer

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Injected

☐ Injection

Other:

☐ Don't know

☐ Prefer not to answer

Suppository

ME15c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

☐ \_\_\_\_\_ times per month

☐ Don't know

☐ Prefer not to answer

ME15d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME15d1. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME15e. Do you take it regularly or only as needed?

☐ Regularly

☐ Only as needed

☐ Don't know

☐ Prefer not to answer

ME15f. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME15g. **Interviewer comments:**

---

ME15h. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → *skip to next section*  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

What is the name of the next prescription medication or over-the-counter drug that you take?

ME16a. ☐ Label product name: \_\_\_\_\_

☐ Label generic name: \_\_\_\_\_

- ☐ Don't know      ☐ Prefer not to answer

ME16b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME16c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME16d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

- ☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME16d1. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg

- ☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

☐ Don't know  
☐ Prefer not to answer

ME16e. Do you take it regularly or only as needed?

☐ Regularly  
☐ Only as needed

☐ Don't know  
☐ Prefer not to answer

ME16f. For how long have you been taking it?

☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months  
☐ For \_\_\_\_\_ years

☐ Don't know  
☐ Prefer not to answer

ME16g. **Interviewer comments:** \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

## **Self-Control**

Using the scale provided, please indicate how much each of the following statements reflects how you typically are.

	Not at all	A little	Somewhat	Fair Amount	Very much
1. I am good at resisting temptation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I have a hard time breaking bad habits.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I am lazy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I say inappropriate things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I do certain things that are bad for me, if they are fun.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I refuse things that are bad for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I wish I had more self-discipline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. People would say that I have iron self-discipline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Pleasure and fun sometimes keep me from getting work done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I have trouble concentrating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I am able to work effectively toward long-term goals.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Sometimes I can't stop myself from doing something, even if I know it is wrong.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I often act without thinking through all the alternatives.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Sense of Control**

The next few statements are about certain ways you may feel about your life. Please indicate how strongly you agree or disagree with each of the following statements: Strongly agree; Agree; Neutral, Disagree, or Strongly disagree

	<b>Strongly agree</b>	<b>Agree</b>	<b>Neutral</b>	<b>Disagree</b>	<b>Strongly disagree</b>	<b>Don't know</b>	<b>Prefer not to answer</b>
<b>SE1.</b> I have little control over the things that happen to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE2.</b> There is really no way I can solve some of the problems I have.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE3.</b> There is little I can do to change many of the important things in my life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE4.</b> I often feel helpless in dealing with the problems of life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE5.</b> Sometimes I feel that I am being pushed around in life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE6.</b> What happens to me in the future mostly depends on me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE7.</b> I can do just about anything I really set my mind to do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Self-Compassion

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

0	1	2	3	4
Almost never				Almost always

- \_\_\_\_\_ 1. When I fail at something important to me I become consumed by feelings of inadequacy.
- \_\_\_\_\_ 2. I try to be understanding and patient towards those aspects of my personality I don't like.
- \_\_\_\_\_ 3. When something painful happens I try to take a balanced view of the situation.
- \_\_\_\_\_ 4. When I'm feeling down, I tend to feel like most other people are probably happier than I am.
- \_\_\_\_\_ 5. I try to see my failings as part of the human condition.
- \_\_\_\_\_ 6. When I'm going through a very hard time, I give myself the caring and tenderness I need.
- \_\_\_\_\_ 7. When something upsets me I try to keep my emotions in balance.
- \_\_\_\_\_ 8. When I fail at something that's important to me, I tend to feel alone in my failure
- \_\_\_\_\_ 9. When I'm feeling down I tend to obsess and fixate on everything that's wrong.
- \_\_\_\_\_ 10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.
- \_\_\_\_\_ 11. I'm disapproving and judgmental about my own flaws and inadequacies.
- \_\_\_\_\_ 12. I'm intolerant and impatient towards those aspects of my personality I don't like.

## **CES-D Depression Inventory**

For each statement, please place a mark in the column that best describes how you have been feeling *in the past week*.

	Rarely or none of the time (less than 1 day)	Some or a little of the time (1 – 2 days)	Occasionally or a moderate amount of the time (3 – 4 days)	Most or all of the time (5 – 7 days)
C1. I was bothered by things that usually don't bother me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C2. I did not feel like eating; my appetite was poor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C3. I felt that I could not shake off the blues, even with the help from family or friends.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C4. I felt that I was just as good as other people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C5. I had trouble keeping my mind on what I was doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C6. I felt depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C7. I felt that everything I did was an effort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C8. I felt hopeful about the future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C9. I thought my life had been a failure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C10. I felt fearful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C11. My sleep was restless.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C12. I was happy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C13. I talked less than usual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C14. I felt lonely.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Rarely or none of the time (less than 1 day)	Some or a little of the time (1 – 2 days)	Occasionally or a moderate amount of the time (3 – 4 days)	Most or all of the time (5 – 7 days)
C15. People were unfriendly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C16. I enjoyed life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C17. I had crying spells.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C18. I felt sad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C19. I felt that people dislike me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C20. I could not get “going”.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



## **Perceived Stress Scale**

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling how often you felt or thought a certain way.

	Never	Almost Never	Sometimes	Fairly Often	Often
P1. In the last month, how often have you been upset because of something that happened unexpectedly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P2. In the last month, how often have you felt that you were unable to control the important things in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P3. In the last month, how often have you felt nervous and “stressed”?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P4. In the last month, how often have you felt confident about your ability to handle your personal problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P5. In the last month, how often have you felt that things were going your way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P6. In the last month, how often have you found that you could not cope with all the things that you had to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P7. In the last month, how often have you been able to control irritations in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P8. In the last month, how often have you felt that you were on top of things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P9. In the last month, how often have you been angered because of things that were outside of your control?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Mindfulness**

Instructions: Below is a collection of statements about your everyday experience. Using the scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what really reflects your experience rather than what you think your experience should be. Please treat each item separately from every other item.

***Please indicate the degree to which you agree with each of the following items using the scale below. Simply check your response to each item***

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never	I do not know	I prefer not to answer
Y5. I could be experiencing some emotion and not be conscious of it until some time later.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y6. I break or spill things because of carelessness, not paying attention, or thinking of something else.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y7. I find it difficult to stay focused on what's happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y8. I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y9. I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never	I do not know	I prefer not to answer
Y10. It seems I am “running on automatic” without much awareness of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y11. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y12. I get so focused on the goal I want to achieve that I lose touch with what I am doing right now to get there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y13. I do jobs or tasks automatically, without being aware of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y14. I find myself listening to someone with one ear, doing something else at the same time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y15. I drive places on “automatic pilot” and then wonder why I went there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y16. I find myself preoccupied with the future or the past.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y17. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never	I do not know	I prefer not to answer
Y18. I snack without being aware that I'm eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes *your own opinion* of what is *generally true for you*.

	Never	Almost Never	Sometimes	Fairly Often	Often
F1. When I'm walking, I deliberately notice the sensations of my body moving.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F2. I'm good at finding words to describe my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F3. I criticize myself for having irrational or inappropriate emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F4. I perceive my feelings and emotions without having to react to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F5. When I do things, my mind wanders off and I'm easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F6. When I take a shower or bath, I stay alert to the sensations of water on my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F7. I can easily put my beliefs, opinions, and expectations into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F8. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F9. I watch my feelings without getting lost in them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F10. I tell myself I shouldn't be feeling the way I'm feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F12. It's hard for me to find the words to describe what I'm thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Almost Never	Sometimes	Fairly Often	Often
F13. I am easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F15. I pay attention to sensations, such as the wind in my hair or sun on my face.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F16. I have trouble thinking of the right words to express how I feel about things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F17. I make judgments about whether my thoughts are good or bad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F18. I find it difficult to stay focused on what's happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F21. In difficult situations, I can pause without immediately reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F23. It seems I am "running on automatic" without much aware- ness of what I'm doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F24. When I have distressing thoughts or images, I feel calm soon after.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F25. I tell myself that I shouldn't be thinking the way I'm thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Almost Never	Sometimes	Fairly Often	Often
F26. I notice the smells and aromas of things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F27. Even when I'm feeling terribly upset, I can find a way to put it into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F28. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F29. When I have distressing thoughts or images, I am able just to notice them without reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F32. My natural tendency is to put my experiences into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F33. When I have distressing thoughts or images, I just notice them and let them go.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F34. I do jobs or tasks automatically without being aware of what I'm doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F35. When I have distressing thoughts or images, I judge myself as good or bad depending what the thought or image is about.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F36. I pay attention to how my emotions affect my thoughts and behavior.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F37. I can usually describe how I feel at the moment in considerable detail.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Almost Never	Someti mes	Fairly Often	Often
F38. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
F39. I disapprove of myself when I have irrational ideas.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



### This Week's Experiences

**Instructions:** Below is a collection of statements about how you find yourself reacting to unpleasant thoughts and feelings. Using the scale below, please indicate how frequently or infrequently you experienced each of the following reactions this week. **Please answer according to what *really reflects your experience this week* rather than what you think your experience should be.**

**This week, when I encountered an unpleasant thought or feeling,**

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always
1. I tried to think pleasant thoughts instead	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I allowed myself to experience it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I got angry or upset at myself for having the thought/emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I felt the desire to make it better or make it go away	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I wished I didn't feel or think that way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I tried to let my thoughts just come and go without getting too entangled with them	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I thought the mood would never change	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I explored the body sensations that accompanied the emotion.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I named the emotion over and over as long as it lasted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I turned to work or other activities to take my mind off things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I named the emotion and then redirected my attention to the present moment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I thought "This mood, too, shall pass"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always
13. I focused on my breathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I took an active interest in how the experience changed over time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I explored my reactions to the thought or emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I thought "my thinking is being distorted by my mood"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Think "Why do I have problems that other people don't have?"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. I forgave myself for having the thought/emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. I challenged the thought's validity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. I asked myself questions about the experience in order to explore it better	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. I tried not to change it because I believe it is important to experience	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. I labelled my thoughts "images" or verbal "talk"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. I thought "Why do I always react this way?"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. I adopted a welcoming stance toward the emotion/thought	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. I went somewhere alone to think about my feelings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. I sent out compassion to all people who struggle with this emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. I restrained myself from doing anything too quickly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always
28. I became genuinely curious about the thought/emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. I laughed or kidded myself about the situation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. I treated the repetitive thought like a "top ten radio tune" that's playing in the background	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. I talked to others about how I was feeling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. I tried to forget about it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. I thought "Why can't I handle things better"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. I tried to come up with a way to make it go away	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. I said to myself "thinking" or "this is just a thought"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. I thought about how much I disliked feeling that way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. I reminded myself thoughts are not accurate reflections of reality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. I thought that that I must be headed into a downward spiral	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. I thought "What I am doing to deserve this?"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



## Emotion Regulation

Please indicate how often the following statements apply to you by checking the box that best describes your experience.

	Almost Never (0-10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)
1. I am clear about my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I pay attention to how I feel.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I experience my emotions as overwhelming and out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I have no idea how I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I have difficulty making sense out of my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I am attentive to my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I know exactly how I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I care about what I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I am confused about how I feel.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. When I'm upset, I acknowledge my emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. When I'm upset, I become angry with myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. When I'm upset, I become embarrassed for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. When I'm upset, I have difficulty getting work done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. When I'm upset, I become out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. When I'm upset, I believe that I will remain that way for a long time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. When I'm upset, I believe that I will end up feeling very depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. When I'm upset, I believe that my feelings are valid and important.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. When I'm upset, I have difficulty focusing on other things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. When I'm upset, I feel out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. When I'm upset, I can still get things done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. When I'm upset, I feel ashamed at myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. When I'm upset, I know that I can find a way to eventually feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never (0-10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)
23. When I'm upset, I feel like I am weak.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. When I'm upset, I feel like I can remain in control of my behaviours.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. When I'm upset, I feel guilty for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. When I'm upset, I have difficulty concentrating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. When I'm upset, I have difficulty controlling my behaviours.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. When I'm upset, I believe there is nothing I can do to make myself feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. When I'm upset, I become irritated at myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. When I'm upset, I start to feel very bad about myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. When I'm upset, I believe that wallowing in it is all I can do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. When I'm upset, I lose control over my behaviour.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. When I'm upset, I have difficulty thinking about anything else.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. When I'm upset I take time to figure out what I'm really feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. When I'm upset, it takes me a long time to feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. When I'm upset, my emotions feel overwhelming.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Beck Anxiety Inventory**

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past month, including today, by circling the number in the corresponding space in the column next to each symptom.

	Not At All	Mildly – it didn't bother me much	Moderately – it wasn't pleasant at all times	Severely – it bothered me a lot
Numbness or tingling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feeling hot	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Wobbliness in legs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unable to relax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fear of worst happening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dizzy or lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heart pounding/racing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Terrified or afraid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nervous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feeling of choking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hands trembling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Shaky/unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fear of losing control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficulty in breathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fear of dying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Scared	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Indigestion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Faint/lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Face flushed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hot/cold sweats	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Parent's Education**

1. Please check the box beside the highest grade or degree that your BIOLOGICAL MOTHER completed.

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I don't know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

2. Please check the box beside the highest grade or degree that your BIOLOGICAL FATHER completed.

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I don't know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>



Now please think of the two most important adults in your home between the time you were born and age 18 years. Please check the category below that best described their level of education during this time period.

3. First adult's highest level of education:

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I don't know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

4. Second adult's highest level of education

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I don't know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

## **Your Childhood Experiences**

The following questions ask about some difficult experiences that you might have had as a child. These questions may be emotionally difficult to answer. Just as a reminder, you do not need answer any questions that you would prefer not to. Your answers to these questions, as with all questions, will remain confidential.

C1. Before you were 18 years old, did a parent or other adult in the household often or very often...

Swear at you, insult you, put you down, or humiliate you?

or

Act in a way that made you afraid that you might be physically hurt?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

C2. Before you were 18 years old, did a parent or other adult in the household often or very often...

Push, grab, slap, or throw something at you?

or

Ever hit you so hard that you had marks or were injured?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

C3. Before you were 18 years old, did an adult or person at least 5 years older than you ever...

Touch or fondle you or have you touch their body in a sexual way?

or

Attempt or actually have oral, anal, or vaginal intercourse with you?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

C4. Before you were 18 years old, did you often or very often feel that ...

No one in your family loved you or thought you were important or special?

or

Your family didn't look out for each other, feel close to each other, or support each other?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

C5. Before you were 18 years old, did you often or very often feel that ...

You didn't have enough to eat, had to wear dirty clothes, and had no one to protect you?

or

Your parents were too drunk or high to take care of you or take you to the doctor if you needed it?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

C6. Before you were 18 years old, was a biological parent ever lost to you through divorce, abandonment, or other reason?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

C7. Before you were 18 years old, was your mother or stepmother:

Often or very often pushed, grabbed, slapped, or had something thrown at her?

or

Sometimes, often, or very often kicked, bitten, hit with a fist, or hit with something hard?

or

Ever repeatedly hit over at least a few minutes or threatened with a gun or knife?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

C8. Before you were 18 years old, did you live with anyone who was a problem drinker or alcoholic, or who used street drugs?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

C9. Before you were 18 years old, was a household member depressed or mentally ill, or did a household member attempt suicide?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

C10. Before you were 18 years old, did a household member go to prison?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

## About You

Y1. How many close friends do you have? By close friends, we mean people that you feel at ease with, and that you can talk to about private matters.

☐ None → *skip to Y2*

\_\_\_\_\_ Number of close friends

☐ I do not know

☐ I prefer not to answer

Y1a. How many of these close friends do you see at least once a month?

\_\_\_\_\_ Number of close friends (*if none, write zero*)

☐ I do not know

☐ I prefer not to answer

Y2. Thinking about your relatives, how many relatives do you feel at ease with, and feel that you can talk to about private matters?

☐ None → *skip to Y3*

\_\_\_\_\_ Number of relatives

☐ I do not know

☐ I prefer not to answer

Y2a. How many of these relatives do you see at least once a month?

\_\_\_\_\_ Number of relatives (*if none, write zero*)

☐ I do not know

☐ I prefer not to answer

Y3. About how often do you participate in groups or clubs, such as religious connected groups, self-help groups, charities, or a public service or community group.

- ☐ Never or almost never
- ☐ A few times a year
- ☐ Once or twice a month
- ☐ Once a week
- ☐ More than once a week
- ☐ I do not know
- ☐ I prefer not to answer

Y4. About how often do you go to religious meetings or services?

- ☐ Never or almost never
- ☐ A few times a year
- ☐ Once or twice a month
- ☐ Once a week
- ☐ More than once a week
- ☐ I do not know
- ☐ I prefer not to answer

## **Loneliness**

INSTRUCTIONS: Indicate how often each of the statements below is descriptive of you.

Statement	Never	Rarely	Sometimes	Often
1. I feel in tune with the people around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I lack companionship	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. There is no one I can turn to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I do not feel alone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I feel part of a group of friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I have a lot in common with the people around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I am no longer close to anyone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. My interests and ideas are not shared by those around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I am an outgoing person	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. There are people I feel close to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I feel left out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. My social relationships are superficial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. No one really knows me well	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I feel isolated from others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I can find companionship when I want it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. There are people who really understand me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. I am unhappy being so withdrawn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. People are around me but not with me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. There are people I can talk to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. There are people I can turn to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Your Sleep**

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. ***Please answer all questions.***

S1. **During the past month**, what time have you usually gone to bed at night?

BED TIME \_\_\_\_\_ AM / PM

- ☐ I do not know
- ☐ I prefer not to answer

S2. **During the past month**, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES \_\_\_\_\_

- ☐ I do not know
- ☐ I prefer not to answer

S3. During the past month, at what time have you usually gotten up in the morning?

GETTING UP TIME \_\_\_\_\_ AM / PM

- ☐ I do not know
- ☐ I prefer not to answer

S4. During the past month, how many hours of actual sleep did you get on average at night?  
(This may be different than the number of hours you spent in bed.)

AVERAGE HOURS OF SLEEP PER NIGHT \_\_\_\_\_

- ☐ I do not know
- ☐ I prefer not to answer



***For each of the remaining questions, check the one best response. Please answer all questions.***

**During the past month**, how often have you had trouble sleeping because you.....

S5. ....Could not get to sleep within 30 minutes?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S6. ....Woke up in the middle of the night or early morning?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S7. ....Had to get up to use the bathroom?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S8. ....Could not breathe comfortably?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S9. ....Coughed or snored loudly?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S10. ....Felt too cold?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S11. ....Felt too hot?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S12. ....Had bad dreams?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S13. ....Had pain?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S14. Other reason(s), **please describe:** \_\_\_\_\_

S14a. How often during the past month have you had trouble sleeping because of this?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S15. **During the past month**, how would you rate your sleep quality overall?

- ☐ Very good
- ☐ Fairly good
- ☐ Fairly bad
- ☐ Very bad
- ☐ I do not know
- ☐ I prefer not to answer

S17. **During the past month**, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S18. **During the past month**, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

S19. **During the past month**, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

- ☐ No problem at all
- ☐ Somewhat of a problem
- ☐ A very big problem
- ☐ I do not know
- ☐ I prefer not to answer

S20. Do you have a bed partner or a room-mate in the same room ?

- ☐ No bed partner or roommate in the same room → *skip to next survey section:*
- ☐ Partner in same bed
- ☐ Room-mate in the same room
- ☐ I do not know
- ☐ I prefer not to answer

If you have a roommate or bed partner, ask him/her how often in the past month you have had .....

S21. ....Loud snoring

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

S22. ....Long pauses between breaths while asleep

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

S23. ....Legs twitching or jerking while you sleep

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

S24. ....Episodes of disorientation or confusion during sleep

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

S25. ....Other restlessness while you sleep; *please describe:*

- 
- S25a.        ☐ Not during the past month
- ☐ Less than once a week
  - ☐ Once or twice a week
  - ☐ Three or more times a week
  - ☐ Unable to ask him/her
  - ☐ he/she does not know
  - ☐ he/she prefers not to answer

## FOCUS GROUP TOPICS

## **Focus Group Topics**

- How is your experience of the class length? Does it seem about right, or would you prefer it longer or shorter? – e.g. length of each class (2.5 hours vs. 1 hour), 9 week duration
- Which modules did you find worked the best for you?
- Are there topics or modules you think would help improve the course?
- Are there areas we should expand?
- Are there areas we should reduce?
- Describe different modules, and ask how well they worked, specifically what they liked, didn't like, and recommendations for what to change and what to keep the same.
  - Hypertension education in the orientation session
  - Class 2: Highly palatable snack practice
  - Class 2: Home practice related to pleasant events calendar on eating and alcohol consumption
  - Class 3: Exploration of physical activity including discussion in class, and home practice of performing physical activity.
  - Class 4: 15 min physical activity module followed by discussion .
  - Class 4: Motivational interviewing module related to diet, alcohol consumption and physical activity
  - Class 4-7: Home practice related to goal for diet, alcohol consumption, physical activity or diet.
  - Class 5: Exploring relationship with medication adherence
  - Class 6: Social support module
  - All-Day: Silent exercise module
  - Booster sessions



# QUESTIONNAIRES ANSWERED BY PARTICIPANTS AT 9 WEEKS, 3 MONTHS AND 6 MONTHS FOLLOW-UP

Questionnaires administered at 9 weeks, 3 months and 6 months follow-up are identical to those administered at baseline, with the exception that questionnaires for which the answers should not change or be informative (i.e. introductory questions, age, race/ethnicity, education, childhood experiences) are not given at follow-ups.

**MINDFULNESS-BASED  
HYPERTENSION THERAPY PILOT STUDY**

**IRB APPLICATION**

**January 5th, 2015**

Eric B. Loucks, PhD  
Assistant Professor  
Department of Epidemiology  
Brown University School of Public Health  
121 South Main St., Box G-S121  
Providence, RI, 02912  
Phone: 401-863-6283  
Email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu)

## COVER LETTER

Thank you for the helpful feedback. Below is an itemized response to the Board's recommendations.

The Board requested the following:

1. **Please ensure the study documents are consistent throughout the entire protocol submission. The Board noted that the protocol, recruitment material, consent document, surveys, and focus group documents contained conflicting information, did not match each other, and referenced sections and procedures that were not included in other documents in the submission.**

**RESPONSE:** Thank you, we apologize for the inconsistencies. Documents should now be consistent throughout.

2. **Please provide further description of the recruitment and consenting processes. The Board noted that the protocol contained too few details about these parts of the study.**

**RESPONSE:** Please see increased information below.

**APPLICATION CHANGE** (pg. 15):

Participants will be recruited through cardiology and family practices via established relationships with physicians at Rhode Island Hospital (e.g. Sam Dudley, MD), Memorial Hospital of Rhode Island (e.g. Charles Eaton, MD), Providence VA Medical Center (e.g. Hank Wu, MD), amongst others. IRB approval will be obtained by hospitals requiring it, such as Rhode Island Hospital and the Providence VA Medical Center. Typically, invitation letters (example text shown in Section F) will be sent to 96 eligible patients in each collaborative hospital. Patient eligibility will be based on medical records of blood pressure and gender. Participants will be recruited in equal numbers based on hypertension status (i.e. pre-hypertensive, controlled hypertensive, and uncontrolled hypertensive), with equal proportions being male and female when possible. This approach will provide important recruitment and participation rate data for future studies. Furthermore, advertisements will be posted throughout Rhode Island inviting participants with pre-hypertension or hypertension to enroll (example advertisement shown in Section F).

3. **Please clarify how many participants you intend to enroll in the study. The Board was unsure if you would enroll the first 60 participants, or if you intend to screen a much higher number of potential participants to enroll a total of 60 people. The Board also questioned how the 60 participants would be stratified across the three prehypertension/hypertension categories described in the protocol.**

**RESPONSE:** This has now been clarified. Please see change below.

**APPLICATION CHANGE** (pg. 15):

For Aims 1-3, we anticipate n=60 participants with equal proportions of males and females, and stratified across prehypertension/hypertension categories, including (1) pre-hypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. This will allow for early indications of potential differential effects of MBHT by gender and prehypertension/hypertension status. Likely substantially greater than 60 participants will need to be recruited for screening, of which a proportion will be eligible based on criteria below and strata requirements above. We expect approximately 120

participants required to be screened for 60 participants to be included in the study. This study will provide more accurate information on recruitment rates, which will inform future randomized controlled trials if the study shows initial evidence of effectiveness. For Aim 4, pilot data from Aim 2 will provide needed effect sizes and statistical variance for power calculations. However, current power calculations were based on SBP and DBP changes in the Mindfulness-Based Stress Reduction RCT performed by Hughes *et al.*<sup>1</sup> Specifically, Hughes *et al.* showed, with mean baseline SBP of 129.5 (6.3 SD) mmHg and DBP of 77.8 (5.5 SD) mmHg, at 8 weeks follow-up a net reduction of 4.2 mmHg SBP and 3.1 mmHg DBP for MBSR vs. active control group.<sup>1</sup> For a sample size of 35 participants per group, power analyses show 80% and 90% power to detect differences of 4.3 and 4.9 mmHg SBP, respectively. This suggests adequate power for main effects analyses. At this time, Aim 4 anticipates 70 participants in the study (35 per treatment arm), of which we expect approximately 140 participants will need to be screened.

**4. Please further clarify when, where, and how participants will be asked to complete the screening and baseline surveys.**

**RESPONSE:** This information has now been clarified in Part 3.7.5 of Section C, as well as changes throughout Section G.

**APPLICATION CHANGES:**

*Pg. 17:*

Interviewer training includes high standards for selection of interviewers who are at ease with strangers, are culturally-sensitive and able to readily establish professional rapport. Interviewers will be thoroughly trained in the administration of the structured interview, anthropometry, and blood pressure assessments. Routine quality control procedures will be in place regarding calibration of scales and blood pressure instruments. Clinical exams will be supervised by Dr. Loucks to at least monthly to evaluate accuracy of technique, particularly for anthropometry and blood pressure assessment. Re-training will be implemented if needed. Data will be entered and cleaned in an ongoing matter to facilitate quality control and preliminary analyses.

*Pp. 18-19:*

**3.7.5 Timing and Locations of Assessments**

*Phone-Based Screening:* For people who indicate interest in the study, this screening will take place by phone using trained research assistants to assess the following exclusion criteria (see Section G for questions): (a) current regular meditation practice (>once/week); (b) serious medical illness precluding regular class attendance; (c) current substance abuse, suicidal ideation or eating disorder, (d) history of bipolar or psychotic disorders or self-injurious behaviors. These participants are excluded because they may disrupt group participation, require additional or specialized treatment, or are already participating in practices similar to the intervention.

*In-Person Screening:* If participants remain eligible after the phone-based screening, they will attend an in-person screening for blood pressure and medication assessment. If mean blood pressure shows hypertension/prehypertension ( $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure or taking antihypertensive medication), participants will be invited to return for a second blood pressure reading. At that time, if the mean blood pressure across both assessment times is  $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure, or the participants is taking antihypertensive medication, they will be invited to participant in the study.

*Baseline Assessments Completed at Home:* Questions about demographics, health behaviors, self control, depressive symptomatology, anxiety symptoms, mindfulness, sleep, childhood experiences,

amongst others will be assessed via internet-based Survey Monkey or via paper-based forms. Please see Section G for the questionnaires.

*Follow-Up Assessments at 8 Weeks and 3 Months Follow-Up:* Identical assessments will take place at 8 weeks and 3 months follow-up, as done with the screening and baseline assessments described above.

*Focus Groups:* Focus group assessments of participants will take place following the final week of class. Descriptions of focus group topics are in Section G.

5. **Please clarify whether the data collected from the screening survey will be destroyed after eligibility is determined, since participants will not go through a consent process before completing this survey.**

**RESPONSE:** Data for these participants will be destroyed.

**APPLICATION CHANGES** (pg. 18):

*Phone-Based Screening:* For people who indicate interest in the study, this screening will take place by phone using trained research assistants to assess the following exclusion criteria (see Section G for questions): (a) current regular meditation practice (>once/week); (b) serious medical illness precluding regular class attendance; (c) current substance abuse, suicidal ideation or eating disorder, (d) history of bipolar or psychotic disorders or self-injurious behaviors. These participants are excluded because they may disrupt group participation, require additional or specialized treatment, or are already participating in practices similar to the intervention. For participants excluded from the study at this stage, data will be destroyed, as participants will not have gone through a consent process prior to completing this survey.

*In-Person Screening:* If participants remain eligible after the phone-based screening, they will attend an in-person screening for blood pressure and medication assessment. If mean blood pressure shows hypertension/prehypertension ( $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure or taking antihypertensive medication), participants will be invited to return for a second blood pressure reading. At that time, if the mean blood pressure across both assessment times is  $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure, or the participants is taking antihypertensive medication, they will be invited to participate in the study. For participants excluded from the study at this stage, data will be destroyed, as participants will not have gone through a consent process prior to completing this survey.

6. **Please ensure the "Confidentiality of Data" section of the protocol is consistent, and specify how the digital data will be protected.**

**RESPONSE:** The sections should now be consistent. Please see pg. 16 for the protection of digital data.

7. **Please describe your and your undergraduate students' training and qualifications related to conducting the psychological assessments of the phone screen survey.**

**RESPONSE:**

I am a social epidemiologist studying psychosocial determinants of health. I received training at the University of Massachusetts Medical School on baseline assessment of participants prior to undergoing Mindfulness-Based Stress Reduction. Similar questions are asked and discussed with

participants at the University of Massachusetts Mindfulness-Based Stress Reduction intervention as is proposed in the study at Brown University. Furthermore, I will work closely with co-investigator and psychologist Dr. Willoughby Britton, who has screening questions identical or similar to these assessed in her Brown University Mindfulness-Based Cognitive Therapy study entitled: "Dismantling Mindfulness: Contributions of attention vs. acceptance" (#1105000399)." She will be available for questions that arise in the context of this survey. Student interviewer training includes high standards for selection of interviewers who are at ease with strangers, are culturally-sensitive and able to readily establish professional rapport. Interviewers will be thoroughly trained in the administration of the structured interview, including the screening questionnaire. A Safety Plan has been developed, which will provide structure in cases of participants indicating mental distress, particularly related to suicidal ideation.

**APPLICATION CHANGE** (*pp. 31-33*):

Please see Safety Plan.

- 8. Please confirm that the "MBHT Phone Screen" face page will not be attached or connected to the phone script or screening data collected.**

**RESPONSE:** This face page will not be attached or connected to the phone script or screening data collected.

- 9. Please identify how data collected from Survey Monkey during the baseline survey will be linked to participants, and how participant e-mail addresses will not be linked with their data.**

**RESPONSE:** For online questionnaires, participants will be provided with a weblink to the survey. Upon going to the weblink, they will enter the survey. First, participants will be asked to enter their study ID #. There will be no opportunities for participants to enter their names, personal addresses or email addresses into the SurveyMonkey data collection forms. Data will then be downloaded and stored within the secure VMScluster at the Brown University Center for Population Health and Clinical Epidemiology. If participants prefer, they will be provided with a paper copy of the questionnaire that can be filled out. Study staff will then manually enter the responses, and the data will be stored on the VMScluster.

- 10. The Board was unsure if the computer is the most effective data collection method for the types of questions in the baseline survey (for example, the lengthy "Medications" section). Please provide a rationale for why this survey should be completed by computer.**

**RESPONSE:** Thank you for pointing this out. The medications will be assessed in-person during the first screening assessment, as blood pressure medication use is one of the screening criteria. Medications will also be assessed during the in-person assessments at 9 weeks and 3 months follow-up. Please see Part 3.7.5 in Section C, as well as Section G, for more details.

- 11. To the baseline survey, please add a disclaimer informing participants that their answers will not be seen immediately, and include psychological and health resources for participant use.**

**RESPONSE:** Thank you, please see the changes below.

**APPLICATION CHANGES** (pg. 77 of questionnaire document in Section H):

Thank you for completing this survey!

Please note that these responses will not be seen immediately. Resources are shown below if you feel that you would like to talk with someone immediately for assistance.

National Suicide Prevention Lifeline: 1-800-273-8255

National Sexual Assault Hotline: 1-800-656-4673

Other options are to:

- Call your doctor's office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

- 12. Please include a more complete safety plan and describe the role of the licensed clinician on the study, as the protocol does not provide sufficient detail of what will be required of them and exactly when they will be contacted during study procedures. Please note that the clinician must be licensed in Rhode Island and have the expertise in behavioral health necessary to address any potential risks that could arise during the course of the study.**

**RESPONSE:** Thank you, a safety plan has been added. We are currently in discussions with clinicians licensed in Rhode Island. Dr. Ellen Flynn, MD, is a Brown professor and RI licensed psychiatrist who has expressed interest in being the licensed clinician for this study. She is currently performing a similar role for collaborator Dr. Willoughby Britton's Brown IRB approved protocol entitled "entitled: "Dismantling Mindfulness: Contributions of attention vs. acceptance" (#1105000399)." We will be meeting in early January 2015 to discuss further. This study will not be initiated until an IRB-approved clinician has been confirmed.

**APPLICATION CHANGE** (*pp. 31-33*):

Please see Safety Plan.

- 13. The Board noted that participants may give answers to particular questions in the screening and baseline surveys that, when looked at individually or in combination with other answers, could indicate potential risk. The Board requested that you review each measure used to determine psychological state and identify the specific questions and responses that may trigger a call to the licensed clinician.**

**RESPONSE:** Thank you. This has now been added to the Safety Plan.

**APPLICATION CHANGE** (*pp. 31-33*):

Please see Safety Plan.

- 14. To the "Advertisement Card" and "Recruitment Letter," please add the restriction that participants cannot be regular meditators.**

**RESPONSE:** This has been done.

**APPLICATION CHANGE** (pg. 29):

This is a 9-week program that includes mindfulness meditation, mindful movements, and education about risk factors for blood pressure. The study is testing whether combining these interventions lowers blood pressure. The program consists of nine weekly sessions that are 2.5 hours (depending on study arm), and an all-day weekend retreat. People who have a current regular meditation practice (i.e. meditate more than once per week) are not eligible.

**The Board requested the following revisions to the consent process:**

- 1. Please add a procedure table for both the "high dose" and "low dose" groups, detailing the different procedures for each group, the amount of time per procedure, and the total time of involvement for each group.**

**RESPONSE:** The high vs. low dose aspect of the protocol has been removed for scientific reasons. A stronger study design is now being employed.

- 2. In the "Explanation of Procedures" section (#8), please clarify the request for participants to notify you if they change their medication.**

**RESPONSE:** We have removed reference to assessing medication use in this section, as medication use will be assessed in person at 8 weeks and 3 months follow-up.

- 3. In the "Explanation of Procedures" section (#9), please clarify the "second packet of questionnaires" participants will be asked to complete, what these questionnaires will ask, and where participants will be asked to complete them.**

**RESPONSE:** We have changed the wording as shown below.

#### **APPLICATION CHANGES:**

*Pp. 18-19:*

##### **3.7.5. Timing and Locations of Assessments**

*Phone-Based Screening:* For people who indicate interest in the study, this screening will take place by phone using trained research assistants to assess the following exclusion criteria (see Section G for questions): (a) current regular meditation practice (>once/week); (b) serious medical illness precluding regular class attendance; (c) current substance abuse, suicidal ideation or eating disorder, (d) history of bipolar or psychotic disorders or self-injurious behaviors. These participants are excluded because they may disrupt group participation, require additional or specialized treatment, or are already participating in practices similar to the intervention. For participants excluded from the study at this stage, data will be destroyed, as participants will not have gone through a consent process prior to completing this survey.

*In-Person Screening:* If participants remain eligible after the phone-based screening, they will attend an in-person screening for blood pressure and medication assessment. If mean blood pressure shows hypertension/prehypertension ( $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure or taking antihypertensive medication), participants will be invited to return for a second blood pressure reading. At that time, if the mean blood pressure across both assessment times is  $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure, or the participants is taking antihypertensive medication, they will be invited to participant in the study. For participants excluded from the study at this stage, data will be



destroyed, as participants will not have gone through a consent process prior to completing this survey.

*Baseline Assessments Completed at Home:* Questions about demographics, health behaviors, self control, depressive symptomatology, anxiety symptoms, mindfulness, sleep, childhood experiences, amongst others will be assessed via internet-based Survey Monkey or via paper-based forms. Please see Section G for the questionnaires.

*Follow-Up Assessments at 8 Weeks and 3 Months Follow-Up:* Identical assessments will take place at 8 weeks and 3 months follow-up, as done with the screening and baseline assessments described above, with the exception that questionnaires for which the answers should not change or be informative (i.e. introductory questions, age, race/ethnicity, education, childhood experiences) are not given at follow-ups.

*Focus Groups:* Focus group assessments of participants will take place following the final week of class. Descriptions of focus group topics are in Section G.

4. **Please revise the "Benefits" section by removing "c," as participants will not gain knowledge about scientific methods in research.**

**RESPONSE:** This has been done.

5. **In the "Refusal/Withdrawal" section, please add that participants' refusal to enroll or decision to withdraw from the study will also not affect their relationship with their physician.**

**RESPONSE:** This has been completed.

**APPLICATION CHANGE** (pg. 26):

#### Refusal/Withdrawal

Participation is voluntary, and you may decide to opt out or refuse any part of participation, including not answering certain questions. If you decide now to participate, you can change your mind later and quit the study. The decision to not participate or to withdraw from the study will not adversely affect current or future interactions with Brown University. The decision to not participate or to withdraw from the study will also not adversely affect your relationship with your physician.

If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

**Section A:**  
**Lay-Person Summary of Proposed Project**

The World Health Organization reported that suboptimal blood pressure (BP) is responsible for more than half of cardiovascular disease mortality world-wide. Furthermore, greater than half of those with hypertension have uncontrolled BP. A 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.” Evidence-based mindfulness interventions, including Mindfulness-Based Stress Reduction, may have some effects on blood pressure, where a recent meta-analysis and systematic review of 4 randomized controlled trials demonstrated significant effects, but evidence of heterogeneity in effect sizes. The methodologically highest quality studies had the smallest effect sizes (range 0-5 mmHg). Mindfulness-Based Stress Reduction (MBSR) has been customized to a number of disease processes, such as Mindfulness-Based Cognitive Therapy for patients with recurrent depression, and Mindfulness-Based Relapse Prevention for patients with substance use addictions. Effect sizes have been increased by customizing mindfulness interventions to diseases of interest. The same may be true for hypertension, however mindfulness interventions customized for prehypertensive/hypertensive patients have never been investigated. Until methodologically rigorous studies to evaluate customized interventions for hypertension are performed, we will not know if the observed preliminary effects of general mindfulness interventions on blood pressure reduction could be much more effective with a tailored approach. Consequently, we propose to conduct a stage I behavioral therapy intervention study to evaluate whether MBSR customized to prehypertensive and hypertensive patients has the potential to provide clinically relevant reductions in BP. Consequently the specific aims are:

#### *Stage 1a: Therapy Development/Manual Writing*

- 1 To outline and evaluate key novel elements of mindfulness-based hypertension therapy (MBHT), customized from the evidence-based MBSR. *We hypothesize that the most important novel element will be generation of mindfulness skills specifically applied to hypertension risk factors such as diet, physical activity, obesity, alcohol consumption and antihypertensive medication adherence.* This aim will be achieved using (1) focus groups of participants undergoing the MBHT behavioral intervention, (2) discussion with experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) prior to, and following pilot testing of MBHT in participants, and (3) clinical judgment of the investigators performing the intervention.
- 2 To determine effectiveness of MBHT on primary outcomes (systolic blood pressure, retention rates, recruitment rates, and adverse effects) and secondary outcomes (hypertension risk factors such as diet, physical activity, obesity, and antihypertensive medication adherence) in hypertension subgroups, specifically participants with (1) prehypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. Initial decisions about the targeted sample based on hypertension status will be made.
- 3 To develop an MBHT therapist manual and training program, including procedures for training, supervising, and evaluating therapists. Furthermore, acceptable therapist characteristics will be developed. The manual and training program will include themes such as specification of unique and common elements of MBHT vs. other interventions, description of interventions excluded from MBHT, and specification of key treatment parameters such as frequency and duration of treatment, session length, topics addressed, sequence of sessions, as well as therapist adherence and competency measures. The MBHT training will consist of a therapist manual, a formal didactic training seminar, and at least one closely supervised training session.

#### *Stage 1b: Pilot Trial*

- 4 To determine whether a mindfulness-based hypertension therapy (MBHT) intervention, customized from the evidence-based MBSR, has promise to be an effective behavioral therapy for participants with hypertension and/or prehypertension. We will perform a randomized controlled pilot trial for MBHT vs. enhanced usual care control. *We hypothesize that MBHT will have adequate recruitment rates ( $\geq 10\%$  of prehypertensive/hypertensive participants invited from physicians' offices), fairly low*

*drop out rates (<15%), and medium effect sizes (e.g. 5-10 mmHg systolic BP) for reduction in blood pressure.*

These findings will provide publishable pilot data that will inform future randomized clinical trials that evaluate effects of MBHT on long-term changes in blood pressure vs. usual care and active control groups. *If proven effective, MBHT could be offered as a complementary program in the prehypertensive/hypertensive patient population that contributes to over half of the cardiovascular disease mortality world-wide.*

**Section B:**

**Application for Funding**

**An Application for the Brown internal Richard B. Salomon Faculty Research Award has been made.**

**These data will provide preliminary findings for an NIH R34 application that is planned to be submitted.**

**Section C:**  
**Specific Aims and Methodology**

# 1 Significance and Innovation

The World Health Organization reported that suboptimal BP is responsible for over half of cardiovascular disease mortality world-wide.<sup>2,3</sup> Furthermore, of those with hypertension, more than half have uncontrolled BP.<sup>4,5</sup> This is despite widespread knowledge of hypertension risk factors and treatments including diet, obesity, physical activity, medication adherence and excessive alcohol consumption.<sup>6,7</sup> Mindfulness interventions appear to improve self-regulation, self-care, and the ability to not respond to cravings for hypertension risk factors such as high caloric palatable foods and sedentary activities (and resulting obesity).<sup>8-12</sup> In fact, a 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.”<sup>13</sup> Evidence-based mindfulness interventions including Mindfulness-Based Stress Reduction (MBSR) may have some effects, where a recent meta-analysis and systematic review of 4 randomized controlled trials (RCTs) demonstrated significant effects, but evidence of heterogeneity in effect sizes.<sup>14</sup> The methodologically highest quality studies had the smallest effect sizes. MBSR has been customized to a number of disease processes, such as recurrent depression, smoking and substance use addiction with resulting increases in effect sizes compared to general mindfulness-based interventions that do not take the disease process of interest into consideration.<sup>11,15,16</sup> The same may be true for hypertension, however this has not yet been studied.

Until methodologically rigorous studies to evaluate customized mindfulness-based interventions for hypertension are performed, we will not know if the observed preliminary effects of mindfulness-based interventions on BP could have much greater effect with a tailored approach. Consequently, we propose to conduct a stage I behavioral therapy intervention study to provide the most rigorous evaluation to date on whether MBSR customized to prehypertensive and hypertensive patients provides clinically relevant reductions in BP. These findings will provide publishable pilot data that will inform future randomized clinical trials that evaluate effects of MBHT on long-term changes in blood pressure vs. usual care and active control groups. If proven effective, MBHT could be offered as a complementary program in the prehypertensive/hypertensive patient population that contributes to over half of the cardiovascular disease mortality world-wide.

# 2 Specific Aims

## Stage 1a: Therapy Development/Manual Writing

- 1 To outline and evaluate key novel elements of mindfulness-based hypertension therapy (MBHT), customized from the evidence-based MBSR. *We hypothesize that the most important novel element will be generation of mindfulness skills specifically applied to hypertension risk factors such as diet, physical activity, obesity, alcohol consumption and antihypertensive medication adherence.* This aim will be achieved using (1) focus groups of participants undergoing the MBHT behavioral intervention, (2) discussion with experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) prior to, and following pilot testing of MBHT in participants, and (3) clinical judgment of the investigators performing the intervention.
- 2 To determine effectiveness of MBHT on primary outcomes (systolic blood pressure, retention rates, recruitment rates, and adverse effects) and secondary outcomes (hypertension risk factors such as diet, physical activity, obesity, and antihypertensive medication adherence) in hypertension subgroups, specifically participants with (1) prehypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. Initial decisions about the targeted sample based on hypertension status will be made.
- 3 To develop an MBHT therapist manual and training program, including procedures for training, supervising, and evaluating therapists. Furthermore, acceptable therapist characteristics will be developed. The manual and training program will include themes such as specification of unique and common elements of MBHT vs. other interventions, description of interventions excluded from MBHT, and specification of key treatment parameters such as frequency and duration of treatment, session length, topics addressed, sequence of sessions, as well as therapist adherence and competency

measures. The MBHT training will consist of a therapist manual, a formal didactic training seminar, and at least one closely supervised training session.

#### *Stage Ib: Pilot Trial*

- 4 To determine whether a mindfulness-based hypertension therapy (MBHT) intervention, customized from the evidence-based MBSR, has promise to be an effective behavioral therapy for participants with hypertension and/or prehypertension. We will perform a randomized controlled pilot trial for MBHT vs. MBSR active control. *We hypothesize that MBHT will have adequate recruitment rates ( $\geq 10\%$  of prehypertensive/hypertensive participants invited from physicians' offices), fairly low drop out rates ( $< 15\%$ ), and medium effect sizes (e.g. 5 mmHg systolic BP) for reduction in blood pressure compared to MBSR.*

### **3 Approach**

#### **3.1 Study Population (Aim 2)**

Participants will be recruited through cardiology and family practices via established relationships with physicians at Rhode Island Hospital (e.g. Sam Dudley, MD), Memorial Hospital of Rhode Island (e.g. Charles Eaton, MD), Providence VA Medical Center (e.g. Hank Wu, MD), amongst others. IRB approval will be obtained by hospitals requiring it, such as Rhode Island Hospital and the Providence VA Medical Center. Typically, invitation letters (example text shown in Section F) will be sent to 96 eligible patients in each collaborative hospital. Patient eligibility will be based on medical records of blood pressure and gender. Participants will be recruited in equal numbers based on hypertension status (i.e. pre-hypertensive, controlled hypertensive, and uncontrolled hypertensive), with equal proportions being male and female when possible. This approach will provide important recruitment and participation rate data for future studies. Furthermore, advertisements will be posted throughout Rhode Island inviting participants with pre-hypertension or hypertension to enroll (example advertisement shown in Section F).

For Aims 1-3, we anticipate  $n=60$  participants with equal proportions of males and females, and stratified across prehypertension/hypertension categories, including (1) pre-hypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. This will allow for early indications of potential differential effects of MBHT by gender and prehypertension/hypertension status. Likely substantially greater than 60 participants will need to be recruited for screening, of which a proportion will be eligible based on criteria below and strata requirements above. We expect approximately 120 participants required to be screened for 60 participants to be included in the study. This study will provide more accurate information on recruitment rates, which will inform future randomized controlled trials if the study shows initial evidence of effectiveness. For Aim 4, pilot data from Aim 2 will provide needed effect sizes and statistical variance for power calculations. However, current power calculations were based on SBP and DBP changes in the Mindfulness-Based Stress Reduction RCT performed by Hughes *et al.*<sup>1</sup> Specifically, Hughes *et al.* showed, with mean baseline SBP of 129.5 (6.3 SD) mmHg and DBP of 77.8 (5.5 SD) mmHg, at 8 weeks follow-up a net reduction of 4.2 mmHg SBP and 3.1 mmHg DBP for MBSR vs. active control group.<sup>1</sup> For a sample size of 35 participants per group, power analyses show 80% and 90% power to detect differences of 4.3 and 4.9 mmHg SBP, respectively. This suggests adequate power for main effects analyses. At this time, Aim 4 anticipates 70 participants in the study (35 per treatment arm), of which we expect approximately 140 participants will need to be screened.

*Inclusion Criterion:* Hypertension/prehypertension ( $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure or taking antihypertensive medication). All genders and racial/ethnic groups are eligible to be included.

*Exclusion Criteria:* Exclusion criteria follow standard guidelines and recommendations:<sup>17</sup> (a) current regular meditation practice ( $> \text{once/week}$ ); (b) serious medical illness precluding regular class attendance; (c) current substance abuse, suicidal ideation or eating disorder, (d) history of bipolar or psychotic



disorders or self-injurious behaviors. These participants are excluded because they may disrupt group participation, require additional or specialized treatment, or are already participating in practices similar to the intervention.

### 3.2 Confidentiality of Data

The clinical data will be de-identified but linked. Private information such as name, date of birth, and address for recontacting will be kept in a password protected, encrypted database on a different disk than the clinical data. Only the principal investigator for the purposes of patient safety or monitoring by the NIH, data safety monitoring boards or HIPPA compliance officer approved agents will be given access to identifiable personal information.

Data which contains person-identifiers is considered highly sensitive. Such data is, by policy, only stored within the VMScLuster at the Brown University Center for Population Health and Clinical Epidemiology. Access is controlled by the VMS ACL mechanism, allowing read-only access to a small group of specific users and read-write access to an even smaller group. Internet access (e.g., via a Web server) is disallowed for such storage areas. Windows security controls are superseded by VMS controls, although Windows access is permitted since some data is acquired on Windows-specific media (e.g., CD-ROM). All uses of privileged necessary to grant/revoke access to any data, as well as any other security-relevant event data, is continuously logged and analyzed in the context of both the VMScLuster and the Windows Domain. Network access is tightly controlled to allow anonymous access only to a small amount of read-only data; all “risky protocols” are disallowed from Internet access. For any given study with person-identifying information, such data is stripped before the data is made accessible to staff not authorized to access such identifiers. In those cases where the data is longitudinal, a non-reversible encryption of the person ID is made in order to provide a unique person ID not traceable to the underlying person. The specific algorithm used for any given set of data is stored in the same fashion and given the same security as the data itself. To make data use simpler, hierarchical “trees” of directories are given consistent access controls tied to a unique identifier, which is then granted to staff authorized to use such data. Programming staff authorized to make individual-level data available to staff not authorized to access the person-identifying components routinely copy the “encrypted” versions from the more-secured tree to a less-secured tree. Security controls are thus relatively automatic, based on the propagation of rights based on the location of a file within the file system and the identity of the user attempting to access it.

For online questionnaires, participants will be provided with a weblink to the survey. Upon going to the weblink, they will enter the survey. First, participants will be asked to enter their study ID #. There will be no opportunities for participants to enter their names, personal addresses or email addresses into the SurveyMonkey data collection forms. Data will then be downloaded and stored within the secure VMScLuster at the Brown University Center for Population Health and Clinical Epidemiology. If participants prefer, they will be provided with a paper copy of the questionnaire that can be filled out. Study staff will then manually enter the responses, and the data will be stored on the VMScLuster.

### 3.3 MBHT Intervention Groups

*MBHT Intervention:* MBHT is based on the standardized MBSR intervention described elsewhere,<sup>18-21</sup> and will likely consist of nine 2.5-hour weekly group sessions and an 8-hour one-day session, led by Dr. Loucks. Dr. Loucks is an expert in cardiovascular physiology, cardiovascular epidemiology, and social epidemiology. He completed MBSR instructor training at UMass Medical School, and has 16 years of mindfulness meditation experience, including teaching and mentoring community members, as well as a recent publication record investigating associations of mindfulness with cardiovascular health.<sup>12,22,23</sup> The unique areas of MBHT are expected to be education on hypertension risk factors, hypertension health effects, and specific mindfulness modules focused on awareness of diet, physical activity, medication adherence, alcohol consumption, stress, and social support for behavior change. A preliminary manual has

been created based on the standardized MBSR manual developed at UMass Medical School, and will be further developed through the Delphi-like approach described above, and sequentially revised based on participant feedback and preliminary findings.<sup>20,21</sup> MBHT sessions contain instruction and practice in mindfulness meditation, and conversations about stress and coping. Students learn a range of mindfulness skills including body scan exercises, meditation and yoga. Homework consists of practicing skills for  $\geq 45$  min/day, 6 days/week. Booster sessions will be offered (likely 2.5-hour sessions every 2 months).

*MBSR Active Control Group:* MBSR will consist of nine 2.5-hour weekly group sessions and an 8-hour one-day session, led by Dr. Eric Loucks, who has completed MBSR instructor training at UMass Medical School.<sup>18,19</sup> MBSR sessions contain instruction and practice in mindfulness meditation, and conversations about stress and coping. Students learn a range of mindfulness skills including body scan exercises, meditation and yoga. Homework consists of practicing skills for  $\geq 45$  min/day, 6 days/week. Booster sessions will be offered (likely 2.5-hour sessions every 2 months).

### 3.4 Measures of Compliance

*Participant Adherence:* Data on treatment protocol adherence will be collected weekly by research staff.

*MBHT Instructor Competency and Treatment Fidelity:* Treatment fidelity strategies will be performed in accordance with recommendations of the NIH Behavior Change consortium.<sup>24</sup>

### 3.5 Blinding

All study staff, including those performing health assessments and contacting participants to schedule follow-up assessments, will be blinded to treatment allocation with the exception of the MBHT/MBSR instructor (Loucks) and data manager (who performs randomization).

### 3.6 Equipoise

This study will be designed to disrupt clinical equipoise, defined as “no consensus within the expert clinical community about the comparative merits of the alternative [trial arms] to be tested.”<sup>25</sup>

### 3.7 Assessments

We will follow study procedures similar to those performed during previous epidemiologic studies by our group. In-person screenings will take place at the Brown University Center for Population Health and Clinical Epidemiology, described in Sections 2.7.1 and 2.7.2 at baseline, completion of the 8-week MBHT course and at 3-months post-intervention. Major assessment variables are shown in **Table 1**. Qualitative interviews (focus groups) will evaluate participants’ experiences such as usefulness of specific modules, duration of sessions, time burden, and overall intervention effectiveness. Interviewer training includes high standards for selection of interviewers who are at ease with strangers, are culturally-sensitive and able to readily establish professional rapport. Interviewers will be thoroughly trained in the administration of the structured interview, anthropometry, and blood pressure assessments. Routine quality control procedures will be in

**Table 1.** Examples of variables proposed to be assessed during RCT.

Variables	Obtained During Study		
	Baseline	8 w	3 m
Race/ethnicity	✓		
Gender	✓		
Adverse childhood experiences	✓		
Socioeconomic status	✓	✓	✓
Depressive symptomatology	✓	✓	✓
Anxiety	✓	✓	✓
Perceived stress	✓	✓	✓
Self efficacy	✓	✓	✓
Mindfulness	✓	✓	✓
Blood pressure	✓	✓	
Smoking	✓	✓	✓
Diet	✓	✓	✓
Physical activity	✓	✓	✓
Alcohol consumption	✓	✓	✓
Body mass index	✓	✓	
Sleep quantity and quality	✓	✓	✓
Social support	✓	✓	✓
Loneliness	✓	✓	✓
Medication use and adherence	✓	✓	✓

m, months; w, weeks

place regarding calibration of scales and blood pressure instruments. Clinical exams will be supervised by Dr. Loucks to at least monthly to evaluate accuracy of technique, particularly for anthropometry and blood pressure assessment. Re-training will be implemented if needed. Data will be entered and cleaned in an ongoing matter to facilitate quality control and preliminary analyses.

### 3.7.1 Primary Outcomes

*Clinic BP Assessment:* Clinic-assessed systolic and diastolic BP remains the standard of care for monitoring hypertension treatment.<sup>4,6,7,26,27</sup> Baseline clinic BP will be determined at two in-person screening visits  $\geq 1$  week apart, completed according to American Heart Association guidelines,<sup>26</sup> followed by in-person assessments at all follow-up periods. BP will be assessed using a calibrated Omron HEM907XL Intellisense automated BP monitor with established validity.<sup>28</sup>

### 3.7.2 Potential Mediators

*Examples of mediators to be assessed include:* (1) *Body Mass Index:* height and weight directly assessed using standard epidemiologic methods. (2) *Physical activity:* MET minutes per week, assessed using actigraphy, which enables the <sup>117</sup>quantification of physical activity.<sup>29-33</sup> (3) *Diet:* diet assessed utilizing Dietary Approaches to Stop Hypertension (DASH) eating pattern score,<sup>34</sup> measured via diet history food frequency questionnaire.<sup>35</sup> (4) *Perceived stress:* measured using Perceived Stress Scale.<sup>36</sup> (5) *Antihypertensive Medication Use:* recorded by trained technicians from medications brought in by participants at baseline assessment.

### 3.7.3 Potential Effect Modifiers

We propose to evaluate 2 potentially important effect modifiers: (1) gender, (2) prehypertension/hypertension category.

### 3.7.4 Qualitative Assessments

Following completion of the MBHT intervention, participants will be asked to participate in a focus group discussion outlined in **Box 1**, shown below. The goal of the focus groups will be to adapt MBHT to the unique needs of this population. Adaptions may include, for example, types of specific mindfulness exercises, sequence in which they are introduced, and relative emphasis on hypertension education vs. mindfulness practice components.

### 3.7.5 Timing and Locations of Assessments

*Phone-Based Screening:* For people who indicate interest in the study, this screening will take place by phone using trained research assistants to assess the following exclusion criteria (see Section G for questions): (a) current regular meditation practice ( $> \text{once/week}$ ); (b) serious medical illness precluding regular class attendance; (c) current substance abuse, suicidal ideation or eating disorder, (d) history of bipolar or psychotic disorders or self-injurious behaviors. These participants are excluded because they may disrupt group participation, require additional or specialized treatment, or are already participating in practices similar to the intervention. For participants excluded from the study at this stage, data will be destroyed, as participants will not have gone through a consent process prior to completing this survey.

*In-Person Screening:* If participants remain eligible after the phone-based screening, they will attend an in-person screening for blood pressure and medication assessment. If mean blood pressure shows hypertension/prehypertension ( $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure or taking antihypertensive medication), participants will be invited to return for a second blood pressure reading. At that time, if the mean blood pressure across both assessment times is  $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure, or the participants is taking antihypertensive medication, they will be invited to participant in the study. For participants excluded from the study at this stage, data will be destroyed, as participants will not have gone through a consent process prior to completing this survey.

*Baseline Assessments Completed at Home:* Questions about demographics, health behaviors, self control, depressive symptomatology, anxiety symptoms, mindfulness, sleep, childhood experiences,

amongst others will be assessed via internet-based Survey Monkey or via paper-based forms. Please see Section G for the questionnaires.

Follow-Up Assessments at 8 Weeks and 3 Months Follow-Up: Identical assessments will take place at 8 weeks and 3 months follow-up, as done with the screening and baseline assessments described above, with the exception that questionnaires for which the answers should not change or be informative (i.e. introductory questions, age, race/ethnicity, education, childhood experiences) are not given at follow-ups.

Focus Groups: Focus group assessments of participants will take place following the final week of class. Descriptions of focus group topics are in Section G.

### 3.8 Intervention Allocation

Stratified randomization will be used.<sup>37,38</sup> Variables used to create strata include gender (male vs. female), race/ethnicity (white vs. non-white), and prehypertension/hypertension status (pre-hypertension, controlled hypertension, uncontrolled hypertension). Simple random sampling will occur within each strata.

### 3.9 Data Analysis

Qualitative analyses will evaluate participant experiences such as usefulness of specific modules, duration of sessions, time burden, and overall intervention effectiveness. Quantitative analyses will incorporate generalized linear models (GLM) with properly chosen link functions, performed using generalized estimating equations (GEE) with robust standard error estimators.<sup>39,40</sup> We will test effects of high vs. low dose MBHT on clinic-assessed systolic and diastolic BP. Following “intention-to-treat” principles, analyses will be conducted on all participants randomized to high vs. low dose, regardless of intervention completion. To test whether effects of MBHT on BP may be effect modified by variables described in Section 2.7.3 we will add product terms between MBHT and each potential effect modifier to models described above. Formal statistical significance tests of product terms will be performed. Analyses are considered statistically underpowered, but will provide effect size estimates and statistical variances for NIH grant applications to support studies with larger sample sizes.

#### Box 1. Focus Group Topics

- How is your experience of the class length? Does it seem about right, or would you prefer it longer or shorter? – e.g. length of each class, 8 week duration
- Which modules did you find worked the best for you?
- Are there topics or modules you think would help improve the course?
- Are there areas we should expand?
- Are there areas we should reduce?
- Describe different modules, and ask how well they worked, specifically what they liked, didn’t like, and recommendations for what to change and what to keep the same.
  - Hypertension education in the orientation session
  - Class 2: Highly palatable snack practice
  - Class 2: Home practice related to pleasant events calendar on eating and alcohol consumption
  - Class 3: Exploration of physical activity including discussion in class, and home practice of performing physical activity.
  - Class 4: 15 min physical activity module followed by discussion .
  - Class 4: Motivational interviewing module related to diet, alcohol consumption and physical activity
  - Class 4-7: Home practice related to goal for diet, alcohol consumption, physical activity or diet.
  - Class 5: Exploring relationship with medication adherence
  - Class 6: Social support module
  - All-Day: Silent exercise module
  - Booster sessions

**Section D:**  
**Possible Risks to Participants**

The following is a statement from NCCAM about the potential risks of meditation practice: “Meditation is considered to be safe for healthy people. There have been rare reports that meditation could cause or worsen symptoms in people who have certain psychiatric problems, but this question has not been fully researched. People with physical limitations may not be able to participate in certain meditative practices involving physical movement. Individuals with existing mental or physical health conditions should speak with their health care providers prior to starting a meditative practice and make their meditation instructor aware of their condition.”<sup>41</sup>

*Discomfort during meditation:* Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable emotions with increased attention to them. In order to minimize risk, instructors encourage participants to be aware of their discomfort and to set their own limitations. Participants are encouraged to alter their postures, including standing, sitting in chairs, lying down, as needed in order to be comfortable. In addition, the curriculum of the training program is specifically geared towards addressing such discomfort.

*Psychological distress:* Research subjects participating in this study may have feelings of loss of privacy from being contacted about participating in the study, and possible psychological distress caused by questions on the diagnostic interview that bring up painful memories or feelings. However, the resulting potential for injury to research subjects is judged to be minimal. We have already contacted and clinically evaluated thousands of participants from the New England Family using similar assessment procedures to this study, with good responses from the participants. With regard to psychological distress from taking part in the MBHT intervention, given that screening questions will exclude participants with substantial mental illness, and given the NCAAM statement above that “Meditation is considered to be safe for healthy people.”,<sup>41</sup> we expect that risk of psychological distress will be low. The risk of increased psychological distress from meditation will be clearly outlined in the consent form and participants will be encouraged to consult with both the course instructor and study staff in the case of any increased distress. One of the co-investigators (Dr. Britton) is a clinical psychologist. She will be available to advise on any psychological events that occur, and provide referrals for treatment if needed.

*Loss of confidentiality:* Likelihood: rare. Minimization: Confidentiality will be maintained by numerically coding all data, by disguising identifying information, and by keeping all hard copies data in locked file drawers. All information obtained from participants will be accessible only to research staff. The clinical data will be de-identified but linked. For electronic data, private information such as name, date of birth, and address for recontacting will be kept in a password protected, encrypted database on a different disk than the clinical data. Only the principal investigator for the purposes of patient safety or monitoring by the NIH, data safety monitoring boards or HIPPA compliance officer approved agents will be given access to identifiable personal information.

*Potential Benefits of the Proposed Research to Human Subjects and Others:* There may be no direct benefits from participating in this study. The potential benefits of participating in the proposed study include improved knowledge on stress reduction techniques and risk for hypertension. Each participant will also be contributing to an important study which will answer questions on whether mindfulness-based stress reduction may influence health.

**Section E:**  
**Informed Consent**

Each potential participant will be fully informed about the nature of the study, its risks and benefits, and about his/her rights as a research subject. The person performing the consent will be either Dr. Loucks or a trained undergraduate trained research assistant. The participant will sign and receive a copy of the document stating that he/she has given his/her informed consent to participate before interviewing is begun. In every instance, project personnel will verbally review the content of the consent form before participants sign.



## **Agreement to Participate in a Research Study**

### ***Investigation of the effects of mindfulness meditation on blood pressure and well-being***

You are being asked to take part in a Brown University research study about the effects of mindfulness and hypertension education on blood pressure and risk factors for hypertension. This form will explain the purpose of the study, how the study will be carried out and what you will be expected to do. It will also explain the possible risks and possible benefits of being in the study. If any part of the following description is not clear to you, you are encouraged to contact the researcher to answer any questions before you decide whether to take part in the study. If you decide to participate, please fill out and sign the last page of this form.

#### **1a. Nature and Purpose of the Study**

The purpose of the study is to investigate the impact of mindfulness practices and health education on blood pressure. You have been selected for this study because you expressed interest and met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program. In order to assess the effects of these practices, you will be asked to complete some questionnaires, and a laboratory assessment before and after learning the mindfulness practices.

#### **1b. Explanation of Procedures**

If you agree to participate, you will be asked to consent to the following:

- 1) Participate in an interview in which you will be asked questions about past and present mental health, including depression and suicide.
- 2) Complete questionnaires about a wide range of topics, including your diet, physical activity, smoking, medication use, personality, emotions, attention and past experiences, including stressful or traumatic experiences. These questions will probe sensitive psychological areas, including physical, emotion and sexual abuse. These questionnaires may take up to 2 hours to complete. By completing the interviews and questionnaires, you are giving the researchers permission to use the information you have provided. You have the right not to answer any of the questions.
- 3) Directly assessed blood pressure, height, weight, waist circumference and hip circumference.
- 4) You will be asked to perform some cognitive tasks. One of these tasks may involve computer-based tests of attention or decision-making. Together these tests may take as long as 45 minutes.
- 5) You will be randomly assigned (like the flip of a coin) to enter one of two 8-week meditation programs.
- 6) You will participate in the 8-week meditation program, which consists of 9 sessions of 2.5 hours each and will include one 8 hour weekend retreat. Daily homework assignments may take as long as one hour and consist of practicing mindfulness exercises with the aid of a guided audio CD and completing worksheets related to stress, thoughts, and common reactions to various types of events.

- 7) Class sessions will be audio taped so we can analyze the quality of the treatment you receive. The recordings will be transcribed so that we may analyze the text. The recordings will be identified by study number, will only be heard by study staff and will be destroyed after transcription.
- 8) You will be asked to complete a few short questionnaires each week during the 8 week condition.
- 9) After 8 weeks, you will be asked to complete questionnaires and return to the laboratory to repeat the same procedures for a second day of testing.
- 10) Three months after the end of the 8 week condition, you will be asked to return to the laboratory to repeat the same testing procedures.

#### Feedback:

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing % change (increase or decrease) on scales of attention, stress, mood, health behaviors and blood pressure across the study.

#### 2. Discomforts and Risks

The questionnaires are routine, standardized forms for epidemiologic research. Certain questions may be upsetting as they may probe sensitive psychological areas and inquire about upsetting or traumatic events, including physical, sexual or emotional abuse and/or current psychiatric symptoms. Since your participation is voluntary, you have the right to skip any questions that make you uncomfortable.

Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable feelings with increased attention to them.

#### 3. Benefits

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) receiving information about your psychological and physical functioning.

#### 4. Alternative Therapies

A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

#### 5. Confidentiality

Your responses for this study will be kept confidential. All data that we collect will be linked to a study ID# instead of your name. All questionnaires in this study will be filled out through an online survey website (SurveyMonkey) or a paper version of the survey if you prefer. All of these questionnaires will be linked solely to your study ID#, so that your identity is protected and your answers are confidential. Although these measures have been taken to protect your personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet.

While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then

a collaborator [provide name] who is a licensed psychiatrist, may contact you to discuss your responses and possible referral to a treatment provider. Questionnaire items that may warrant follow-up include endorsements of statements about hurting yourself, any high scores in depression, anxiety, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires researchers to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a unique code number and initials. All study records and specimens will be stored in a secure storage area.

*Keeping study records:* The Principal Investigator for this study will keep your research records indefinitely for research purposes.

#### 6. Refusal/Withdrawal

Participation is voluntary, and you may decide to opt out or refuse any part of participation, including not answering certain questions. If you decide now to participate, you can change your mind later and quit the study. The decision to not participate or to withdraw from the study will not adversely affect current or future interactions with Brown University. The decision to not participate or to withdraw from the study will also not adversely affect your relationship with your physician.

If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

#### 7. Contact Information

If you have questions about study procedures at any time you may contact the researchers: Dr. Eric B. Loucks, email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu), telephone (401) 863-6283. If you would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Brown University Research Protections Office, telephone number 1-866-309-2095 or 401-863-3050.

**CONSENT FORM:**  
**Please sign and return.**

Please read the following agreement and sign to consent to participating.

**I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY.**

\_\_\_\_\_  
**PRINT NAME**

\_\_\_\_\_  
**Signature of participant**

\_\_\_\_\_  
**Date**

**CONTACT INFORMATION**

**Name (print):** \_\_\_\_\_


**Permanent Address:** \_\_\_\_\_

**Email(s):** \_\_\_\_\_

**Telephone:** \_\_\_\_\_ **(cell)** \_\_\_\_\_ **(other)** \_\_\_\_\_


**Section F:**  
**Recruiting Materials**

### Front of Advertisement Card:



Brown University  
School of Public Health  
Department of Epidemiology

**RESEARCH STUDY:  
Mindfulness-Based Intervention for  
Blood Pressure Reduction**



**Free to qualified participants**

### Back of Advertisement Card:

This is a 8-week program that includes mindfulness meditation, mindful movements, and education about risk factors for blood pressure. The study is testing whether combining these interventions lowers blood pressure. The program consists of nine weekly sessions that are 2.5 hours (depending on study arm), and an all-day weekend retreat. People who have a current regular meditation practice (i.e. meditate more than once per week) are not eligible.

Research participation includes interviews, questionnaires and measurements of blood pressure, height, weight, and waist circumference, before and after the meditation program.

Contact: For more information, or to see if you qualify, call the Brown Sociobiology Laboratory at 401-863-6283, or email [SBL@gmail.com](mailto:SBL@gmail.com). See website at [URL needs to be created].

**Sample Text of Recruitment Letter (placed on Dr. Loucks' letterhead):**

[Date]

Dear \_\_\_\_\_,

Your physician [name of physician] identified you as someone with prehypertension or hypertension who may be interested in participating in a new study at Brown University that is designed to evaluate effects of an intervention called Mindfulness-Based Hypertension Therapy (MBHT). MBHT combines mindfulness practices such as meditation and mindful movements with education about hypertension management and prevention. The aim of MBHT is to create a skill set and supportive environment to help to reduce blood pressure, and improve overall well-being. Your involvement in this study could help us better understand if MBHT is effective, and how it could be improved. The MBHT intervention will take place over 8 weeks, and would involve you attending a class once per week that would be between 1 and 2.5 hours, depending on which group you are assigned to. You may also be assigned to participate in a full day mindfulness retreat that would be about 7.5 hours duration. Also, health assessments would be performed before you start the intervention, and again immediately at the end of the 8-week intervention, as well as at 3 months and 6 months follow-up. The assessments would include measures such as blood pressure, height, weight, diet, physical activity, smoking, depression, stress, and medication use. These assessments will take 1-2 hours to complete.

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing your changes on scales of attention, stress, mood, health behaviors and blood pressure across the study.

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) gaining first-hand knowledge about the most current scientific methods in scientific research d) receiving information about your psychological and physical functioning.

If you are interested in participating in this study, please call 401-863-6283, or email [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu).

Sincerely yours,

A handwritten signature in black ink, appearing to read "Eric Loucks", written over a light blue horizontal line.

Eric B. Loucks, Ph.D.  
Assistant Professor

## **Section G: Safety Plan**



# **SAFETY PLAN**

If a participant's interview or questionnaire responses indicate that he/she poses a serious danger to him/herself or to another person, then the safety plan described below will be triggered into effect.

## **1 HOW QUESTIONNAIRES WILL BE USED TO DETERMINE RISK**

### **1.1 Beck Anxiety Inventory (BAI)**

The BAI was designed to measure clinical anxiety in a way that minimizes the overlap between depression and anxiety.<sup>1</sup> A BAI score of 26-63 represents severe anxiety.<sup>1</sup> Questionnaires will be reviewed within one week of completion. If participants score  $\geq 26$  on the BAI, study staff will notify the PI within 24 hours of seeing this information, who will in turn notify the collaborating clinical psychologist within 24 hours to determine need for a psychological consultation.

### **1.2 Centers for Epidemiologic Studies Depression Revised (CESD-R) Scale**

The 20 items in CESD-R scale measure symptoms of depression in nine different groups as defined by the American Psychiatric Association Diagnostic and Statistical Manual, fourth edition.<sup>2</sup> These symptom groups are shown below, with their associated scale question numbers.

1. Sadness (dysphoria): Question numbers 2, 4, 6
2. Loss of Interest (anhedonia): Question numbers 8, 10
3. Appetite: Question numbers 1, 18
4. Sleep: Question numbers 5, 11, 19
5. Thinking / concentration: Question numbers 3, 20
6. Guilt (worthlessness): Question numbers 9, 17
7. Tired (fatigue): Question numbers 7, 16
8. Movement (agitation): Question numbers 12, 13
9. Suicidal ideation: Question numbers 14, 15

Questionnaires will be reviewed within one week of completion.

Participants are considered to meet criteria for major depressive episode if they have anhedonia or dysphoria nearly every day for the past two weeks, plus symptoms in an additional 4 DSM symptom groups noted as occurring nearly every day for the past two weeks.<sup>2</sup> If participants meet criteria for major depressive episode, study staff will notify the PI within 24 hours of seeing this information, who will in turn notify the collaborating clinical psychologist within 24 hours to determine need for a psychological consultation.

If participants respond having any suicidal ideation (CESD-R questions 14 or 15), this will trigger the safety plan where our collaborating clinical psychologist will be notified directly by study staff to contact this participant immediately for suicidality evaluation and counseling. The PI will be informed that this has taken place.

### 1.3 Other Triggers for the Safety Plan

Although current suicidality is not assessed during verbal interviews, history of suicide attempts is asked verbally. If participants indicate current suicidal ideation at any time during the screening or other verbal interviews, study staff will be instructed to immediately end the interview in a sensitive way, and let participants know that a trained clinical psychologist will contact them to offer help. The staff member will provide the following information to study participants.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor's office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

## 2 References

1. Beck AT, Epstein N, Brown G, Steer RA. An inventory for measuring clinical anxiety: psychometric properties. *Journal of consulting and clinical psychology*. Dec 1988;56(6):893-897.
2. Van Dam NT, Earleywine M. Validation of the Center for Epidemiologic Studies Depression Scale--Revised (CESD-R): pragmatic depression assessment in the general population. *Psychiatry research*. Mar 30 2011;186(1):128-132.

## References

1. Hughes JW, Fresco DM, Myerscough R, van Dulmen M, Carlson LE, Josephson R. Randomized controlled trial of Mindfulness-Based Stress Reduction for prehypertension. *Psychosom Med*. 2013;75:721-728.
2. Mendis S, Puska P, Norrving B. *Global atlas on cardiovascular disease prevention and control*. Geneva: World Health Organization;2011.
3. Hoyert DL, Xu J. Deaths: Preliminary Data for 2011. *National Vital Statistics Reports*. 2012;61(6):1-65.
4. Chobanian AV, Bakris GL, Black HR, et al. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Hypertension*. Dec 2003;42(6):1206-1252.
5. United States Centers for Disease Control and Prevention. Getting blood pressure under control. *CDC Vital signs*. 2012;September.
6. James PA, Oparil S, Carter BL, et al. 2014 evidence-based guideline for the management of high blood pressure in adults: report from the panel members appointed to the Eighth Joint National Committee (JNC 8). *JAMA*. Feb 5 2014;311(5):507-520.
7. Weber MA, Schiffrin EL, White WB, et al. Clinical practice guidelines for the management of hypertension in the community a statement by the American Society of Hypertension and the International Society of Hypertension. *J Hypertens*. Jan 2014;32(1):3-15.
8. Epstein RM. Mindful practice. *JAMA*. Sep 1 1999;282(9):833-839.
9. Sedlmeier P, Eberth J, Schwarz M, et al. The psychological effects of meditation: a meta-analysis. *Psychol Bull*. Nov 2012;138(6):1139-1171.
10. Lutz A, Slagter HA, Dunne JD, Davidson RJ. Cognitive-emotional interactions - Attention regulation and monitoring in meditation. *Trends Cogn Sci*. Apr 2008;12(4):163-169.
11. Brewer JA, Mallik S, Babuscio TA, et al. Mindfulness training for smoking cessation: results from a randomized controlled trial. *Drug and alcohol dependence*. Dec 1 2011;119(1-2):72-80.
12. Loucks EB, Britton WB, Howe CJ, Eaton CB, Buka SL. Positive associations of dispositional mindfulness with cardiovascular health: The New England Family Study. *Int J Behav Med*. 2014:DOI 10.1007/s12529-12014-19448-12529.
13. Institute of Medicine. *Initial National Priorities for Comparative Effectiveness Research*. Washington, D.C.2009.
14. Abbott RA, Whear R, Rodgers LR, et al. Effectiveness of mindfulness-based stress reduction and mindfulness based cognitive therapy in vascular disease: A systematic review and meta-analysis of randomised controlled trials. *J Psychosom Res*. May 2014;76(5):341-351.
15. Goyal M, Singh S, Sibinga EM, et al. Meditation programs for psychological stress and well-being: A systematic review and meta-analysis. *JAMA internal medicine*. Mar 1 2014;174(3):357-368.
16. Bowen S, Witkiewitz K, Clifasefi SL, et al. Relative Efficacy of Mindfulness-Based Relapse Prevention, Standard Relapse Prevention, and Treatment as Usual for Substance Use Disorders: A Randomized Clinical Trial. *JAMA psychiatry*. Mar 19 2014.
17. Santorelli SF, Kabat-Zinn J. *MBSR Curriculum Guide and Supporting Materials. Mindfulness Based Stress Reduction Professional Training*. . Worcester, MA: University of Massachusetts Center for Mindfulness; 2003.
18. Kabat-Zinn J. An outpatient program in behavioral medicine for chronic pain patients based on the practice of mindfulness meditation: theoretical considerations and preliminary results. *Gen Hosp Psychiatry*. Apr 1982;4(1):33-47.
19. Kabat-Zinn J, Massion AO, Kristeller J, et al. Effectiveness of a meditation-based stress reduction program in the treatment of anxiety disorders. *Am J Psychiatry*. Jul 1992;149(7):936-943.

20. Santorelli S, Bonus K, McCallum C, et al. Mindfulness-Based Stress Reduction: Guidelines and Standards of Practice. *Integrative Medicine Mindfulness Program at University of Wisconsin-Madison and the Center for Mindfulness, University of Massachusetts*. 2004.
21. MacCoon DG, Imel ZE, Rosenkranz MA, et al. The validation of an active control intervention for Mindfulness Based Stress Reduction (MBSR). *Behaviour research and therapy*. Jan 2012;50(1):3-12.
22. Loucks EB. Meditation intervention reviews: selecting ideal control groups for meditation interventions. *JAMA internal medicine*. Jul 2014;174(7):1194-1195.
23. Loucks EB, Britton WB, Howe CJ, et al. Associations of dispositional mindfulness with obesity and central adiposity: The New England Family Study. Under Review.
24. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol*. Sep 2004;23(5):443-451.
25. Freedman B. Equipoise and the ethics of clinical research. *N Engl J Med*. Jul 16 1987;317(3):141-145.
26. Pickering TG, Hall JE, Appel LJ, et al. Recommendations for blood pressure measurement in humans and experimental animals: part 1: blood pressure measurement in humans: a statement for professionals from the Subcommittee of Professional and Public Education of the American Heart Association Council on High Blood Pressure Research. *Circulation*. Feb 8 2005;111(5):697-716.
27. Williams B, Lindholm LH, Sever P. Systolic pressure is all that matters. *Lancet*. Jun 28 2008;371(9631):2219-2221.
28. El Assaad MA, Topouchian JA, Darne BM, Asmar RG. Validation of the Omron HEM-907 device for blood pressure measurement. *Blood Press Monit*. Aug 2002;7(4):237-241.
29. Chen KY, Acra SA, Majchrzak K, et al. Predicting energy expenditure of physical activity using hip- and wrist-worn accelerometers. *Diabetes technology & therapeutics*. 2003;5(6):1023-1033.
30. Crouter SE, Clowers KG, Bassett DR, Jr. A novel method for using accelerometer data to predict energy expenditure. *J Appl Physiol (1985)*. Apr 2006;100(4):1324-1331.
31. Troiano RP. Translating accelerometer counts into energy expenditure: advancing the quest. *J Appl Physiol (1985)*. Apr 2006;100(4):1107-1108.
32. Esliger DW, Tremblay MS. Technical reliability assessment of three accelerometer models in a mechanical setup. *Med Sci Sports Exerc*. Dec 2006;38(12):2173-2181.
33. Heil DP. Predicting activity energy expenditure using the Actical activity monitor. *Research quarterly for exercise and sport*. Mar 2006;77(1):64-80.
34. Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics--2012 update: a report from the American Heart Association. *Circulation*. Jan 3 2012;125(1):e2-e220.
35. Subar AF, Thompson FE, Kipnis V, et al. Comparative validation of the Block, Willett, and National Cancer Institute food frequency questionnaires : the Eating at America's Table Study. *American journal of epidemiology*. Dec 15 2001;154(12):1089-1099.
36. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. Dec 1983;24(4):385-396.
37. Kernan WN, Viscoli CM, Makuch RW, Brass LM, Horwitz RI. Stratified randomization for clinical trials. *J Clin Epidemiol*. 1999;52(1):19-26.
38. Friedman LM, Furberg CD, DeMets DL. *Fundamentals of Clinical Trials*. New York, NY: Springer; 2010.
39. Liang K-Y, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika*. 1986;73(1):13-22.
40. Zeger SL, Liang K-Y. Longitudinal data analysis for discrete and continuous outcomes. *Biometrics*. 1986;42:121-130.
41. (NCCAM) NCfCaAM. Meditation: An Introduction.  
<http://nccam.nih.gov/health/meditation/overview.htm - sideeffects> 2013. Accessed April 26, 2013.

42. Beck AT, Epstein N, Brown G, Steer RA. An inventory for measuring clinical anxiety: psychometric properties. *Journal of consulting and clinical psychology*. Dec 1988;56(6):893-897.
43. Van Dam NT, Earleywine M. Validation of the Center for Epidemiologic Studies Depression Scale--Revised (CESD-R): pragmatic depression assessment in the general population. *Psychiatry research*. Mar 30 2011;186(1):128-132.

**MINDFULNESS-BASED  
HYPERTENSION THERAPY PILOT STUDY  
REVISED IRB APPLICATION**

**February 11th, 2015**

Eric B. Loucks, PhD  
Assistant Professor  
Department of Epidemiology  
Brown University School of Public Health  
121 South Main St., Box G-S121  
Providence, RI, 02912  
Phone: 401-863-6283  
Email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu)

## COVER LETTER

Thank you for the helpful feedback. Below is an itemized response to the Board's recommendations.

The Board requested the following:

1. **The Board noted that Dr. Ellen Flynn will act as the new clinical psychologist on the study and asked that you confer with her regarding the safety plan. The Board specifically requested that participant responses on the "Center for Epidemiologic Studies Depression Revised Scale" (CESD-R) be reviewed immediately, since the proposed plan details a potential nine-day delay from a participant's completion of the CESD-R to when they may be contacted by Dr. Flynn for evaluation.**

**RESPONSE:** Thank you for this request. Dr. Flynn has reviewed the safety plan and provided comments for improvement. Those improvements are shown below in the safety plan and the initial phone-based screening questionnaire. Participants' scores on the CESD-R are now planned to be reviewed much more quickly, as described in the updated safety plan below.

**CHANGE:** Please see underlined sections of Safety Plan (pp. 12-13) and Phone-Based Screening Questionnaire (pp. 16-18).

2. **To the consent document's procedure section, please add a table detailing the different procedures, the amount of time per procedure, and the total time of involvement for participants.**

**RESPONSE:** The table shown below has been added to the consent document.

**CHANGE** (pg. 7):

**Table Summarizing Activities and Time Commitment for this Study.**

Activity	Time Commitment
First blood pressure screen	30 minutes
Second blood pressure screen	30 minutes
Baseline health assessments, such as questionnaires, height, weight and waist circumference.	2 hours
Mindfulness course.	9 sessions that are 2.5 hours each. 1 retreat day on a Saturday that will be 8 hours Total course time: 30.5 hours
Home mindfulness practices assigned during course.	1 hour per day, 6 days per week, for 8 weeks. Total time: 48 hours.
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place immediately after course completion.	2 hours
Health assessments, such as questionnaires, blood	2 hours



pressure, height, weight and waist circumference, that take place that take place 3 months after course completion.	
<b>TOTAL TIME COMMITMENT FOR STUDY</b>	<b>85 hours</b>

3. To the consent documents' "Confidentiality" section (pg. 26, 2nd paragraph), please correct the title "Department of Elderly Affairs" to "Division of Elderly Affairs."

**RESPONSE:** This has been changed as requested, shown below.

**CHANGE** (pg. 8 para. 5):

State law also requires researchers to report abuse or neglect of people age 60 and older to the Division of Elderly Affairs.

## **Informed Consent**

Each potential participant will be fully informed about the nature of the study, its risks and benefits, and about his/her rights as a research subject. The person performing the consent will be either Dr. Loucks or a trained undergraduate trained research assistant. The participant will sign and receive a copy of the document stating that he/she has given his/her informed consent to participate before interviewing is begun. In every instance, project personnel will verbally review the content of the consent form before participants sign.

## Agreement to Participate in a Research Study

### *Investigation of the effects of mindfulness meditation on blood pressure and well-being*

You are being asked to take part in a Brown University research study about the effects of mindfulness and hypertension education on blood pressure and risk factors for hypertension. This form will explain the purpose of the study, how the study will be carried out and what you will be expected to do. It will also explain the possible risks and possible benefits of being in the study. If any part of the following description is not clear to you, you are encouraged to contact the researcher to answer any questions before you decide whether to take part in the study. If you decide to participate, please fill out and sign the last page of this form.

#### 1a. Nature and Purpose of the Study

The purpose of the study is to investigate the impact of mindfulness practices and health education on blood pressure. You have been selected for this study because you expressed interest and met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program. In order to assess the effects of these practices, you will be asked to complete some questionnaires, and a laboratory assessment before and after learning the mindfulness practices.

#### 1b. Explanation of Procedures

If you agree to participate, you will be asked to consent to the following:

- 1) Participate in an interview in which you will be asked questions about past and present mental health, including depression and suicide.
- 2) Complete questionnaires about a wide range of topics, including your diet, physical activity, smoking, medication use, personality, emotions, attention and past experiences, including stressful or traumatic experiences. These questions will probe sensitive psychological areas, including physical, emotion and sexual abuse. These questionnaires may take up to 1.5 hours to complete. By completing the interviews and questionnaires, you are giving the researchers permission to use the information you have provided. You have the right not to answer any of the questions.
- 3) Directly assessed blood pressure, height, weight, waist circumference and hip circumference.
- 4) You will be asked to perform some cognitive tasks. One of these tasks may involve computer-based tests of attention or decision-making. Together these tests may take as long as 30 minutes.
- 5) You may be randomly assigned (like the flip of a coin) to enter one of two different 8-week meditation programs.
- 6) You will participate in an 8-week meditation program, which consists of 9 sessions of 2.5 hours each and will include one 8-hour weekend retreat. Daily homework assignments may take as long as one hour and consist of practicing mindfulness exercises with the aid of a guided audio CD and completing worksheets related to stress, thoughts, and common reactions to various types of events.

- 7) Class sessions will be audio taped so we can analyze the quality of the treatment you receive. The recordings may be transcribed so that we can analyze the text. The recordings will be identified by study number, will only be heard by study staff and will be destroyed after transcription.
- 8) You will be asked to complete a few short questionnaires each week during the 8 week condition.
- 9) After 8 weeks, you will be asked to complete questionnaires and return to the laboratory to repeat the same procedures for a second day of testing.
- 10) Three months after the end of the 8 week condition, you will be asked to return to the laboratory to repeat the same testing procedures.

**Table Summarizing Activities and Time Commitment for this Study.**

<b><u>Activity</u></b>	<b><u>Time Commitment</u></b>
<u>First blood pressure screen</u>	<u>30 minutes</u>
<u>Second blood pressure screen</u>	<u>30 minutes</u>
<u>Baseline health assessments, such as questionnaires, height, weight and waist circumference.</u>	<u>2 hours</u>
<u>Mindfulness course</u>	<u>9 sessions that are 2.5 hours each.</u> <u>1 retreat day on a Saturday that will be 8 hours</u> <u>Total course time: 30.5 hours</u>
<u>Home mindfulness practices assigned during course.</u>	<u>1 hour per day, 6 days per week, for 8 weeks.</u> <u>Total time: 48 hours.</u>
<u>Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place immediately after course completion.</u>	<u>2 hours</u>
<u>Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place that take place 3 months after course completion.</u>	<u>2 hours</u>
<b><u>TOTAL TIME COMMITMENT FOR STUDY</u></b>	<b><u>85 hours</u></b>

#### Feedback:

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing % change (increase or decrease) on scales of attention, stress, mood, health behaviors, weight, and blood pressure across the study.

#### 2. Discomforts and Risks

The questionnaires are routine, standardized forms for epidemiologic research. Certain questions may be upsetting as they may probe sensitive psychological areas and inquire about upsetting or traumatic events, including physical, sexual or emotional abuse and/or current psychiatric symptoms. Since your participation is voluntary, you have the right to skip any questions that make you uncomfortable.

Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable feelings with increased attention to them.

### 3. Benefits

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) receiving information about your psychological and physical functioning.

### 4. Alternative Therapies

A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

### 5. Confidentiality

Your responses for this study will be kept confidential. All data that we collect will be linked to a study ID# instead of your name. All questionnaires in this study will be filled out through an online survey website (SurveyMonkey) or a paper version of the survey if you prefer. All of these questionnaires will be linked solely to your study ID#, so that your identity is protected and your answers are confidential. Although these measures have been taken to protect your personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet.

While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then a collaborator [provide name] who is a licensed psychiatrist, may contact you to discuss your responses and possible referral to a treatment provider. Questionnaire items that may warrant follow-up include endorsements of statements about hurting yourself, any high scores in depression, anxiety, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires researchers to report abuse or neglect of people age 60 and older to the Division of Elderly Affairs.

The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a unique code number and initials. All study records and specimens will be stored in a secure storage area.

*Keeping study records:* The Principal Investigator for this study will keep your research records indefinitely for research purposes.

### 6. Refusal/Withdrawal

Participation is voluntary, and you may decide to opt out or refuse any part of participation, including not answering certain questions. If you decide now to participate, you can change your mind later and quit the study. The decision to not participate or to withdraw from the study will not adversely affect current or future interactions with Brown University. The decision to not participate or to withdraw from the study will also not adversely affect your relationship with your physician.

If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

7. Contact Information

If you have questions about study procedures at any time you may contact the researchers: Dr. Eric B. Loucks, email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu), telephone (401) 863-6283. If you would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Brown University Research Protections Office, telephone number 1-866-309-2095 or 401-863-3050.

**CONSENT FORM:**  
**Please sign and return.**

Please read the following agreement and sign to consent to participating.

**I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY.**

\_\_\_\_\_  
**PRINT NAME**

\_\_\_\_\_  
**Signature of participant**

\_\_\_\_\_  
**Date**

**CONTACT INFORMATION**

**Name (print):** \_\_\_\_\_

**Permanent Address:** \_\_\_\_\_

**Email(s):** \_\_\_\_\_

**Telephone:** \_\_\_\_\_ **(cell)** \_\_\_\_\_ **(other)**



## **Safety Plan**

# SAFETY PLAN

If a participant's interview or questionnaire responses indicate that he/she poses a serious danger to him/herself or to another person, then the safety plan described below will be triggered into effect.

## 1 HOW QUESTIONNAIRES WILL BE USED TO DETERMINE RISK

### 1.1 Beck Anxiety Inventory (BAI)

The BAI was designed to measure clinical anxiety in a way that minimizes the overlap between depression and anxiety.<sup>1</sup> A BAI score of 26-63 represents severe anxiety.<sup>1</sup> Questionnaires will be reviewed within 48 hours of completion. If participants score  $\geq 26$  on the BAI, study staff will immediately notify the PI, Dr. Eric Loucks, and the collaborating psychiatrist, Dr. Ellen Flynn, to determine need for a psychiatric consultation.

### 1.2 Centers for Epidemiologic Studies Depression Revised (CESD-R) Scale

The 20 items in CESD-R scale measure symptoms of depression in nine different groups as defined by the American Psychiatric Association Diagnostic and Statistical Manual, fourth edition.<sup>2</sup> These symptom groups are shown below, with their associated scale question numbers.

1. Sadness (dysphoria): Question numbers 2, 4, 6
2. Loss of Interest (anhedonia): Question numbers 8, 10
3. Appetite: Question numbers 1, 18
4. Sleep: Question numbers 5, 11, 19
5. Thinking / concentration: Question numbers 3, 20
6. Guilt (worthlessness): Question numbers 9, 17
7. Tired (fatigue): Question numbers 7, 16
8. Movement (agitation): Question numbers 12, 13
9. Suicidal ideation: Question numbers 14, 15

Questionnaires will be reviewed within 48 hours of completion.

Participants are considered to meet criteria for major depressive episode if they have anhedonia or dysphoria nearly every day for the past two weeks, plus symptoms in an additional 4 DSM symptom groups noted as occurring nearly every day for the past two weeks.<sup>2</sup> If participants meet criteria for major depressive episode, study staff will immediately notify the PI, Dr. Eric Loucks, and the collaborating psychiatrist, Dr. Ellen Flynn, to determine need for a psychiatric consultation.

If participants respond having any suicidal ideation (CESD-R questions 14 or 15), this will trigger the safety plan where Dr. Flynn will be immediately notified directly by study staff to contact this participant immediately for suicidality evaluation and counseling. The PI will be informed that this has taken place.

### 1.3 Other Triggers for the Safety Plan

During the phone-based screening, if participants respond yes to "Are you currently suicidal?", the interviewer will immediately have 911 and Dr. Ellen Flynn called by a colleague who has been informed beforehand that this is a possibility. Specifically, while keeping the participant on the phone, the text shown below in bold italics will be visually shown to the colleague.

**I have a study participant on the phone who is currently suicidal. Please call 911 immediately, and tell them:**

**“I am calling on behalf of [my name] who is performing a research study at Brown University, and has a participant on the phone who says they are currently suicidal.” Please provide the participants’ contact information to the 911 operator (i.e. name, address, phone #, email address) as requested. This information is on page 1 of the screening questionnaire right here [interviewer has this information].**

**Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.**

While keeping the participant on the phone, questions to be asked, in this order, include:

1. “Do you have a plan?”
2. If yes... “What are you planning?”
3. “Do you have the means to commit suicide?”
4. “Do you have access to a gun?”
5. “We are really concerned about you, and are calling 911.”

Other questions that could be asked in order to keep them on the phone:

- “Tell me what is going on.”
- “What’s happening right now?”

The following information can be provided to study participants if they state they have had considered killing themselves in the past month. If they are currently suicidal, the main priority is to keep them on the phone while 911 and Dr. Flynn are being contacted.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020

SCREENING QUESTIONNAIRE  
(PHONE-DELIVERED)

## MBHT PHONE SCREEN

**Date of Screen:** \_\_\_\_\_ **Interviewer:** \_\_\_\_\_

**Screening #:** \_\_\_\_\_ (month.date.year.hour.minute)

**Name:** \_\_\_\_\_

**Address:** \_\_\_\_\_

**Phone number(s):** \_\_\_\_\_

**Email address (or mailing if no email):** \_\_\_\_\_

**Notes from Interviewer:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

My name is \_\_\_\_\_. I am calling from the Brown University School of Public Health, because you expressed interest in participating in our mindfulness study. I want to do 10-15 minutes phone interview with you to determine if you are a good match for this particular study. Is now a good time to speak? [If yes, proceed. If no, ask for other times and note in Potential Subject Log].

There are a few things that I'd like to make clear before we start the interview. First of all, some of the questions will be very personal and sensitive. Are you in a private place to talk? Because this interview is of a personal nature, it is important that you understand that everything you say will be kept strictly confidential. No one outside of our project will ever be able to see your answers, and we will not keep your name in the same place as any of your answers. If you are not eligible after the phone screen, we will destroy your information. If you like, though, we can keep your information on file for future studies.



EXCLUSION: CURRENT (check timeframe)			
PTSD	<p>Would you say you have a trauma history?  <u>[If yes...]</u>  <u>In the past month, have you had any problems with dissociation (memory loss)?</u>  <u>In the past month, have you had any flashbacks (i.e. sudden and disturbing vivid memory) about the trauma?</u></p>	<p><u>YES</u>   <u>NO</u>  <u>YES</u>   <u>NO</u></p>	
OCD	<p><u>In the past month, have you had any problems with obsessions or compulsions, such as washing your hands or checking the oven over and over again?</u>  <u>[If yes...]</u> Has anyone diagnosed you with obsessive compulsive disorder?</p>	<p>YES   NO  <u>YES</u>   <u>NO</u></p>	
PANIC	<u>In the past month, have you had a panic attack (i.e. sweating, heart palpitations, nausea, trouble breathing, fear of dying/choking/going crazy)?</u>	YES   NO	
ALCOHOL	<u>Have you had any problems with alcoholism or drug use in the past year?</u>	YES   NO	
EATING DIS	<u>In the past year, have you had an eating disorder, such as starving, binge eating, or vomiting?</u>	YES   NO	
MEDITATION	<u>Do you currently practice meditation more than once per week? (yoga does not count as meditation in this context)</u>	YES   NO	
MED ILL	This class will take place at Brown University in-person. Do you have any medical or mobility issues that would affect you being able to attend class?	YES   NO	
DECISION	PASS      NO PASS      QUERY		

PASS FORM: Initial appropriate boxes with dates		Date/initials
NO PASS	<p><u>Thank you for taking the time to answer these questions.</u> According to this test, it doesn't look like you are going to be a good fit for the study. There may be other studies you qualify for. Would you like me to keep your information to pass on to these studies? Otherwise, our copy of this information can be destroyed.</p>	
QUERY	<p><u>Thank you for taking the time to answer these questions.</u> There are a few items I need to check with my supervisor about. <u>I will contact him right now, and we will get back in touch with you shortly about your participation in this study.</u></p>	
PASS: Study description and requirements Time commitment	<p><u>Thank you for taking the time to answer these questions. You qualify for the next stage of screening, which is to take your blood pressure at two different times at least a week apart from each other. Before we go on to book this, I would like to tell you a little more about the study. If you want to continue, the next phase would require an interview, a packet of questionnaires and visit to the laboratory before the 8-week meditation program. After the program, you would fill out the same questionnaires and do the lab visit again twice – once right after the course, and again 3 months later. This study involves an 8-week program that will provide training in mindfulness meditation, yoga and health behaviours related to blood pressure control. The mindfulness program takes place in a group setting meeting for 2 ½ hours once a week, 9 times over an 8 week period. For example if it were on a Monday, we would meet on 9 Mondays in a row. The program requires up to an hour of mindfulness practice every day. There will also be an all-day retreat on a Saturday part way through the course, that will be about 8 hours long. Is this something that you would be able to make time for in your schedule?</u></p>	YES    NO
SCHEDULE Available for current program?	<p>It's important to attend all 9 sessions.            The next program is:            Availability:            Mon 9:00-11:30, 4:00-6:30 pm            Tues 9:00-11:30, 4:00-6:30 pm            Wed 9:00-11:30, 4:00-6:30 pm            Thurs 9:00-11:30, 4:00-6:30 pm              Other:</p>	YES    NO



## References

1. Beck AT, Epstein N, Brown G, Steer RA. An inventory for measuring clinical anxiety: psychometric properties. *Journal of consulting and clinical psychology*. Dec 1988;56(6):893-897.
2. Van Dam NT, Earleywine M. Validation of the Center for Epidemiologic Studies Depression Scale--Revised (CESD-R): pragmatic depression assessment in the general population. *Psychiatry research*. Mar 30 2011;186(1):128-132.

**MINDFULNESS-BASED  
HYPERTENSION THERAPY PILOT STUDY  
REVISED IRB APPLICATION**

**February 15th, 2015**

Eric B. Loucks, PhD  
Assistant Professor  
Department of Epidemiology  
Brown University School of Public Health  
121 South Main St., Box G-S121  
Providence, RI, 02912  
Phone: 401-863-6283  
Email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu)

## COVER LETTER

Thank you for the helpful feedback. Below is an itemized response to the Board's recommendations.

The Board requested the following:

1. **The plan says that Dr. Flynn will be notified immediately if participants meet the criteria for a major depressive episode or suicidality, but right above that, Section 1.2 says that the questionnaires will be reviewed within 48 hours of completion. Will these questionnaire not be immediately reviewed? Since these measures will not be completed in-person, if they may not be reviewed for 48 hours, Dr. Flynn may not interact with a participant in trouble for 2 days. The IRB feels that this is too long a delay to review these measures.**

**RESPONSE:** The anxiety and depressive symptomatology questionnaires have now been moved to be completed in-person instead of at home. Responses will be reviewed immediately upon completion of the in-person assessments. Values of concern will be reported immediately to Dr. Flynn.

**CHANGE:** Please see underlined changes to the safety plan on pg. 11.

2. **The IRB also feels that the RA should not ask the types of clinical questions, as described in Section 1.3's script for talking to suicidal participants. The exact language the RA will use when speaking with participants does not need to be reviewed by the IRB, but once a participant expresses suicidal ideation, (step 1) Dr. Flynn should be contacted and (step 2) the RA should speak calmly with the participants about what the RA is doing (calling Dr. Flynn) and why. The RA can speak with participants to keep them on the phone, but the discussion should not be clinical in nature.**

**RESPONSE:** The clinical questions have been removed. Recommended steps 1 and 2 have been implemented.

**CHANGE:** Please see underlined changes to the Safety Plan on pg. 12.

3. **The revised consent document's new activities/time table (pg. 7) says the total time commitment is 85 hours, but when I add up the time, it comes to 85.5 hours. Would you correct the consent document?**

**RESPONSE:** This has been changed to 85.5 hours as suggested.

**CHANGE:** Please see underlined change to the consent document on pg. 6.

## **Informed Consent**

Each potential participant will be fully informed about the nature of the study, its risks and benefits, and about his/her rights as a research subject. The person performing the consent will be either Dr. Loucks or a trained undergraduate trained research assistant. The participant will sign and receive a copy of the document stating that he/she has given his/her informed consent to participate before interviewing is begun. In every instance, project personnel will verbally review the content of the consent form before participants sign.

## **Agreement to Participate in a Research Study**

### ***Investigation of the effects of mindfulness meditation on blood pressure and well-being***

You are being asked to take part in a Brown University research study about the effects of mindfulness and hypertension education on blood pressure and risk factors for hypertension. This form will explain the purpose of the study, how the study will be carried out and what you will be expected to do. It will also explain the possible risks and possible benefits of being in the study. If any part of the following description is not clear to you, you are encouraged to contact the researcher to answer any questions before you decide whether to take part in the study. If you decide to participate, please fill out and sign the last page of this form.

#### **1a. Nature and Purpose of the Study**

The purpose of the study is to investigate the impact of mindfulness practices and health education on blood pressure. You have been selected for this study because you expressed interest and met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program. In order to assess the effects of these practices, you will be asked to complete some questionnaires, and a laboratory assessment before and after learning the mindfulness practices.

#### **1b. Explanation of Procedures**

If you agree to participate, you will be asked to consent to the following:

- 1) Participate in an interview in which you will be asked questions about past and present mental health, including depression and suicide.
- 2) Complete questionnaires about a wide range of topics, including your diet, physical activity, smoking, medication use, personality, emotions, attention and past experiences, including stressful or traumatic experiences. These questions will probe sensitive psychological areas, including physical, emotion and sexual abuse. These questionnaires may take up to 1.5 hours to complete. By completing the interviews and questionnaires, you are giving the researchers permission to use the information you have provided. You have the right not to answer any of the questions.
- 3) Directly assessed blood pressure, height, weight, waist circumference and hip circumference.
- 4) You will be asked to perform some cognitive tasks. One of these tasks may involve computer-based tests of attention or decision-making. Together these tests may take as long as 30 minutes.
- 5) You may be randomly assigned (like the flip of a coin) to enter one of two different 8-week meditation programs.
- 6) You will participate in an 8-week meditation program, which consists of 9 sessions of 2.5 hours each and will include one 8-hour weekend retreat. Daily homework assignments may take as long as one hour and consist of practicing mindfulness exercises with the aid of a guided audio CD and completing worksheets related to stress, thoughts, and common reactions to various types of events.

- 7) Class sessions will be audio taped so we can analyze the quality of the treatment you receive. The recordings may be transcribed so that we can analyze the text. The recordings will be identified by study number, will only be heard by study staff and will be destroyed after transcription.
- 8) You will be asked to complete a few short questionnaires each week during the 8 week condition.
- 9) After 8 weeks, you will be asked to complete questionnaires and return to the laboratory to repeat the same procedures for a second day of testing.
- 10) Three months after the end of the 8 week condition, you will be asked to return to the laboratory to repeat the same testing procedures.

**Table Summarizing Activities and Time Commitment for this Study.**

<b>Activity</b>	<b>Time Commitment</b>
First blood pressure screen	30 minutes
Second blood pressure screen	30 minutes
Baseline health assessments, such as questionnaires, height, weight and waist circumference.	2 hours
Mindfulness course	9 sessions that are 2.5 hours each. 1 retreat day on a Saturday that will be 8 hours Total course time: 30.5 hours
Home mindfulness practices assigned during course.	1 hour per day, 6 days per week, for 8 weeks. Total time: 48 hours.
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place immediately after course completion.	2 hours
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place that take place 3 months after course completion.	2 hours
<b>TOTAL TIME COMMITMENT FOR STUDY</b>	<b>85.5 hours</b>

#### Feedback:

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing % change (increase or decrease) on scales of attention, stress, mood, health behaviors, weight, and blood pressure across the study.

#### 2. Discomforts and Risks

The questionnaires are routine, standardized forms for epidemiologic research. Certain questions may be upsetting as they may probe sensitive psychological areas and inquire about upsetting or traumatic events, including physical, sexual or emotional abuse and/or current psychiatric symptoms. Since your participation is voluntary, you have the right to skip any questions that make you uncomfortable.



Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable feelings with increased attention to them.

### 3. Benefits

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) receiving information about your psychological and physical functioning.

### 4. Alternative Therapies

A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

### 5. Confidentiality

Your responses for this study will be kept confidential. All data that we collect will be linked to a study ID# instead of your name. All questionnaires in this study will be filled out through an online survey website (SurveyMonkey) or a paper version of the survey if you prefer. All of these questionnaires will be linked solely to your study ID#, so that your identity is protected and your answers are confidential. Although these measures have been taken to protect your personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet.

While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then a collaborator [provide name] who is a licensed psychiatrist, may contact you to discuss your responses and possible referral to a treatment provider. Questionnaire items that may warrant follow-up include endorsements of statements about hurting yourself, any high scores in depression, anxiety, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires researchers to report abuse or neglect of people age 60 and older to the Division of Elderly Affairs.

The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a unique code number and initials. All study records and specimens will be stored in a secure storage area.

*Keeping study records:* The Principal Investigator for this study will keep your research records indefinitely for research purposes.

### 6. Refusal/Withdrawal

Participation is voluntary, and you may decide to opt out or refuse any part of participation, including not answering certain questions. If you decide now to participate, you can change your mind later and quit the study. The decision to not participate or to withdraw from the study will not adversely affect current or future interactions with Brown University. The decision to not participate or to withdraw from the study will also not adversely affect your relationship with your physician.

If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

7. Contact Information

If you have questions about study procedures at any time you may contact the researchers: Dr. Eric B. Loucks, email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu), telephone (401) 863-6283. If you would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Brown University Research Protections Office, telephone number 1-866-309-2095 or 401-863-3050.

**CONSENT FORM:**  
**Please sign and return.**

Please read the following agreement and sign to consent to participating.

**I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY.**

\_\_\_\_\_  
**PRINT NAME**

\_\_\_\_\_  
**Signature of participant**

\_\_\_\_\_  
**Date**

**CONTACT INFORMATION**

**Name (print):** \_\_\_\_\_

**Permanent Address:** \_\_\_\_\_

**Email(s):** \_\_\_\_\_

**Telephone:** \_\_\_\_\_ **(cell)** \_\_\_\_\_ **(other)** \_\_\_\_\_

## **Safety Plan**

# SAFETY PLAN

If a participant's interview or questionnaire responses indicate that he/she poses a serious danger to him/herself or to another person, then the safety plan described below will be triggered into effect.

## 1 HOW QUESTIONNAIRES WILL BE USED TO DETERMINE RISK

### 1.1 Beck Anxiety Inventory (BAI)

The BAI was designed to measure clinical anxiety in a way that minimizes the overlap between depression and anxiety.<sup>1</sup> A BAI score of 26-63 represents severe anxiety.<sup>1</sup> The BAI will be administered during the in-person assessment visits, and scores will be reviewed immediately upon completion of the in-person assessments. If participants score  $\geq 26$  on the BAI, study staff will immediately notify the PI, Dr. Eric Loucks, and the collaborating psychiatrist, Dr. Ellen Flynn, to determine need for a psychiatric consultation.

### 1.2 Centers for Epidemiologic Studies Depression Revised (CESD-R) Scale

The 20 items in CESD-R scale measure symptoms of depression in nine different groups as defined by the American Psychiatric Association Diagnostic and Statistical Manual, fourth edition.<sup>2</sup> These symptom groups are shown below, with their associated scale question numbers. The CESD-R will be administered during the in-person assessment visits, and scores will be reviewed immediately upon completion of the in-person assessments.

1. Sadness (dysphoria): Question numbers 2, 4, 6
2. Loss of Interest (anhedonia): Question numbers 8, 10
3. Appetite: Question numbers 1, 18
4. Sleep: Question numbers 5, 11, 19
5. Thinking / concentration: Question numbers 3, 20
6. Guilt (worthlessness): Question numbers 9, 17
7. Tired (fatigue): Question numbers 7, 16
8. Movement (agitation): Question numbers 12, 13
9. Suicidal ideation: Question numbers 14, 15

Participants are considered to meet criteria for major depressive episode if they have anhedonia or dysphoria nearly every day for the past two weeks, plus symptoms in an additional 4 DSM symptom groups noted as occurring nearly every day for the past two weeks.<sup>2</sup> If participants meet criteria for major depressive episode, study staff will immediately notify the PI, Dr. Eric Loucks, and the collaborating psychiatrist, Dr. Ellen Flynn, to determine need for a psychiatric consultation.

If participants respond having any suicidal ideation (CESD-R questions 14 or 15), this will trigger the safety plan where Dr. Flynn will be immediately notified directly by study staff to contact this participant immediately for suicidality evaluation and counselling. The PI will be informed that this has taken place.

### 1.3 Other Triggers for the Safety Plan

During the phone-based screening, if participants respond yes to "Are you currently suicidal?", the interviewer should perform the following 2 steps:

1. Immediately have 911 and Dr. Ellen Flynn called by a colleague who has been informed beforehand that this is a possibility.

Specifically, while keeping the participant on the phone, the text shown below in bold italics will be visually shown to the colleague.

***I have a study participant on the phone who is currently suicidal. Please call 911 immediately, and tell them:***

***“I am calling on behalf of [my name] who is performing a research study at Brown University. She has a participant on the phone who says they are currently suicidal.” Please provide the participants’ contact information to the 911 operator (i.e. name, address, phone #, email address) as requested. This information is on page 1 of the screening questionnaire right here [interviewer has this information].***

***Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.***

2. While speaking calmly with the participant, let them know what you are doing. Specifically, let them know we are calling our study’s psychiatrist Dr. Flynn and 911, and why you are doing that (i.e. because we are concerned about you). You can speak with participant to keep him/her on the phone, but the discussion should not be clinical in nature.

Examples of questions that could be asked in order to keep them on the phone:

- “Tell me what is going on.”
- “What’s happening right now?”
- Tell me more about why you are interesting in being part of this study.
- What are you hoping to get out of this study?

The following information can be provided to study participants if they state they have had considered killing themselves in the past month. If they are currently suicidal, the main priority is to keep them on the phone while 911 and Dr. Flynn are being contacted.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020

## References

1. Beck AT, Epstein N, Brown G, Steer RA. An inventory for measuring clinical anxiety: psychometric properties. *Journal of consulting and clinical psychology*. Dec 1988;56(6):893-897.
2. Van Dam NT, Earleywine M. Validation of the Center for Epidemiologic Studies Depression Scale--Revised (CESD-R): pragmatic depression assessment in the general population. *Psychiatry research*. Mar 30 2011;186(1):128-132.



**Brown University**  
Research Protections Office  
Institutional Review Board  
Amendment Request

**Date of Request:** 6/17/15 **Investigator's Name and Title:** Eric Loucks, Assistant Professor  
**Study Title:** Mindfulness-Based Hypertension Therapy Pilot Study (#1412001171)

**Original Type of Review:** ☐ Exempt ☐ Expedited ☒ Full Board

- 1) Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project. (Attach summary to this form) Please see attached.
- 2) Provide a detailed description of the changes being requested (Use additional pages, if necessary):  
Please see attached.
- 3.) State the reason (justification) for the requested amendment. (Use additional pages, if necessary):  
Please see attached.
- 4.) What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?  
Please see attached.
- 5.) Does the requested amendment require new documents or changes to the approved consent form or other documents?
  - ☒ Consent/assent documents (attach revised version with changes highlighted)
  - ☒ New/revised instruments (attach - if revised, highlight changes)
  - ☐ New/revised advertising materials (attach - if revised, highlight changes)

**Do you have a conflict of interest on this project according to Brown's policy?** ☐ YES ☒ NO

**If YES, has this conflict been previously disclosed to the IRB?** ☐ YES ☐ NO

PI signature: \_\_\_\_\_



Date: 6/17/15

**1) Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project.**

The World Health Organization reported that suboptimal blood pressure (BP) is responsible for more than half of cardiovascular disease mortality world-wide. Furthermore, greater than half of those with hypertension have uncontrolled BP. A 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.” Evidence-based mindfulness interventions, including Mindfulness-Based Stress Reduction, may have some effects on blood pressure, where a recent meta-analysis and systematic review of 4 randomized controlled trials demonstrated significant effects, but evidence of heterogeneity in effect sizes. The methodologically highest quality studies had the smallest effect sizes (range 0-5 mmHg). Mindfulness-Based Stress Reduction (MBSR) has been customized to a number of disease processes, such as Mindfulness-Based Cognitive Therapy for patients with recurrent depression, and Mindfulness-Based Relapse Prevention for patients with substance use addictions. Effect sizes have been increased by customizing mindfulness interventions to diseases of interest. The same may be true for hypertension, however mindfulness interventions customized for prehypertensive/hypertensive patients have never been investigated. Until methodologically rigorous studies to evaluate customized interventions for hypertension are performed, we will not know if the observed preliminary effects of general mindfulness interventions on blood pressure reduction could be much more effective with a tailored approach. Consequently, we propose to conduct a stage I behavioral therapy intervention study to evaluate whether MBSR customized to prehypertensive and hypertensive patients has the potential to provide clinically relevant reductions in BP. Consequently the specific aims are:

**Stage 1a: Therapy Development/Manual Writing**

- 1 To outline and evaluate key novel elements of mindfulness-based hypertension therapy (MBHT), customized from the evidence-based MBSR. *We hypothesize that the most important novel element will be generation of mindfulness skills specifically applied to hypertension risk factors such as diet, physical activity, obesity, alcohol consumption and antihypertensive medication adherence.* This aim will be achieved using (1) focus groups of participants undergoing the MBHT behavioral intervention, (2) discussion with experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) prior to, and following pilot testing of MBHT in participants, and (3) clinical judgment of the investigators performing the intervention.
- 2 To determine effectiveness of MBHT on primary outcomes (systolic blood pressure, retention rates, recruitment rates, and adverse effects) and secondary outcomes (hypertension risk factors such as diet, physical activity, obesity, and antihypertensive medication adherence) in hypertension subgroups, specifically participants with (1) prehypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. Initial decisions about the targeted sample based on hypertension status will be made.
- 3 To develop an MBHT therapist manual and training program, including procedures for training, supervising, and evaluating therapists. Furthermore, acceptable therapist characteristics will be developed. The manual and training program will include themes such as specification of unique and common elements of MBHT vs. other interventions, description of interventions excluded from MBHT, and specification of key treatment parameters such as frequency and duration of treatment, session length, topics addressed,

sequence of sessions, as well as therapist adherence and competency measures. The MBHT training will consist of a therapist manual, a formal didactic training seminar, and at least one closely supervised training session.

*Stage 1b: Pilot Trial*

- 4 To determine whether a mindfulness-based hypertension therapy (MBHT) intervention, customized from the evidence-based MBSR, has promise to be an effective behavioral therapy for participants with hypertension and/or prehypertension. We will perform a randomized controlled pilot trial for MBHT vs. enhanced usual care control. *We hypothesize that MBHT will have adequate recruitment rates ( $\geq 10\%$  of prehypertensive/hypertensive participants invited from physicians' offices), fairly low drop out rates ( $< 15\%$ ), and medium effect sizes (e.g. 5-10 mmHg systolic BP) for reduction in blood pressure.*

These findings will provide publishable pilot data that will inform future randomized clinical trials that evaluate effects of MBHT on long-term changes in blood pressure vs. usual care and active control groups. *If proven effective, MBHT could be offered as a complementary program in the prehypertensive/hypertensive patient population that contributes to over half of the cardiovascular disease mortality world-wide.*

## **2) Provide a detailed description of the changes being requested (Use additional pages, if necessary):**

1. Survey software:
  - a. We changed the survey software from SurveyMonkey to Qualtrics. We will ensure that all software options that allow for personally identifiable information to be automatically obtained from Qualtrics (e.g. IP addresses) have been turned off. This is done through the "Anonymize Response" Survey Option that ensures IP addresses and panel information are removed from each survey.
2. Phone screening questionnaire:
  - a. We updated the script for Research Assistants to use, to improve clarity. The changes to the script are shown in yellow highlighted text on pp. 3, 4, 5, 7, 8 of the Phone Screening Questionnaire in Appendix 1.
3. First in-person screening assessment:
  - a. We clarified the Safety Plan for the Research Assistants, shown in highlighted yellow on pg. 19 in Appendix 2. The protocol has not been changed; only the language so that the exact steps have been clarified to the Research Assistants.
4. Consent form:
  - a. Reference to the SurveyMonkey software was removed
  - b. Reference to the control group was removed, as we are not using a control during the initial pilot testing of the novel intervention.
  - c. The time commitment for the questionnaires has been updated to more accurately reflect the expected time commitment.
  - d. The text now states that the class sessions "will be" audio recorded instead of "may be" audio recorded, as this better reflects the needs of the study to evaluate intervention fidelity.

5. Baseline Survey:
  - a. Three questionnaires have been added to the baseline survey, shown below. The specific questions are shown in yellow highlighted text in the attached Baseline Questionnaire on pp. 56-59 in Appendix 4.
    - i. Multidimensional Assessment of Interoceptive Awareness (IA).<sup>1</sup>
    - ii. Experiences Questionnaire (measure of reperiencing/decentering) (EQ).<sup>2</sup>
    - iii. Cognitive Emotion Regulation Scale (CR).<sup>3</sup>
6. Protocol for Physicians to Refer Patients to Mindfulness-Based Hypertension Therapy Study
  - a. We were contacted by a physician named Cathleen Hood who would like to refer some of her patients to the study. A protocol that we will provide to her and other interested physicians for patient referral is attached (Appendix 5).

*References:*

1. Mehling WE, Price C, Daubenmier JJ, Acree M, Bartmess E, Stewart A. The Multidimensional Assessment of Interoceptive Awareness (MAIA). *PLoS One* 2012; **7**(11): e48230.
2. Fresco DM, Moore MT, van Dulmen MH, Segal ZV, Ma SH, Teasdale JD *et al.* Initial psychometric properties of the experiences questionnaire: validation of a self-report measure of decentering. *Behavior therapy* 2007; **38**(3): 234-46.
3. Garnefski N, Kraaij V, Spinhoven P. Negative life events, cognitive emotion regulation and emotional problems. *Personality Individ Differences* 2001; **30**: 1311-1327.

**3.) State the reason (justification) for the requested amendment:**

Amendment 1 above was done due to a respected colleague (Prof. Melissa Clark) recommending Qualtrics as a higher quality survey software compared to SurveyMonkey. Amendments 2-4 above were done to improve clarity. Amendment 5 above was done to improve identification of the mechanisms by which mindfulness intervention may improve blood pressure.

**4.) What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

I do not expect any changes to the risk/benefit ratio or willingness of individuals to participate.

**5.) Does the requested amendment require new documents or changes to the approved consent form or other documents?**

Yes. Please see attached appendices 1-3. Changes are shown in yellow highlight or track changes.

## **APPENDIX 1**

### **PHONE SCREENING QUESTIONNAIRE**

# PHONE-DELIVERED SCREENING QUESTIONNAIRE

# PHONE SCREENING QUESTIONNAIRE PART 1

The script is shown below in **bold italics**.

PID. Participant ID: \_\_\_\_\_

SQ01. Staff ID: \_\_\_\_\_

SQ02. Today's Date (MMDDYY): \_\_\_\_\_

SQ03. Current Time (24 hour time, e.g. 14:45): \_\_\_\_\_

Please now call the participant.

SQ04. Was the participant reached? YES NO

***Hello, my name is \_\_\_\_\_. I am calling from the Brown University School of Public Health because (name of participant) expressed interest in participating in our mindfulness blood pressure study. Is he/she available to talk at this time?***

***I would like to do a 10-15 minute phone interview with you to determine if you are a good match for this particular study.***

SQ05. ***Is now a good time to speak?***

*[If yes, proceed to SQ05 script below]*

If no... ***When would be a good time to talk?***

SQ06. Day to call back (DDMMYY) \_\_\_\_\_

SQ07. Time to call back \_\_\_\_\_ AM/PM

***OK, great. How about I give a quick overview of the study, and can then answer any questions you may have to see if it is a good fit for you. We will then go through a screening questionnaire to see if you qualify for the study. Does this sound OK?***

***A basic overview of the study is that it is looking to see if mindfulness practices improve blood pressure, and if education about hypertension risk factors may also improve blood pressure. Specifically, we will provide training in meditation, mindful movements, and the roles of things like diet, physical activity and medication in reducing blood pressure. You will be taught by a very experienced teacher who is an expert in these fields. The course takes place weekly for 9 weeks, where you come to a class once each week for 2.5 hours each time. There is also a one-day retreat on a Saturday that will be 8 hours long. Also, we will ask you to participate in health assessments before and after the study. Health assessments include measures such as blood pressure, height and weight, and questionnaires about your health and experiences.***

**Can I answer any questions about the study that you may have? [answer any they may have.]**

**SQ08. Does this study sound like something you would be interested in doing? Yes No**

[If yes, proceed to next statement below. If no, politely thank the participant for considering being in this study, and end the call].

**Great. There are a few things that I would like to make clear before we start the interview. First of all, some of the questions that I will ask now to figure out if you are eligible to be in this study will be very personal and sensitive.**

**SQ09. Are you in a private place to talk?**

[If yes, proceed to text below. If no, reschedule meeting using variables SQ04 and SQ05 above].

**Because this interview is of a personal nature, it is important that you understand that everything you say will be kept strictly confidential. No one outside of our project will ever be able to see your answers, and we will not keep your name in the same place as any of your answers. If you are not eligible after the phone screen, we will destroy your information. If you like, though, we can keep your information on file for future studies.**

SQ10. Participant's First Name: \_\_\_\_\_

SQ11. Participant's Last Name: \_\_\_\_\_

Participant's Address:

SQ12a. Street address: \_\_\_\_\_

SQ12b. City: \_\_\_\_\_

SQ12c. State: \_\_\_\_\_

SQ12d. Zip Code: \_\_\_\_\_

SQ13a. Participant's Phone number #1 \_\_\_\_\_

SQ13b. Participant's Phone number #2 \_\_\_\_\_

SQ14. Participant's email address (or mailing address if no email): \_\_\_\_\_

SQ15. Notes from interviewer related to participants' contact information (if any):

---

---

---



## PHONE SCREENING QUESTIONNAIRE PART 2

PID. Participant ID #: \_\_\_\_\_

INCLUSION CRITERIA: All answers in 3 <sup>rd</sup> column must be YES. If an answer is NO, immediately proceed to question SQ40.			
			Comments
SQ26.	<b>What is your age?</b> (At least 18 years old)	YES NO	
SQ27.	<b>Can you read and write in English?</b>	YES NO	
EXCLUSION CRITERIA: All answers in 3 <sup>rd</sup> column must be NO with the exception of SQ32a and SQ33a. If an answer (other than SQ32a and SQ33a) is YES, then immediately proceed to question SQ40.			
			Comments
SQ28.	<b>Has anyone ever told you that you have bipolar disorder or manic depression?</b>	YES NO	
SQ29.	<b>Has anyone ever used the word "Borderline" to describe you?</b>	YES NO	
SQ30a.	<b>Have you ever had a hallucination or seen things that other people can't see, or hear things other people can't hear?</b>	YES NO	
SQ30b.	<b>Have you ever been diagnosed with schizophrenia or psychosis?</b>	YES NO	
SQ31_1	<b>Have you ever taken any of the following medications that I am about to read to you?</b> <b>Lithium</b>	YES NO	
SQ31_2	<b>Seroquel (quetiapine)</b>	YES NO	
SQ31_3	<b>Abilify (aripiprazole)</b>	YES NO	
SQ31_4	<b>Zyprexa (olanzapine)</b>	YES NO	
SQ31_5	<b>Clozaril (clozapine)</b>	YES NO	
SQ31_6	<b>Haldol/Haloperidol</b>	YES NO	
SQ31_7	<b>Geodon (ziprasidone)</b>	YES NO	
SQ31_8	<b>Risperdal (risperidone)</b>	YES NO	
SQ32a	<b>Have you ever had a suicide attempt?</b>	YES NO	
SQ32b	<b>[If yes, ask...] Have you considered killing yourself during the past month?</b>	YES NO	
SQ32c	<b>[If yes, ask...] Are you currently suicidal?</b>  <b>[If yes, keep participant on the phone, and follow suicide safety plan below]</b>	YES NO	
SQ32d	<b>[If no, ask...] Are you getting any help for that? If not, then provide list of resources from Safety Plan including Gateway, Anchor and The Providence Center] Not urgent, but inform Dr. Flynn about what was discussed.</b>	YES NO	

**EXCLUSION CRITERIA:** All answers in 3<sup>rd</sup> column must be NO with the exception of SQ32a and SQ33a. If an answer (other than SQ32a and SQ33a) is YES, then immediately proceed to question SQ40.

SQ33a	<b>Would you say you have a trauma history?</b> <i>[If yes...]</i>	YES NO	
SQ33b	<b>In the past month, have you had any problems with dissociation (memory loss)?</b>	YES NO	
SQ33c	<b>In the past month, have you had any flashbacks (i.e. sudden and disturbing vivid memory) about the trauma?</b>	YES NO	
SQ34a	<b>In the past month, have you had any problems with obsessions or compulsions, such as washing your hands or checking the oven over and over again?</b>	YES NO	
SQ34b	<i>[If yes...]</i> <b>Has anyone diagnosed you with obsessive compulsive disorder?</b>	YES NO	
SQ35	<b>In the past month, have you had a panic attack (i.e. sweating, heart palpitations, nausea, trouble breathing, fear of dying/choking/going crazy)?</b>	YES NO	
SQ36	<b>Have you had any problems with alcoholism or drug use in the past year?</b>	YES NO	
SQ37	<b>In the past year, have you had an eating disorder, such as starving, binge eating, or vomiting?</b>	YES NO	
SQ38a	<b>Do you currently have a mindfulness practice, such as meditation or yoga?</b>	YES NO	
SQ38b	<b>Please tell me more about your mindfulness practice, including how often you practice per week.</b>	Fill in response in comments section to the right	
SQ38c	<b>Do you currently practice meditation more than once per week? (yoga does not count as meditation in this context)</b>	YES NO	
SQ39	<b>This class will take place at Brown University in-person. Do you have any medical or mobility issues that would affect you being able to attend class?</b>	YES NO	
SQ40	Participant qualifies for next step of study (next step is 1 <sup>st</sup> blood pressure screening)	YES NO  If YES go to question SQ41.  If NO, go to question SQ42.	

SQ41. **Thank you for taking the time to answer these questions. You qualify for the next stage of screening, which is to take your blood pressure at two different times at least a week apart from each other. Let's book the in-person screening sessions** [Book both sessions. We can cancel the second session if they do not qualify].

**Thank you for taking the time to answer these questions, and for your interest in this study. We look forward to meeting you in person. Do you have any questions before we end this call?**

SQ42a. **Thank you for taking the time to answer these questions. According to the survey, you do not qualify for the study at this time.** There may be other studies you qualify for.

SQ42b. **Would you like me to keep your information to pass on to these studies?** YES / NO

SQ42c. [If yes...] **OK, thank you. We will keep this information for future studies you may qualify for. Thank you for taking the time to talk with me today. Can I answer any questions before hanging up?**

SQ42d. [If no...] **OK, our copy of this information will be destroyed. Thank you for taking the time to talk with me today. Can I answer any questions before hanging up?**

## SAFETY PLAN

During the phone-based screening, if participants respond yes to “Are you currently suicidal?”, the interviewer should perform the following 2 steps:

1. **Immediately have 911 and Dr. Ellen Flynn called by a colleague who has been informed beforehand that this is a possibility.**

**Specifically, while keeping the participant on the phone, show the text below in bold italics to a colleague.**

***I have a study participant on the phone who is currently suicidal. Please call 911 immediately, and tell them:***

***“I am calling on behalf of [my name] who is performing a research study at Brown University. She has a participant on the phone who says they are currently suicidal.” Please provide the participants’ contact information to the 911 operator (i.e. name, address, phone #, email address) as requested. This information is on page 1 of the screening questionnaire right here [interviewer has this information].***

***Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.***

2. **While speaking calmly with the participant, let them know what you are doing. Specifically, let them know we are calling our study’s psychiatrist Dr. Flynn and 911, and why you are doing that (i.e. because we are concerned about you). You can speak with participant to keep him/her on the phone, but the discussion should not be clinical in nature.**

Examples of questions that could be asked in order to keep them on the phone:

- “Tell me what is going on.”
- “What’s happening right now?”
- Tell me more about why you are interesting in being part of this study.
- What are you hoping to get out of this study?

The following information can be provided to study participants if they state they have had considered killing themselves in the past month. If they are currently suicidal, the main priority is to keep them on the phone while 911 and Dr. Flynn are being contacted.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701; Anchor Counseling Center: 401-475-9979;

The Providence Center: 401-276-4020

## **APPENDIX 2**

### **FIRST IN-PERSON SCREENING ASSESSMENT**

# FIRST IN-PERSON VISIT SCREENING QUESTIONNAIRE AND ASSESSMENT FORMS

PID. Participant ID # \_\_\_\_\_  
BA01. Staff ID # \_\_\_\_\_  
BA02. Today's date (MMDDYY): \_\_\_\_\_

Blood Pressure:

BA03a. Blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03b. Blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03c. Blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03d. Blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03e. Blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03f. Blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03g. Blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03h. Blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03i. Blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03j. Blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA04. Were the 4<sup>th</sup> and 5<sup>th</sup> systolic blood pressure readings within 20 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA05. Were the 4<sup>th</sup> and 5<sup>th</sup> diastolic blood pressure readings within 10 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA06a. Repeated blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06b. Repeated blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06c. Repeated blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06d. Repeated blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06e. Repeated blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06f. Repeated blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06g. Repeated blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06h. Repeated blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06i. Repeated blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06j. Repeated blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA07. Blood pressure cuff size used: ☐ S ☐ Reg ☐ L ☐ XL

BA08. Arm that cuff was placed on: ☐ L ☐ R

BA09. Height: \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

BA10. Weight: \_\_\_\_\_ . \_\_\_\_ kg (one decimal place)

Waist Circumference:

BA11a. Measurement 1 \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)  
BA11b. Measurement 2 \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

BA12. Is the difference between Measurement 1 and Measurement 2 greater than 1.0cm?

- ☐ Yes (**repeat measurements 3&4**)  
☐ No

BA13a. Measurement 3 \_\_\_\_\_ . \_\_\_\_ cm

BA13b. Measurement 4 \_\_\_\_\_ . \_\_\_\_ cm

## **Medications (ME)**

ME01. Do you take any prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

ME02a. What is the name of the first prescription medication or over-the-counter drug that you take?

☐ Label product name:

---

☐ Label generic name:

---

☐ Don't know

☐ Prefer not to answer

ME02b. What is the dosage form?

### Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

### Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

### Inhaled

- ☐ Inhaler or nebulizer

### Injected

- ☐ Injection

### Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

### Other:

- ☐ Don't know  
☐ Prefer not to answer

ME02c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer



ME02d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME02e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME02f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME02g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME02h. **Interviewer comments:**

ME02i. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

ME03a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME03b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule
- ☐ Sublingual or orally-disintegrating tablet
- ☐ Liquid solution or suspension (drink, syrup)
- ☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know
- ☐ Prefer not to answer

ME03c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

- ☐ Don't know
- ☐ Prefer not to answer

ME03d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME03e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME3f. Do you take it regularly or only as needed?

- ☐ Regularly
- ☐ Only as needed

- ☐ Don't know
- ☐ Prefer not to answer

ME03g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks

- ☐ For \_\_\_\_\_ months
- ☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME03h. **Interviewer comments:**

---

ME03i. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications questions**

☐ Yes

☐ Don't know

☐ Prefer not to answer

ME04a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

---

☐ Label generic name:

---

☐ Don't know

☐ Prefer not to answer

ME04b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME04c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

☐ \_\_\_\_\_ times per month

☐ Don't know

☐ Prefer not to answer

ME04d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:

☐ Prefer not to answer

☐ Don't know

ME04e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ Other unit:

☐ \_\_\_\_\_ mg

\_\_\_\_\_

☐ \_\_\_\_\_ mcg

☐ Don't know

☐ \_\_\_\_\_ grams

☐ Prefer not to answer

☐ \_\_\_\_\_ I.U.

ME04f. Do you take it regularly or only as needed?

☐ Regularly

☐ Don't know

☐ Only as needed

☐ Prefer not to answer

ME04g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ years

☐ For \_\_\_\_\_ weeks

☐ Don't know

☐ For \_\_\_\_\_ months

☐ Prefer not to answer

ME04h. **Interviewer comments:**

\_\_\_\_\_

ME04i. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications section**

☐ Don't know

☐ Yes

☐ Prefer not to answer

ME05a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME05b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Liquid solution or suspension (drink, syrup)

☐ Sublingual or orally-disintegrating tablet

☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Inhaled

- ☐ Inhaler or nebulizer

ME05c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

Other:

- ☐ Don't know
- ☐ Prefer not to answer

- ☐ Don't know
- ☐ Prefer not to answer

ME05d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_

- ☐ Don't know
- ☐ Prefer not to answer

ME05e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_

- ☐ Don't know
- ☐ Prefer not to answer

ME05f. Do you take it regularly or only as needed?

- ☐ Regularly
- ☐ Only as needed

- ☐ Don't know
- ☐ Prefer not to answer

ME05g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks
- ☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years
- ☐ Don't know
- ☐ Prefer not to answer

ME05h. **Interviewer comments:**

---

ME05i. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of end of medications questions**
- ☐ Yes

- ☐ Don't know
- ☐ Prefer not to answer

ME06a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

- ☐ Don't know
- ☐ Prefer not to answer

ME06b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule
- ☐ Sublingual or orally-disintegrating tablet
- ☐ Liquid solution or suspension (drink, syrup)
- ☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know
- ☐ Prefer not to answer

ME06c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

- ☐ Don't know
- ☐ Prefer not to answer

ME06d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME06e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
 \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME06e. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed  
☐ Don't know  
☐ Prefer not to answer

ME06f. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months  
☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME06g. **Interviewer comments:**

ME06h. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → *skip to next section*  
☐ Yes  
☐ Don't know  
☐ Prefer not to answer

ME06i. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → ***skip to end of medications questions***  
☐ Yes  
☐ Don't know  
☐ Prefer not to answer

ME07a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

- ☐ Don't know  
☐ Prefer not to answer

ME07b. What is the dosage form?

- Oral  
☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know
- ☐ Prefer not to answer

ME07c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

- ☐ Don't know
- ☐ Prefer not to answer

ME07d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME07e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME07f. Do you take it regularly or only as needed?

- ☐ Regularly
- ☐ Only as needed

- ☐ Don't know
- ☐ Prefer not to answer

ME07g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks
- ☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years
- ☐ Don't know
- ☐ Prefer not to answer

ME07h. **Interviewer comments:**



ME07i. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**
- ☐ Yes

- ☐ Don't know
- ☐ Prefer not to answer

ME08a. What is the name of the next prescription medication or over-the-counter drug that you take?

- ☐ Label product name: \_\_\_\_\_
- ☐ Label generic name: \_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME08b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule
- ☐ Sublingual or orally-disintegrating tablet
- ☐ Liquid solution or suspension (drink, syrup)
- ☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know
- ☐ Prefer not to answer

ME08c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

- ☐ Don't know
- ☐ Prefer not to answer

ME08d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME08e. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
 \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME08f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed  
☐ Don't know  
☐ Prefer not to answer

ME08g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months  
☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME08h. **Interviewer comments:**

ME08i. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**  
☐ Yes  
☐ Don't know  
☐ Prefer not to answer

ME09a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

- ☐ Don't know ☐ Prefer not to answer

ME09b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)

- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME09c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ Don't know

☐ \_\_\_\_\_ times per week

☐ Prefer not to answer

☐ \_\_\_\_\_ times per month

ME09d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ Other unit:

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ Don't know

☐ \_\_\_\_\_ grams

☐ Prefer not to answer

☐ \_\_\_\_\_ I.U.

ME09e. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ Other unit:

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ Don't know

☐ \_\_\_\_\_ grams

☐ Prefer not to answer

☐ \_\_\_\_\_ I.U.

ME09f. Do you take it regularly or only as needed?

☐ Regularly

☐ Don't know

☐ Only as needed

☐ Prefer not to answer

ME09g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ years

☐ For \_\_\_\_\_ weeks

☐ Don't know

☐ For \_\_\_\_\_ months

☐ Prefer not to answer

ME09h. **Interviewer comments:**

---

ME09i. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications questions**

☐ Don't know

☐ Yes

☐ Prefer not to answer

ME10a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME10b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME10c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

☐ \_\_\_\_\_ times per month

☐ Don't know

☐ Prefer not to answer

ME10d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:

\_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME10e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:

\_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME10f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME10g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months  
☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME10h. **Interviewer comments:** \_\_\_\_\_

**Questions for Participants to Answer on Their Own In-Person on Computer:**

For each statement, please place a mark in the column that best describes how you have been feeling.

	Not at all or less than 1 day last week	1 or 2 days last week	3 to 4 days last week	5 to 7 days last week	Nearly every day for two weeks	I do not know	I prefer not to answer
DS_1. My appetite was poor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_2. I could not shake off the blues.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_3. I had trouble keeping my mind on what I was doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_4. I felt depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_5. My sleep was restless.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_6. I felt sad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_7. I could not get going.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_8. Nothing made me happy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C_9. I felt like a bad person.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_10. I lost interest in my usual activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_11. I slept much more than usual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_12. I felt like I was moving too slowly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_13. I felt fidgety.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_14. I wished I were dead.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_15. I wanted to hurt myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_16. I was tired all the time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_17. I did not like myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_18. I lost a lot of weight without trying to.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_19. I had a lot of trouble getting to sleep.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_20. I could not focus on the important things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past month, including today, by marking the box in the corresponding space in the column next to each symptom.

	Not At All	Mildly – it didn't bother me much	Moderately – it wasn't pleasant at all times	Severely – it bothered me a lot	I do not know	I prefer not to answer
BA_1. Numbness or tingling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_2. Feeling hot	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_3. Wobbliness in legs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_4. Unable to relax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_5. Fear of worst happening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_6. Dizzy or lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_7. Heart pounding/racing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_8. Unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_9. Terrified or afraid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_10. Nervous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_11. Feeling of choking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_12. Hands trembling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_13. Shaky/unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_14. Fear of losing control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_15. Difficulty in breathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_16. Fear of dying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_17. Scared	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_18. Indigestion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_19. Faint/lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_20. Face flushed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BA_21. Hot/cold sweats	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **SAFETY PLAN**

After the participant has completed the Beck Anxiety Inventory questionnaire and the Centers for Epidemiologic Studies Depressive Symptomatology questionnaire, ask the participant to wait for a few minutes while you check that all forms and assessments are completed. While the participant is waiting in a different room, check the scores according to the criteria below. If any scores trigger the safety plan, move forward with steps below as written.

### **Beck Anxiety Inventory (BA)**

If participant scores  $\geq 26$  on the Beck Anxiety Inventory, while having the participant wait, immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and your phone # will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, please leave a phone message for her with your contact information and provide her with the Beck Anxiety Inventory results on the message. If Dr. Flynn is not immediately reachable, or following participant release after consulting with Dr. Flynn, immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).

### **Depressive Symptomatology (DS)**

The CESD-R will be administered during the in-person assessment visits, and scores will be reviewed immediately upon completion of the in-person assessments.

1. Sadness (dysphoria): Question numbers 2, 4, 6
2. Loss of Interest (anhedonia): Question numbers 8, 10
3. Appetite: Question numbers 1, 18
4. Sleep: Question numbers 5, 11, 19
5. Thinking / concentration: Question numbers 3, 20
6. Guilt (worthlessness): Question numbers 9, 17
7. Tired (fatigue): Question numbers 7, 16
8. Movement (agitation): Question numbers 12, 13
9. Suicidal ideation: Question numbers 14, 15

Participants are considered to meet criteria for major depressive episode if they have anhedonia or dysphoria nearly every day for the past two weeks, plus symptoms in an additional 4 DSM symptom groups noted as occurring nearly every day for the past two weeks. If participants meet criteria for major depressive episode, while having the participant wait, immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and your phone # will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, please leave a phone message for her with your contact information and provide her with the Depressive Symptomatology results on the message. If Dr. Flynn is not immediately reachable, or following participant release after consulting with Dr. Flynn, immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).



If participants respond having any suicidal ideation (DS questions 14 or 15), perform the following 2 steps:

1. Immediately call 911 and Dr. Ellen Flynn.

**Specifically, while the participant is in the waiting room, call 911 immediately, and tell them:**

***“My name is \_\_\_\_\_. I am working on a research study at Brown University. I have a study participant in the waiting room who has shared that he/she is currently suicidal.” Please provide the participants’ name to the 911 operator, as requested.***

***Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.***

2. While speaking calmly with the participant, let them know that you have called 911 and Dr. Flynn, and why (i.e. because we are concerned about you). You can speak with participant to keep him/her in the waiting room if 911 has sent assistance, but the discussion should not be clinical in nature.

Examples of questions that could be asked in order to keep them in the waiting room:

- “Tell me what is going on.”
- “What’s happening right now?”
- Tell me more about why you are interesting in being part of this study.
- What are you hoping to get out of this study?

The following information can be provided to study participants.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020

**APPENDIX 3**

**BASELINE QUESTIONNAIRE**

QUESTIONNAIRES ANSWERED BY PARTICIPANTS  
AT BASELINE (VIA ONLINE OR PAPER FORM)

## **Questionnaire Table of Contents**

<b>Introductory Questions .....</b>	<b>3</b>
<b>Background Questions .....</b>	<b>5</b>
<b>Physical Activity .....</b>	<b>8</b>
<b>Diet .....</b>	<b>10</b>
<b>Eating Practices .....</b>	<b>16</b>
<b>Alcohol Consumption .....</b>	<b>18</b>
<b>Smoking .....</b>	<b>19</b>
<b>About You .....</b>	<b>20</b>
<b>Parent's Education .....</b>	<b>41</b>
<b>Your Childhood Experiences.....</b>	<b>43</b>
<b>Relationships .....</b>	<b>46</b>
<b>Your Sleep .....</b>	<b>49</b>

**Introduction**

We appreciate you taking the time to participate in this research study. These questionnaires will ask a series of questions on various aspects of your health, health behaviours, family, and other life circumstances. It should take approximately one hour. Please keep in mind that you can refuse to answer any questions that you are not comfortable with.

**Introductory Questions**

IQ1\_01. Please enter the 3-digit ID number you were given. \_\_\_\_ \_\_\_\_ \_\_\_\_.

IQ1\_02. What is your main reason for participating in this study?

IQ1\_03. What do you care about most?

IQ1\_04. What gives you the most pleasure in your life?

IQ1\_05. What are your greatest worries?

**Please list three personal goals you have for taking this mindfulness program:**

**PG1\_01.** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**PG1\_02.** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**PG1\_03.** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## **Background Questions**

BQ1\_01. How many years old are you?

BQ1\_02. Are you Latino or Hispanic?

- ☐ No → **skip to B3**
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

B1\_02a. Which of the following represents your family's country of origin? (**check all that apply**)

- |  |   |
|--|---|
| <input type="checkbox"/> Cuba          | <input type="checkbox"/> Dominican Republic     |
| <input type="checkbox"/> Mexico        | <input type="checkbox"/> Other Central American |
| <input type="checkbox"/> Puerto Rico   | <input type="checkbox"/> Other: _____           |
| <input type="checkbox"/> Spain         | <input type="checkbox"/> I do not know          |
| <input type="checkbox"/> South America | <input type="checkbox"/> I prefer not to answer |
| <input type="checkbox"/> Columbia      |   |

BQ1\_03. If you were asked to put yourself into only one of these groups, in which one would you place yourself? (**select one only**):

- |   |   |
|---|---|
| <input type="checkbox"/> Asian                  | <input type="checkbox"/> Native American        |
| <input type="checkbox"/> Pacific Islander       | <input type="checkbox"/> Other : _____          |
| <input type="checkbox"/> African American/Black | <input type="checkbox"/> I do not know          |
| <input type="checkbox"/> Caucasian/White        | <input type="checkbox"/> I prefer not to answer |

BQ1\_04. Which of the following best describes your current work situation? (**select one only**)

- |   |  |
|---|--|
| <input type="checkbox"/> Working full-time                          | <input type="checkbox"/> Keeping house or raising children full-time |
| <input type="checkbox"/> Working part-time                          | <input type="checkbox"/> Military                                    |
| <input type="checkbox"/> Retired                                    | <input type="checkbox"/> Full-time student                           |
| <input type="checkbox"/> Unemployed: Looking for work               | <input type="checkbox"/> Other: _____                                |
| <input type="checkbox"/> Unemployed: Not currently looking for work | <input type="checkbox"/> I do not know                               |
| <input type="checkbox"/> Unemployed due to disability               | <input type="checkbox"/> I prefer not to answer                      |

BQ1\_05. What is the highest grade or level of regular school you have completed?

- ☐ Elementary School
- ☐ Junior High
- ☐ High School
- ☐ College
- ☐ Graduate School
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_06. What is the highest degree you earned? (***select one only***)

- |  |  |
|--|--|
| <input type="checkbox"/> Elementary school                 | <input type="checkbox"/> Master's degree                       |
| <input type="checkbox"/> Some high school, but no GED      | <input type="checkbox"/> Doctorate (PhD, EdD, etc)             |
| <input type="checkbox"/> GED                               | <input type="checkbox"/> Professional (MD, JD, DDS, DVM, etc.) |
| <input type="checkbox"/> High school                       | <input type="checkbox"/> Other: _____                          |
| <input type="checkbox"/> Associate degree (Junior College) | <input type="checkbox"/> I do not know                         |
| <input type="checkbox"/> Bachelor's degree                 | <input type="checkbox"/> I prefer not to answer                |

BQ1\_07. Did you ever attend any other school like a technical, vocational, or trade school?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_08. In total, about how many full-time years of education have you had, including 1<sup>st</sup> grade and all years of school after 1<sup>st</sup> grade?

\_\_\_\_\_ years



BQ1\_09a. Do you currently live alone?

- ☐ No
- ☐ Yes → *skip to BQ\_10*
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_09b. How many people currently live in your household, including yourself?

\_\_\_\_\_

BQ1\_09c. Of these people, how many are under 18?

\_\_\_\_\_

BQ1\_09d. Of the adults in your household (including yourself), how many bring income into the household?

\_\_\_\_\_

## **Physical Activity**

Physical activities are activities where you move and increase your heart rate above its resting rate, whether you do them for pleasure, work, or transportation. The following questions ask about the amount and intensity of physical activity you usually do. The intensity of the activity is related to *the amount of energy* you use doing these activities.

### **Examples of physical activity intensity levels:**

#### **Light activities**

Your heart beats slightly faster than normal  
You can talk and sing



Light exercise



Light stretching



Light vacuuming  
or yard work

#### **Moderate activities**

Your heart beats faster than normal  
You can talk but not sing



Brisk walking



Aerobics class



Strength training



Swim gently

#### **Vigorous activities**

Your heart rate increases a lot  
You can't talk, or your talking is broken  
up by large breaths



Aerobics classes



Jogging, Running,  
or Power Walking



Singles tennis,  
Racquetball, Pickle ball

## How physically active are you?

	YES	NO	I do not know	I prefer not to answer
PA1_01. I rarely or never do any physical activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_02. I do some light and/or moderate physical activities, but not every week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_03. I do some light physical activity every week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_04. I do moderate physical activity every week but less than 5 days per week or less than 30 minutes on those days.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_05. I do vigorous physical activities every week, but less than 3 days per week or less than 20 minutes on those days.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_06. I do 30 minutes or more per day of moderate physical activities 5 or more days per week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_07. I do 20 minutes or more per day of vigorous physical activities 3 or more days per week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_08. I do activities to increase muscle strength, such as lifting weights or calisthenics, once a week or more.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_09. I do activities to improve flexibility, such as stretching or yoga, once a week or more.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Diet**

The first set of questions ask about foods you usually eat or drink. For each food, please place an X in the box (e.g. ☒) for the answer that best matches how often you eat or drink it. Remember to count fruit or vegetables that were part of another dish, like a banana on cereal or vegetables in a stew. Also, please pay attention to the serving sizes. For example, one serving size of bread is one slice, so a sandwich would contain 2 servings of bread. Please include all foods you eat, both at home and away from home. Enclosed are pictures of common serving sizes to assist you in filling out your questionnaire.

## The secret to serving size is in your hand.



### A fist or cupped hand = 1 cup

1 cup = 1½-2 servings of fruit juice  
1 oz. of cold cereal  
2 oz. of cooked cereal, rice or pasta  
8 oz. of milk or yogurt

### A thumb = 1 oz. of cheese

Consuming low-fat cheese helps you meet the required servings from the milk, yogurt and cheese group.  
1½ oz. of low-fat cheese counts as 8 oz. of milk or yogurt.



### Handful = 1-2 oz. of snack food

Snacking can add up.  
Remember, 1 handful equals 1 oz. of nuts and small candies.  
For chips and pretzels, 2 handfuls equal 1 oz.



### Palm = 3 oz. of meat

Choose lean poultry, fish, shellfish and beef. One palm size portion equals 3 oz. for an adult and 1½-2 oz. for a child under 5.

### Thumb tip = 1 teaspoon

Keep high-fat foods, such as peanut butter and mayonnaise, at a minimum. One teaspoon is equal to the end of your thumb, from the knuckle up. Three teaspoons equals 1 tablespoon.



### 1 tennis ball = ½ cup of fruit and vegetables

Healthy diets include a variety of colorful fruits and vegetables every day.

Because hand sizes vary, compare your fist size to an actual measuring cup.

Iowa WIC Program - Iowa Department of Public Health - 2007  
Adapted from North Carolina Nutrition Network

### How Often You Eat or Drink This Item

	Never or less than 1 per month	1-3 per month	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	More than 5 per day	I do not know
<b>DT1_01.</b> Skim/low fat milk (8 oz. glass)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_02.</b> Whole milk (8 oz. glass)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_03.</b> Ice cream (1 cup)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_04.</b> Yogurt (1 cup)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_05.</b> Cottage or ricotta cheese (1/2 cup)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_06.</b> Butter, added to food or bread (1 pat), exclude use in cooking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_07.</b> Fruit (not including fruit juice. A serving = 1 piece, or 1/2 grapefruit, or 1/2 cup berries)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_08.</b> 100% fruit juice, not including fruit drinks (small glass)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### How Often You Eat or Drink This Item

	Never or less than 1 per month	1-3 per month	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	More than 5 per day	I do not know	I prefer not to answer
<b>DT1_09.</b> Vegetables - raw and cooked (1/2 cup), including mixed dishes such as soups, casseroles and lasagna. Do not include potatoes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_10.</b> Eggs (do not include egg beaters) (1)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_11.</b> Chicken or turkey (4-6 oz.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_12.</b> Processed meat (1 piece sausage, 1 slice salami, 2 pieces bacon)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_13.</b> Hot dog/ hamburger	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### How Often You Eat or Drink This Item

	Never or less than 1 per month	1-3 per month	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	More than 5 per day	I do not know	I prefer not to answer
<b>DT1_14.</b> Beef, pork, or lamb as a sandwich or mixed dish, e.g. stew, casserole, lasagna, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_15.</b> Beef, pork, or lamb as a main dish, e.g. steak, roast, ham, etc. (4-6 oz.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_16.</b> Fish (including canned tuna) (3-5 oz.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_17.</b> Shellfish such as shrimp, lobster, scallops and clams as a main dish	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_18.</b> White bread (including pita bread) (slice)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_19.</b> Dark bread (including whole wheat and rye) (slice)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_20.</b> Bakery items (cookies, brownies, doughnuts, cake) (1 piece or slice)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_21.</b> Nuts (small packet, 1 oz., 1 Tbs peanut butter)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_22.</b> Pasta (e.g. spaghetti, and macaroni and cheese; 1 cup cooked)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_23.</b> Potatoes, baked, boiled or mashed (do not include French fries/chips) (1 potato or 1 cup)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**How Often You Eat or Drink This Item**

	Never or less than 1 per month	1-3 per month	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	More than 5 per day	I do not know	I prefer not to answer
<b>DT1_24.</b> Regular soft drinks (including caffeine free, but NOT including diet colas) (consider the serving size as 1 glass, bottle or can)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_25.</b> Coffee (regular or decaf) (1 cup)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Eating Practices**

	Definitely True	Mostly True	Mostly False	Definitely False	I Do Not Know	I Prefer Not to Answer
EE1_01. I deliberately take small helpings to control my weight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_02. I start to eat when I feel anxious.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_03. Sometimes when I start eating, I just can't seem to stop.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_04. When I feel sad, I often eat too much.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_05. I don't eat some foods because they make me fat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_06. Being with someone who is eating, often makes me want to also eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_07. When I feel tense or "wound up", I often feel I need to eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_08. I often get so hungry that my stomach feels like a bottomless pit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_09. I'm always so hungry that it's hard for me to stop eating before finishing all of the food on my plate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_10. When I feel lonely, I console myself by eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_11. I consciously hold back on how much I eat at meals to keep from gaining weight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_12. When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating even if I've just finished a meal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_13. I'm always hungry enough to eat at any time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_14. If I feel nervous, I try to calm down by eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_15. When I see something that looks very delicious, I often get so hungry that I have to eat right away.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_16. When I feel depressed, I want to eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Seldom	Usually	Almost Always	I Do Not Know	I Prefer Not to Answer
EE1_17. How often do you avoid ‘stocking up’ on tempting foods?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Unlikely	A little likely	Somewhat likely	Very likely	I Do Not Know	I Prefer Not to Answer
EE1_18. How likely are you to make an effort to eat less than you want?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Rarely	Sometimes	At least once a week	I Do Not Know	I Prefer Not to Answer
EE1_19. Do you go on eating binges even though you’re not hungry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Only at mealtimes	Sometimes between meals	Often between meals	Almost always	I Do Not Know	I Prefer Not to Answer
EE1_20. How often do you feel hungry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	1	2	3	4	5	6	7	8	I Do Not Know	I Prefer Not to Answer
EE1_21. On a scale from 1 to 8, where 1 means no restraint in eating and 8 means total restraint, what number would you give yourself? Mark the number that best applies to you:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Alcohol Consumption**

A drink of alcohol is defined as 1 can or bottle of beer, 1 glass of wine, 1 can or bottle of wine cooler, 1 cocktail, or 1 shot of liquor.

AC1\_01. During the past 30 days, how many days per week or per month did you have at least 1 drink of any alcoholic beverage? [if none, **STOP**]

---

AC1\_02. On the days when you drank, about how many drinks did you drink on average?

---

AC1\_03. **Men:** Considering all types of alcoholic beverages, how many times during the past 30 days did you have **5** or more drinks on an occasion?

**Women:** Considering all types of alcoholic beverages, how many times during the past 30 days did you have **4** or more drinks on an occasion?

---

## **Smoking**

SM1\_01. Have you smoked at least 100 cigarettes in your entire life?

- ☐ Yes
- ☐ No
- ☐ I Do Not Know
- ☐ Prefer not to answer

SM1\_02. Did you ever become a daily smoker (that is, smoke every day or nearly every day for two months or longer)?

- ☐ Yes
- ☐ No → *skip to SC1\_01*
- ☐ I Do Not Know
- ☐ Prefer not to answer

SM1\_03. How old were you when you last smoked daily?

Age \_\_\_\_\_ (in years)

- ☐ I Do Not Know
- ☐ Prefer not to answer
- ☐ Still smoking daily

SM1\_04. Do you smoke cigarettes now?

- ☐ Yes
- ☐ No → *skip to next section*
- ☐ I Do Not Know
- ☐ Prefer not to answer

SM1\_04a. How many cigarettes per day do you smoke? (One pack equals 20 cigarettes)

Number of cigarettes \_\_\_\_\_

- ☐ I Do Not Know
- ☐ Prefer not to answer

## About You

Using the scale provided, please indicate how much each of the following statements reflects how you typically are.

	Not at all	A little	Somewhat	Fair Amount	Very much	I do not know	I prefer not to answer
SC1_01. I am good at resisting temptation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_02. I have a hard time breaking bad habits.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_03. I am lazy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_04. I say inappropriate things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_05. I do certain things that are bad for me, if they are fun.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_06. I refuse things that are bad for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_07. I wish I had more self-discipline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_08. People would say that I have iron self-discipline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_09. Pleasure and fun sometimes keep me from getting work done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_10. I have trouble concentrating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_11. I am able to work effectively toward long-term goals.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_12. Sometimes I can't stop myself from doing something, even if I know it is wrong.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_13. I often act without thinking through all the alternatives.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The next few statements are about certain ways you may feel about your life. Please indicate how strongly you agree or disagree with each of the following statements: Strongly agree; Agree; Neutral, Disagree, or Strongly disagree

	<b>Strongly agree</b>	<b>Agree</b>	<b>Neutral</b>	<b>Disagree</b>	<b>Strongly disagree</b>	<b>I Do Not Know</b>	<b>Prefer not to answer</b>
<b>SE1_01.</b> I have little control over the things that happen to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE1_02.</b> There is really no way I can solve some of the problems I have.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE1_03.</b> There is little I can do to change many of the important things in my life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE1_04.</b> I often feel helpless in dealing with the problems of life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE1_05.</b> Sometimes I feel that I am being pushed around in life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE1_06.</b> What happens to me in the future mostly depends on me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>SE1_07.</b> I can do just about anything I really set my mind to do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

	Almo st never	Not very often	Sometimes	Frequently	Almost always	I Do Not Know	Prefer not to answer
C1_O1. When I fail at something important to me, I become consumed by feelings of inadequacy.							
C1_O2. I try to be understanding and patient towards those aspects of my personality I don't like.							
C1_O3. When something painful happens I try to take a balanced view of the situation.							
C1_O4. When I'm feeling down, I tend to feel like most other people are probably happier than I am.							
C1_O5. I try to see my failings as part of the human condition.							
C1_O6. When I'm going through a very hard time, I give myself the caring and tenderness I need.							
C1_O7. When something upsets me I try to keep my emotions in balance.							
C1_O8. When I fail at something that's important to me, I tend to feel alone in my failure							
C1_O9. When I'm feeling down I tend to obsess and fixate on everything that's wrong.							



	Almost never	<u>Not very often</u>	<u>Sometimes</u>	<u>Frequently</u>	Almost always	<u>I Do Not Know</u>	<u>Prefer not to answer</u>
CO1_10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.							
CO1_11. I'm disapproving and judgmental about my own flaws and inadequacies.							
CO1_12. I'm intolerant and impatient towards those aspects of my personality I don't like.							

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling how often you felt or thought a certain way.

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
PS1_01. In the last month, how often have you been upset because of something that happened unexpectedly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_02. In the last month, how often have you felt that you were unable to control the important things in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_03. In the last month, how often have you felt nervous and “stressed”?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_04. In the last month, how often have you felt confident about your ability to handle your personal problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_05. In the last month, how often have you felt that things were going your way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_06. In the last month, how often have you found that you could not cope with all the things that you had to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_07. In the last month, how often have you been able to control irritations in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_08. In the last month, how often have you felt that you were on top of things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_09. In the last month, how often have you been angered because of things that were outside of your control?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Instructions: Below is a collection of statements about your everyday experience. Using the scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what really reflects your experience rather than what you think your experience should be. Please treat each item separately from every other item.

***Please indicate the degree to which you agree with each of the following items using the scale below. Simply check your response to each item***

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never	I do not know	I prefer not to answer
MA1_01. I could be experiencing some emotion and not be conscious of it until some time later.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_02. I break or spill things because of carelessness, not paying attention, or thinking of something else.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_03. I find it difficult to stay focused on what's happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_04. I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_05. I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_06. I forget a person's name almost as soon as I've been told it for the first time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never	I do not know	I prefer not to answer
MA1_07. It seems I am “running on automatic” without much awareness of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_08. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_09. I get so focused on the goal I want to achieve that I lose touch with what I am doing right now to get there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_10. I do jobs or tasks automatically, without being aware of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_11. I find myself listening to someone with one ear, doing something else at the same time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_12. I drive places on “automatic pilot” and then wonder why I went there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_13. I find myself preoccupied with the future or the past.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_14. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_15. I snack without being aware that I’m eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes *your own opinion* of what is *generally true for you*.

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_01. When I'm walking, I deliberately notice the sensations of my body moving.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_02. I'm good at finding words to describe my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_03. I criticize myself for having irrational or inappropriate emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_04. I perceive my feelings and emotions without having to react to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_05. When I do things, my mind wanders off and I'm easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_06. When I take a shower or bath, I stay alert to the sensations of water on my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_07. I can easily put my beliefs, opinions, and expectations into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_08. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_09. I watch my feelings without getting lost in them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_10. I tell myself I shouldn't be feeling the way I'm feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_12. It's hard for me to find the words to describe what I'm thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_13. I am easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_15. I pay attention to sensations, such as the wind in my hair or sun on my face.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_16. I have trouble thinking of the right words to express how I feel about things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_17. I make judgments about whether my thoughts are good or bad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_18. I find it difficult to stay focused on what's happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_21. In difficult situations, I can pause without immediately reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_23. It seems I am "running on automatic" without much aware- ness of what I'm doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_24. When I have distressing thoughts or images, I feel calm soon after.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_25. I tell myself that I shouldn't be thinking the way I'm thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_26. I notice the smells and aromas of things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_27. Even when I'm feeling terribly upset, I can find a way to put it into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_28. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_29. When I have distressing thoughts or images, I am able just to notice them without reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_32. My natural tendency is to put my experiences into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_33. When I have distressing thoughts or images, I just notice them and let them go.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_34. I do jobs or tasks automatically without being aware of what I'm doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_35. When I have distressing thoughts or images, I judge myself as good or bad depending what the thought or image is about.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_36. I pay attention to how my emotions affect my thoughts and behavior.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_37. I can usually describe how I feel at the moment in consider- able detail.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Almost Never	Someti mes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_38. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_39. I disapprove of myself when I have irrational ideas.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



### This Week's Experiences

**Instructions:** Below is a collection of statements about how you find yourself reacting to unpleasant thoughts and feelings. Using the scale below, please indicate how frequently or infrequently you experienced each of the following reactions this week. **Please answer according to what *really reflects your experience this week* rather than what you think your experience should be.**

**This week, when I encountered an unpleasant thought or feeling,**

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always	I do not know	I prefer not to answer
MS1_01. I tried to think pleasant thoughts instead	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_02. I allowed myself to experience it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_03. I got angry or upset at myself for having the thought/emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_04. I felt the desire to make it better or make it go away	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_05. I wished I didn't feel or think that way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_06. I tried to let my thoughts just come and go without getting too entangled with them	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always	I do not know	I prefer not to answer
MS1_07. I thought the mood would never change	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_08. I explored the body sensations that accompanied the emotion.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_09. I named the emotion over and over as long as it lasted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_10. I turned to work or other activities to take my mind off things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_11. I named the emotion and then redirected my attention to the present moment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_12. I thought "This mood, too, shall pass"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always	I do not know	I prefer not to answer
MS1_13. I focused on my breathi	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_14. I took an active interest in how the experience changed over time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_15. I explored my reactions to the thought or emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_16. I thought "my thinking is being distorted by my mood"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_17. Think "Why do I have problems that other people don't have?"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_18. I forgave myself for having the thought/emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_19. I challenged the thought's validity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_20. I asked myself questions about the experience in order to explore it better	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always	I do not know	I prefer not to answer
MS1_21. I tried not to change it because I believe it is important to experience	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_22. I labelled my thoughts "images" or verbal "talk"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_23. I thought "Why do I always react this way?"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_24. I adopted a welcoming stance toward the emotion/thought	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_25. I went somewhere alone to think about my feelings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_26. I sent out compassion to all people who struggle with this emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_27. I restrained myself from doing anything too quickly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always	I do not know	I prefer not to answer
MS1_28. I became genuinely curious about the thought/emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_29. I laughed or kidded myself about the situation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_30. I treated the repetitive thought like a “top ten radio tune” that's playing in the background	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_31. I talked to others about how I was feeling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_32. I tried to forget about it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_33. I thought "Why can't I handle things better"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_34. I tried to come up with a way to make it go away	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_35. I said to myself "thinking" or "this is just a thought"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_36. I thought about how much I disliked feeling that way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_37. I reminded myself thoughts are not accurate reflections of reality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always	I do not know	I prefer not to answer
MS1_38. I thought that that I must be headed into a downward spiral	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_39. I thought "What I am doing to deserve this?"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Please indicate how often the following statements apply to you by checking the box that best describes your experience.**

	Almost Never (0-10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_01. I am clear about my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_02. I pay attention to how I feel.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_03. I experience my emotions as overwhelming and out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_04. I have no idea how I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_05. I have difficulty making sense out of my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_06. I am attentive to my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_07. I know exactly how I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_08. I care about what I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_09. I am confused about how I feel.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_10. When I'm upset, I acknowledge my emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_11. When I'm upset, I become angry with myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_12. When I'm upset, I become embarrassed for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never (0-10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_13. When I'm upset, I have difficulty getting work done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_14. When I'm upset, I become out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_15. When I'm upset, I believe that I will remain that way for a long time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_16. When I'm upset, I believe that I will end up feeling very depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_17. When I'm upset, I believe that my feelings are valid and important.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_18. When I'm upset, I have difficulty focusing on other things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_19. When I'm upset, I feel out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_20. When I'm upset, I can still get things done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_21. When I'm upset, I feel ashamed at myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_22. When I'm upset, I know that I can find a way to eventually feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



	Almost Never (0- 10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_23. When I'm upset, I feel like I am weak.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_24. When I'm upset, I feel like I can remain in control of my behaviours.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_25. When I'm upset, I feel guilty for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_26. When I'm upset, I have difficulty concentrating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_27. When I'm upset, I have difficulty controlling my behaviours.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_28. When I'm upset, I believe there is nothing I can do to make myself feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_29. When I'm upset, I become irritated at myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_30. When I'm upset, I start to feel very bad about myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_31. When I'm upset, I believe that wallowing in it is all I can do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_32. When I'm upset, I lose control over my behaviour.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never (0- 10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_33. When I'm upset, I have difficulty thinking about anything else.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_34. When I'm upset I take time to figure out what I'm really feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_35. When I'm upset, it takes me a long time to feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_36. When I'm upset, my emotions feel overwhelming.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Parent's Education**

CS1\_01. Please check the box beside the highest grade or degree that your BIOLOGICAL MOTHER completed.

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

CS1\_02. Please check the box beside the highest grade or degree that your BIOLOGICAL FATHER completed.

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

Now please think of the two most important adults in your home between the time you were born and age 18 years. Please check the category below that best described their level of education during this time period.

CS1\_03. First adult's highest level of education:

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

CS1\_04. Second adult's highest level of education

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

## **Your Childhood Experiences**

The following questions ask about some difficult experiences that you might have had as a child. These questions may be emotionally difficult to answer. Just as a reminder, you do not need answer any questions that you would prefer not to. Your answers to these questions, as with all questions, will remain confidential.

CE1\_01. Before you were 18 years old, did a parent or other adult in the household often or very often...

Swear at you, insult you, put you down, or humiliate you?

or

Act in a way that made you afraid that you might be physically hurt?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_02. Before you were 18 years old, did a parent or other adult in the household often or very often...

Push, grab, slap, or throw something at you?

or

Ever hit you so hard that you had marks or were injured?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_03. Before you were 18 years old, did an adult or person at least 5 years older than you ever...

Touch or fondle you or have you touch their body in a sexual way?

or

Attempt or actually have oral, anal, or vaginal intercourse with you?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_04. Before you were 18 years old, did you often or very often feel that ...

No one in your family loved you or thought you were important or special?

or

Your family didn't look out for each other, feel close to each other, or support each other?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_05. Before you were 18 years old, did you often or very often feel that ...

You didn't have enough to eat, had to wear dirty clothes, and had no one to protect you?

or

Your parents were too drunk or high to take care of you or take you to the doctor if you needed it?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_06. Before you were 18 years old, was a biological parent ever lost to you through divorce, abandonment, or other reason?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_07. Before you were 18 years old, was your mother or stepmother:

Often or very often pushed, grabbed, slapped, or had something thrown at her?

or

Sometimes, often, or very often kicked, bitten, hit with a fist, or hit with something hard?

or

Ever repeatedly hit over at least a few minutes or threatened with a gun or knife?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_08. Before you were 18 years old, did you live with anyone who was a problem drinker or alcoholic, or who used street drugs?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_09. Before you were 18 years old, was a household member depressed or mentally ill, or did a household member attempt suicide?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_10. Before you were 18 years old, did a household member go to prison?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

## **Relationships**

SN1\_01. How many close friends do you have? By close friends, we mean people that you feel at ease with, and that you can talk to about private matters.

☐ None → *skip to Y2*

\_\_\_\_\_ Number of close friends

☐ I do not know

☐ I prefer not to answer

Y1a. How many of these close friends do you see at least once a month?

\_\_\_\_\_ Number of close friends (*if none, write zero*)

☐ I do not know

☐ I prefer not to answer

SN1\_02. Thinking about your relatives, how many relatives do you feel at ease with, and feel that you can talk to about private matters?

☐ None → *skip to Y3*

\_\_\_\_\_ Number of relatives

☐ I do not know

☐ I prefer not to answer

Y2a. How many of these relatives do you see at least once a month?

\_\_\_\_\_ Number of relatives (*if none, write zero*)

☐ I do not know

☐ I prefer not to answer



SN1\_03.About how often do you participate in groups or clubs, such as religious connected groups, self-help groups, charities, or a public service or community group.

- ☐ Never or almost never
- ☐ A few times a year
- ☐ Once or twice a month
- ☐ Once a week
- ☐ More than once a week
- ☐ I do not know
- ☐ I prefer not to answer

SN1\_04.About how often do you go to religious meetings or services?

- ☐ Never or almost never
- ☐ A few times a year
- ☐ Once or twice a month
- ☐ Once a week
- ☐ More than once a week
- ☐ I do not know
- ☐ I prefer not to answer

INSTRUCTIONS: Indicate how often each of the statements below is descriptive of you.

Statement	Never	Rarely	Sometimes	Often	I Do Not Know	Prefer not to answer
LS1_01. I feel in tune with the people around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	S
LS1_02. I lack companionship	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_03. There is no one I can turn to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_04. I do not feel alone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_05. I feel part of a group of friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_06. I have a lot in common with the people around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_07. I am no longer close to anyone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_08. My interests and ideas are not shared by those around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_09. I am an outgoing person	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_10. There are people I feel close to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_11. I feel left out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_12. My social relationships are superficial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_13. No one really knows me well	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_14. I feel isolated from others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_15. I can find companionship when I want it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_16. There are people who really understand me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_17. I am unhappy being so withdrawn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_18. People are around me but not with me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_19. There are people I can talk to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_20. There are people I can turn to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **Your Sleep**

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. ***Please answer all questions.***

SL1\_01. **During the past month**, what time have you usually gone to bed at night?

BED TIME \_\_\_\_\_ AM / PM

- ☐ I do not know
- ☐ I prefer not to answer

SL1\_02. **During the past month**, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES \_\_\_\_\_

- ☐ I do not know
- ☐ I prefer not to answer

SL1\_03. During the past month, at what time have you usually gotten up in the morning?

GETTING UP TIME \_\_\_\_\_ AM / PM

- ☐ I do not know
- ☐ I prefer not to answer

SL1\_04. During the past month, how many hours of actual sleep did you get on average at night?  
(This may be different than the number of hours you spent in bed.)

AVERAGE HOURS OF SL1\_EEP PER NIGHT \_\_\_\_\_

- ☐ I do not know
- ☐ I prefer not to answer

***For each of the remaining questions, check the one best response. Please answer all questions.***

**During the past month**, how often have you had trouble sleeping because you.....

SL1\_05. ....Could not get to sleep within 30 minutes?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_06. ....Woke up in the middle of the night or early morning?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_07. ....Had to get up to use the bathroom?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_08. ....Could not breathe comfortably?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_09. ....Coughed or snored loudly?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_10. ....Felt too cold?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_11. ....Felt too hot?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_12. ....Had bad dreams?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_13. ....Had pain?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_14a. Other reason(s), **please describe:** \_\_\_\_\_

SL1\_14b. How often during the past month have you had trouble sleeping because of this?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_15. **During the past month**, how would you rate your sleep quality overall?

- ☐ Very good
- ☐ Fairly good
- ☐ Fairly bad
- ☐ Very bad
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_16. **During the past month**, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_17. **During the past month**, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_18. **During the past month**, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

- ☐ No problem at all
- ☐ Somewhat of a problem
- ☐ A very big problem
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_19. Do you have a bed partner or a room-mate in the same room ?

- ☐ No bed partner or roommate in the same room → *skip to next survey section:*
- ☐ Partner in same bed
- ☐ Room-mate in the same room
- ☐ I do not know
- ☐ I prefer not to answer

If you have a roommate or bed partner, ask him/her how often in the past month you have had .....

SL1\_20. ....Loud snoring

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

SL1\_21. ....Long pauses between breaths while asleep

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

SL1\_22. ....Legs twitching or jerking while you sleep

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer



SL1\_23. ....Episodes of disorientation or confusion during sleep

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

SL1\_24a. ....Other restlessness while you sleep; *please describe:*

---

SL1\_24b. ☐ Not during the past month

- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

Below you will find a list of statements. Please indicate how often each statement applies to you generally in daily life.

	0- Never	1	2	3	4	5 - Always
IA1_01. When I am tense I notice where the tension is located in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_02. I notice when I am uncomfortable in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_03. I notice where in my body I am comfortable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_04. I notice changes in my breathing, such as whether it slows down or speeds up.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_05. I do not notice (I ignore) physical tension or discomfort until they become more severe.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_06. I distract myself from sensations of discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_07. When I feel pain or discomfort, I try to power through it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_08. When I feel physical pain, I become upset.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_09. I start to worry that something is wrong if I feel any discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_10. I can notice an unpleasant body sensation without worrying about it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_11. I can pay attention to my breath without being distracted by things happening around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_12. I can maintain awareness of my inner bodily sensations even when there is a lot going on around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_13. When I am in conversation with someone, I can pay attention to my posture.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_14. I can return awareness to my body if I am distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_15. I can refocus my attention from thinking to sensing my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_16. I can maintain awareness of my whole body even when a part of me is in pain or discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_17. I am able to consciously focus on my body as a whole.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_18. I notice how my body changes when I am angry.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_19. When something is wrong in my life I can feel it in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_20. I notice that my body feels different after a peaceful experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_21. I notice that my breathing becomes free and easy when I feel comfortable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_22. I notice how my body changes when I feel happy / joyful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	0- Never	1	2	3	4	5 - Always
IA1_23. When I feel overwhelmed I can find a calm place inside.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_24. When I bring awareness to my body I feel a sense of calm.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_25. I can use my breath to reduce tension.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_26. When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_27. I listen for information from my body about my emotional state.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_28. When I am upset, I take time to explore how my body feels.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_29. I listen to my body to inform me about what to do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_30. I am at home in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_31. I feel my body is a safe place.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_32. I trust my body sensations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

We are interested in your recent experiences. Below is a list of things that people sometimes experience. Next to each item are five choices: “never”, “rarely”, “sometimes”, “often”, and “all the time”. Please darken one of these to indicate how much you currently have experiences similar to those described.

Please do not spend too long on each item—it is your first response that we are interested in. Please be sure to answer every item.

	Never	Rarely	Sometimes	Often	All the time
RD1_01. I think about what will happen in the future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_02. I remind myself that thoughts aren't facts.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_03. I am better able to accept myself as I am.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_04. I notice all sorts of little things and details in the world around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_05. I am kinder to myself when things go wrong.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_06. I can slow my thinking at times of stress.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_07. I wonder what kind of person I really am.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_08. I am not so easily carried away by my thoughts and feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_09. I notice that I don't take difficulties so personally.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_10. I can separate myself from my thoughts and feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_11. I analyze why things turn out the way they do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_12. I can take time to respond to difficulties.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_13. I think over and over again about what others have said to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_14. I can treat myself kindly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_15. I can observe unpleasant feelings without being drawn into them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_16. I have the sense that I am fully aware of what is going on around me and inside me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_17. I can actually see that I am not my thoughts.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_18. I am consciously aware of a sense of my body as a whole.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_19. I think about the ways in which I am different from other people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_20. I view things from a wider perspective.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## How do you cope with events?

Everyone gets confronted with negative or unpleasant events now and then and everyone responds to them in his or her own way. By the following questions you are asked to indicate what you generally think, when you experience negative or unpleasant events.

	(Almost) Never	Some- times	Regularly	Often	(Almost) Always
CR1_01. I think that I have to accept that this has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_02. I often think about how I feel about what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_03. I think I can learn something from the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_04. I feel that I am the one who is responsible for what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_05. I think that I have to accept the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_06. I am preoccupied with what I think and feel about what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_07. I think of pleasant things that have nothing to do with it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_08. I think that I can become a stronger person as a result of what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_09. I keep thinking about how terrible it is what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_10. I feel that others are responsible for what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_11. I think of something nice instead of what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_12. I think about how to change the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_13. I think that it hasn't been too bad compared to other things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_14. I think that basically the cause must lie within myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_15. I think about a plan of what I can do best.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_16. I tell myself that there are worse things in life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_17. I continually think how horrible the situation has been.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_18. I feel that basically the cause lies with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Thank you for completing this survey!

Please note that these responses will not be seen immediately. Resources are shown below if you feel that you would like to talk with someone immediately for assistance.

National Suicide Prevention Lifeline: 1-800-273-8255

National Sexual Assault Hotline: 1-800-656-4673

Other options are to:

- Call your doctor's office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

**APPENDIX 4**

**INFORMED CONSENT FORM**

## Agreement to Participate in a Research Study

### *Investigation of the Effects of Mindfulness on Blood Pressure and Well-Being*

You are being asked to take part in a Brown University research study about the effects of mindfulness and hypertension education on blood pressure and risk factors for hypertension. This form will explain the purpose of the study, how the study will be carried out and what you will be expected to do. It will also explain the possible risks and possible benefits of being in the study. If any part of the following description is not clear to you, you are encouraged to contact the researcher to answer any questions before you decide whether to take part in the study. If you decide to participate, please fill out and sign the last page of this form.

#### 1a. Nature and Purpose of the Study

The purpose of the study is to investigate the impact of mindfulness practices and health education on blood pressure. You have been selected for this study because you expressed interest and met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program. In order to assess the effects of these practices, you will be asked to complete some questionnaires, and a laboratory assessment before and after learning the mindfulness practices.

#### 1b. Explanation of Procedures

If you agree to participate, you will be asked to consent to the following:

- 1) Participate in an interview in which you will be asked questions about past and present mental health, including depression and suicide.
- 2) Complete questionnaires about a wide range of topics, including your diet, physical activity, smoking, medication use, personality, emotions, attention and past experiences, including stressful or traumatic experiences. These questions will probe sensitive psychological areas, including physical, emotion and sexual abuse. These questionnaires may take up to 2 hours to complete. By completing the interviews and questionnaires, you are giving the researchers permission to use the information you have provided. You have the right not to answer any of the questions.
- 3) Directly assessed blood pressure, height, weight, waist circumference and hip circumference.
- 4) You will be asked to perform some cognitive tasks. One of these tasks may involve computer-based tests of attention or decision-making. Together these tests may take as long as 45 minutes.
- 5) You will participate in the mindfulness program, which consists of 9 weekly sessions of 2.5 hours each and will include one 8 hour weekend retreat. Daily homework assignments may take as long as one hour and consist of practicing mindfulness exercises with the aid of a guided audio CD and completing worksheets related to stress, thoughts, and common reactions to various types of events.

Eric Loucks/6/2/2015 5:51 PM

**Comment [1]:** This random assignment text was deleted, as we are not currently using a control group. The control group will be added in future research after the initial pilot testing phase.

Eric Loucks/6/17/2015 11:58 AM

**Formatted:** Underline, Highlight

Eric Loucks/6/17/2015 11:58 AM

**Formatted:** Underline

Eric Loucks/6/2/2015 5:48 PM

**Deleted:** ... [1]

Eric Loucks/6/17/2015 11:08 AM

**Deleted:** the 9-week meditation



- 6) Class sessions will be audio taped so we can analyze the quality of the treatment you receive. The recordings will be transcribed so that we may analyze the text. The recordings will be identified by study number, will only be heard by study staff and will be destroyed after transcription.
- 7) You will be asked to complete a few short questionnaires each week during the 9 week condition.
- 8) After 9 weeks, you will be asked to complete questionnaires and return to the laboratory to repeat the same procedures for a second day of testing.
- 9) Three months after the end of the 9 week condition, you will be asked to return to the laboratory to repeat the same testing procedures.

Eric Loucks 5/17/2015 11:56 AM  
Formatted: Underline, Highlight

**Table Summarizing Activities and Time Commitment for this Study.**

Activity	Time Commitment
First blood pressure screen	30 minutes
Second blood pressure screen	30 minutes
Baseline health assessments, such as questionnaires, height, weight and waist circumference.	<u>2 hours</u>
Mindfulness course	9 sessions that are 2.5 hours each. 1 retreat day on a Saturday that will be 8 hours Total course time: 30.5 hours
Home mindfulness practices assigned during course.	1 hour per day, 6 days per week, for 8 weeks. Total time: 48 hours.
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place immediately after course completion.	2 hours
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place that take place 3 months after course completion.	2 hours
TOTAL TIME COMMITMENT FOR STUDY	<u>85.5 hours</u>

Eric Loucks 5/17/2015 11:57 AM  
Formatted: Highlight

Feedback:

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing % change (increase or decrease) on scales of attention, stress, mood, health behaviors, weight, and blood pressure across the study.

## 2. Discomforts and Risks

The questionnaires are routine, standardized forms for epidemiologic research. Certain questions may be upsetting as they may probe sensitive psychological areas and inquire about upsetting or traumatic events, including physical, sexual or emotional abuse and/or current psychiatric symptoms. Since your participation is voluntary, you have the right to skip any questions that make you uncomfortable.

Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable feelings with increased attention to them.

## 3. Benefits

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) receiving information about your psychological and physical functioning.

## 4. Alternative Therapies

A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

## 5. Confidentiality

Your responses for this study will be kept confidential. All data that we collect will be linked to a study ID# instead of your name. All questionnaires in this study will be filled out through an online survey or a paper version of the survey if you prefer. All of these questionnaires will be linked solely to your study ID#, so that your identity is protected and your answers are confidential. Although these measures have been taken to protect your personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet.

While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then a collaborator (Dr. Ellen Flynn) who is a licensed psychiatrist, may contact you to discuss your responses and possible referral to a treatment provider. Questionnaire items that may warrant follow-up include endorsements of statements about hurting yourself, any high scores in depression, anxiety, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires researchers to report abuse or neglect of people age 60 and older to the Division of Elderly Affairs.

The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a

Eric Loucks 6/2/2015 5:47 PM  
Deleted: website (SurveyMonkey)

unique code number and initials. All study records and specimens will be stored in a secure storage area.

*Keeping study records:* The Principal Investigator for this study will keep your research records indefinitely for research purposes.

#### 6. Refusal/Withdrawal

Participation is voluntary, and you may decide to opt out or refuse any part of participation, including not answering certain questions. If you decide now to participate, you can change your mind later and quit the study. The decision to not participate or to withdraw from the study will not adversely affect current or future interactions with Brown University. The decision to not participate or to withdraw from the study will also not adversely affect your relationship with your physician.

If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

#### 7. Contact Information

If you have questions about study procedures at any time you may contact the researchers: Dr. Eric B. Loucks, email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu), telephone (401) 863-6283. If you would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Brown University Research Protections Office, telephone number 1-866-309-2095 or 401-863-3050.

**CONSENT FORM:**  
**Please sign and return.**

Please read the following agreement and sign to consent to participating.

**I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY  
QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, I AGREE TO  
PARTICIPATE IN THIS RESEARCH STUDY.**

\_\_\_\_\_  
**PRINT NAME**

\_\_\_\_\_  
**Signature of participant**

\_\_\_\_\_  
**Date**

**CONTACT INFORMATION**

**Name (print):** \_\_\_\_\_

**Permanent Address:** \_\_\_\_\_

**Email(s):** \_\_\_\_\_

**Telephone:** \_\_\_\_\_ **(cell)** \_\_\_\_\_ **(other)**

You may be randomly assigned (like the flip of a coin) to enter one of two different 8-week meditation programs.

## **APPENDIX 5**

### **PROTOCOL FOR PHYSICIANS TO REFER PATIENTS TO MINDFULNESS-BASED HYPERTENSION THERAPY STUDY**

# **Protocol for Physicians to Refer Patients to Mindfulness-Based Hypertension Therapy Study**

## **Protocol**

### *Option 1:*

1. Physicians will inform their patients about the study, and then ask if they would be interested in being contacted by the research study staff to explore if they would like to be in the study.
2. If the patient is interested, the physician will ask if the patient would be willing to have their contact information shared with the researchers, including name, phone number and email address.
3. If the patient agrees, the physician will forward this information to Dr. Loucks.

### *Option 2:*

A second option is for physicians to provide an advertisement card (supplied by the research study staff) to their patients and invite them to contact the research study staff if they are interested in it. This may result in lower participant recruitment rates, but is a very acceptable method if the physician prefers this approach.

## **Ways that physicians can inform study participants about the study**

1. Providing information on the study, such as the script below.

“I wonder if you may be interested in a research study taking place at Brown University, called Mindfulness-Based Hypertension Therapy. The intervention includes teachings on mindfulness meditation, mindful movements, education about hypertension, and support for reducing hypertension risk factors. The study is testing whether this intervention lowers blood pressure. The program consists of nine weekly sessions that are 2.5 hours long, and a one-day retreat on a weekend that will be 8 hours long. People who have a current regular meditation practice (i.e. meditate more than once per week) are not eligible. Research participation includes interviews, questionnaires and measurements of blood pressure, height, weight, and waist circumference, before and after the meditation program.”
2. Providing a handout, such as the advertisement card previously approved by the IRB and distributed to physicians interested in the study for their patients.

**Brown University**  
Research Protections Office  
Institutional Review Board  
Amendment Request

**Date of Request:** 7/15/15 **Investigator's Name and Title:** Eric Loucks, Assistant Professor  
**Study Title:** Mindfulness-Based Hypertension Therapy Pilot Study (#1412001171)

**Original Type of Review:** ☐ Exempt ☐ Expedited ☒ Full Board

1) Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project. (Attach summary to this form) Please see attached.

2) Provide a detailed description of the changes being requested (Use additional pages, if necessary):  
Please see attached.

3.) State the reason (justification) for the requested amendment. (Use additional pages, if necessary):  
Please see attached.

4.) What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?  
Please see attached.

5.) Does the requested amendment require new documents or changes to the approved consent form or other documents?

- ☒ Consent/assent documents (attach revised version with changes highlighted)  
☒ New/revised instruments (attach - if revised, highlight changes)  
☐ New/revised advertising materials (attach - if revised, highlight changes)

Do you have a conflict of interest on this project according to Brown's policy? ☐ YES ☒ NO

If YES, has this conflict been previously disclosed to the IRB? ☐ YES ☐ NO

PI signature: \_\_\_\_\_



Date: 7/15/15



**1) Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project.**

The World Health Organization reported that suboptimal blood pressure (BP) is responsible for more than half of cardiovascular disease mortality world-wide. Furthermore, greater than half of those with hypertension have uncontrolled BP. A 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.” Evidence-based mindfulness interventions, including Mindfulness-Based Stress Reduction, may have some effects on blood pressure, where a recent meta-analysis and systematic review of 4 randomized controlled trials demonstrated significant effects, but evidence of heterogeneity in effect sizes. The methodologically highest quality studies had the smallest effect sizes (range 0-5 mmHg). Mindfulness-Based Stress Reduction (MBSR) has been customized to a number of disease processes, such as Mindfulness-Based Cognitive Therapy for patients with recurrent depression, and Mindfulness-Based Relapse Prevention for patients with substance use addictions. Effect sizes have been increased by customizing mindfulness interventions to diseases of interest. The same may be true for hypertension, however mindfulness interventions customized for prehypertensive/hypertensive patients have never been investigated. Until methodologically rigorous studies to evaluate customized interventions for hypertension are performed, we will not know if the observed preliminary effects of general mindfulness interventions on blood pressure reduction could be much more effective with a tailored approach. Consequently, we propose to conduct a stage I behavioral therapy intervention study to evaluate whether MBSR customized to prehypertensive and hypertensive patients has the potential to provide clinically relevant reductions in BP. Consequently the specific aims are:

**Stage 1a: Therapy Development/Manual Writing**

- 1 To outline and evaluate key novel elements of mindfulness-based hypertension therapy (MBHT), customized from the evidence-based MBSR. *We hypothesize that the most important novel element will be generation of mindfulness skills specifically applied to hypertension risk factors such as diet, physical activity, obesity, alcohol consumption and antihypertensive medication adherence.* This aim will be achieved using (1) focus groups of participants undergoing the MBHT behavioral intervention, (2) discussion with experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) prior to, and following pilot testing of MBHT in participants, and (3) clinical judgment of the investigators performing the intervention.
- 2 To determine effectiveness of MBHT on primary outcomes (systolic blood pressure, retention rates, recruitment rates, and adverse effects) and secondary outcomes (hypertension risk factors such as diet, physical activity, obesity, and antihypertensive medication adherence) in hypertension subgroups, specifically participants with (1) prehypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. Initial decisions about the targeted sample based on hypertension status will be made.
- 3 To develop an MBHT therapist manual and training program, including procedures for training, supervising, and evaluating therapists. Furthermore, acceptable therapist characteristics will be developed. The manual and training program will include themes such as specification of unique and common elements of MBHT vs. other interventions, description of interventions excluded from MBHT, and specification of key treatment parameters such as frequency and duration of treatment, session length, topics addressed, sequence of sessions, as well as therapist adherence and competency measures. The MBHT training will consist of a therapist manual, a formal didactic training seminar, and at least one closely supervised training session.

**Stage 1b: Pilot Trial**

- 4 To determine whether a mindfulness-based hypertension therapy (MBHT) intervention, customized from the evidence-based MBSR, has promise to be an effective behavioral therapy for participants with hypertension and/or prehypertension. We will perform a randomized controlled pilot trial for MBHT vs.

enhanced usual care control. *We hypothesize that MBHT will have adequate recruitment rates ( $\geq 10\%$  of prehypertensive/hypertensive participants invited from physicians' offices), fairly low drop out rates ( $< 15\%$ ), and medium effect sizes (e.g. 5-10 mmHg systolic BP) for reduction in blood pressure.*

These findings will provide publishable pilot data that will inform future randomized clinical trials that evaluate effects of MBHT on long-term changes in blood pressure vs. usual care and active control groups. *If proven effective, MBHT could be offered as a complementary program in the prehypertensive/hypertensive patient population that contributes to over half of the cardiovascular disease mortality world-wide.*

## **2) Provide a detailed description of the changes being requested (Use additional pages, if necessary):**

1. NEFS Recruitment Letter
  - a. We plan on increasing the participant pool by recruiting participants from the Harvard/Brown University follow-up studies for the National Collaborative Perinatal Project, specifically the New England Family Study (NEFS). We will distribute letters to eligible participants of the NEFS providing a brief overview of the MBHT study and inquire about their interest in participating in the MBHT. Interested participants will then be introduced into the screening process and included in the study, if eligible.
2. In-Person Screening Assessments
  - a. Prior IRB applications did not provide clear documentation that there are 2 (not 1) in-person screening assessments. There are 2 screening assessment to allow for blood pressure to be assessed on two different days, at least one week apart from each other. This allows for daily changes in blood pressure (e.g. due to changes in stress levels) to be accounted for. Both in-person screening assessments are now included in Appendix 2.
  - b. For the medication questions (pp. 3-17), a question was added asking participants what the medication is used for. This question was added to help identify participants' intended use of medications.
3. Phone Screening Questionnaire
  - a. Minor wording changes were made to improve clarity to participants, shown in Appendix 3 using track changes.
  - b. We added a question to ask participants time availability for the intervention, shown on pg. 6 of the Phone Screening Questionnaire.
  - c. To the Safety Plan, we added an area to write down participant contact info (contact info is already provided by participants earlier in the phone screening questionnaire), so that it can be presented to a staff member if the safety plan is triggered (pg. 7 of the Phone Screening Questionnaire). This information is important to be provided to the 911 operator.
4. Consent Form
  - a. We added a footer to the consent form, showing the version number, date, and page numbering (Appendix 4).

## **3.) State the reason (justification) for the requested amendment:**

Please see justification in Section 2 above.

## **4.) What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

I do not expect any changes to the risk/benefit ratio or willingness of individuals to participate.

**5.) Does the requested amendment require new documents or changes to the approved consent form or other documents?**

Yes. Please see Appendices.

## APPENDIX 1

### New England Family Study Recruitment Letter

[Date]

Dear \_\_\_\_\_,

You recently participated in one of our Harvard/Brown University follow-up studies of the National Collaborative Perinatal Project. Our group, known as the New England Family Study, is very grateful for your participation and this ongoing work has been important in improving our understanding of long-term health and development.

Based on your blood pressure readings from the last study we evaluated your blood pressure in, you may qualify for another New England Family Study research project at Brown University. The study is designed to evaluate effects of an intervention called Mindfulness-Based Hypertension Therapy (MBHT). MBHT combines mindfulness practices such as meditation and mindful movements with education about hypertension management and prevention. The aim of MBHT is to create a skill set and supportive environment to help to reduce blood pressure, and improve overall well-being. Your involvement in this study could help us better understand if MBHT is effective, and how it could be improved. The MBHT intervention will take place over 9 weeks, and would involve you attending a class once per week that would be 2.5 hours long. You would also be asked to participate in a full day mindfulness retreat that would be about 8 hours duration. Also, health assessments would be performed before you start the intervention, and again afterwards. The assessments would include measures such as blood pressure, height, weight, diet, physical activity, smoking, life experiences, stress, and medication use.

At the end of the study, you will receive individual feedback about the changes in your health that occurred since the first assessment.

If you think you may be interested in participating in this study, please give us a call at 401-369-0443 or reply to this letter using the enclosed form and stamped envelope. We can then set up a time to give you a call to discuss the study more, and do a screening assessment to see if you qualify for the study. Thank you for participating in the New England Family Study. We are incredibly grateful for your continuing contributions. We look forward to speaking with you.

Sincerely yours,

A handwritten signature in purple ink, appearing to read "Eric Loucks", is written over a light beige rectangular background.

Eric B. Loucks, Ph.D.  
Assistant Professor  
Department of Epidemiology  
Brown University School of Public Health

## RESPONSE FORM

We would appreciate knowing when a member of our staff could reach you. It would be helpful if you could complete this form and return it in the enclosed self-addressed, stamped envelope.

1. If you no longer go by the name \_\_\_\_\_, please make any corrections on the line below:  
\_\_\_\_\_
2. What is the best time of day for someone to contact you?  
\_\_\_\_\_ mornings  
\_\_\_\_\_ afternoons  
\_\_\_\_\_ evenings
3. What is the best phone number for us to reach you during the:  
daytime \_\_\_\_\_  
evening \_\_\_\_\_
4. Do you prefer to be contacted in person or by the telephone?  
\_\_\_\_\_ In person  
\_\_\_\_\_ Over the phone  
\_\_\_\_\_ Either
5. Are there certain days of the week that are more convenient for you?  
\_\_\_\_\_
6. Please mark your level of interest below (optional):  
\_\_\_\_\_ I might be interested; please contact me  
\_\_\_\_\_ I might be interested, please send me more information before contacting me  
\_\_\_\_\_ Do not contact me again at this time; you may contact me in the future to see if I am interested then  
\_\_\_\_\_ Do not contact me at this time or in the future; I do not want any further contact with this project

You may also reach us at 401-369-0443 to further discuss the study, or your intent to participate. We look forward to speaking with you. Please feel free to call us with any questions. Thank you very much for your assistance.

## ***About the NCPP.....***

The National Collaborative Perinatal Project was conducted from 1959 through 1965 at more than ten sites in the United States. Follow-up continued through the early 1970s. More than 60,000 women and their children participated in this study nationwide, while in the Boston area more than 12,000 families participated. In the Boston area the study was known as the Maternal and Infant Health Study.

The National Collaborative Perinatal Project began when it became clear that events that occur before birth and for the first years of a person's life can have an impact on their later life. Information was taken on the health of the women participating in the study, their family's health, and their living conditions (such as whether or not the household had pets, and who else lived with the mother and child). Once the children were born, they came for regular check-ups to follow their development. The children were followed until they were seven years old.

The National Collaborative Perinatal Project was a great success. Data were collected that helped prove that pre-birth conditions had an influence on the life and development of children. It helped to establish that conditions like low-birth weight and premature birth may increase a child's chances of having health problems, although this is not always the case. It also helped to establish that children who were in play groups or pre-school at an early age often performed very well in school. Support and funding for pre-school programs were increased in part because of the information provided by this study. As a result of this study, programs were funded that helped all women get medical care while they were pregnant and medical care for their infants.

There have been many follow-up studies that have used the data collected by the National Collaborative Perinatal Project. One of these studies looked at whether women whose mothers had a difficult time during labor were more likely to have a difficult time when they themselves gave birth. With information from this study, doctors are now better able to help women who may have difficult pregnancies to take precautions and get extra medical assistance.

Thanks to the women who participated in the National Collaborative Perinatal Project in the 1960s and early 1970s, we now know that what happens to children before they are born and during their first years of life has a great effect on their development. As a result of this study, hospitals have developed better ways to care for all women before they have their babies. In addition, children around the country have greater access to medical care.

In the last few years, many children who were a part of the National Collaborative Perinatal Project participated in an important follow-up study. This study will also help to understand how early life events can affect not only early development, but also development into adulthood. The adults who participated in the follow-up study were asked questions about their education, family and emotional health to determine how people's lives have changed since childhood. In addition, they were asked to complete numerous tasks in order to understand things such as memory and attention and how these factors relate to development. This current phase of the study is still continuing and the results are proving to be useful, in large part because of the tremendous amount of time so many study children have contributed to the project.

## APPENDIX 2A

### First In-Person Screening Assessment Form



PID. Participant ID # \_\_\_\_\_  
BA2\_01. Staff ID # \_\_\_\_\_  
BA2\_02. Today's date (MMDDYY): \_\_\_\_\_

Blood Pressure:

BA2\_03a. Blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03b. Blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03c. Blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03d. Blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03e. Blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03f. Blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03g. Blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03h. Blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03i. Blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03j. Blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA2\_04. Were the 4<sup>th</sup> and 5<sup>th</sup> systolic blood pressure readings within 20 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA2\_05. Were the 4<sup>th</sup> and 5<sup>th</sup> diastolic blood pressure readings within 10 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA2\_06a. Repeated blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06b. Repeated blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06c. Repeated blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06d. Repeated blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06e. Repeated blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06f. Repeated blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06g. Repeated blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06h. Repeated blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06i. Repeated blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06j. Repeated blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA2\_07. Blood pressure cuff size used: ☐ S ☐ Reg ☐ L ☐ XL

BA2\_08. Arm that cuff was placed on: ☐ L ☒ R

**Commented [EL1]:** Note that height, weight, and waist circumference assessments previously here have been moved to the second in-person baseline assessment in order to reduce participant burden for those who do not meet blood pressure eligibility criteria at the first in-person assessment. As height and weight are not part of the eligibility criteria, we felt it was best to assess it after we determine if participants are eligible to be in study (i.e. have mean systolic/diastolic blood pressure  $\geq 120/80$  after first and second baseline assessments).

## **Medications (ME)**

ME01. Do you take any prescription medications or over-the-counter drugs?

- ☐ No → ***skip to end of medications questions***  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

ME02a. What is the name of the first prescription medication or over-the-counter drug that you take?

☐ Label product name:

---

☐ Label generic name:

---

☐ Don't know

☐ Prefer not to answer

ME02b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME02c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME02d. What is the strength? (***Record strength of how it is actually taken, not how it is prescribed.***)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

- ☐ Don't know  
☐ Prefer not to answer

ME02e. Total dosage per day. (Record strength of how it is actually taken, not how it is prescribed.)

- |                                      |  |
|--------------------------------------|--|
| <input type="checkbox"/> _____ %     | <input type="checkbox"/> _____ Other unit: _____ |
| <input type="checkbox"/> _____ mg    |  |
| <input type="checkbox"/> _____ mcg   | <input type="checkbox"/> Don't know              |
| <input type="checkbox"/> _____ grams | <input type="checkbox"/> Prefer not to answer    |
| <input type="checkbox"/> _____ I.U.  |  |

ME02f. Do you take it regularly or only as needed?

- |   |   |
|---|---|
| <input type="checkbox"/> Regularly      | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Only as needed | <input type="checkbox"/> Prefer not to answer |

ME02g. For how long have you been taking it?

- |   |   |
|---|---|
| <input type="checkbox"/> For _____ days   | <input type="checkbox"/> For _____ years      |
| <input type="checkbox"/> For _____ weeks  | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> For _____ months | <input type="checkbox"/> Prefer not to answer |

ME02h. What is the medication used for?

\_\_\_\_\_

**Commented [EL2]:** This was added to help identify participants' intended use of medications.

ME02i. **Interviewer comments:**

\_\_\_\_\_

ME02j. Do you take any other prescription medications or over-the-counter drugs?

- |   |   |
|---|---|
| <input type="checkbox"/> No → <b>skip to end of medications questions</b> | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Yes  | <input type="checkbox"/> Prefer not to answer |

ME03a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

☐ Don't know      ☐ Prefer not to answer

ME03b. What is the dosage form?

Oral

- |   |   |
|---|---|
| <input type="checkbox"/> Pill, tablet, or capsule                   | <input type="checkbox"/> Liquid solution or suspension (drink, syrup) |
| <input type="checkbox"/> Sublingual or orally-disintegrating tablet | <input type="checkbox"/> Powder                                       |

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

ME03c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know
- ☐ Prefer not to answer

- ☐ Don't know
- ☐ Prefer not to answer

ME03d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME03e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME3f. Do you take it regularly or only as needed?

- ☐ Regularly
- ☐ Only as needed

- ☐ Don't know
- ☐ Prefer not to answer

ME03g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks
- ☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years
- ☐ Don't know
- ☐ Prefer not to answer

ME03h. What is the medication used for?

ME03i. *Interviewer comments:*

ME03j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications questions**

☐ Yes

☐ Don't know

☐ Prefer not to answer

ME04a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME04b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME04c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

☐ \_\_\_\_\_ times per month

☐ Don't know

☐ Prefer not to answer

ME04d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_

☐ Don't know  
☐ Prefer not to answer

ME04e. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME04f. Do you take it regularly or only as needed?

☐ Regularly  
☐ Only as needed

☐ Don't know  
☐ Prefer not to answer

ME04g. For how long have you been taking it?

☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME04h. What is the medication used for?

\_\_\_\_\_

ME04i. *Interviewer comments:*

\_\_\_\_\_

ME04j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications section**  
☐ Yes

☐ Don't know  
☐ Prefer not to answer

ME05a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

☐ Don't know      ☐ Prefer not to answer

ME05b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME05c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME05d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME05e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME05f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME05g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME05h. What is the medication used for?

ME05i. *Interviewer comments:*

ME05j. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of end of medications questions**
- ☐ Yes

- ☐ Don't know
- ☐ Prefer not to answer

ME06a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

- ☐ Don't know
- ☐ Prefer not to answer

ME06b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule
- ☐ Sublingual or orally-disintegrating tablet
- ☐ Liquid solution or suspension (drink, syrup)
- ☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know
- ☐ Prefer not to answer

ME06c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

- ☐ Don't know
- ☐ Prefer not to answer

ME06d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)



- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
☐ Don't know  
☐ Prefer not to answer

ME06e. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
☐ Don't know  
☐ Prefer not to answer

ME06f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME06g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME06h. What is the medication used for?

ME06i. *Interviewer comments:*

ME06i. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

ME07a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

- ☐ Don't know  
☐ Prefer not to answer

ME07b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME07c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME07d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME07e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME07f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME07g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME07h. What is the medication used for?

ME07i. *Interviewer comments:*

ME07j. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

ME08a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME08b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME08c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week

- ☐ \_\_\_\_\_ times per month  
☐ Don't know

☐ Prefer not to answer

ME08d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- |                                      |   |
|--------------------------------------|---|
| <input type="checkbox"/> _____ %     | <input type="checkbox"/> _____ Other unit:<br>_____ |
| <input type="checkbox"/> _____ mg    | <input type="checkbox"/> Don't know                 |
| <input type="checkbox"/> _____ mcg   | <input type="checkbox"/> Prefer not to answer       |
| <input type="checkbox"/> _____ grams |   |
| <input type="checkbox"/> _____ I.U.  |   |

ME08e. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

- |                                      |   |
|--------------------------------------|---|
| <input type="checkbox"/> _____ %     | <input type="checkbox"/> _____ Other unit:<br>_____ |
| <input type="checkbox"/> _____ mg    | <input type="checkbox"/> Don't know                 |
| <input type="checkbox"/> _____ mcg   | <input type="checkbox"/> Prefer not to answer       |
| <input type="checkbox"/> _____ grams |   |
| <input type="checkbox"/> _____ I.U.  |   |

ME08f. Do you take it regularly or only as needed?

- |   |   |
|---|---|
| <input type="checkbox"/> Regularly      | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Only as needed | <input type="checkbox"/> Prefer not to answer |

ME08g. For how long have you been taking it?

- |   |   |
|---|---|
| <input type="checkbox"/> For _____ days   | <input type="checkbox"/> For _____ years      |
| <input type="checkbox"/> For _____ weeks  | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> For _____ months | <input type="checkbox"/> Prefer not to answer |

ME08h. What is the medication used for?

\_\_\_\_\_

ME08i. *Interviewer comments:*

\_\_\_\_\_

ME08j. Do you take any other prescription medications or over-the-counter drugs?

- |   |   |
|---|---|
| <input type="checkbox"/> No → <b>skip to end of medications questions</b> | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Yes  | <input type="checkbox"/> Prefer not to answer |

ME09a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

- ☐ Don't know      ☐ Prefer not to answer

ME09b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME09c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME09d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME09e. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME09f. Do you take it regularly or only as needed?

- ☐ Regularly      ☐ Only as needed

☐ Don't know

☐ Prefer not to answer

ME09g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME09h. What is the medication used for?

ME09i. *Interviewer comments:*

ME09j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications questions**

☐ Yes

☐ Don't know

☐ Prefer not to answer

ME10a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME10b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME10c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

- ☐ \_\_\_\_\_ times per month  
☐ Don't know

☐ Prefer not to answer

ME10d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME10e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME10f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed  
☐ Don't know  
☐ Prefer not to answer

ME10g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks
- ☐ For \_\_\_\_\_ months
- ☐ For \_\_\_\_\_ years
- ☐ Don't know
- ☐ Prefer not to answer

ME10h. What is the medication used for?

ME10i. *Interviewer comments:* \_\_\_\_\_

**Commented [EL3]:** Note that questionnaires on anxiety and depression previously here have been moved to the second in-person baseline assessment in order to reduce participant burden for those who do not meet blood pressure eligibility criteria at the first in-person assessment. As these depression and anxiety questionnaires are not part of the eligibility criteria, we felt it was best to assess it after we determine if participants are eligible to be in study (i.e. have mean systolic/diastolic blood pressure  $\geq 120/80$  after first and second baseline assessments).



## APPENDIX 2b

### Second In-Person Visit Screening Questionnaire and Assessment Forms

## SECOND IN-PERSON VISIT SCREENING QUESTIONNAIRE AND ASSESSMENT FORMS

**Commented [EL1]:** Note that this is the second in-person screening. The first in-person screening is just for blood pressure, as it is the only inclusion/exclusion criteria for the in-person screening. Blood pressure will be assessed on two different days at least a week apart from each other, to account for daily variations in blood pressure due to conditions such as stress. The second in-person screening measures blood pressure, in addition to other variables previously approved by the IRB including height, weight, waist circumference, depression and anxiety.

PID. Participant ID # \_\_\_\_\_

BA01. Staff ID # \_\_\_\_\_

BA02. Today's date (MMDDYY): \_\_\_\_\_

Blood Pressure:

BA03a. Blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA03b. Blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA03c. Blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA03d. Blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA03e. Blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA03f. Blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA03g. Blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA03h. Blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA03i. Blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA03j. Blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA04. Were the 4<sup>th</sup> and 5<sup>th</sup> systolic blood pressure readings within 20 mmHg of each other?

☐ Yes

☐ No (**repeat measurements**)

BA05. Were the 4<sup>th</sup> and 5<sup>th</sup> diastolic blood pressure readings within 10 mmHg of each other?

☐ Yes

☐ No (**repeat measurements**)

BA06a. Repeated blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA06b. Repeated blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA06c. Repeated blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA06d. Repeated blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA06e. Repeated blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA06f. Repeated blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA06g. Repeated blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA06h. Repeated blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA06i. Repeated blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA06j. Repeated blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA07. Blood pressure cuff size used:    ☐ S    ☐ Reg    ☐ L    ☐ XL

BA08. Arm that cuff was placed on:        ☐ L    ☐ R

BA09. Height:        \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

BA10. Weight:        \_\_\_\_\_ . \_\_\_\_ kg (one decimal place)

Waist Circumference:

BA11a. Measurement 1 \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

BA11b. Measurement 2 \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

BA12. Is the difference between Measurement 1 and Measurement 2 greater than 1.0cm?

☐ Yes (**repeat measurements 3&4**)

☐ No

BA13a. Measurement 3 \_\_\_\_\_ . \_\_\_\_ cm

BA13b. Measurement 4 \_\_\_\_\_ . \_\_\_\_ cm

**Questions for Participants to Answer on Their Own In-Person on Paper:**

For each statement, please place a mark in the column that best describes how you have been feeling.

	Not at all or less than 1 day last week	1 or 2 days last week	3 to 4 days last week	5 to 7 days last week	Nearly every day for two weeks	I do not know	I prefer not to answer
DS_1. My appetite was poor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_2. I could not shake off the blues.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_3. I had trouble keeping my mind on what I was doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_4. I felt depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_5. My sleep was restless.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_6. I felt sad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_7. I could not get going.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_8. Nothing made me happy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C_9. I felt like a bad person.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_10. I lost interest in my usual activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_11. I slept much more than usual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_12. I felt like I was moving too slowly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_13. I felt fidgety.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_14. I wished I were dead.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_15. I wanted to hurt myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_16. I was tired all the time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_17. I did not like myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_18. I lost a lot of weight without trying to.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_19. I had a lot of trouble getting to sleep.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_20. I could not focus on the important things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past month, including today, by marking the box in the corresponding space in the column next to each symptom.

	Not At All	Mildly – it didn't bother me much	Moderately – it wasn't pleasant at all times	Severely – it bothered me a lot	I do not know	I prefer not to answer
BE_1. Numbness or tingling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_2. Feeling hot	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_3. Wobbliness in legs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_4. Unable to relax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_5. Fear of worst happening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_6. Dizzy or lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_7. Heart pounding/racing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_8. Unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_9. Terrified or afraid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_10. Nervous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_11. Feeling of choking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_12. Hands trembling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_13. Shaky/unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_14. Fear of losing control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_15. Difficulty in breathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_16. Fear of dying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_17. Scared	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_18. Indigestion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_19. Faint/lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_20. Face flushed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_21. Hot/cold sweats	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## SAFETY PLAN

After the participant has completed the Beck Anxiety Inventory questionnaire and the Centers for Epidemiologic Studies Depressive Symptomatology questionnaire, ask the participant to wait for a few minutes while you check that all forms and assessments are completed. While the participant is waiting in a different room, check the scores according to the criteria below. If any scores trigger the safety plan, move forward with steps below as written.

### Beck Anxiety Inventory (BA)

If participant scores  $\geq 26$  on the Beck Anxiety Inventory, while having the participant wait, immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and your phone # will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, please leave a phone message for her with your contact information and provide her with the Beck Anxiety Inventory results on the message. If Dr. Flynn is not immediately reachable, or following participant release after consulting with Dr. Flynn, immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).

### Depressive Symptomatology (DS)

The CESD-R will be administered during the in-person assessment visits, and scores will be reviewed immediately upon completion of the in-person assessments.

1. Sadness (dysphoria): Question numbers 2, 4, 6
2. Loss of Interest (anhedonia): Question numbers 8, 10
3. Appetite: Question numbers 1, 18
4. Sleep: Question numbers 5, 11, 19
5. Thinking / concentration: Question numbers 3, 20
6. Guilt (worthlessness): Question numbers 9, 17
7. Tired (fatigue): Question numbers 7, 16
8. Movement (agitation): Question numbers 12, 13
9. Suicidal ideation: Question numbers 14, 15

Participants are considered to meet criteria for major depressive episode if they have anhedonia or dysphoria nearly every day for the past two weeks, plus symptoms in an additional 4 DSM symptom groups noted as occurring nearly every day for the past two weeks. If participants meet criteria for major depressive episode, while having the participant wait, immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and your phone # will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, please leave a phone message for her with your contact information and provide her with the Depressive Symptomatology results on the message. If Dr. Flynn is not immediately reachable, or following participant release after consulting with Dr. Flynn, immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).

If participants respond having any suicidal ideation (DS questions 14 or 15), perform the following 2 steps:

1. Immediately call 911 and Dr. Ellen Flynn.

**Specifically, while the participant is in the waiting room, call 911 immediately, and tell them:**

***“My name is \_\_\_\_\_. I am working on a research study at Brown University. I have a study participant in the waiting room who has shared that he/she is currently suicidal.” Please provide the participants’ name to the 911 operator, as requested.***

***Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.***

2. While speaking calmly with the participant, let them know that you have called 911 and Dr. Flynn, and why (i.e. because we are concerned about you). You can speak with participant to keep him/her in the waiting room if 911 has sent assistance, but the discussion should not be clinical in nature.

Examples of questions that could be asked in order to keep them in the waiting room:

- “Tell me what is going on.”
- “What’s happening right now?”
- Tell me more about why you are interesting in being part of this study.
- What are you hoping to get out of this study?

The following information can be provided to study participants.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020



## APPENDIX 3

### Phone-Delivered Screening Questionnaire

## PHONE SCREENING QUESTIONNAIRE PART 1

*The script is shown below in bold italics.*

PID. Participant ID: \_\_\_\_\_

SQ01. Staff ID: \_\_\_\_\_

SQ02. Today's Date (MMDDYY): \_\_\_\_\_

SQ03. Current Time (24 hour time, e.g. 14:45): \_\_\_\_\_

Please now call the participant.

SQ04. Was the participant reached? YES NO

***Hello, my name is \_\_\_\_\_. I am calling from the Brown University School of Public Health because (name of participant) expressed interest in participating in our mindfulness blood pressure study. Is he/she available to talk at this time?***

***I would like to do a 10-15 minute phone interview with you to determine if you are a good match for this particular study.***

SQ05. ***Is now a good time to speak?***

*[If yes, proceed to SQ05 script below]*

If no... ***When would be a good time to talk?***

SQ06. Day to call back (DDMMYY) \_\_\_\_\_

SQ07. Time to call back \_\_\_\_\_ AM/PM

***OK, great. How about I give a quick overview of the study, and can then answer any questions you may have to see if it is a good fit for you. We will then go through a screening questionnaire to see if you qualify for the study. Does this sound OK?***

***A basic overview of the study is that it is looking to see if mindfulness practices improve blood pressure, and if education about hypertension risk factors may also improve blood pressure. Specifically, we will provide training in meditation, mindful movements, and the roles of things like diet, physical activity and medication in reducing blood pressure. You will be taught by a very experienced teacher who is an expert in these fields. The course takes place over a 9-week period, where you come to a class once each week for 2.5 hours each time. There is also a one-day retreat on a Saturday that will be 8 hours long. Also, we will ask you to participate in health assessments before and after the study. Health assessments include measures such as blood pressure, height and weight, and questionnaires about your health and experiences.***

**Can I answer any questions about the study that you may have? [answer any they may have.]**

**SQ08. Does this study sound like something you would be interested in doing? Yes No**

[If yes, proceed to next statement below. If no, politely thank the participant for considering being in this study, and end the call].

**Great. There are a few things that I would like to make clear before we start the interview. First of all, some of the questions that I will ask now to figure out if you are eligible to be in this study will be of personal nature, including asking about your mental health and life's experiences.**

**SQ09. Are you in a private place to talk?**

[If yes, proceed to text below. If no, reschedule meeting using variables SQ04 and SQ05 above].

**Because this interview is of a personal nature, it is important that you understand that everything you say will be kept strictly confidential. No one outside of our project will ever be able to see your answers, and we will not keep your name in the same place as any of your answers. If you are not eligible after the phone screen, we will destroy your information. If you like, though, we can keep your information on file for future studies.**

**SQ10. Participant's First Name:** \_\_\_\_\_

**SQ11. Participant's Last Name:** \_\_\_\_\_

**Participant's Address (in case we need to send any study materials to you):**

**SQ12a. Street address:** \_\_\_\_\_

**SQ12b. City:** \_\_\_\_\_

**SQ12c. State:** \_\_\_\_\_

**SQ12d. Zip Code:** \_\_\_\_\_

**SQ13a. Participant's Phone number #1 (in case we need to contact you by phone)**

\_\_\_\_\_

**SQ13b. Participant's Phone number #2** \_\_\_\_\_

**SQ14. Participant's email address (or mailing address if no email):** \_\_\_\_\_

**SQ15. Notes from interviewer related to participants' contact information (if any):**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Commented [EL1]:** We added this to help participants understand why we are asking for their personal information.

**Commented [EL2]:** We added this to help participants understand why we are asking for their personal information.

## PHONE SCREENING QUESTIONNAIRE PART 2

PID. Participant ID #: \_\_\_\_\_

INCLUSION CRITERIA: All answers in 3<sup>rd</sup> column must be YES. If an answer is NO, immediately proceed to question SQ40.

		YES	NO	Comments
SQ26.	<b>What is your age?</b> [Is age at least 18 years?]	YES	NO	
SQ27.	<b>Can you read and write in English?</b>	YES	NO	

EXCLUSION CRITERIA: All answers in 3<sup>rd</sup> column must be NO with the exception of SQ32a and SQ33a. If an answer (other than SQ32a and SQ33a) is YES, then immediately proceed to question SQ40.

		YES	NO	Comments
<b>I will now start to ask some questions about your mental health.</b>				
SQ28.	<b>Has anyone ever told you that you have bipolar disorder or manic depression?</b>	YES	NO	
SQ29.	<b>Has anyone ever used the word "Borderline" to describe you?</b>	YES	NO	
SQ30a.	<b>Have you ever had a hallucination or seen things that other people can't see, or hear things other people can't hear?</b>	YES	NO	
SQ30b.	<b>Have you ever been diagnosed with schizophrenia or psychosis?</b>	YES	NO	
SQ31_1	<b>Have you ever taken any of the following medications that I am about to read to you?</b> <b>Lithium</b>	YES	NO	DK
SQ31_2	<b>Seroquel (quetiapine)</b>	YES	NO	DK
SQ31_3	<b>Abilify (aripiprazole)</b>	YES	NO	DK
SQ31_4	<b>Zyprexa (olanzapine)</b>	YES	NO	DK
SQ31_5	<b>Clozaril (clozapine)</b>	YES	NO	DK
SQ31_6	<b>Haldol/Haloperidol</b>	YES	NO	DK
SQ31_7	<b>Geodon (ziprasidone)</b>	YES	NO	DK
SQ31_8	<b>Risperdal (risperidone)</b>	YES	NO	DK
SQ32a	<b>Have you ever had a suicide attempt?</b>	YES	NO	
SQ32b	<b>[If yes, ask...] Have you considered killing yourself during the past month?</b>	YES	NO	
SQ32c	<b>[If yes, ask...] Are you currently suicidal?</b> <b>[If yes, keep participant on the phone, and follow suicide safety plan below]</b>	YES	NO	
SQ32d	<b>[If no, ask...] Are you getting any help for that? If not, then provide list of resources from Safety Plan including Gateway, Anchor and The Providence Center] Not urgent, but inform Dr. Flynn about what was discussed.</b>	YES	NO	

EXCLUSION CRITERIA: All answers in 3 <sup>rd</sup> column must be NO with the exception of SQ32a and SQ33a. If an answer (other than SQ32a and SQ33a) is YES, then immediately proceed to question SQ40.			
SQ33a	<b>Would you say you have a trauma history?</b>	YES NO	
SQ33b	<b>[If yes...]</b>	YES NO	
SQ33c	<b>In the past month, have you had any problems with dissociation (memory loss)?</b>	YES NO	
	<b>In the past month, have you had any flashbacks (i.e. sudden and disturbing vivid memory) about the trauma?</b>	YES NO	
SQ34a	<b>In the past month, have you had any problems with obsessions or compulsions, such as washing your hands or checking the oven over and over again?</b>	YES NO	
SQ34b	<b>[If yes...]</b> Has anyone diagnosed you with obsessive compulsive disorder?	YES NO	
SQ35	<b>In the past month, have you had a panic attack (i.e. sweating, heart palpitations, nausea, trouble breathing, fear of dying/choking/going crazy)?</b>	YES NO	
SQ36	<b>Have you had any problems with alcoholism or drug use in the past year?</b>	YES NO	
SQ37	<b>In the past year, have you had an eating disorder, such as starving, binge eating, or vomiting?</b>	YES NO	
SQ38a	<b>Do you currently have a mindfulness practice, such as meditation or yoga?</b>	YES NO	
SQ38b	<b>Please tell me more about your mindfulness practice, including how often you practice per week.</b>	Fill in response in comments section to the right	
SQ38c	<b>Do you currently practice meditation more than once per week? (yoga does not count as meditation in this context)</b>	YES NO	
SQ39	<b>This class will take place at Brown University in-person. Do you have any medical or mobility issues that would affect you being able to attend class?</b>	YES NO	
SQ40	Participant qualifies for next step of study (next step is 1 <sup>st</sup> blood pressure screening)	YES NO  If YES go to SQ41.  If NO, go to SQ42.	

SQ41a. ***Thank you for taking the time to answer these questions. You qualify for the next stage of screening, which is to take your blood pressure at two different times at least a week apart from each other. Let's book the in-person screening sessions*** [Book both sessions. We can cancel the second session if they do not qualify].

SQ41b. ***We will be scheduling the mindfulness intervention at a time that works best with most of the participants. What days and times of the week typically work best with your schedule? Please keep in mind that the sessions are 2.5 hours long, and take place once per week for 9 weeks.***

Commented [EL3]: This was added to help schedule the intervention at a time best for most participants.

***Thank you for your time and interest in this study. We look forward to meeting you in person. Do you have any questions before we end this call?***

SQ42a. ***Thank you for taking the time to answer these questions. According to the survey, you do not qualify for the study at this time. There may be other studies you qualify for.***

SQ42b. ***Would you like me to keep your information to pass on to these studies?*** YES / NO

SQ42c. [If yes...] ***OK, thank you. We will keep this information for future studies you may qualify for. Thank you for taking the time to talk with me today. Can I answer any questions before hanging up?***

SQ42d. [If no...] ***OK, our copy of this information will be destroyed. Thank you for taking the time to talk with me today. Can I answer any questions before hanging up?***

## SAFETY PLAN

Enter details below on paper during screening (These variables should also be entered in the survey via questions SQ10-SQ13). Destroy this paper after screening is complete.

Participant's First Name: \_\_\_\_\_

Participant's Last Name: \_\_\_\_\_

Participant's Address:

Street address: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Zip Code: \_\_\_\_\_

Participant's Phone number #1: \_\_\_\_\_

Participant's Phone number #2: \_\_\_\_\_

During the phone-based screening, if participants respond yes to "Are you currently suicidal?", the interviewer should perform the following 2 steps:

1. Immediately have 911 and Dr. Ellen Flynn called by a colleague who has been informed beforehand that this is a possibility.

**Specifically, while keeping the participant on the phone, show the text below in the box to a colleague.**

***I have a study participant on the phone who is currently suicidal. Please call 911 immediately, and tell them:***

***"I am calling on behalf of [my name] who is performing a research study at Brown University. He has a participant on the phone who says they are currently suicidal." Please provide the participants' contact information to the 911 operator (i.e. name, address, phone #, email address) as requested. This information is shown above.***

***Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.***

2. While speaking calmly with the participant, let them know what you are doing. Specifically, let them know we are calling our study's psychiatrist Dr. Flynn and 911, and why you are doing that (i.e. because we are concerned about you). You can speak with participant to keep him/her on the phone, but the discussion should not be clinical in nature.

**Commented [EL4]:** This is data entered by staff on paper as participants provide this information above. If participants state they are currently suicidal, we can then bring this paper to another staff member to call 911, and it will have the participants' contact info immediately available for the 911 operator.

**Commented [EL5]:** This box was added to increase clarity to person who would make 911 call.

Examples of questions that could be asked in order to keep them on the phone:

- “Tell me what is going on.”
- “What’s happening right now?”
- Tell me more about why you are interesting in being part of this study.
- What are you hoping to get out of this study?

The following information can be provided to study participants if they state they have had considered killing themselves in the past month. If they are currently suicidal, the main priority is to keep them on the phone while 911 and Dr. Flynn are being contacted.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020



## APPENDIX 4

### Informed Consent Form

## **Agreement to Participate in a Research Study**

### ***Investigation of the Effects of Mindfulness on Blood Pressure and Well-Being***

You are being asked to take part in a Brown University research study about the effects of mindfulness and hypertension education on blood pressure and risk factors for hypertension. This form will explain the purpose of the study, how the study will be carried out and what you will be expected to do. It will also explain the possible risks and possible benefits of being in the study. If any part of the following description is not clear to you, you are encouraged to contact the researcher to answer any questions before you decide whether to take part in the study. If you decide to participate, please fill out and sign the last page of this form.

#### **1a. Nature and Purpose of the Study**

The purpose of the study is to investigate the impact of mindfulness practices and health education on blood pressure. You have been selected for this study because you expressed interest and met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program. In order to assess the effects of these practices, you will be asked to complete some questionnaires, and a laboratory assessment before and after learning the mindfulness practices.

#### **1b. Explanation of Procedures**

If you agree to participate, you will be asked to consent to the following:

- 1) Participate in an interview in which you will be asked questions about past and present mental health, including depression and suicide.
- 2) Complete questionnaires about a wide range of topics, including your diet, physical activity, smoking, medication use, personality, emotions, attention and past experiences, including stressful or traumatic experiences. These questions will probe sensitive psychological areas, including physical, emotion and sexual abuse. These questionnaires may take up to 2 hours to complete. By completing the interviews and questionnaires, you are giving the researchers permission to use the information you have provided. You have the right not to answer any of the questions.
- 3) Directly assessed blood pressure, height, weight, waist circumference and hip circumference.
- 4) You will be asked to perform some cognitive tasks. One of these tasks may involve computer-based tests of attention or decision-making. Together these tests may take as long as 45 minutes.
- 5) You will participate in the mindfulness program, which consists of 9 weekly sessions of 2.5 hours each and will include one 8 hour weekend retreat. Daily homework assignments may take as long as one hour and consist of practicing mindfulness exercises with the aid of a guided audio CD and completing worksheets related to stress, thoughts, and common reactions to various types of events.

- 6) Class sessions will be audio taped so we can analyze the quality of the treatment you receive. The recordings will be transcribed so that we may analyze the text. The recordings will be identified by study number, will only be heard by study staff and will be destroyed after transcription.
- 7) You will be asked to complete a few short questionnaires each week during the 9 week condition.
- 8) After 9 weeks, you will be asked to complete questionnaires and return to the laboratory to repeat the same procedures for a second day of testing.
- 9) Three months after the end of the 9 week condition, you will be asked to return to the laboratory to repeat the same testing procedures.

**Table Summarizing Activities and Time Commitment for this Study.**

<b>Activity</b>	<b>Time Commitment</b>
First blood pressure screen	30 minutes
Second blood pressure screen	30 minutes
Baseline health assessments, such as questionnaires, height, weight and waist circumference.	2 hours
Mindfulness course	9 sessions that are 2.5 hours each. 1 retreat day on a Saturday that will be 8 hours Total course time: 30.5 hours
Home mindfulness practices assigned during course.	1 hour per day, 6 days per week, for 8 weeks. Total time: 48 hours.
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place immediately after course completion.	2 hours
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place that take place 3 months after course completion.	2 hours
<b>TOTAL TIME COMMITMENT FOR STUDY</b>	<b><u>85.5 hours</u></b>

Feedback:

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing % change (increase or decrease) on scales of attention, stress, mood, health behaviors, weight, and blood pressure across the study.

## 2. Discomforts and Risks

The questionnaires are routine, standardized forms for epidemiologic research. Certain questions may be upsetting as they may probe sensitive psychological areas and inquire about upsetting or traumatic events, including physical, sexual or emotional abuse and/or current psychiatric symptoms. Since your participation is voluntary, you have the right to skip any questions that make you uncomfortable.

Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable feelings with increased attention to them.

## 3. Benefits

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) receiving information about your psychological and physical functioning.

## 4. Alternative Therapies

A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

## 5. Confidentiality

Your responses for this study will be kept confidential. All data that we collect will be linked to a study ID# instead of your name. All questionnaires in this study will be filled out through an online survey or a paper version of the survey if you prefer. All of these questionnaires will be linked solely to your study ID#, so that your identity is protected and your answers are confidential. Although these measures have been taken to protect your personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet.

While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then a collaborator (Dr. Ellen Flynn) who is a licensed psychiatrist, may contact you to discuss your responses and possible referral to a treatment provider. Questionnaire items that may warrant follow-up include endorsements of statements about hurting yourself, any high scores in depression, anxiety, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires researchers to report abuse or neglect of people age 60 and older to the Division of Elderly Affairs.

The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a

unique code number and initials. All study records and specimens will be stored in a secure storage area.

*Keeping study records:* The Principal Investigator for this study will keep your research records indefinitely for research purposes.

#### 6. Refusal/Withdrawal

Participation is voluntary, and you may decide to opt out or refuse any part of participation, including not answering certain questions. If you decide now to participate, you can change your mind later and quit the study. The decision to not participate or to withdraw from the study will not adversely affect current or future interactions with Brown University. The decision to not participate or to withdraw from the study will also not adversely affect your relationship with your physician.

If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

#### 7. Contact Information

If you have questions about study procedures at any time you may contact the researchers: Dr. Eric B. Loucks, email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu), telephone (401) 863-6283. If you would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Brown University Research Protections Office, telephone number 1-866-309-2095 or 401-863-3050.

**CONSENT FORM:**  
**Please sign and return.**

Please read the following agreement and sign to consent to participating.

**I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY.**

\_\_\_\_\_  
PRINT NAME

\_\_\_\_\_  
Signature of participant

\_\_\_\_\_  
Date

**CONTACT INFORMATION**

Name (print): \_\_\_\_\_

Permanent Address: \_\_\_\_\_

Email(s): \_\_\_\_\_

Telephone: \_\_\_\_\_ (cell) \_\_\_\_\_ (other)

**Brown University**  
Research Protections Office  
Institutional Review Board  
Amendment Request

Date of Request: 9/1/15 Investigator's Name and Title: Eric Loucks, Assistant Professor  
Study Title: Mindfulness-Based Hypertension Therapy Pilot Study (#1412001171)  
Original Type of Review: ☐ Exempt ☐ Expedited ☒ Full Board

- 1) Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project. (Attach summary to this form) Please see attached.
- 2) Provide a detailed description of the changes being requested (Use additional pages, if necessary):  
Please see attached.
- 3.) State the reason (justification) for the requested amendment. (Use additional pages, if necessary):  
Please see attached.
- 4.) What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?  
Please see attached.
- 5.) Does the requested amendment require new documents or changes to the approved consent form or other documents?
  - ☒ Consent/assent documents (attach revised version with changes highlighted)
  - ☒ New/revised instruments (attach - if revised, highlight changes)
  - ☐ New/revised advertising materials (attach - if revised, highlight changes)

Do you have a conflict of interest on this project according to Brown's policy? ☐ YES ☒ NO  
If YES, has this conflict been previously disclosed to the IRB? ☐ YES ☐ NO

PI signature: \_\_\_\_\_



Date: 9/1/15

**1) Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project.**

The World Health Organization reported that suboptimal blood pressure (BP) is responsible for more than half of cardiovascular disease mortality world-wide. Furthermore, greater than half of those with hypertension have uncontrolled BP. A 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.” Evidence-based mindfulness interventions, including Mindfulness-Based Stress Reduction, may have some effects on blood pressure, where a recent meta-analysis and systematic review of 4 randomized controlled trials demonstrated significant effects, but evidence of heterogeneity in effect sizes. The methodologically highest quality studies had the smallest effect sizes (range 0-5 mmHg). Mindfulness-Based Stress Reduction (MBSR) has been customized to a number of disease processes, such as Mindfulness-Based Cognitive Therapy for patients with recurrent depression, and Mindfulness-Based Relapse Prevention for patients with substance use addictions. Effect sizes have been increased by customizing mindfulness interventions to diseases of interest. The same may be true for hypertension, however mindfulness interventions customized for prehypertensive/hypertensive patients have never been investigated. Until methodologically rigorous studies to evaluate customized interventions for hypertension are performed, we will not know if the observed preliminary effects of general mindfulness interventions on blood pressure reduction could be much more effective with a tailored approach. Consequently, we propose to conduct a stage I behavioral therapy intervention study to evaluate whether MBSR customized to prehypertensive and hypertensive patients has the potential to provide clinically relevant reductions in BP. Consequently the specific aims are:

**Stage 1a: Therapy Development/Manual Writing**

- 1 To outline and evaluate key novel elements of mindfulness-based hypertension therapy (MBHT), customized from the evidence-based MBSR. *We hypothesize that the most important novel element will be generation of mindfulness skills specifically applied to hypertension risk factors such as diet, physical activity, obesity, alcohol consumption and antihypertensive medication adherence.* This aim will be achieved using (1) focus groups of participants undergoing the MBHT behavioral intervention, (2) discussion with experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) prior to, and following pilot testing of MBHT in participants, and (3) clinical judgment of the investigators performing the intervention.
- 2 To determine effectiveness of MBHT on primary outcomes (systolic blood pressure, retention rates, recruitment rates, and adverse effects) and secondary outcomes (hypertension risk factors such as diet, physical activity, obesity, and antihypertensive medication adherence) in hypertension subgroups, specifically participants with (1) prehypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. Initial decisions about the targeted sample based on hypertension status will be made.
- 3 To develop an MBHT therapist manual and training program, including procedures for training, supervising, and evaluating therapists. Furthermore, acceptable therapist characteristics will be developed. The manual and training program will include themes such as specification of unique and common elements of MBHT vs. other interventions, description of interventions excluded from MBHT, and specification of key treatment parameters such as frequency and duration of treatment, session length, topics addressed, sequence of sessions, as well as therapist adherence and competency measures. The MBHT training will consist of a therapist manual, a formal didactic training seminar, and at least one closely supervised training session.

**Stage 1b: Pilot Trial**

- 4 To determine whether a mindfulness-based hypertension therapy (MBHT) intervention, customized from the evidence-based MBSR, has promise to be an effective behavioral therapy for participants with hypertension and/or prehypertension. We will perform a randomized controlled pilot trial for MBHT vs.



enhanced usual care control. *We hypothesize that MBHT will have adequate recruitment rates ( $\geq 10\%$  of prehypertensive/hypertensive participants invited from physicians' offices), fairly low drop out rates ( $< 15\%$ ), and medium effect sizes (e.g. 5-10 mmHg systolic BP) for reduction in blood pressure.*

These findings will provide publishable pilot data that will inform future randomized clinical trials that evaluate effects of MBHT on long-term changes in blood pressure vs. usual care and active control groups. *If proven effective, MBHT could be offered as a complementary program in the prehypertensive/hypertensive patient population that contributes to over half of the cardiovascular disease mortality world-wide.*

## 2) Provide a detailed description of the changes being requested (Use additional pages, if necessary):

1. Change in funding source
  - a. We have an NIH grant application (1 UH2 AT009145-01 entitled "Mindfulness Influences on Self-Regulation: Mental and Physical Health Implications") pending that would provide funding to this project.
2. Change in scope
  - a. The NIH grant would provide approximately \$5 million over 5 years to support secondary data analyses on data for which personally identifiable information is removed, and hence not human subjects-related. Furthermore, the grant would provide additional measures to the MBHT study above, as well as potentially providing additional measures to three other studies named in the grant application as Concurrent Study B1, B2 and C (more details below). Note that Concurrent Study A in the grant (currently approved by Brown IRB) is nearing completion, and no additional measures will be added. All of these studies are currently funded and underway. IRB approval has been obtained for all studies by the host institutions (IRB approval certificates shown in **Appendix 1**). The current grant will add some fairly low participant burden measures to each study. Each of the study's host institutions proposes to perform the following additional measures, with associated timeline. IRB approval will be obtained by the host institutions prior to any additional measures being assessed.
    - i. Concurrent Study B1: Yoga Program and Dietary Health Behaviors (PI: Sara Lazar, Massachusetts General Hospital, Harvard Medical School)
      1. The grant proposes to add neuroimaging to study participants. This imaging is scheduled to take place no earlier than January 2016.
    - ii. Concurrent Study B2: Mindfulness-Based Stress Reduction and Dietary Health Behaviors (PI: Carl Fulwiler, UMass Medical School, Worcester).
      1. Additional measures may not be needed for this study, as the major variables are being assessed. If it appears that additional variables are needed, IRB approval will be obtained.
    - iii. Concurrent Study C: MINDFUL-PC Study (PI: Zev Schuman-Olivier, Cambridge Health Alliance, Harvard Medical School). All of the following additional measures proposed in the grant will go through IRB approval at the host institution, and should represent a fairly low increase in participant burden.
      1. During Phase 1 (years 2016-2017), we will adapt and pilot mechanistic targets that we found to be associated with successful behavioral self-regulation during MBI trials for addiction (smoking cessation).<sup>250,251</sup> We will pilot an fMRI-compatible stop-signal task measuring inhibitory control,<sup>252</sup> self-report measures of self-management self-efficacy, as well as self-report<sup>106,151</sup> and neuroimaging tasks assessing self-compassion<sup>253</sup> and trait non-judgment of self.<sup>254</sup> We will adapt and test these targets in this primary care population in order to assess

their applicability to medical regimen adherence, and assess them for relevance and feasibility in the context of the MTPC study.

2. During Phase 2 (2016-2018), we will test the best performing targets from the three domain working groups by recruiting patients with poor medical regimen adherence and difficulty with daily medication adherence with the most promising self-report, behavioral, physiologic, and neuroimaging targets. These targets will be identified in Phase 1, and appropriate IRB amendments will be submitted as the targets are identified.
3. Measures to be added to Concurrent Study C beginning in January 2016 are as follows:
  - a. *The Edinburgh Handedness Inventory (EHI)*<sup>1</sup> is used to document the degree of right handedness. A score of >40 is a reliable indicator of right handedness. Participants must be right handed for admission into fMRI study. This will be completed at screening visit in subjects otherwise eligible for fMRI experiment. (3 min)
  - b. *Urine or Saliva toxicology*: We will conduct urine or saliva toxicology screens for alcohol and illicit drugs at screening visit and before each MRI session. (5 min)
  - c. *Urine pregnancy screen*: We will conduct a urine pregnancy screen at screening visit and before each MRI session. (2 min)
  - d. *Body Mass Index*: Weight and height will be measured during screening visit and BMI will be calculated. (2 min)
  - e. *Stop-Signal Task (SST)*<sup>2</sup> The SST is a two-choice reaction time task in which participants are required to respond to one or more go stimuli. At irregular intervals and unpredictably for the participants, a stop signal is presented.<sup>3</sup> Following this stop signal, participants are required to attempt to inhibit their response to the go signal. We will use two versions of the SST. The first (original SST) is similar to previous versions of the task used in neuroimaging studies. A second version (controlled SST) was designed to control for the attentional confound inherent in the original version. In both versions, subjects are presented with an initial fixation cross for 350 ms. This is followed by a go signal lasting 1,400 ms in the form of a left- or right-pointing arrow in the direction of the required response. Finger presses are made with the index finger of each hand. Unpredictably, on 20% of the trials, a red circle (the stop signal) appears above the location of the go stimulus. This stop signal indicates the need to attempt to inhibit the button press. The delay between the presentation of the go and stop signals is termed the stop signal delay (SSD). The ability to stop a response is a function of the length of the SSD. The longer the SSD, the more difficult it is to stop. The SSD will be varied from trial to trial using a staircase procedure that converges subjects toward an overall performance of 50% for each run. In the controlled version of the SST, a continue signal is introduced in the form of a green circle presented below the go signal. Subjects are instructed that, on some trials, this continue signal will appear unpredictably, but this should not alter their response, i.e., the initiated response to the go signal should be completed. The continue signal occurs on the same number of trials (20%) as the stop signal and with the same timing as the previous stop signal. The duration of both stop and continue cues is 1,400 msec minus the current SSD. Continue trials thus provide a control condition for the attentional processing associated with the presentation of an unexpected

perceptual event in a context in which response inhibition is not required. (10 min)

- f. *Barratt Impulsiveness Scale (BIS-11)*<sup>4</sup> is a 30-item scale of impulsiveness (rated on 4-point scales from 1-rarely/never to 4-almost always/always). The BIS-11 provides three sub-scores: attentional impulsivity (inability to focus on the task at hand and having intrusive, racing thoughts), motor impulsivity (acting without thinking and lacking perseverance), and non-planning impulsivity (inability to plan or think carefully about or do challenging tasks). It also provides a total impulsivity score that is reported to be an internally consistent measure of impulsiveness with clinical utility for differentiating normal individuals from psychiatric patients, substance abusers, and prison inmates. (4 min)
- g. *Behavioral Inhibition System/Behavioral Activation System (BIS/BAS)*<sup>5</sup> is a 24-item questionnaire rated on a 4-point scale (strong agreement – strong disagreement) measuring several domains of impulsivity based on Gray's model of personality. In Gray's view, there are two basic brain systems that control behavior and emotions: the aversive system or behavioral inhibition system (BIS) and the appetitive system or behavioral approach system (BAS). BIS is activated by conditioned stimuli associated with punishment or the termination of reward. BAS is activated by stimuli associated with reward or termination of punishment in order to guide the organism to appetitive stimuli. Gray's personality theory is based on the principle that individual differences in personality reflect the variation in sensitivity toward stimuli associated with negative and positive reinforcement, respectively BIS and BAS. The BIS/BAS scales consist of 20 items that can be allocated to two primary scales: the Behavioral Inhibition System scale (BIS; 7 items) and the Behavioral Approach System scale (BAS; 13 items). The BAS can be divided into 3 subscales: fun seeking (BAS fun), reward responsiveness (BAS reward), and drive (BAS drive). Drug addicts have higher scores on BAS drive, BAS fun, and BAS total score than controls<sup>6</sup>. (4 min)
- h. *MRI Neuroimaging Experiments* will be conducted at week 0 and/or weeks 8-9 sessions. Participants enrolled into the neuroimaging experiment may undergo fMRI brain imaging sessions. These sessions may include resting state functional connectivity,<sup>7</sup> two fMRI-compatible Stop-Signal Tasks<sup>2,8</sup> for response inhibition, as well as fMRI tasks measuring self-compassion<sup>9</sup> and trait non-judgment of self.<sup>10</sup> Total duration is approximately 60 minutes.
- i. *Electronic Medication Adherence Monitoring* will be measured continuously after screening visit for the add-on pilot study using electronic medication bottle caps. Participants taking daily medication for chronic illness will be included. Medication adherence is calculated as the percent of days during which medication was taken as prescribed. These devices simply replace the pill bottle caps of study participants' normal medication bottles. Participants will be trained in the use of the devices, which should take no longer than 5-10 minutes. The rationale for this assessment is that medication use for chronic illness has large impacts on outcome, and directly assessed measures are more accurate than self-report.<sup>11</sup> By embedding a CPU within a cap designed to fit a standard medication vial, the cap records each time the vial is opened to take a tablet or capsule. The cap is reusable at the time of refilling. Patients will be asked to bring in all current medication bottles to each study visit. At

the time of each study visit, the adherence data are downloaded via a RFID desktop Reader. The Software can display the information immediately on a PC via an intuitive interface. No patient information is stored on the devices, ensuring confidentiality. Download session may take 15 minutes, but can be completed while participants are completing self-report measures.

- b. The NIH grant would somewhat expand the scope of the MBHT intervention, as follows:
- i. Addition of an active control group. This control group will be Mindfulness-Based Stress Reduction (MBSR), which is time- and attention-matched with MBHT. MBHT is based on MBSR, but MBHT customizes MBSR to hypertension and hypertension risk factors. This control group is not expected to be added until approximately 2018. MBSR will be performed by certified instructors. MBSR teacher certification is fairly extensive, and accreditation occurs through the University of Massachusetts Medical School Center for Mindfulness in Medicine, Health Care and Society. MBSR will consist of nine 2.5-hour weekly group sessions and an 8-hour one-day session. MBSR sessions contain instruction and practice in mindfulness meditation, and conversations about stress and coping. Students learn a range of mindfulness skills including body scan exercises, meditation and yoga. Homework consists of practicing skills for  $\geq 45$  min/day, 6 days/week. The MBSR classes will be composed only of study participants. The rationale for adding this control group is that MBSR already exists in hundreds of medical centers around the USA and worldwide. If MBHT is not more effective than an existing manualized, standardized, general mindfulness-based intervention such as MBSR, it is not needed.
  - ii. Addition of electronically-measured medication adherence monitoring: measured continuously after randomization using electronic medication bottle caps. Participants taking medication to treat hypertension will qualify. Medication adherence is calculated as the percent of days during which medication was taken as prescribed. These devices simply replace the pill bottle caps of study participants' normal medication bottles. Participants will be trained in the use of the devices, which should take no longer than 5-10 minutes. The rationale for this assessment is that antihypertensive medication use has large impacts on blood pressure, and directly assessed measures are more accurate than self-report.
  - iii. Addition of actigraphy monitoring devices. Participants will be asked to wear actigraphy monitoring devices at baseline and follow-up assessments for one week duration each time. These devices provide direct assessments of physical activity. The rationale for this assessment is that physical activity influences blood pressure, and directly assessed physical activity is more accurate than self-report.
  - iv. Fidelity of MBSR and MBHT treatment: We will assess participants' perceptions of provider warmth and credibility using brief measures based on the validated Working Alliance Inventory,<sup>12</sup> and Empathy Scale.<sup>13</sup> These have been added to the assessments at Weeks 4 and 8 of the intervention. Please see **Appendix 2** for the questionnaires. The rationale for these assessments is that it is important to evaluate fidelity of the intervention, and these are standard measures of instructor effectiveness.
  - v. Participants' mindfulness practice diaries will assess regularity of meditation and mindfulness practices. Please see **Appendix 3** for the diaries. The rationale for these assessments is that it has been shown that those who perform greater amounts of mindfulness practices outside of the classroom tend to have greater effects on mental health outcomes. The same may be true of blood pressure.
  - vi. Focus group assessments of experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) will occur prior to, and following pilot testing of MBHT in participants. The rationale for doing these focus groups is to maximize MBHT efficacy, drawing on the knowledge of experts in relevant fields.

Adaptions may include, for example, types of specific mindfulness exercises, sequence in which modules are introduced, and relative emphasis on different types of modules (e.g. mindfulness practices customized to prehypertension/hypertension risk factors vs. general mindfulness practices). Inclusion criteria for the focus groups will be the experts being one of the professions listed above. Questions will include topics such as those shown below.

1. What about this intervention do think is most valuable, and has the greatest likelihood of influencing blood pressure, and determinants of blood pressure such as physical activity, diet and antihypertensive medication use?
  2. Are there any elements of the intervention you feel could be pruned out, as they may be unlikely to have an effect on blood pressure and determinants of blood pressure? If so, what are they? Why do you think they would not have an effect?
  3. All interventions can be improved. How do you think this intervention could be improved?
- vii. Focus groups of participants undergoing the MBHT behavioral intervention will take place following the final week of class. The rationale of doing these focus groups is to better adapt MBHT to the unique needs of this population, and maximize intervention efficacy. Adaptions may include, for example, types of specific mindfulness exercises, sequence in which modules are introduced, relative emphasis on different types of modules (e.g. mindfulness practices customized to prehypertension/hypertension risk factors vs. general mindfulness practices), and class duration. Inclusion criteria for the focus groups will be being study participants. Questions will include topics such as those shown below.
1. Think back to the beginning of the course. Have you noticed some changes in yourself or your life since then? If yes, what have you noticed?
  2. Can use card sort that will be anonymous – e.g. cards showing different modules. “Put cards for modules you really liked in one pile, modules you didn’t like in another pile, and modules you thought were OK but not great in a 3<sup>rd</sup> pile. Then have buckets for people to put their cards in for “liked module” “didn’t like module” or “module was OK”.
  3. What did you most like about this course? What was most helpful?
  4. We want to make this intervention better. You have been through it once. How do you think we can make it better?”
  5. Take a vote – raise your hand if you think the session should be 2 h, 2.5 h; same for 3 hours. Same for retreat day – 5 h, 6 h, 7 h, 8 h.
  6. Every instructor can improve. How can this instructor improve?

### **3.) State the reason (justification) for the requested amendment:**

Please see justifications in Section 2 above.

### **4.) What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

These assessments should add some participant burden, primarily time associated with questionnaire completion, training and use of medication adherence devices and actigraphy, neuroimaging, and partaking in the focus group.

Potential benefits to participants include that completing the meditation diaries in the MBHT study may increase intervention effectiveness, as participants may feel more committed to complete the mindfulness exercises because their “homework” is being checked and followed up on. A participant in the most recent cycle of the MBHT intervention shared with me that she felt she would have done more of the assigned home

mindfulness practices if she was asked to fill out such a diary. In addition, MBHT participants receive feedback on their health pre- vs. post intervention. The direct assessments of physical activity and medication adherence will provide more accurate and higher quality feedback to participants.

I do not expect these changes to influence participation or risk/benefit ratio in meaningful ways.

## 5.) Does the requested amendment require new documents or changes to the approved consent form or other documents?

Yes. Please see **Appendices 2-4**. We have not added the MBHT control group to the consent form at this time, as it will not be offered until approximately 2017. The consent form will be modified accordingly, prior to including this control group.

## References

1. Oldfield RC. The assessment and analysis of handedness: the Edinburgh inventory. *Neuropsychologia*. 1971;9(1):97-113.
2. Sharp DJ, Bonnelle V, De Boissezon X, et al. Distinct frontal systems for response inhibition, attentional capture, and error processing. *Proc Natl Acad Sci U S A*. 107(13):6106-6111.
3. Aron AR, Fletcher PC, Bullmore ET, Sahakian BJ, Robbins TW. Stop-signal inhibition disrupted by damage to right inferior frontal gyrus in humans. *Nat Neurosci*. 2003;6(2):115-116.
4. Patton JH, Stanford MS, Barratt ES. Factor structure of the Barratt impulsiveness scale. *J Clin Psychol*. 1995;51(6):768-774.
5. Carver CS. Negative affects deriving from the behavioral approach system. *Emotion*. 2004;4(1):3-22.
6. Franken IH, Muris P, Georgieva I. Gray's model of personality and addiction. *Addict Behav*. 2006;31(3):399-403.
7. Cordes D, Haughton VM, Arfanakis K, et al. Mapping functionally related regions of brain with functional connectivity MR imaging. *AJNR Am J Neuroradiol*. 2000;21(9):1636-1644.
8. Aron AR, Poldrack RA. Cortical and subcortical contributions to Stop signal response inhibition: role of the subthalamic nucleus. *J Neurosci*. 2006;26(9):2424-2433.
9. Simon-Thomas ER, Godzik J, Castle E, et al. An fMRI study of caring vs self-focus during induced compassion and pride. *Soc Cogn Affect Neurosci*. 2012;7(6):635-648.
10. Longe O, Maratos FA, Gilbert P, et al. Having a word with yourself: neural correlates of self-criticism and self-reassurance. *Neuroimage*. 2010;49(2):1849-1856.
11. Wiens MO, MacLeod S, Musiime V, et al. Adherence to antiretroviral therapy in HIV-positive adolescents in Uganda assessed by multiple methods: a prospective cohort study. *Paediatric drugs*. 2012;14(5):331-335.
12. Horvath AO, Greenberg LS. Development and Validation of the Working Alliance Inventory. *J Couns Psychol*. 1989;36(2):223-233.
13. Burns DD, Auerbach A. Therapeutic empathy in cognitive-behavioural therapy: does it really make a difference? In: Salkovskis P, ed. *Frontiers of Cognitive Therapy*. New York: Guilford; 1996.

## **APPENDIX 1**

### **IRB Approval Documents for Concurrent Studies**



BROWN

Research Protections Office  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Willoughby Britton, Box G-BH  
**From:** Research Protections Office  
**Date:** April 17, 2015  
**RE:** Protocol Entitled: Dismantling Mindfulness: Contributions of Attention vs. Acceptance (#1105000399).  
Continuing Review #4

The above referenced progress report received a full board review and approval by the Brown University IRB on April 16, 2015. Continuation of this study is approved through May 16, 2016.

Should the research continue, the next progress report must be submitted two months prior to the expiration date for review and approval.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is April 30, 2015.

All pertinent federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Research Protections Office (RPO) at <http://www.brown.edu/research/institutional-review-board-irb>. This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



## **Continuing Review: Notification of IRB Approval/Activation Protocol #: 2013P001153/MGH**

Date: June 17, 2015

To: Sara W Lazar, Ph.D  
MGH  
Psychiatry

From: Partners Human Research Committee  
116 Huntington Avenue, Suite 1002  
Boston, MA 02116

Title of Protocol:	Psychological mechanisms of change in a mind-body training program
Version/Number:	v2
Version Date:	6/12/2015
Sponsor/Funding Support:	NIH-NCCAM National Center for Complementary and Alternative Medicine
Study Population:	Adults
Consent/Authorization:	Required (Mild deception with appropriate debriefing)
Documentation of Consent:	Written
Informed Consent From:	Adult Subject
Informed Consent By:	Other Study Staff (PS page 8 (study coordinator or study staff))
IRB Continuing Review #:	3
IRB Review Type:	Expedited
Expedited Category/ies:	(7)
IRB Approval Date:	6/17/2015
Approval Activation Date:	6/17/2015
IRB Expiration Date:	6/24/2016

This project has been reviewed by MGH IRB . During the review of this project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for obtaining and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

Please note that if an IRB member had a conflict of interest with regard to the review of this project, consistent with IRB policies and procedures, the member was required to leave the room during the discussion and vote on this project except to provide information requested by the IRB.

**The following protocol documents have been approved and supporting documents noted by**

**the IRB:**

**Protocol summary (v. 06/12/2015)**

**Detailed protocol (v. 06/12/2015)**

**Consent form**

**Advertisements (2)**

**Flyer**

**Recruitment letter**

**Instruments/ questionnaires (25)**

**Diaries**

**Manual of operations**

**Debriefing script**

**Data collection form**

As Principal Investigator, you are responsible for ensuring that this project is conducted in compliance with all applicable federal, state and local laws and regulations, institutional policies, and requirements of the IRB, which include, but are not limited to, the following:

1. Submission of any and all proposed changes to this project (e.g., protocol, recruitment materials, consent form, status of the study, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB as an unanticipated problem.
2. Submission of continuing review submissions for re-approval of the project prior to expiration of IRB approval and a final continuing review submission when the project has been completed.
3. Submission of any and all unanticipated problems, including adverse event(s) in accordance with the IRB's policy on reporting unanticipated problems including adverse events.
4. Obtaining informed consent from subjects or their legally authorized representative prior to initiation of research procedures when and as required by the IRB and, when applicable, documenting informed consent using the current IRB approved consent form(s) with the IRB-approval stamp in the document footer.
5. Informing all investigators and study staff listed on the project of changes and unanticipated problems, including adverse events, involving risks to subjects or others.
6. When investigator financial disclosure forms are required, updating your financial interests in Insight and for informing all site responsible investigators, co-investigators and any other members of the study staff identified by you as being responsible for the design, conduct, or reporting of this research study of their obligation to update their financial interest disclosures in Insight if (a) they have acquired new financial interests related to the study and/or (b) any of their previously reported financial interests related to the study have changed.

**The IRB has the authority to terminate projects that are not in compliance with these requirements.**

Questions related to this project may be directed to Ednice Depina-Monteiro, EEMONTEIRO@PARTNERS.ORG, 617-424-4144.

CC: Thomas Dylan Calahan, MGH - Psychiatry, Non-Study Staff

Thomas Dylan Calahan, MGH - Psychiatry, Non-Study Staff



Cambridge Health Alliance

**NOTICE OF IRB APPROVAL – EXPEDITED NEW STUDY**

October 15, 2014

Zev Schuman-Olivier, MD  
Department of Psychiatry  
Cambridge Health Alliance  
26 Central Street  
Somerville, MA 02143

Dear Dr. Schuman-Olivier,

The protocol titled, “**Integrating Mindfulness into the Patient-Centered Medical home (MINDFUL-PC)**” meets federal guidelines for a minimal risk study. Therefore, it was approved under the expedited review process (45 CFR 46.110). This is notification that I have approved the study and wish to communicate the following:

Type of Review	:	Expedited Review
Action Taken	:	Approved
Date Approved	:	October 9, 2014
Next Review Date	:	October 8, 2015
IRB #	:	CHA-IRB-1002/08/14
Protocol Version	:	v19 – September 29, 2014
Patient ICF version	:	v12 – September 19, 2014
PCP ICF Version	:	v11 – September 19, 2014

The convened IRB will be notified of the approval; the research may begin immediately. Please note the following:

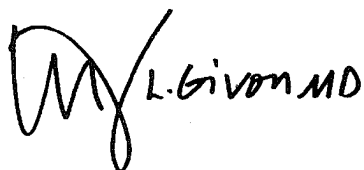
- In accordance with 45 CFR 46.117[c][2] the IRB granted a waiver of documentation of consent as it relates to the portion of the study that is conducted electronically : the research presents no more than minimal risk and involves no procedures for which written consent is normally required.
- Previously identified stipulations have been addressed and resolved. Requested documentation was received from the study team 10/06/14; it was reviewed and the study was approved 10/09/14.
- Any and all changes to this project (e.g., protocol, recruitment materials, consent form, study completion) **must be** submitted to the IRB for review and approval prior to initiation of the change(s). **Only** in circumstances where changes are necessary to eliminate apparent immediate hazards to the subject(s), changes can be implemented prior to IRB approval and submitted to the IRB subsequently for review and approval (45 CFR 46.103).
- Any and all unanticipated problems involving risks to human subjects or others that occur during the course of this project must be reported in accordance with the IRB’s policy on adverse event reporting.
- Any non-compliance with IRB policies or regulations governing human subject protections must be reported to the IRB immediately.
- Use only IRB approved copies of the consent form(s), questionnaire(s), letter(s), advertisement(s) etc., in your research. Do not use expired consent forms.
- For funded studies: Research must not begin without authorization from the Office for Sponsored Research.

- As a reminder, the HIPAA Privacy and Security Rule apply to this study. If you create, receive, store, or transmit electronic PHI you must meet institutional Security Rule standards.

**Federal regulations (45 CFR 46.109(e)) require IRBs to conduct continuing review of research at intervals appropriate to the degree of risk of the study, but not less than once a year. Non-compliance with continuing review procedures could result in a suspension of research activities.**

Please direct questions, correspondence, and forms (*e.g.*, continuing reviews, amendments, adverse events, and safety reports) to Ida Rego, [irego@challiance.org](mailto:irego@challiance.org), 617-499-8302.

Sincerely,

A handwritten signature in black ink that reads "Lior Givon MD". The signature is stylized, with the first name "Lior" written in a cursive-like script and "Givon MD" in a more straightforward, slightly slanted font.

Lior Givon, MD, PhD  
Chair, Institutional Review Board

***THIS LETTER MUST BE RETAINED WITH YOUR FILES.***

August 12, 2014

Carl Fulwiler, MD, PhD  
Psychiatry

Dear Dr. Fulwiler:

The IRB reviewed the following:

Type of Submission:	Modification
Review Type:	Non-Committee
Project Title:	Keeping weight off: Brain Changes Associated with Healthy Behaviors
Investigator:	Carl Fulwiler, MD, PhD
IRB ID:	H00001808 4
Funding Agency:	NATIONAL INSTITUTES OF HEALTH
Grant Title:	Mind your health: Developing a neural marker for mindfulness as a pathway to wellness
Grant ID:	1 R34 AT006963-01A1
IND or IDE:	None
IRB Review Date:	8/8/2014
Documents Reviewed:	UMMS HRP-503 - Fulwiler R34 V.4 6_29_14.docx Consent Fulwiler R34 V.2 3 31 14

The IRB approved the modification effective on 8/8/2014.

In conducting this research, you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

Allison Blodgett, PhD  
IRB Assistant Manager

cc: Lazaridou, Asimina

## **APPENDIX 2**

Working Alliance Inventory (WA)

Empathy Scale (EA)

Administered to participants at intervention weeks 4 and 8.

**Please answer the questions below about your experiences with the group leader.**

	0 strongly disagree	1 moderately disagree	2 somewhat disagree	3 no opinion	4 slightly agree	5 moderately agree	6 strongly agree
ES1_01. I felt that I could trust the group leader during today's session.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ES1_02. The group leader felt I was worthwhile.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ES1_03. The group leader was friendly and warm towards me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ES1_04. The group leader understood what I said during today's session.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ES1_05. The group leader was sympathetic and concerned about me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ES1_06. Sometimes the group leader did not seem to be completely genuine.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ES1_07. The group leader pretended to like me more than he/she really does.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ES1_08. The group leader did not always seem to care about me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ES1_09. The group leader did not always understand the way I felt inside.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ES1_10. The group leader acted condescending and talked down to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



	<div style="display: flex; align-items: center; justify-content: space-between;"> <span>Not At All True</span> <span>←————→</span> <span>Very True</span> </div>						
	1	2	3	4	5	6	7
WA1_01. I feel uncomfortable with the group leader.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_02. What I am doing in the mindfulness intervention gives me new ways of looking at my problem.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_03. The group leader and I understand each other.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_04. I believe the group leader likes me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_05. I believe the group leader is genuinely concerned for my welfare.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_06. The group leader and I respect each other.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_07. I feel that the group leader is not totally honest about his/her feelings towards me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_08. I am confident in the group leader's ability to help me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_09. I feel that the group leader appreciates me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_10. The group leader and I trust one another.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_11. My relationship with the group leader is very important to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_12. I have the feeling that if I say or do the wrong things, the group leader will stop working with me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
WA1_13. I feel the group leader cares about me even when I do things that he/she does not approve of.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## **APPENDIX 3**

### Participants' Mindfulness Practice Diaries

# Daily Practice Record Form – MBHT Week 1

ID #: \_\_\_\_\_

Please record each time you practice. Please make a note of anything that comes up in the homework so that we can talk about it at the next meeting.

Day/ Date	1.) Body Scan	2.) Mindful Eating/Meals		3.) Comments
	# Minutes	Meal	# Minutes	
<b>Mon</b> Date:	W1_D1_1. # Minutes	W1_D1_2a. Meal	W1_D1_2b. # Minutes	W1_D1_3.
<b>Tues</b> Date:	W1_D2_1. # Minutes	W1_D2_2a. Meal	W1_D2_2b. # Minutes	W1_D2_3.
<b>Wed</b> Date:	W1_D3_1. # Minutes	W1_D3_2a. Meal	W1_D3_2b. # Minutes	W1_D3_3.
<b>Thurs</b> Date:	W1_D4_1. # Minutes	W1_D4_2a. Meal	W1_D4_2b. # Minutes	W1_D4_3.
<b>Fri</b> Date:	W1_D5_1. # Minutes	W1_D5_2a. Meal	W1_D5_2b. # Minutes	W1_D5_3.
<b>Sat</b> Date:	W1_D6_1. # Minutes	W1_D6_2a. Meal	W1_D6_2b. # Minutes	W1_D6_3.
<b>Sun</b> Date:	W1_D7_1. # Minutes	W1_D7_2a. Meal	W1_D7_2b. # Minutes	W1_D7_3.

## Daily Practice Record Form – MBHT Week 2

ID #: \_\_\_\_\_

Please record each time you practice. Please make a note of anything that comes up in the homework so that we can talk about it at the next meeting.

Day/ Date	1.) Body Scan Meditation	2.) Breath Awareness Practice	3.) Mindful Activity		4.) Comments
	# Minutes	# Minutes	Activity	# Minutes	
<b>Mon</b> Date:	W2_D1_1. # Minutes	W2_D1_2. # Minutes	W2_D1_3a. Activity	W2_D1_3b. # Minutes	W2_D1_4.
<b>Tues</b> Date:	W2_D2_1. # Minutes	W2_D2_2. # Minutes	W2_D2_3a. Activity	W2_D2_3b. # Minutes	W2_D2_4.
<b>Wed</b> Date:	W2_D3_1. # Minutes	W2_D3_2. # Minutes	W2_D3_3a. Activity	W2_D3_3b. # Minutes	W2_D3_4.
<b>Thurs</b> Date:	W2_D4_1. # Minutes	W2_D4_2. # Minutes	W2_D4_3a. Activity	W2_D4_3b. # Minutes	W2_D4_4.
<b>Fri</b> Date:	W2_D5_1. # Minutes	W2_D5_2. # Minutes	W2_D5_3a. Activity	W2_D5_3b. # Minutes	W2_D5_4.
<b>Sat</b> Date:	W2_D6_1. # Minutes	W2_D6_2. # Minutes	W2_D6_3a. Activity	W2_D6_3b. # Minutes	W2_D6_4.
<b>Sun</b> Date:	W2_D7_1. # Minutes	W2_D7_2. # Minutes	W2_D7_3a. Activity	W2_D7_3b. # Minutes	W2_D7_4.

# Daily Practice Record Form – MBHT Week 3

ID #: \_\_\_\_\_

Please record each time you practice. Please make a note of anything that comes up in the homework so that we can talk about it at the next meeting.

Day/ Date	1.) Body Scan	2.) Yoga	3.) Breath Awareness	4.) Physical Activity		5.) Comments
	# Minutes	# Minutes	# Minutes	Activity	# Minutes	
<b>Mon</b> Date:	W3_D1_1. # Minutes	W3_D1_2. # Minutes	W3_D1_2. # Minutes	W3_D1_3a. Activity	W3_D1_3b. # Minutes	W3_D1_4.
<b>Tues</b> Date:	W3_D2_1. # Minutes	W3_D2_2. # Minutes	W3_D2_2. # Minutes	W3_D2_3a. Activity	W3_D2_3b. # Minutes	W3_D2_4.
<b>Wed</b> Date:	W3_D3_1. # Minutes	W3_D3_2. # Minutes	W3_D3_2. # Minutes	W3_D3_3a. Activity	W3_D3_3b. # Minutes	W3_D3_4.
<b>Thurs</b> Date:	W3_D4_1. # Minutes	W3_D4_2. # Minutes	W3_D4_2. # Minutes	W3_D4_3a. Activity	W3_D4_3b. # Minutes	W3_D4_4.
<b>Fri</b> Date:	W3_D5_1. # Minutes	W3_D5_2. # Minutes	W3_D5_2. # Minutes	W3_D5_3a. Activity	W3_D5_3b. # Minutes	W3_D5_4.
<b>Sat</b> Date:	W3_D6_1. # Minutes	W3_D6_2. # Minutes	W3_D6_2. # Minutes	W3_D6_3a. Activity	W3_D6_3b. # Minutes	W3_D6_4.
<b>Sun</b> Date:	W3_D7_1. # Minutes	W3_D7_2. # Minutes	W3_D7_2. # Minutes	W3_D7_3a. Activity	W3_D7_3b. # Minutes	W3_D7_4.

## Daily Practice Record Form – MBHT Week 4

ID #: \_\_\_\_\_

Please record each time you practice. Please make a note of anything that comes up in the homework so that we can talk about it at the next meeting.

Day/ Date	1.) Body Scan	2.) Yoga	3.) Sitting Meditation	4.) Physical Activity		5.) Comments
	# Minutes	# Minutes	# Minutes	Activity	# Minutes	
<b>Mon Date:</b>	W4_D1_1. # Minutes	W4_D1_2. # Minutes	W4_D1_3. # Minutes	W4_D1_4a. Activity	W4_D1_4b. # Minutes	W4_D1_5.
<b>Tues Date:</b>	W4_D2_1. # Minutes	W4_D2_2. # Minutes	W4_D2_3. # Minutes	W4_D2_4a. Activity	W4_D2_4b. # Minutes	W4_D2_5.
<b>Wed Date:</b>	W4_D3_1. # Minutes	W4_D3_2. # Minutes	W4_D3_3. # Minutes	W4_D3_4a. Activity	W4_D3_4b. # Minutes	W4_D3_5.
<b>Thurs Date:</b>	W4_D4_1. # Minutes	W4_D4_2. # Minutes	W4_D4_3. # Minutes	W4_D4_4a. Activity	W4_D4_4b. # Minutes	W4_D4_5.
<b>Fri Date:</b>	W4_D5_1. # Minutes	W4_D5_2. # Minutes	W4_D5_3. # Minutes	W4_D5_4a. Activity	W4_D5_4b. # Minutes	W4_D5_5.
<b>Sat Date:</b>	W4_D6_1. # Minutes	W4_D6_2. # Minutes	W4_D6_3. # Minutes	W4_D6_4a. Activity	W4_D6_4b. # Minutes	W4_D6_5.
<b>Sun Date:</b>	W4_D7_1. # Minutes	W4_D7_2. # Minutes	W4_D7_3. # Minutes	W4_D7_4a. Activity	W4_D7_4b. # Minutes	W4_D7_5.

## Daily Practice Record Form – MBHT Week 5

ID #: \_\_\_\_\_

Please record each time you practice. Please make a note of anything that comes up in the homework so that we can talk about it at the next meeting.

Day/ Date	1.) Body Scan	2.) Yoga	3.) Sitting Meditation	4.) S-T-O-P Practice	5.) Comments
	# Minutes	# Minutes	# Minutes	# Minutes	
<b>Mon</b> Date:	W5_D1_1. # Minutes	W5_D1_2. # Minutes	W5_D1_3. # Minutes	W5_D1_4. # Minutes	W5_D1_5.
<b>Tues</b> Date:	W5_D2_1. # Minutes	W5_D2_2. # Minutes	W5_D2_3. # Minutes	W5_D2_4. # Minutes	W5_D2_5.
<b>Wed</b> Date:	W5_D3_1. # Minutes	W5_D3_2. # Minutes	W5_D3_3. # Minutes	W5_D3_4. # Minutes	W5_D3_5.
<b>Thurs</b> Date:	W5_D4_1. # Minutes	W5_D4_2. # Minutes	W5_D4_3. # Minutes	W5_D4_4. # Minutes	W5_D4_5.
<b>Fri</b> Date:	W5_D5_1. # Minutes	W5_D5_2. # Minutes	W5_D5_3. # Minutes	W5_D5_4. # Minutes	W5_D5_5.
<b>Sat</b> Date:	W5_D6_1. # Minutes	W5_D6_2. # Minutes	W5_D6_3. # Minutes	W5_D6_4. # Minutes	W5_D6_5.
<b>Sun</b> Date:	W5_D7_1. # Minutes	W5_D7_2. # Minutes	W5_D7_3. # Minutes	W5_D7_4. # Minutes	W5_D7_5.

## Daily Practice Record Form – MBHT Week 6

ID #: \_\_\_\_\_

Please record each time you practice. Please make a note of anything that comes up in the homework so that we can talk about it at the next meeting.

Day/ Date	1.) Body Scan	2.) Yoga	3.) Sitting Meditation	4.) Comments
	# Minutes	# Minutes	# Minutes	
<b>Mon</b> Date:	W6_D1_1. # Minutes	W6_D1_2. # Minutes	W6_D1_3. # Minutes	W6_D1_4.
<b>Tues</b> Date:	W6_D2_1. # Minutes	W6_D2_2. # Minutes	W6_D2_3. # Minutes	W6_D2_4.
<b>Wed</b> Date:	W6_D3_1. # Minutes	W6_D3_2. # Minutes	W6_D3_3. # Minutes	W6_D3_4.
<b>Thurs</b> Date:	W6_D4_1. # Minutes	W6_D4_2. # Minutes	W6_D4_3. # Minutes	W6_D4_4.
<b>Fri</b> Date:	W6_D5_1. # Minutes	W6_D5_2. # Minutes	W6_D5_3. # Minutes	W6_D5_4.
<b>Sat</b> Date:	W6_D6_1. # Minutes	W6_D6_2. # Minutes	W6_D6_3. # Minutes	W6_D6_4.
<b>Sun</b> Date:	W6_D7_1. # Minutes	W6_D7_2. # Minutes	W6_D7_3. # Minutes	W6_D7_4.



# **Daily Practice Record Form – MBHT Week 7**

ID #: \_\_\_\_\_

Please record each time you practice. Please make a note of anything that comes up in the homework so that we can talk about it at the next meeting.

Day/ Date	1.) Mindfulness Practice		2.) Nourishing Activity		3.) Refraining-From-Poisoning Activity		4.) Accepting-What-I-Can't-Control Activity		5.) Comments
	Practice Type(s)	# Minutes	Activity	# Minutes	Activity	# Minutes	Activity	# Minutes	
<b>Mon Date:</b>	W7_D1_1a. Type(s)	W7_D1_1b. # Min	W7_D1_2a. Activity	W7_D1_2b. # Min	W7_D1_3a. Activity	W7_D1_3b. # Min	W7_D1_4a. Activity	W7_D1_4b. # Min	W7_D1_5.
<b>Tues Date:</b>	W7_D2_1a. Type(s)	W7_D2_1b. # Min	W7_D2_2a. Activity	W7_D2_2b. # Min	W7_D2_3a. Activity	W7_D2_3b. # Min	W7_D2_4a. Activity	W7_D2_4b. # Min	W7_D2_5.
<b>Wed Date:</b>	W7_D3_1a. Type(s)	W7_D3_1b. # Min	W7_D3_2a. Activity	W7_D3_2b. # Min	W7_D3_3a. Activity	W7_D3_3b. # Min	W7_D3_4a. Activity	W7_D3_4b. # Min	W7_D3_5.

Day/ Date	1.) Mindfulness Practice		2.) Nourishing Activity		3.) Refraining-From-Poisoning Activity		4.) Accepting-What-I-Can't-Control Activity		5.) Comments
	Practice Type(s)	# Minutes	Activity	# Minutes	Activity	# Minutes	Activity	# Minutes	
<b>Thurs Date:</b>	W7_D4_1a. Type(s)	W7_D4_1b. # Min	W7_D4_2a. Activity	W7_D4_2b. # Min	W7_D4_3a. Activity	W7_D4_3b. # Min	W7_D4_4a. Activity	W7_D4_4b. # Min	W7_D4_5.
<b>Fri Date:</b>	W7_D5_1a. Type(s)	W7_D5_1b. # Min	W7_D5_2a. Activity	W7_D5_2b. # Min	W7_D5_3a. Activity	W7_D5_3b. # Min	W7_D5_4a. Activity	W7_D5_4b. # Min	W7_D5_5.
<b>Sat Date:</b>	W7_D6_1a. Type(s)	W7_D6_1b. # Min	W7_D6_2a. Activity	W7_D6_2b. # Min	W7_D6_3a. Activity	W7_D6_3b. # Min	W7_D6_4a. Activity	W7_D6_4b. # Min	W7_D6_5.
<b>Sun Date:</b>	W7_D7_1a. Type(s)	W7_D7_1b. # Min	W7_D7_2a. Activity	W7_D7_2b. # Min	W7_D7_3a. Activity	W7_D7_3b. # Min	W7_D7_4a. Activity	W7_D7_4b. # Min	W7_D7_5.

W4\_GO\_7. Goal for This Week Related to Diet, Alcohol Consumption, Physical Activity or Stress Reaction/Response:

---



---



---

W4\_GO\_8. How Goal Will Be Measured:

---



---



---

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Mon Date:</b>	W4_GO_D1_1.	W4_GO_D1_2a. <b>Before:</b>  W4_GO_D1_2b. <b>During:</b>  W4_GO_D1_2c. <b>After:</b>	W4_GO_D1_3a. <b>Before:</b>  W4_GO_D1_3b. <b>During:</b>  W4_GO_D1_3c. <b>After:</b>	W4_GO_D1_4.	W4_GO_D1_5.

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Tues Date:</b>	W4_GO_D2_1.	W4_GO_D2_1.	W4_GO_D2_2a. <b>Before:</b>  W4_GO_D2_2b. <b>During:</b>  W4_GO_D2_2c. <b>After:</b>	W4_GO_D2_3a. <b>Before:</b>  W4_GO_D2_3b. <b>During:</b>  W4_GO_D2_3c. <b>After:</b>	W4_GO_D2_4.
<b>Wed Date:</b>	W4_GO_D3_1.	W4_GO_D3_1.	W4_GO_D3_2a. <b>Before:</b>  W4_GO_D3_2b. <b>During:</b>  W4_GO_D3_2c. <b>After:</b>	W4_GO_D3_3a. <b>Before:</b>  W4_GO_D3_3b. <b>During:</b>  W4_GO_D3_3c. <b>After:</b>	W4_GO_D3_4.

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Thurs Date:</b>	W4_GO_D4_1.	W4_GO_D4_1.	<p>W4_GO_D4_2a. <b>Before:</b></p> <p>W4_GO_D4_2b. <b>During:</b></p> <p>W4_GO_D4_2c. <b>After:</b></p>	<p>W4_GO_D4_3a. <b>Before:</b></p> <p>W4_GO_D4_3b. <b>During:</b></p> <p>W4_GO_D4_3c. <b>After:</b></p>	W4_GO_D4_4.
<b>Fri Date:</b>	W4_GO_D5_1.	W4_GO_D5_1.	<p>W4_GO_D5_2a. <b>Before:</b></p> <p>W4_GO_D5_2b. <b>During:</b></p> <p>W4_GO_D5_2c. <b>After:</b></p>	<p>W4_GO_D5_3a. <b>Before:</b></p> <p>W4_GO_D5_3b. <b>During:</b></p> <p>W4_GO_D5_3c. <b>After:</b></p>	W4_GO_D5_4.

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Sat Date:</b>	W4_GO_D6_1.	W4_GO_D6_1.	W4_GO_D6_2a. <b>Before:</b>  W4_GO_D6_2b. <b>During:</b>  W4_GO_D6_2c. <b>After:</b>	W4_GO_D6_3a. <b>Before:</b>  W4_GO_D6_3b. <b>During:</b>  W4_GO_D6_3c. <b>After:</b>	W4_GO_D6_4.
<b>Sun Date:</b>	W4_GO_D7_1.	W4_GO_D7_1.	W4_GO_D7_2a. <b>Before:</b>  W4_GO_D7_2b. <b>During:</b>  W4_GO_D7_2c. <b>After:</b>	W4_GO_D7_3a. <b>Before:</b>  W4_GO_D7_3b. <b>During:</b>  W4_GO_D7_3c. <b>After:</b>	W4_GO_D7_4.

## **Week 4: Goal Related to Diet, Alcohol Consumption, Physical Activity, or Stress Reaction/Response**

W4\_GO\_1. What is your goal related to diet, alcohol consumption, physical activity, or stress reaction/response for the week?

W4\_GO\_2. On a scale of 1-10, where 10 is high, how MOTIVATED are you to achieve this goal?

W4\_GO\_3. On a scale of 1-10, how CONFIDENT are you that you will achieve the goal?

W4\_GO\_4. What could you do that would bring your motivation or confidence a little higher?

W4\_GO\_5. What might make it difficult to achieve the goal this week, and if that happens, what will you do?

W4\_GO\_6. What is a way to measure this goal that resonates with you?

W5\_GO\_7. Goal for This Week Related to Diet, Alcohol Consumption, Physical Activity, Stress Reaction/Response, or Antihypertensive Medication Use:

---

---

---

W5\_GO\_8. How Goal Will Be Measured:

---

---

---

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Mon Date:</b>	W5_GO_D1_1.	W5_GO_D1_2a. <b>Before:</b>  W5_GO_D1_2b. <b>During:</b>  W5_GO_D1_2c. <b>After:</b>	W5_GO_D1_3a. <b>Before:</b>  W5_GO_D1_3b. <b>During:</b>  W5_GO_D1_3c. <b>After:</b>	W5_GO_D1_4.	W5_GO_D1_5.



Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Tues Date:</b>	W5_GO_D2_1.	W5_GO_D2_1.	W5_GO_D2_2a. <b>Before:</b>  W5_GO_D2_2b. <b>During:</b>  W5_GO_D2_2c. <b>After:</b>	W5_GO_D2_3a. <b>Before:</b>  W5_GO_D2_3b. <b>During:</b>  W5_GO_D2_3c. <b>After:</b>	W5_GO_D2_4.
<b>Wed Date:</b>	W5_GO_D3_1.	W5_GO_D3_1.	W5_GO_D3_2a. <b>Before:</b>  W5_GO_D3_2b. <b>During:</b>  W5_GO_D3_2c. <b>After:</b>	W5_GO_D3_3a. <b>Before:</b>  W5_GO_D3_3b. <b>During:</b>  W5_GO_D3_3c. <b>After:</b>	W5_GO_D3_4.

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Thurs Date:</b>	W5_GO_D4_1.	W5_GO_D4_1.	W5_GO_D4_2a. <b>Before:</b>  W5_GO_D4_2b. <b>During:</b>  W5_GO_D4_2c. <b>After:</b>	W5_GO_D4_3a. <b>Before:</b>  W5_GO_D4_3b. <b>During:</b>  W5_GO_D4_3c. <b>After:</b>	W5_GO_D4_4.
<b>Fri Date:</b>	W5_GO_D5_1.	W5_GO_D5_1.	W5_GO_D5_2a. <b>Before:</b>  W5_GO_D5_2b. <b>During:</b>  W5_GO_D5_2c. <b>After:</b>	W5_GO_D5_3a. <b>Before:</b>  W5_GO_D5_3b. <b>During:</b>  W5_GO_D5_3c. <b>After:</b>	W5_GO_D5_4.

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Sat Date:</b>	W5_GO_D6_1.	W5_GO_D6_1.	W5_GO_D6_2a. <b>Before:</b>   W5_GO_D6_2b. <b>During:</b>   W5_GO_D6_2c. <b>After:</b>	W5_GO_D6_3a. <b>Before:</b>   W5_GO_D6_3b. <b>During:</b>   W5_GO_D6_3c. <b>After:</b>	W5_GO_D6_4.
<b>Sun Date:</b>	W5_GO_D7_1.	W5_GO_D7_1.	W5_GO_D7_2a. <b>Before:</b>   W5_GO_D7_2b. <b>During:</b>   W5_GO_D7_2c. <b>After:</b>	W5_GO_D7_3a. <b>Before:</b>   W5_GO_D7_3b. <b>During:</b>   W5_GO_D7_3c. <b>After:</b>	W5_GO_D7_4.

**Week 5: Goal Related to Diet, Alcohol Consumption, Physical Activity,  
Stress Reaction/Response, or Antihypertensive Medication Use**

W5\_GO\_1. What is your goal related to diet, alcohol consumption, physical activity, or stress reaction/response, or antihypertensive medication use for the week?

W5\_GO\_2. On a scale of 1-10, where 10 is high, how MOTIVATED are you to achieve this goal?

W5\_GO\_3. On a scale of 1-10, how CONFIDENT are you that you will achieve the goal?

W5\_GO\_4. What could you do that would bring your motivation or confidence a little higher?

W5\_GO\_5. What might make it difficult to achieve the goal this week, and if that happens, what will you do?

W5\_GO\_6. What is a way to measure this goal that resonates with you?

W6\_GO\_7. Goal for This Week Related to Diet, Alcohol Consumption, Physical Activity, Stress Reaction/Response, Antihypertensive Medication Use, or Social Support:

---



---



---

W6\_GO\_8. How Goal Will Be Measured:

---



---



---

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Mon Date:</b>	W6_GO_D1_1.	W6_GO_D1_2a. <b>Before:</b>  W6_GO_D1_2b. <b>During:</b>  W6_GO_D1_2c. <b>After:</b>	W6_GO_D1_3a. <b>Before:</b>  W6_GO_D1_3b. <b>During:</b>  W6_GO_D1_3c. <b>After:</b>	W6_GO_D1_4.	W6_GO_D1_5.

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Tues Date:</b>	W6_GO_D2_1.	W6_GO_D2_1.	<p>W6_GO_D2_2a. <b>Before:</b></p> <p>W6_GO_D2_2b. <b>During:</b></p> <p>W6_GO_D2_2c. <b>After:</b></p>	<p>W6_GO_D2_3a. <b>Before:</b></p> <p>W6_GO_D2_3b. <b>During:</b></p> <p>W6_GO_D2_3c. <b>After:</b></p>	W6_GO_D2_4.
<b>Wed Date:</b>	W6_GO_D3_1.	W6_GO_D3_1.	<p>W6_GO_D3_2a. <b>Before:</b></p> <p>W6_GO_D3_2b. <b>During:</b></p> <p>W6_GO_D3_2c. <b>After:</b></p>	<p>W6_GO_D3_3a. <b>Before:</b></p> <p>W6_GO_D3_3b. <b>During:</b></p> <p>W6_GO_D3_3c. <b>After:</b></p>	W6_GO_D3_4.

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Thurs Date:</b>	W6_GO_D4_1.	W6_GO_D4_1.	<p>W6_GO_D4_2a. <b>Before:</b></p> <p>W6_GO_D4_2b. <b>During:</b></p> <p>W6_GO_D4_2c. <b>After:</b></p>	<p>W6_GO_D4_3a. <b>Before:</b></p> <p>W6_GO_D4_3b. <b>During:</b></p> <p>W6_GO_D4_3c. <b>After:</b></p>	W6_GO_D4_4.
<b>Fri Date:</b>	W6_GO_D5_1.	W6_GO_D5_1.	<p>W6_GO_D5_2a. <b>Before:</b></p> <p>W6_GO_D5_2b. <b>During:</b></p> <p>W6_GO_D5_2c. <b>After:</b></p>	<p>W6_GO_D5_3a. <b>Before:</b></p> <p>W6_GO_D5_3b. <b>During:</b></p> <p>W6_GO_D5_3c. <b>After:</b></p>	W6_GO_D5_4.

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Sat Date:</b>	W6_GO_D6_1.	W6_GO_D6_1.	<p>W6_GO_D6_2a. <b>Before:</b></p> <p>W6_GO_D6_2b. <b>During:</b></p> <p>W6_GO_D6_2c. <b>After:</b></p>	<p>W6_GO_D6_3a. <b>Before:</b></p> <p>W6_GO_D6_3b. <b>During:</b></p> <p>W6_GO_D6_3c. <b>After:</b></p>	W6_GO_D6_4.
<b>Sun Date:</b>	W6_GO_D7_1.	W6_GO_D7_1.	<p>W6_GO_D7_2a. <b>Before:</b></p> <p>W6_GO_D7_2b. <b>During:</b></p> <p>W6_GO_D7_2c. <b>After:</b></p>	<p>W6_GO_D7_3a. <b>Before:</b></p> <p>W6_GO_D7_3b. <b>During:</b></p> <p>W6_GO_D7_3c. <b>After:</b></p>	W6_GO_D7_4.



**Week 6: Goal Related to Diet, Alcohol Consumption, Physical Activity,  
Stress Reaction/Response, Antihypertensive Medication Use,  
or Social Support**

W6\_GO\_1. What is your goal related to diet, alcohol consumption, physical activity, stress reaction/response, antihypertensive medication use, or social support for the week?

W6\_GO\_2. On a scale of 1-10, where 10 is high, how MOTIVATED are you to achieve this goal?

W6\_GO\_3. On a scale of 1-10, how CONFIDENT are you that you will achieve the goal?

W6\_GO\_4. What could you do that would bring your motivation or confidence a little higher?

W6\_GO\_5. What might make it difficult to achieve the goal this week, and if that happens, what will you do?

W6\_GO\_6. What is a way to measure this goal that resonates with you?

W7\_GO\_7. Goal for This Week Related to Diet, Alcohol Consumption, Physical Activity, Stress Reaction/Response, Antihypertensive Medication Use, or Social Support:

---



---



---

W7\_GO\_8. How Goal Will Be Measured:

---



---



---

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Mon Date:</b>	W7_GO_D1_1.	W7_GO_D1_2a. <b>Before:</b>  W7_GO_D1_2b. <b>During:</b>  W7_GO_D1_2c. <b>After:</b>	W7_GO_D1_3a. <b>Before:</b>  W7_GO_D1_3b. <b>During:</b>  W7_GO_D1_3c. <b>After:</b>	W7_GO_D1_4.	W7_GO_D1_5.

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Tues Date:</b>	W7_GO_D2_1.	W7_GO_D2_1.	<p>W7_GO_D2_2a. <b>Before:</b></p> <p>W7_GO_D2_2b. <b>During:</b></p> <p>W7_GO_D2_2c. <b>After:</b></p>	<p>W7_GO_D2_3a. <b>Before:</b></p> <p>W7_GO_D2_3b. <b>During:</b></p> <p>W7_GO_D2_3c. <b>After:</b></p>	W7_GO_D2_4.
<b>Wed Date:</b>	W7_GO_D3_1.	W7_GO_D3_1.	<p>W7_GO_D3_2a. <b>Before:</b></p> <p>W7_GO_D3_2b. <b>During:</b></p> <p>W7_GO_D3_2c. <b>After:</b></p>	<p>W7_GO_D3_3a. <b>Before:</b></p> <p>W7_GO_D3_3b. <b>During:</b></p> <p>W7_GO_D3_3c. <b>After:</b></p>	W7_GO_D3_4.

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Thurs Date:</b>	W7_GO_D4_1.	W7_GO_D4_1.	<p>W7_GO_D4_2a. <b>Before:</b></p> <p>W7_GO_D4_2b. <b>During:</b></p> <p>W7_GO_D4_2c. <b>After:</b></p>	<p>W7_GO_D4_3a. <b>Before:</b></p> <p>W7_GO_D4_3b. <b>During:</b></p> <p>W7_GO_D4_3c. <b>After:</b></p>	W7_GO_D4_4.
<b>Fri Date:</b>	W7_GO_D5_1.	W7_GO_D5_1.	<p>W7_GO_D5_2a. <b>Before:</b></p> <p>W7_GO_D5_2b. <b>During:</b></p> <p>W7_GO_D5_2c. <b>After:</b></p>	<p>W7_GO_D5_3a. <b>Before:</b></p> <p>W7_GO_D5_3b. <b>During:</b></p> <p>W7_GO_D5_3c. <b>After:</b></p>	W7_GO_D5_4.

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
<b>Sat Date:</b>	W7_GO_D6_1.	W7_GO_D6_1.	<p>W7_GO_D6_2a. <b>Before:</b></p> <p>W7_GO_D6_2b. <b>During:</b></p> <p>W7_GO_D6_2c. <b>After:</b></p>	<p>W7_GO_D6_3a. <b>Before:</b></p> <p>W7_GO_D6_3b. <b>During:</b></p> <p>W7_GO_D6_3c. <b>After:</b></p>	W7_GO_D6_4.
<b>Sun Date:</b>	W7_GO_D7_1.	W7_GO_D7_1.	<p>W7_GO_D7_2a. <b>Before:</b></p> <p>W7_GO_D7_2b. <b>During:</b></p> <p>W7_GO_D7_2c. <b>After:</b></p>	<p>W7_GO_D7_3a. <b>Before:</b></p> <p>W7_GO_D7_3b. <b>During:</b></p> <p>W7_GO_D7_3c. <b>After:</b></p>	W7_GO_D7_4.

**Week 7: Goal Related to Diet, Alcohol Consumption, Physical Activity,  
Stress Reaction/Response, Antihypertensive Medication Use,  
or Social Support**

W7\_GO\_1. What is your goal related to diet, alcohol consumption, physical activity, stress reaction/response, antihypertensive medication use, or social support for the week?

W7\_GO\_2. On a scale of 1-10, where 10 is high, how MOTIVATED are you to achieve this goal?

W7\_GO\_3. On a scale of 1-10, how CONFIDENT are you that you will achieve the goal?

W7\_GO\_4. What could you do that would bring your motivation or confidence a little higher?

W7\_GO\_5. What might make it difficult to achieve the goal this week, and if that happens, what will you do?

W7\_GO\_6. What is a way to measure this goal that resonates with you?

## **APPENDIX 4**

### Informed Consent Form

## Agreement to Participate in a Research Study

### *Investigation of the Effects of Mindfulness on Blood Pressure and Well-Being*

You are being asked to take part in a Brown University research study about the effects of mindfulness and hypertension education on blood pressure and risk factors for hypertension. This form will explain the purpose of the study, how the study will be carried out and what you will be expected to do. It will also explain the possible risks and possible benefits of being in the study. If any part of the following description is not clear to you, you are encouraged to contact the researcher to answer any questions before you decide whether to take part in the study. If you decide to participate, please fill out and sign the last page of this form.

#### 1a. Nature and Purpose of the Study

The purpose of the study is to investigate the impact of mindfulness practices and health education on blood pressure. You have been selected for this study because you expressed interest and met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program. In order to assess the effects of these practices, you will be asked to complete some questionnaires, and a laboratory assessment before and after learning the mindfulness practices.

#### 1b. Explanation of Procedures

If you agree to participate, you will be asked to consent to the following:

- 1) Participate in an interview in which you will be asked questions about past and present mental health, including depression and suicide.
- 2) Complete questionnaires about a wide range of topics, including your diet, physical activity, smoking, medication use, personality, emotions, attention and past experiences, including stressful or traumatic experiences. These questions will probe sensitive psychological areas, including physical, emotion and sexual abuse. These questionnaires may take up to 2 hours to complete. By completing the interviews and questionnaires, you are giving the researchers permission to use the information you have provided. You have the right not to answer any of the questions.
- 3) Directly assessed blood pressure, height, weight, waist circumference, hip circumference, physical activity, and antihypertensive medication use.
- 4) You will be asked to perform some cognitive tasks. One of these tasks may involve computer-based tests of attention or decision-making. Together these tests may take as long as 45 minutes.
- 5) You will participate in the mindfulness program, which consists of 9 weekly sessions of 2.5 hours each and will include one 8 hour weekend retreat. Daily homework assignments may take as long as one hour and consist of practicing mindfulness exercises with the aid of a

Eric Loucks 9/1/2015 9:23 PM

Deleted: and

Eric Loucks 9/1/2015 9:21 PM

Deleted: 2

Eric Loucks 9/1/2015 9:21 PM

Deleted: July 15



guided audio CD and completing worksheets related to stress, thoughts, and common reactions to various types of events.

- 6) Class sessions will be audio taped so we can analyze the quality of the treatment you receive. The recordings will be transcribed so that we may analyze the text. The recordings will be identified by study number, will only be heard by study staff and will be destroyed after transcription.
- 7) You will be asked to complete a few short questionnaires each week during the 9 week condition.
- 8) After 9 weeks, you will be asked to complete questionnaires and return to the laboratory to repeat the same procedures for a second day of testing. You will also be invited to participate in a focus group to share any advice you may have on how to improve the intervention.
- 9) Three months after the end of the 9 week condition, you will be asked to return to the laboratory to repeat the same testing procedures.

**Table Summarizing Activities and Time Commitment for this Study.**

Activity	Time Commitment
First blood pressure screen	30 minutes
Second blood pressure screen	30 minutes
Baseline health assessments, such as questionnaires, height, weight and waist circumference.	2 hours
Mindfulness course	9 sessions that are 2.5 hours each. 1 retreat day on a Saturday that will be 8 hours Total course time: 30.5 hours
Home mindfulness practices assigned during course.	1 hour per day, 6 days per week, for 8 weeks. Total time: 48 hours.
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place immediately after course completion.	2 hours
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place that take place 3 months after course completion.	2 hours
<u>Participate in focus group after intervention completion to share any advice you may have on how to improve the intervention.</u>	<u>1.5 hours</u>
<b>TOTAL TIME COMMITMENT FOR STUDY</b>	<u><b>87.0 hours</b></u>

Eric Loucks 9/1/2015 9:23 PM

Deleted: 5.5

Eric Loucks 9/1/2015 9:21 PM

Deleted: 2

Eric Loucks 9/1/2015 9:21 PM

Deleted: July 15

#### Feedback:

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing % change (increase or decrease) on scales of attention, stress, mood, health behaviors, weight, and blood pressure across the study.

#### 2. Discomforts and Risks

The questionnaires are routine, standardized forms for epidemiologic research. Certain questions may be upsetting as they may probe sensitive psychological areas and inquire about upsetting or traumatic events, including physical, sexual or emotional abuse and/or current psychiatric symptoms. Since your participation is voluntary, you have the right to skip any questions that make you uncomfortable.

Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable feelings with increased attention to them.

#### 3. Benefits

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) receiving information about your psychological and physical functioning.

#### 4. Alternative Therapies

A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

#### 5. Confidentiality

Your responses for this study will be kept confidential. All data that we collect will be linked to a study ID# instead of your name. All questionnaires in this study will be filled out through an online survey or a paper version of the survey if you prefer. All of these questionnaires will be linked solely to your study ID#, so that your identity is protected and your answers are confidential. Although these measures have been taken to protect your personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet.

While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then a collaborator (Dr. Ellen Flynn) who is a licensed psychiatrist, may contact you to discuss your responses and possible referral to a treatment provider.

Questionnaire items that may warrant follow-up include endorsements of statements about hurting yourself, any high scores in depression, anxiety, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law

Eric Loucks 9/1/2015 9:21 PM

Deleted: 2

Eric Loucks 9/1/2015 9:21 PM

Deleted: July 15

also requires researchers to report abuse or neglect of people age 60 and older to the Division of Elderly Affairs.

The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a unique code number and initials. All study records and specimens will be stored in a secure storage area.

*Keeping study records:* The Principal Investigator for this study will keep your research records indefinitely for research purposes.

#### 6. Refusal/Withdrawal

Participation is voluntary, and you may decide to opt out or refuse any part of participation, including not answering certain questions. If you decide now to participate, you can change your mind later and quit the study. The decision to not participate or to withdraw from the study will not adversely affect current or future interactions with Brown University. The decision to not participate or to withdraw from the study will also not adversely affect your relationship with your physician.

If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

#### 7. Contact Information

If you have questions about study procedures at any time you may contact the researchers: Dr. Eric B. Loucks, email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu), telephone (401) 863-6283. If you would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Brown University Research Protections Office, telephone number 1-866-309-2095 or 401-863-3050.

Eric Loucks 9/1/2015 9:21 PM

Deleted: 2

Eric Loucks 9/1/2015 9:21 PM

Deleted: July 15

**CONSENT FORM:**  
**Please sign and return.**

Please read the following agreement and sign to consent to participating.

**I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY.**

\_\_\_\_\_  
PRINT NAME

\_\_\_\_\_  
Signature of participant

\_\_\_\_\_  
Date

**CONTACT INFORMATION**

Name (print): \_\_\_\_\_

Permanent Address: \_\_\_\_\_

Email(s): \_\_\_\_\_

Telephone: \_\_\_\_\_ (cell) \_\_\_\_\_ (other)

Eric Loucks 9/1/2015 9:21 PM

Deleted: 2

Eric Loucks 9/1/2015 9:21 PM

Deleted: July 15

**Brown University**  
Research Protections Office  
Institutional Review Board  
**Amendment Request**

**Date of Request:** 11/11/15 **Investigator's Name and Title:** Eric Loucks, Assistant Professor  
**Study Title:** Mindfulness-Based Hypertension Therapy Pilot Study (#1412001171)  
**Original Type of Review:** ☐ Exempt ☐ Expedited ☒ Full Board

- 1) **Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project.** (Attach summary to this form) Please see attached.
- 2) **Provide a detailed description of the changes being requested** (Use additional pages, if necessary):  
Please see attached.
- 3.) **State the reason (justification) for the requested amendment.** (Use additional pages, if necessary):  
Please see attached.
- 4.) **What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**  
Please see attached.
- 5.) **Does the requested amendment require new documents or changes to the approved consent form or other documents?**
  - ☒ Consent/assent documents (attach revised version with changes highlighted)
  - ☒ New/revised instruments (attach - if revised, highlight changes)
  - ☐ New/revised advertising materials (attach - if revised, highlight changes)

**Do you have a conflict of interest on this project according to Brown's policy?** ☐ YES ☒ NO  
**If YES, has this conflict been previously disclosed to the IRB?** ☐ YES ☐ NO

PI signature: \_\_\_\_\_



Date: 11/11/15

**1. Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project.**

The World Health Organization reported that suboptimal blood pressure (BP) is responsible for more than half of cardiovascular disease mortality world-wide. Furthermore, greater than half of those with hypertension have uncontrolled BP. A 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.” Evidence-based mindfulness interventions, including Mindfulness-Based Stress Reduction, may have some effects on blood pressure, where a recent meta-analysis and systematic review of 4 randomized controlled trials demonstrated significant effects, but evidence of heterogeneity in effect sizes. The methodologically highest quality studies had the smallest effect sizes (range 0-5 mmHg). Mindfulness-Based Stress Reduction (MBSR) has been customized to a number of disease processes, such as Mindfulness-Based Cognitive Therapy for patients with recurrent depression, and Mindfulness-Based Relapse Prevention for patients with substance use addictions. Effect sizes have been increased by customizing mindfulness interventions to diseases of interest. The same may be true for hypertension, however mindfulness interventions customized for prehypertensive/hypertensive patients have never been investigated. Until methodologically rigorous studies to evaluate customized interventions for hypertension are performed, we will not know if the observed preliminary effects of general mindfulness interventions on blood pressure reduction could be much more effective with a tailored approach. Consequently, we propose to conduct a stage I behavioral therapy intervention study to evaluate whether MBSR customized to prehypertensive and hypertensive patients has the potential to provide clinically relevant reductions in BP. Consequently the specific aims are:

**Stage 1a: Therapy Development/Manual Writing**

1. To outline and evaluate key novel elements of mindfulness-based hypertension therapy (MBHT), customized from the evidence-based MBSR. *We hypothesize that the most important novel element will be generation of mindfulness skills specifically applied to hypertension risk factors such as diet, physical activity, obesity, alcohol consumption and antihypertensive medication adherence.* This aim will be achieved using (1) focus groups of participants undergoing the MBHT behavioral intervention, (2) discussion with experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) prior to, and following pilot testing of MBHT in participants, and (3) clinical judgment of the investigators performing the intervention.
2. To determine effectiveness of MBHT on primary outcomes (systolic blood pressure, retention rates, recruitment rates, and adverse effects) and secondary outcomes (hypertension risk factors such as diet, physical activity, obesity, and antihypertensive medication adherence) in hypertension subgroups, specifically participants with (1) prehypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. Initial decisions about the targeted sample based on hypertension status will be made.
3. To develop an MBHT therapist manual and training program, including procedures for training, supervising, and evaluating therapists. Furthermore, acceptable therapist characteristics will be developed. The manual and training program will include themes such as specification of unique and common elements of MBHT vs. other interventions, description of interventions excluded from MBHT, and specification of key treatment parameters such as frequency and duration of treatment, session length, topics addressed, sequence of sessions, as well as therapist adherence and competency

measures. The MBHT training will consist of a therapist manual, a formal didactic training seminar, and at least one closely supervised training session.

#### *Stage 1b: Pilot Trial*

4. To determine whether a mindfulness-based hypertension therapy (MBHT) intervention, customized from the evidence-based MBSR, has promise to be an effective behavioral therapy for participants with hypertension and/or prehypertension. We will perform a randomized controlled pilot trial for MBHT vs. enhanced usual care control. *We hypothesize that MBHT will have adequate recruitment rates ( $\geq 10\%$  of prehypertensive/hypertensive participants invited from physicians' offices), fairly low drop out rates ( $< 15\%$ ), and medium effect sizes (e.g. 5-10 mmHg systolic BP) for reduction in blood pressure.*

These findings will provide publishable pilot data that will inform future randomized clinical trials that evaluate effects of MBHT on long-term changes in blood pressure vs. usual care and active control groups. *If proven effective, MBHT could be offered as a complementary program in the prehypertensive/hypertensive patient population that contributes to over half of the cardiovascular disease mortality world-wide.*

## **2. Provide a detailed description of the changes being requested (Use additional pages, if necessary):**

#### Study Protocol

We would like to update you on the following changes made to the overall study protocol...

- **NIH funding** – On September 14, 2015, we received notification from the NIH that our grant [Award # 1UH2AT009145-01] has been approved and will be funded in full.
- **Control group** – we had initially thought we would introduce a control group further down the road in 2017 or 2018, but our funding agency (NCCIH) has asked that we add a control group at this time. For this reason, we will be randomly selecting eligible participants to take part in the intervention. Those not selected, will receive enhanced usual care and will be invited to participate in the mindfulness training program around six months after the intervention group. Enhanced usual care in the setting of this study refers to participants obtaining hypertensive treatment through the services typically available to them. However, we will help participants access these services if needed.
- **Participant incentive** – we now have sufficient funds to offer participants a small participant incentive for their involvement in the study. Study participants will be given a participant incentive of \$100 USD at the time of their last follow up. Only participants who have completed the study will be given the incentive.
- **Safety Monitoring** – as part of the NCCIH submission, a formal Safety Monitoring Protocol was created. We have included that here as part of the study protocol (see Appendix 1).

- **Assessment Name Changes** - Several of the assessment document names have been changed. We did this both for internal consistency and in order to clarify the timing and purpose of each assessment. Specific name changes are noted below.
- **Consent Form Modifications** – we have modified the consent form (see below for details as well as Appendix 3 for the revised consent form, v.1.4)
- **Additional Follow-up Added** – we have decided to add an additional follow up to the study, which will take place at 1 year post-baseline. The assessments conducted at this follow up will be identical to those administered at the 10 week and 6 month follow up visits.
- **Questionnaire Revisions** - we have made changes to several of the individual Assessments (see below for details as well as Appendices 4-7 for revised assessments)

#### Consent Form (v.1.4, See Appendix 3)

We have made the following changes to the study consent form:

- Added clarifying language on study procedures.
- Added in language about a control group. We had initially thought we would hold off on including a control group until a later date, but our funding agency (NCCIH) has asked that we add a control group at this time. For this reason, we will be randomly selecting eligible participants to take part in the intervention. Those not selected, will receive enhanced usual care and will be invited to participate in the mindfulness training program around six months after the intervention group.
- Added more detail about physical activity monitoring (i.e., use of actigraphy monitors) as well medication use monitoring (i.e., the use of electronic bottle caps).
- Added information about focus group involvement post-intervention.
- Added language on risk of physical injury.
- We have decided to offer a participant incentive in the amount of \$100 USD, paid at the time of final follow up visit. This has been added to the consent form.
- Added information about the 1 year follow up assessment.
- Updated the Table Summarizing Activities and Time Commitment for the study

#### Phone Screener: (v.1.4, See Appendix 4)

- Modified language to make more concise and clear
- Added information about the randomization process / control group
- Added in information about the participant incentive
- Corrected typos
- Removed the script about scheduling the second In-Person visit. This will be done at the time of the In-Person screener, if the person is found to be eligible for the study and is still interested in participating.



#### In-Person Screening: (v.1.4, See Appendix 5)

- **Changed the name.** It was formally called the “First In-Person Visit Screening Assessment Form”
- **Moved “Medication Use” to the In-Person Baseline Assessment** – the primary purpose of the In-Person Screening Assessment is to determine whether or not an individual is eligible for the study (i.e., have mean systolic/diastolic blood pressure  $\geq 120/80$  after first and second baseline assessments). For this reason, we decided to move medication use, which was originally found in the “First In-Person Visit Assessment Form” to the In-Person Baseline Assessment since it is not part of the eligibility criteria. This will help to reduce participant burden for those individuals who are not eligible.
- *NOTE that the only assessment conducted during the In-Person Screening is Blood Pressure measurements.*

#### Home Baseline Assessment: (v.1.4, See Appendix 6)

- Changed the name. It was formally called the “Baseline Questionnaire”
- Corrected typos, including skip errors
- Updated the Table of Contents and Sub-headings in questionnaire
- Removed Diet questions (DT1\_01 – DT1\_25); we will assess diet during the In-Person Baseline Assessment using the Harvard University 80-item Food Frequency Questionnaire
- Added a question (TS01\_01) on table salt use
- Added the 11 item validated Craving Experience Questionnaire (CEQ)
- Moved around some of the sub-scales for ease of administration (noted in text).
- Removed Social Network questions (SN1\_01 – SN1\_04) and replaced with the validated 12-item Interpersonal Support Evaluation List (ISEL-12)
- Removed the Social Network questions (SN1\_01 – SN1\_04)
- Added Blood Pressure Medication Use questions (BM1\_01 – BM1\_09), which includes the validated Morisky 8-item questionnaire<sup>1</sup>.
- Added questions that measure “Readiness to change for hypertension risk factors” (RC1\_01 – RC1\_14)
- Added Family History of Hypertension questions (FH1\_01 – FH1\_04), which assess biological parents’ history of having hypertension, based on questions from New England Family Study LEAP Project.
- Dropped several of the sleep items (SL1\_05 – SL1\_14a; SL1\_16 – SL1\_21b) to reduce ppt burden.

### In-Person Baseline Assessment (v.1.4, See Appendix 7)

- Changed the name. It was formally called the “Second In-Person Visit Screening Assessment”
- Added Medication use questions (ME01 – ME10i)
- Added the validated Harvard University three page Food Frequency Questionnaire, known as “80-out”. It is designed to take around 20 minutes to complete and is self-administered with paper and pencil. A proof of the questionnaire is included in this Amendment Request.
- Added two computer-based tests that measure Attention Control. They are:
  - The Attention Network Test (ANT)* is a brief computerized battery measuring three independent behavioral components of attention: Conflict resolution (ability to overcome distracting stimuli), spatial Orienting (the benefit of valid spatial pre-cues), and Alerting (the benefit of temporal pre-cues). Efficiency of orienting is examined by changes in RT that accompany cues indicating where the target will occur. The efficiency of the executive conflict resolution network is examined by requiring the subject to respond by pressing two keys indicating the direction (left or right) of a central arrow surrounded by congruent, incongruent or neutral flankers. Moderate to high reliabilities are found for all networks. The ANT takes around 20min to complete.
  - The Sustained Attention to Response Task (SART)* is a computerized test of sustained attention, response inhibition (executive function) and self-regulation. Subjects are instructed to press a key in response to rapidly displayed integers (1-9) and withhold response to a designated "no-go" integer. SART errors consist of summed commission errors (button press on no-go trial) and omission errors (button not pressed on "go" integers). SART performance is associated with prefrontal cortex functioning, has been found to increase with mindfulness training and is correlated with scores on mindfulness questionnaires (specifically, the Mindful Attention Awareness Scale). The SART takes around 15min to complete.

### **3. State the reason (justification) for the requested amendment:**

Please see justifications in Section 2 above.

### **4. What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

Overall the changes we have made in this amendment affect the risk/benefit ratio in small ways. We have added some question items to the assessments, but have also removed some items in order to minimize participant burden. Assessment time has increased by about 1 hour per assessment.

The addition of a participant incentive adds a tangible benefit to participants and serves as a potential motivation to complete the study.

The inclusion of a formalized Safety Monitoring protocol helps reduce participant risk by predicting potential areas of concern and by outlining clear procedures with how to manage incidents that may come up.

## **5. Does the requested amendment require new documents or changes to the approved consent form or other documents?**

Yes. Please see **Appendices 1-7**.

Appendix 1	Safety Monitoring Protocol
Appendix 2	Summary of Assessments
Appendix 3	Consent Form (v.1.4)
Appendix 4	Phone Screener (v.1.4)
Appendix 5	In-person Screener (v.1.4)
Appendix 6	Home Baseline Assessment (v.1.4)
Appendix 7	In-Person Baseline Assessment (v.1.4)

## **References**

<sup>1</sup> Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care. 1986;24(1):67-74.

# **Appendix 1:**

# **Safety Monitoring Protocol**

*(Language Taken from the NCCIH Protocol Submission)*

**Safety Monitoring** – *as part of the NCCIH submission, a formal Safety Monitoring Protocol was created. It is outlined below.*

Oversight of internal monitoring of the participants' safety will be conducted by the PIs, Dr. Eric Loucks and Dr. Willoughby Britton. Oversight of the external Data and Safety Monitoring Committee will be conducted by the chair (Dr. Edmondson). The Data and Safety Monitoring Committee will include experts in cardiology, psychology/psychiatry, epidemiology, and biostatistics.

*Entities Conducting Monitoring*

The Institutional Review Board (IRBs) at Brown University will review all research procedures, and will provide oversight. Internal monitoring will be done by the Brown University principal investigators (Dr. Loucks and Dr. Britton) and the Brown University IRB. The Data Safety Monitoring Committee will provide external monitoring, and will meet every six months by phone or in-person. They will be provided data every six months to evaluate potential effects of the RCT on major outcomes (e.g. medical regimen adherence). Any serious adverse effects will be immediately reported to the principal investigators (Loucks, Britton) and the committee chair.

*What is Monitored*

Monitoring is done of all procedures to ensure that they conform to the approved protocol; of unforeseen circumstances that might arise and affect safety; of all reports of serious adverse events as defined in US Department of Health and Human Services regulations for the protection of human research subjects 45 CFR Part 46, and the FDA 312.32 (death, life-threatening experience, new or prolonged hospitalization, persistent or significant disability/incapacity); of other significant adverse events (adverse events that lead to drop out by participant or termination by the investigator); of unexpected adverse events resulting from the study; and of expected adverse events.

Monitoring is done of all study inclusion and exclusion criteria. During this clinical trial, we will notify officials, as mandated by law, if a participant reports intentions to harm him/herself or others, or reports child abuse or abuse of an elder. Dr. Ellen Flynn, a licensed psychiatrist, will be available to advise on any psychological events that occur, and provide referrals for treatment if needed.

*Frequency of Monitoring*

All adverse events will be continuously monitored by the PI. Participants will be given contact information so that they can inform us of events that occur in between study visits. Dr. Loucks will conduct daily oversight of participant safety. He will meet weekly with staff to review participant progress and their experiences with the experimental procedures, including adverse events. Any adverse events that are observed and/or reported will be immediately reported to Dr. Loucks, Dr. Britton, and the Data Safety Monitoring Committee chair. The Investigators and Data Safety Monitoring Committee will be available to meet outside of the regularly scheduled meetings (scheduled semiannually), if necessary, due to concerns regarding a particular participant or any problems that may arise for participants. If necessary, they will make appropriate recommendations for changes in protocol, or terminate the study. The Brown University IRB conducts the monitoring at the continuing reviews as scheduled, whenever modification requests are considered, and upon receiving reports of serious adverse events from the PI or anyone else.

*Reporting Plan*

Any serious adverse events that are observed and/or reported will be immediately reported to Dr. Loucks and the Data Safety Monitoring Committee Chair. Serious adverse events are

then reported to the Brown University IRB and to NIH. Brown's IRB requires fatalities related to the study be reported within 24 hours. All serious adverse events related to this study will be reported to the Brown University IRB immediately by telephone and by written report within 48 hours of our receipt of information regarding the event. All other adverse events related to the study will be reported at the continuing review. Serious adverse events will also be reported in writing to the NIH Project Officer within 48 hours. All serious adverse events related to the study will be reported annually in the Progress Report sent to the NIH Project Officer.

Any actions taken by the IRB, other than acceptance of the adverse event report, will be reported to the NIH along with any changes or amendments to the protocol requested by the IRB in response to these reports. Proposed changes or amendments to the protocol in general must be requested first in writing to the Brown and IRB, which will then grant or deny permission to make the requested change or amendment in protocol. NIH will subsequently be informed of any substantive changes or amendments in approved protocol.

*Injury due to physical activities:* It is possible that injuries could be sustained from (1) the gentle mindful movements (yoga), or (2) physical activities that participants engage in as a result of the intervention encouraging exploration of physical activity as a way to reduce blood pressure.

- (1) Mindful movements: Participants receive a handout during the orientation showing the yoga poses that will be offered during the course. They are encouraged to explore limits in their body related to movement, but not to go beyond those limits. Participants are asked to listen to what their body is telling them more closely than what the mindful movement instructor is telling them. Modifications of poses are available, including for those limited to chairs or wheelchairs. Participants are encouraged to bring the handout of poses to their health care providers if they have any physical limitations, so that the providers can advise on which poses to do, and which to avoid.
- (2) Physical activities: Participants are encouraged to explore physical activities that promote strength and conditioning as a way to reduce blood pressure. As with the mindful movements, they are encouraged to explore limits in their body related to movement, but not to go beyond those limits. Participants are asked to listen to what their body is telling them more closely than what the mindful movement instructor is telling them. Furthermore, they are encouraged to ask their healthcare provider about advised physical activities if they have any physical limitations.

All patients will be monitored by study staff at weekly intervals in person or by telephone and assessed every two weeks with questionnaires about physical injuries, specifically the following questions:

1. Have you sustained any physical injuries during the past 2 weeks?

If yes,

- (a) please describe the injury
- (b) please describe what happened to cause the injury.
- (c) did this injury include
  - i. Broken bone(s) yes/no
  - ii. Lacerations requiring stitches yes/no
  - iii. Concussion yes/no

If injuries include any of the following, it will be reported to Data Safety Monitoring Committee member Dr. Hank Wu, MD, who is a practicing physician and researcher. He will advise on any follow-up needed. It will also be reported to the chair of the Data Safety Monitoring Board.

- a. Broken bone(s)
- b. Lacerations requiring stitches
- c. Concussion

*Non-Response to Treatment:* The possibility that the treatment will not yield benefit is another possible risk and will be explained during informed consent procedures. Non-responders (identified as minimal change in medical regimen adherence from baseline assessment) will be provided with referrals to other treatment, if desired.

## **INTERVENTION DISCONTINUATION**

If serious adverse events are significantly higher in the treatment vs. control groups, the study will be terminated.

## **COMMITTEES**

### *Data Safety Monitoring Board:*

Oversight of internal monitoring of the participants' safety will be conducted by the PIs, Dr. Eric Loucks and Dr. Willoughby Britton. Investigators on this application have extensive experience with clinical trials for mindfulness-based interventions and cardiovascular outcomes. Oversight of the external Data and Safety Monitoring Committee will be conducted by the chair, Dr. Donald Edmondson, PhD, is Assistant Professor of Behavioral Medicine at Columbia University Medical Center. He is a Psychologist, and has extensive research experience in evaluating effects of stress and psychosocial factors on cardiovascular disease outcomes.<sup>246-264</sup> The Data and Safety Monitoring committee will also include Dr. Wen-Chih (Hank) Wu and Dr. Tao Liu. Dr. Wu, MD, is Associate Professor of Medicine and Associate Professor of Epidemiology at Brown University. He is a practicing clinical cardiologist with research in preventive cardiology,<sup>265-272</sup> and will be able to advise on clinical outcomes and any cardiovascular complications arising from the study, in addition to methodological concerns. Dr. Liu, PhD, is an Assistant Professor of Biostatistics at Brown University, experienced in clinical trials.<sup>273,274</sup> He will receive all preliminary analyses from the primary statistician, and will have access to all data from the study, to evaluate any evidence of serious adverse effects or other concerns.

### *Entities Conducting Monitoring*

The Institutional Review Board (IRBs) at Brown University will review all research procedures, and will provide oversight. Internal monitoring will be done by the principal investigators (Dr. Loucks and Dr. Britton) and the Brown University IRB. The Data Safety Monitoring Committee will provide external monitoring, and will meet every six months by phone or in-person. During the randomized-controlled trial phase (phase 4), they will be provided data every six months to evaluate potential effects of the RCT on the primary outcome (i.e. medical regimen adherence). Any serious adverse effects will be immediately reported to the principal investigator (Loucks) and the committee chair (Edmondson).

## **Appendix 2:**

# **Summary of Assessments**



## **Summary of Assessments (e.g., timing and intent of assessment):**

### **(1) Phone Screener**

- Previously called the “Phone Screening Questionnaire”
- Completed by phone any time prior to the intervention
- Used to screen individuals for the following eligibility criteria: age, language, mental health, and mindfulness practices (see protocol for details on eligibility requirements). Blood pressure, the primary eligibility criteria of interest, will be measured in person at the in-person screening.
- Phone screener provides talking guidelines for the RA to use in order to set up appointments for the in-person screening and to find out about general availability. Also provides the interested individual with information about the study.

### **(2) In-Person Screening**

- Previously called the “First In-Person Visit Screening Assessment Form”
- Completed up to three months prior to intervention
- 1<sup>st</sup> BP reading taken in order to determine eligibility
- Takes place at 121 South Main Street (office/laboratory)
- If eligible, Consent Form is completed at this visit
- Estimated time to complete is 20-30 minutes

### **(3) Home Baseline Assessment**

- Previously called the “Baseline Questionnaire”
- Completed up to three weeks prior to commencement of intervention
- Done online by participant at home or other location of choice. Participant will be sent a link to the online survey or will be provided with a paper version (if preferred).
- Questionnaire will take around 2-2.5 hrs to complete

### **(4) In-Person Baseline Assessment**

- Previously called the “Second In-Person Visit Screening Assessment”
- Completed up to three weeks prior to intervention
- 2<sup>nd</sup> BP reading will be taken as well as the following assessments:
  - Height, weight, and hip and waist circumference
  - Medication use
  - Diet
  - Anxiety and depressive symptomology
  - Attention control activities (ANT and SART)
- Takes place at 121 South Main Street (office/laboratory)
- Estimated time to complete is around 1.5 to 2 hrs

### **(5) Mindfulness Course**

- 9 sessions that are 2.5 hrs each as well as 1 retreat day on a Saturday that will be 8hrs long
- Participants will be given mindfulness ‘homework’ to practice daily (around 1hr per day, 6 days per week for 8 weeks)
- Participants will be asked to complete mindfulness assignments from home during the course. These assessments have already been approved by the IRB.
- Also approved are Teacher Fidelity assessments that will be administered during weeks 4 and 8.

**(6) 10 Week Post-Intervention Assessments (HOME and IN-PERSON)**

- To take place roughly 10 weeks from Baseline, after the Mindfulness Training is complete.
- Similar to assessments administered at Baseline, there will be both an online component that can be completed by the participant at home, and an in-person component that will take place at 121 South Main Street (office/laboratory)
- Questionnaires and assessments to be completed at this visit are identical to those administered at the In-Person Baseline Assessment, with the exception of question items for which the answers should not change or be informative (e.g., age, race/ethnicity, education, adverse childhood experiences, family history of hypertension).
- Additionally, adverse events are monitored at the 10 week, 6 month and 1 year follow-ups.
- Estimated time to complete is up to 3 hrs

**(7) Focus Group**

- Participants will be invited to take part in a focus group after the intervention is complete in order to share any advice they may have on how to improve the intervention
- Takes place at 121 South Main Street
- Estimated time is 1.5 hrs

**(8) 6 Month Post-Intervention Assessments (HOME and IN-PERSON)**

- To take place roughly 6 months from Baseline, after the Mindfulness Training is complete.
- Similar to assessments administered at Baseline, there will be both an online component that can be completed by the participant at home, and an in-person component that will take place at 121 South Main Street (office/laboratory)
- Questionnaires and assessments to be completed at this visit are identical to those administered at the In-Person Baseline Assessment, with the exception of question items for which the answers should not change or be informative (e.g., age, race/ethnicity, education, adverse childhood experiences, family history of hypertension).
- Additionally, adverse events are monitored at this follow up.
- Estimated time to complete is up to 3 hrs

**(9) 1 Year Post-Intervention Assessments (HOME and IN-PERSON) \*\*NEW**

- To take place roughly 1 year from Baseline, after the Mindfulness Training is complete.
- Similar to assessments administered at Baseline, there will be both an online component that can be completed by the participant at home, and an in-person component that will take place at 121 South Main Street (office/laboratory)
- Questionnaires and assessments to be completed at this visit are identical to those administered at the In-Person Baseline Assessment, with the exception of question items for which the answers should not change or be informative (e.g., age, race/ethnicity, education, adverse childhood experiences, family history of hypertension).
- Additionally, adverse events are monitored at this follow up.
- Estimated time to complete is up to 3 hrs

# **Appendix 3: Revised Consent Form with Track Changes**

*(v.1.4 – November 6, 2015)*

## Agreement to Participate in a Research Study

### *Investigation of the Effects of Mindfulness on Blood Pressure and Well-Being*

You are being asked to take part in a Brown University research study about the effects of mindfulness and hypertension education on blood pressure and risk factors for hypertension. This form will explain the purpose of the study, how the study will be carried out and what you will be expected to do. It will also explain the possible risks and possible benefits of being in the study. If any part of the following description is not clear to you, you are encouraged to contact the researcher to answer any questions before you decide whether to take part in the study. If you decide to participate, please fill out and sign the last page of this form.

#### 1a. Nature and Purpose of the Study

The purpose of the study is to investigate the impact of mindfulness practices and health education on blood pressure. You have been selected for this study because you expressed interest in the project and because you met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program.

In order to assess the effects of these practices, you will be asked to complete some questionnaires and laboratory assessments before and after learning the mindfulness practices.

Assessments will be completed at: baseline, 10 weeks, 6 months and 1 year. If you complete the study, you will be given \$100 USD at the time of completion for your participation, to express our gratitude.

Participation in this study involves receiving training in mindfulness practices as well as health education on blood pressure. If eligible, you will be randomly assigned to either receive the training now or in about six months from now (if still available and interested).

Deleted: a

#### 1b. Explanation of Procedures

If you agree to participate, you will be asked to consent to the following:

- 1) Participate in an interview in which you will be asked questions about past and present mental health, including depression and suicide.
- 2) Complete questionnaires about a wide range of topics, including your diet, physical activity, smoking, medication use, personality, emotions, attention and past experiences, including stressful or traumatic experiences. These questions will probe sensitive psychological areas, including physical, emotion and sexual abuse. These questionnaires may take up to 3 hours to complete. By completing the interviews and questionnaires, you are giving the researchers permission to use the information you have provided. You have the right not to answer any of the questions.
- 3) Directly assessed blood pressure, height, weight, waist circumference, hip circumference, physical activity, and antihypertensive (blood pressure) medication use at baseline and after the mindfulness course. Physical activity will be assessed for a week at a time using small

Deleted: 2

Deleted: and

Deleted: .

actigraphy monitors that attach to your wrist and hip. If you take antihypertensive medication, we will provide you with an electronic bottle cap that will automatically record when the pill bottle is opened during the study. This will help us measure how often the medication is used.

- 4) You will be asked to perform some cognitive tasks. ~~Some~~ of these tasks may involve computer-based tests of attention or decision-making. Together these tests may take as long as 45 minutes.
- 5) You will participate in the mindfulness program, which consists of 9 weekly sessions of 2.5 hours each and will include one 8 hour weekend retreat. Daily homework assignments may take as long as one hour and consist of practicing mindfulness exercises with the aid of a guided audio CD and completing worksheets related to stress, thoughts, and common reactions to various types of events.
- 6) Class sessions will be audio taped so we can analyze the quality of the treatment you receive. The recordings will be transcribed so that we may analyze the text. The recordings will be identified by study number, will only be heard by study staff and will be destroyed after transcription.
- 7) You will be asked to complete a few short questionnaires each week during the 9 week condition.
- 8) After 10 weeks, you will be asked to complete questionnaires and return to the laboratory to repeat the same procedures for a second day of testing. You will also be invited to participate in a focus group to share any advice you may have on how to improve the intervention.
- 9) Six months and one year after the beginning of the study, you will be asked to return to the laboratory to repeat the same testing procedures.

Deleted: One

Deleted: 9

Deleted: Three

Deleted: the end of the 9 week condition

**Table Summarizing Activities and Time Commitment for this Study.**

Activity	Time Commitment	
First blood pressure screen	30 minutes	
Second blood pressure screen	30 minutes	
Baseline health assessments, such as questionnaires, height, weight and waist circumference.	<u>3 hours</u>	Deleted: 2 hours
Mindfulness course <i>In-person</i>	9 sessions that are 2.5 hours each. 1 retreat day on a Saturday that will be 8 hours <i>Total course time: 30.5 hours</i>	
Home practices assigned during <u>mindfulness</u> course.	1 hour per day, 6 days per week, for 8 weeks. <i>Total practice time: 48 hours</i>	Deleted: mindfulness
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place <i>immediately after course completion</i> .	<u>3 hours</u>	Deleted: 2 hours
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that <u>begin 6 months after baseline</u> .	<u>3 hours</u>	Deleted: 2 hours
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that <u>begin 1 year after baseline</u> .	<u>3 hours</u>	Deleted: take place that take place 3 Deleted: course completion
<u>Participate in focus group after intervention completion to share any advice you may have on how to improve the intervention.</u>	<u>1.5 hours</u>	
<b>TOTAL TIME COMMITMENT FOR STUDY</b>	<b><u>93.0 hours</u></b>	Deleted: <u>87.0 hours</u>

#### Feedback:

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing % change (increase or decrease) on scales of attention, stress, mood, health behaviours, weight, and blood pressure across the study.

#### 2. Discomforts and Risks

The risks to you in this study are small. The questionnaires used in the study are routine, standardized forms for epidemiologic research. Certain questions may be upsetting as they may probe sensitive psychological areas and inquire about upsetting or traumatic events, including physical, sexual or emotional abuse and/or current psychiatric symptoms. Since your participation is voluntary, you have the right to skip any questions that make you uncomfortable.

Meditation-based interventions may results in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable feelings with increased attention to them.

It is possible that injuries could be sustained during the study either from the gentle mindful movements (i.e., yoga), or from physical activities that participants engage in as a way to reduce blood pressure. To help limit this, you will receive a handout showing the yoga poses that will be offered during the course that you can show your health care provider so that they can advise on which poses to do, and which to avoid. Modifications of poses will be available as needed. None of the poses (or the yoga as a whole) are mandatory to be done. You will also be encouraged to explore physical activities that promote strength and conditioning as a way to reduce blood pressure. You will be encouraged to not go beyond any physical limits of your body, and will be encouraged to ask your healthcare provider about advised physical activities and mindful movements if you have any physical limitations.

### 3. Benefits

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) receiving information about your psychological and physical functioning.

To express our gratitude, at the end of your last follow-up visit, you will receive \$100 USD for your participation in the study.

### 4. Alternative Therapies

A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

### 5. Confidentiality

Your responses for this study will be kept confidential. All data that we collect will be linked to a study ID# instead of your name. All questionnaires in this study will be filled out through an online survey or a paper version of the survey if you prefer. All of these questionnaires will be linked solely to your study ID#, so that your identity is protected and your answers are confidential. Although these measures have been taken to protect your personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet.

While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then a collaborator (Dr. Ellen Flynn) who is a licensed psychiatrist, may contact you to discuss your responses and possible referral to a treatment provider. Questionnaire items that may warrant follow-up include endorsements of statements about hurting yourself, any high scores in depression, anxiety, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law

also requires researchers to report abuse or neglect of people age 60 and older to the Division of Elderly Affairs.

The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a unique code number and initials. All study records and specimens will be stored in a secure storage area.

*Keeping study records:* The Principal Investigator for this study will keep your research records indefinitely for research purposes.

#### 6. Refusal/Withdrawal

Participation is voluntary, and you may decide to opt out or refuse any part of participation, including not answering certain questions. If you decide now to participate, you can change your mind later and quit the study. The decision to not participate or to withdraw from the study will not adversely affect current or future interactions with Brown University. The decision to not participate or to withdraw from the study will also not adversely affect your relationship with your physician.

If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

#### 7. Contact Information

If you have questions about study procedures at any time you may contact the researchers: Dr. Eric B. Loucks, email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu), telephone (401) 863-6283. If you would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Brown University Research Protections Office, telephone number 1-866-309-2095 or 401-863-3050.



**CONSENT FORM:**  
**Please sign and return.**

Please read the following agreement and sign to consent to participating.

**I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY  
QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, I AGREE TO  
PARTICIPATE IN THIS RESEARCH STUDY.**

\_\_\_\_\_  
PRINT NAME

\_\_\_\_\_  
Signature of participant

\_\_\_\_\_  
Date

**CONTACT INFORMATION**

Name (print): \_\_\_\_\_

Permanent Address: \_\_\_\_\_

Email(s): \_\_\_\_\_

Telephone: \_\_\_\_\_ (cell) \_\_\_\_\_ (other)

# **Appendix 4: Revised Phone Screener with Track Changes**

*(v.1.4 – November 6, 2015)*

# PHONE-DELIVERED SCREENING QUESTIONNAIRE

## PHONE SCREENING QUESTIONNAIRE PART 1

The script is shown below in **bold italics**.

PID. Participant ID: \_\_\_\_\_

SQ01. Staff ID: \_\_\_\_\_

SQ02. Today's Date (MMDDYY): \_\_\_\_\_

SQ03. Current Time (24 hour time, e.g. 14:45): \_\_\_\_\_

Please now call the participant.

SQ04. Was the participant reached? YES NO

***Hello, my name is \_\_\_\_\_. I am calling from the Brown University School of Public Health because (name of participant) expressed interest in participating in our mindfulness blood pressure study. Is he/she available to talk at this time?***

***I would like to do a 10-15 minute phone interview with you to determine if you are a good match for this particular study.***

SQ05. ***Is now a good time to speak?***

*[If yes, proceed to SQ05 script below]*

If no... ***When would be a good time to talk?***

SQ06. Day to call back (DDMMYY) \_\_\_\_\_

SQ07. Time to call back \_\_\_\_\_ AM/PM

***OK, great. How about I give a quick overview of the study, and can then answer any questions you may have to see if it is a good fit for you. We will then go through a screening questionnaire to see if you qualify for the study. Does this sound OK?***

***In this study, we are looking to see if mindfulness practices improve blood pressure, and if education about hypertension risk factors may also improve blood pressure. If eligible and if selected to participate, we will provide you with training in meditation, mindful movements, and the roles of things like diet, physical activity and medication in reducing blood pressure. You will be taught by a very experienced teacher who is an expert in these fields. The course is free and will take place over a 9-week period, where you come to a class once each week for 2.5 hours each time. There is also a one-day retreat on a Saturday that will be 8 hours long. As part of the project, we will also ask you to participate in health assessments before and after the study. Health assessments include measures such as blood pressure, height and weight, and questionnaires about your health and experiences. At the end of the study, you will be given \$100 USD to express our gratitude.***

Deleted: A basic overview of the study is that it is

Deleted: Specifically

Deleted: Y

Deleted: s

Deleted: Also, w

***Do you have any questions about the study?*** [answer questions]

Deleted: Can I answer any questions about the study that you may have

SQ08. ***Does this study sound like something you would be interested in doing?*** Yes No

[If yes, proceed to next statement below. If no, politely thank the participant for considering being in this study, and end the call].

***Great. There are a few things that I would like to make clear before we start the interview. First of all, some of the questions that I will ask now to figure out if you are eligible to be in this study will be of personal nature, including asking about your mental health and life's experiences.***

SQ09. ***Are you in a private place to talk?***

[If yes, proceed to text below. If no, reschedule meeting using variables SQ06 and SQ07 above].

Deleted: SQ04

Deleted: SQ05

***Because this interview is of a personal nature, it is important that you understand that everything you say will be kept strictly confidential. No one outside of our project will ever be able to see your answers, and we will not keep your name in the same place as any of your answers. If you are not eligible after the phone screen, we will destroy your information. If you like, though, we can keep your information on file for future studies.***

SQ10. Participant's First Name: \_\_\_\_\_

SQ11. Participant's Last Name: \_\_\_\_\_

Participant's Address (in case we need to send any study materials to you):

SQ12a. Street address: \_\_\_\_\_

SQ12b. City: \_\_\_\_\_

SQ12c. State: \_\_\_\_\_

SQ12d. Zip Code: \_\_\_\_\_

SQ13a. Participant's Phone number #1 (in case we need to contact you by phone)

\_\_\_\_\_

SQ13b. Participant's Phone number #2 \_\_\_\_\_

SQ14. Participant's email address (or mailing address if no email): \_\_\_\_\_

SQ15. Notes from interviewer related to participants' contact information (if any):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## PHONE SCREENING QUESTIONNAIRE PART 2

PID. Participant ID #: \_\_\_\_\_

INCLUSION CRITERIA: All answers in 3 <sup>rd</sup> column must be YES. If an answer is NO, immediately proceed to question SQ40.			
			Comments
SQ26.	<b>What is your age?</b> [Is age at least 18 years?]	YES NO	
SQ27.	<b>Can you read and write in English?</b>	YES NO	

EXCLUSION CRITERIA: All answers in 3 <sup>rd</sup> column must be NO with the exception of SQ32a and SQ33a. If an answer (other than SQ32a and SQ33a) is YES, then immediately proceed to question SQ40.			
			Comments
<b><i>I will now start to ask some questions about your mental health.</i></b>			
SQ28.	<b>Has anyone ever told you that you have bipolar disorder or manic depression?</b>	YES NO	
SQ29.	<b>Has anyone ever used the word "Borderline" to describe you?</b>	YES NO	
SQ30a.	<b>Have you ever had a hallucination or seen things that other people can't see, or hear things other people can't hear?</b>	YES NO	
SQ30b.	<b>Have you ever been diagnosed with schizophrenia or psychosis?</b>	YES NO	
SQ31_1	<b>Have you ever taken any of the following medications that I am about to read to you?</b> <b>Lithium</b>	YES NO DK	
SQ31_2	<b>Seroquel (quetiapine)</b>	YES NO DK	
SQ31_3	<b>Abilify (aripiprazole)</b>	YES NO DK	
SQ31_4	<b>Zyprexa (olanzapine)</b>	YES NO DK	
SQ31_5	<b>Clozaril (clozapine)</b>	YES NO DK	
SQ31_6	<b>Haldol/Haloperidol</b>	YES NO DK	
SQ31_7	<b>Geodon (ziprasidone)</b>	YES NO DK	
SQ31_8	<b>Risperdal (risperidone)</b>	YES NO DK	
SQ32a	<b>Have you ever had a suicide attempt?</b>	YES NO	
SQ32b	<b>[If yes, ask...] Have you considered killing yourself during the past month?</b>	YES NO	
SQ32c	<b>[If yes, ask...] Are you currently suicidal?</b>  <b>[If yes, keep participant on the phone, and follow suicide safety plan below]</b>	YES NO	
SQ32d	<b>[If no, ask...] Are you getting any help for that? If not, then provide list of resources from Safety Plan including Gateway, Anchor and The Providence Center] Not urgent, but inform Dr. Flynn about what was discussed.</b>	YES NO	
EXCLUSION CRITERIA: All answers in 3 <sup>rd</sup> column must be NO with the exception of SQ32a and			

SQ33a. If an answer (other than SQ32a and SQ33a) is YES, then immediately proceed to question SQ40.			
SQ33a	<b>Would you say you have a trauma history?</b>	YES NO	
SQ33b	<b>[If yes...]</b>	YES NO	
SQ33c	<b>In the past month, have you had any problems with dissociation (memory loss)?</b>	YES NO	
	<b>In the past month, have you had any flashbacks (i.e. sudden and disturbing vivid memory) about the trauma?</b>	YES NO	
SQ34a	<b>In the past month, have you had any problems with obsessions or compulsions, such as washing your hands or checking the oven over and over again?</b>	YES NO	
SQ34b	<b>[If yes...] Has anyone diagnosed you with obsessive compulsive disorder?</b>	YES NO	
SQ35	<b>In the past month, have you had a panic attack (i.e. sweating, heart palpitations, nausea, trouble breathing, fear of dying/choking/going crazy)?</b>	YES NO	
SQ36	<b>Have you had any problems with alcoholism or drug use in the past year?</b>	YES NO	
SQ37	<b>In the past year, have you had an eating disorder, such as starving, binge eating, or vomiting?</b>	YES NO	
SQ38a	<b>Do you currently have a mindfulness practice, such as meditation or yoga?</b>	YES NO	
SQ38b	<b>Please tell me more about your mindfulness practice, including how often you practice per week.</b>	Fill in response in comments section to the right	
SQ38c	<b>Do you currently practice meditation more than once per week? (yoga does not count as meditation in this context)</b>	YES NO	
SQ39	<b>This class will take place at Brown University in-person. Do you have any medical or mobility issues that would affect you being able to attend class?</b>	YES NO	
SQ40	Participant qualifies for next step of study (next step is 1 <sup>st</sup> blood pressure screening)	YES NO  If YES go to SQ41.  If NO, go to SQ42.	

SQ41a. Thank you for taking the time to answer these questions. You qualify for the next stage of screening, which is to take your blood pressure at our office. If you're still interested, we'd like to schedule a time to have you come in to complete the in-person screener. It will only take 30 minutes or less and will involve taking your blood pressure 3-5 times. Is there a day or time that works best for you? [Schedule the In-Person Screening visit now]

SQ41b. As I mentioned earlier, there is a mindfulness intervention that is part of this study. If you are eligible based on the In-Person screening AND are one of the individuals randomly selected to receive the intervention, you will then be invited to take part in a 9 week Mindfulness Course. We will be scheduling the mindfulness intervention at a time that works best with most of the participants. What days and times of the week typically work best with your schedule? Please keep in mind that the sessions are 2.5 hours long, and take place once per week for 9 weeks.

[Record participant's availability for Intervention and then proceed with the script]

Thank you for your time and interest in this study. We look forward to meeting you in person on [DATE / TIME]. Do you have any questions before we end this call?

**IF INELIGIBLE:**

SQ42a. Thank you for taking the time to answer these questions. According to the survey, you do not qualify for the study at this time. There may be other studies you qualify for.

SQ42b. Would you like me to keep your information to pass on to these studies? YES / NO

SQ42c. [If yes...] OK, thank you. We will keep this information for future studies you may qualify for. Thank you for taking the time to talk with me today. Can I answer any questions before hanging up?

SQ42d. [If no...] OK, our copy of this information will be destroyed. Thank you for taking the time to talk with me today. Can I answer any questions before hanging up?

Deleted: at two different times at least a week apart from each other. Let's book the in-person screening sessions [Book both sessions. We can cancel the second session if they do not qualify].

Deleted:



## SAFETY PLAN

Enter details below on paper during screening (These variables should be entered in the survey via questions SQ10-SQ13). Destroy this paper after screening is complete.

Participant's First Name: \_\_\_\_\_

Participant's Last Name: \_\_\_\_\_

Participant's Address:

Street address: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Zip Code: \_\_\_\_\_

Participant's Phone number #1: \_\_\_\_\_

Participant's Phone number #2: \_\_\_\_\_

During the phone-based screening, if participants respond yes to "Are you currently suicidal?", the interviewer should perform the following 2 steps:

1. Immediately have 911 and Dr. Ellen Flynn called by a colleague who has been informed beforehand that this is a possibility.

**Specifically, while keeping the participant on the phone, show the text below in the box to a colleague.**

***I have a study participant on the phone who is currently suicidal. Please call 911 immediately, and tell them:***

***"I am calling on behalf of [my name] who is performing a research study at Brown University. He has a participant on the phone who says they are currently suicidal." Please provide the participants' contact information to the 911 operator (i.e. name, address, phone #, email address) as requested. This information is shown above.***

***Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.***

2. While speaking calmly with the participant, let them know what you are doing. Specifically, let them know we are calling our study's psychiatrist Dr. Flynn and 911, and why you are doing that (i.e. because we are concerned about you). You can speak with participant to keep him/her on the phone, but the discussion should not be clinical in nature.

Examples of questions that could be asked in order to keep them on the phone:

- “Tell me what is going on.”
- “What’s happening right now?”
- Tell me more about why you are interested in being part of this study.
- What are you hoping to get out of this study?

The following information can be provided to study participants if they state they have had considered killing themselves in the past month. If they are currently suicidal, the main priority is to keep them on the phone while 911 and Dr. Flynn are being contacted.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020

# **Appendix 5: Revised In-Person Screener with Track Changes**

*(v.1.4 – November 6, 2015)*

**~~FIRST~~ IN-PERSON ~~VISIT~~ SCREENING  
ASSESSMENT FORM**

PID. Participant ID # \_\_\_\_\_  
BA2\_01. Staff ID # \_\_\_\_\_  
BA2\_02. Today's date (MMDDYY): \_\_\_\_\_

Blood Pressure:

BA2\_03a. Blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03b. Blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03c. Blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03d. Blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03e. Blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03f. Blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03g. Blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03h. Blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03i. Blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03j. Blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA2\_04. Were the 4<sup>th</sup> and 5<sup>th</sup> systolic blood pressure readings within 20 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA2\_05. Were the 4<sup>th</sup> and 5<sup>th</sup> diastolic blood pressure readings within 10 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA2\_06a. Repeated blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06b. Repeated blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06c. Repeated blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06d. Repeated blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06e. Repeated blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06f. Repeated blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06g. Repeated blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06h. Repeated blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06i. Repeated blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06j. Repeated blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA2\_07. Blood pressure cuff size used: ☐ S ☐ Reg ☐ L ☐ XL

BA2\_08. Arm that cuff was placed on: ☐ L ☐ R

## Medications (ME)

**Comment [SF1]:** In order to reduce participant burden, Medication Use has been moved to the In-Person baseline assessment since it is not part of the eligibility criteria.

ME01. Do you take any prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**
- ☐ Yes

- ☐ Don't know
- ☐ Prefer not to answer

ME02a. What is the name of the first prescription medication or over-the-counter drug that you take?

☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME02b. What is the dosage form?

~~Oral~~

- ☐ Pill, tablet, or capsule
- ☐ Sublingual or orally disintegrating tablet
- ☐ Liquid solution or suspension (drink, syrup)
- ☐ Powder

~~Inhaled~~

☐ Inhaler or nebulizer

~~Injected~~

☐ Injection

~~Suppository~~

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

~~Topical~~

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

~~Other:~~

☐ Don't know

☐ Prefer not to answer

ME02c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

☐ Don't know

☐ Prefer not to answer

ME02d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME02e. Total dosage per day. (~~Record strength of how it is actually taken, not how it is prescribed.~~)

- |                                      |  |
|--------------------------------------|--|
| <input type="checkbox"/> _____ %     | <input type="checkbox"/> _____ Other unit: _____ |
| <input type="checkbox"/> _____ mg    |  |
| <input type="checkbox"/> _____ meg   | <input type="checkbox"/> - Don't know            |
| <input type="checkbox"/> _____ grams | <input type="checkbox"/> - Prefer not to answer  |
| <input type="checkbox"/> _____ I.U.  |  |

ME02f. Do you take it regularly or only as needed?

- |   |   |
|---|---|
| <input type="checkbox"/> - Regularly      | <input type="checkbox"/> - Don't know           |
| <input type="checkbox"/> - Only as needed | <input type="checkbox"/> - Prefer not to answer |

ME02g. For how long have you been taking it?

- |   |   |
|---|---|
| <input type="checkbox"/> - For _____ days   | <input type="checkbox"/> - For _____ years      |
| <input type="checkbox"/> - For _____ weeks  | <input type="checkbox"/> - Don't know           |
| <input type="checkbox"/> - For _____ months | <input type="checkbox"/> - Prefer not to answer |

ME02h. What is the medication used for?

\_\_\_\_\_

ME02i. ~~Interviewer comments:~~

\_\_\_\_\_

ME02j. ~~Do you take any other prescription medications or over-the-counter drugs?~~

- |   |   |
|---|---|
| <input type="checkbox"/> - No → <del>skip to end of medications questions</del> | <input type="checkbox"/> - Don't know           |
| <input type="checkbox"/> - Yes  | <input type="checkbox"/> - Prefer not to answer |

ME03a. What is the name of the next prescription medication or over-the-counter drug that you take?

- |  |   |
|--|---|
| <input type="checkbox"/> - Label product name: | _____   |
| <input type="checkbox"/> - Label generic name: | _____   |
| <input type="checkbox"/> - Don't know          | <input type="checkbox"/> - Prefer not to answer |

ME03b. What is the dosage form?

- |   |   |
|---|---|
| Oral _____  | <input type="checkbox"/> - Liquid solution or suspension (drink, syrup) |
| <input type="checkbox"/> - Pill, tablet, or capsule                   | <input type="checkbox"/> - Powder                                       |
| <input type="checkbox"/> - Sublingual or orally disintegrating tablet |   |

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know
- ☐ Prefer not to answer

ME03c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

- ☐ Don't know
- ☐ Prefer not to answer

ME03d. What is the strength? (~~Record strength of how it is actually taken, not how it is prescribed.~~)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ meg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME03e. Total dosage per day. (~~Record strength of how it is actually taken, not how it is prescribed.~~)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ meg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME3f. Do you take it regularly or only as needed?

- ☐ Regularly
- ☐ Only as needed

- ☐ Don't know
- ☐ Prefer not to answer

ME03g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks
- ☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years
- ☐ Don't know
- ☐ Prefer not to answer



ME03h. What is the medication used for?

ME03i. Interviewer comments:

ME03j. Do you take any other prescription medications or over the counter drugs?

- ☐ No → **skip to end of medications questions**
- ☐ Yes

- ☐ Don't know
- ☐ Prefer not to answer

ME04a. What is the name of the next prescription medication or over the counter drug that you take?

\_\_\_\_\_ ☐ Label product name:

\_\_\_\_\_ ☐ Label generic name:

\_\_\_\_\_ ☐ Don't know \_\_\_\_\_ ☐ Prefer not to answer

ME04b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule
- ☐ Sublingual or orally disintegrating tablet
- ☐ Liquid solution or suspension (drink, syrup)
- ☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know
- ☐ Prefer not to answer

ME04c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

- ☐ Don't know
- ☐ Prefer not to answer

ME04d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg

- ☐ \_\_\_\_\_ meg
- ☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.  
☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_

☐ - Don't know  
☐ - Prefer not to answer

ME04e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ meg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ - Don't know  
☐ - Prefer not to answer

ME04f. Do you take it regularly or only as needed?

☐ - Regularly  
☐ - Only as needed

☐ - Don't know  
☐ - Prefer not to answer

ME04g. For how long have you been taking it?

☐ - For \_\_\_\_\_ days  
☐ - For \_\_\_\_\_ weeks  
☐ - For \_\_\_\_\_ months

☐ - For \_\_\_\_\_ years  
☐ - Don't know  
☐ - Prefer not to answer

ME04h. What is the medication used for?

\_\_\_\_\_  
\_\_\_\_\_

ME04i. **Interviewer comments:**

\_\_\_\_\_  
\_\_\_\_\_

ME04j. Do you take any other prescription medications or over the counter drugs?

☐ - No → **skip to end of medications section**  
☐ - Yes

☐ - Don't know  
☐ - Prefer not to answer

ME05a. What is the name of the next prescription medication or over the counter drug that you take?

\_\_\_\_\_ ☐ - Label product name:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_ ☐ - Label generic name:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_ ☐ - Don't know \_\_\_\_\_ ☐ - Prefer not to answer

ME05b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME05c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME05d. What is the strength? (~~Record strength of how it is actually taken, not how it is prescribed.~~)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ meg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME05e. Total dosage per day. (~~Record strength of how it is actually taken, not how it is prescribed.~~)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ meg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME05f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME05g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME05h. What is the medication used for?

ME05i. *Interviewer comments:*

ME05j. Do you take any other prescription medications or over the counter drugs?

- ☐ No → *skip to end of medications questions*  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

ME06a. What is the name of the next prescription medication or over the counter drug that you take?

\_\_\_\_\_ ☐ Label product name:

\_\_\_\_\_ ☐ Label generic name:

- ☐ Don't know \_\_\_\_\_  
☐ Prefer not to answer

ME06b. What is the dosage form?

Oral \_\_\_\_\_

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME06c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME06d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ meg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ -Don't know  
☐ -Prefer not to answer

ME06e. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ meg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ -Don't know  
☐ -Prefer not to answer

ME06f. Do you take it regularly or only as needed?

☐ -Regularly  
☐ -Only as needed

☐ -Don't know  
☐ -Prefer not to answer

ME06g. For how long have you been taking it?

☐ -For \_\_\_\_\_ days  
☐ -For \_\_\_\_\_ weeks  
☐ -For \_\_\_\_\_ months

☐ -For \_\_\_\_\_ years  
☐ -Don't know  
☐ -Prefer not to answer

ME06h. What is the medication used for?

\_\_\_\_\_  
\_\_\_\_\_

ME06i. *Interviewer comments:*

\_\_\_\_\_  
\_\_\_\_\_

ME06i. Do you take any other prescription medications or over the counter drugs?

☐ -No → *skip to end of medications questions*  
☐ -Yes

☐ -Don't know  
☐ -Prefer not to answer

ME07a. What is the name of the next prescription medication or over the counter drug that you take?

\_\_\_\_\_ ☐ -Label product name:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_ ☐ -Label generic name:

\_\_\_\_\_  
\_\_\_\_\_

- ☐ Don't know
- ☐ Prefer not to answer

ME07b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule
- ☐ Sublingual or orally disintegrating tablet
- ☐ Liquid solution or suspension (drink, syrup)
- ☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)
- ☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know
- ☐ Prefer not to answer

ME07c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

- ☐ Don't know
- ☐ Prefer not to answer

ME07d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ meg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME07e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %
- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ meg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME07f. Do you take it regularly or only as needed?

- ☐ Regularly
- ☐ Only as needed

- ☐ Don't know
- ☐ Prefer not to answer

ME07g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME07h. What is the medication used for?

ME07i. *Interviewer comments:*

ME07j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications questions**

☐ Yes

☐ Don't know

☐ Prefer not to answer

ME08a. What is the name of the next prescription medication or over-the-counter drug that you take?

\_\_\_\_\_ ☐ Label product name:

\_\_\_\_\_ ☐ Label generic name:

\_\_\_\_\_ ☐ Don't know

☐ Prefer not to answer

ME08b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME08c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

☐ \_\_\_\_\_ times per month

☐ Don't know

☐ -Prefer not to answer

ME08d. What is the strength? (~~Record strength of how it is actually taken, not how it is prescribed.~~)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_

☐ \_\_\_\_\_ mg

☐ -Don't know

☐ \_\_\_\_\_ meg

☐ -Prefer not to answer

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

ME08e. Total dosage per day. (~~Record strength of how it is actually taken, not how it is prescribed.~~)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_

☐ \_\_\_\_\_ mg

☐ -Don't know

☐ \_\_\_\_\_ meg

☐ -Prefer not to answer

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

ME08f. Do you take it regularly or only as needed?

☐ -Regularly

☐ -Don't know

☐ -Only as needed

☐ -Prefer not to answer

ME08g. For how long have you been taking it?

☐ -For \_\_\_\_\_ days

☐ -For \_\_\_\_\_ years

☐ -For \_\_\_\_\_ weeks

☐ -Don't know

☐ -For \_\_\_\_\_ months

☐ -Prefer not to answer

ME08h. What is the medication used for?

ME08i. **Interviewer comments:**

ME08j. Do you take any other prescription medications or over the counter drugs?

☐ -No → **skip to end of medications questions**

☐ -Don't know

☐ -Yes

☐ -Prefer not to answer

ME09a. What is the name of the next prescription medication or over the counter drug that you take?

\_\_\_\_\_ ☐ -Label product name:

\_\_\_\_\_ ☐ -Label generic name:



☐ Don't know ☐ Prefer not to answer

ME09b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME09c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME09d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ meg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME09e. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ meg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME09f. Do you take it regularly or only as needed?

- ☐ Regularly ☐ Only as needed

☐ -Don't know

☐ -Prefer not to answer

ME09g. For how long have you been taking it?

☐ -For \_\_\_\_\_ days

☐ -For \_\_\_\_\_ years

☐ -For \_\_\_\_\_ weeks

☐ -Don't know

☐ -For \_\_\_\_\_ months

☐ -Prefer not to answer

ME09h. What is the medication used for?

ME09i. **Interviewer comments:**

ME09j. Do you take any other prescription medications or over-the-counter drugs?

☐ -No → **skip to end of medications questions**

☐ -Don't know

☐ -Yes

☐ -Prefer not to answer

ME10a. What is the name of the next prescription medication or over-the-counter drug that you take?

\_\_\_\_\_ ☐ -Label product name:

\_\_\_\_\_ ☐ -Label generic name:

\_\_\_\_\_ ☐ -Don't know \_\_\_\_\_ ☐ -Prefer not to answer

ME10b. What is the dosage form?

Oral \_\_\_\_\_

☐ -Pill, tablet, or capsule

☐ -Sublingual or orally disintegrating tablet

☐ -Liquid solution or suspension (drink, syrup)

☐ -Powder

Topical

☐ -Liquid, cream, gel, or ointment

☐ -Ear drops (otic)

☐ -Eye drops (ophthalmic)

☐ -Skin patch (transdermal)

Inhaled

☐ -Inhaler or nebulizer

Injected

☐ -Injection

Suppository

☐ -Rectal (e.g., enema)

☐ -Vaginal (e.g., douche, pessary)

Other:

☐ -Don't know

☐ -Prefer not to answer

ME10c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

☐ \_\_\_\_\_ times per month  
☐ Don't know

☐ Prefer not to answer

ME10d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME10e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME10f. Do you take it regularly or only as needed?

☐ Regularly  
☐ Only as needed  
☐ Don't know  
☐ Prefer not to answer

ME10g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks
- ☐ For \_\_\_\_\_ months
- ☐ For \_\_\_\_\_ years
- ☐ Don't know
- ☐ Prefer not to answer

ME10h. What is the medication used for?

---

---

ME10i. *Interviewer comments:* \_\_\_\_\_

# **Appendix 6: Revised Home Baseline Assessment with Track Changes**

*(v.1.4 – November 11, 2015)*

# **HOME BASELINE ASSESSMENT**

QUESTIONNAIRES ANSWERED BY PARTICIPANTS  
AT BASELINE (VIA ONLINE OR PAPER FORM)

## Questionnaire Table of Contents

<u>Introductory Questions.....</u>	<u>3</u>
<u>Background Questions.....</u>	<u>5</u>
<u>Physical Activity .....</u>	<u>8</u>
<u>Eating Practices .....</u>	<u>10</u>
<u>Alcohol Consumption.....</u>	<u>13</u>
<u>Smoking.....</u>	<u>14</u>
<u>About You .....</u>	<u>15</u>
<u>Parent’s Education.....</u>	<u>43</u>
<u>Your Childhood Experiences .....</u>	<u>45</u>
<u>Blood Pressure Medication Use .....</u>	<u>48</u>
<u>More About You.....</u>	<u>49</u>
<u>Family History of Hypertension .....</u>	<u>53</u>
<u>Your Sleep.....</u>	<u>54</u>

### **Introduction**

We appreciate you taking the time to participate in this research study. These questionnaires will ask a series of questions on various aspects of your health, health behaviours, family, and other life circumstances. It should take approximately one hour. Please keep in mind that you can refuse to answer any questions that you are not comfortable with.

### **Introductory Questions**

IQ1\_01. Please enter the 4-digit ID number you were given. \_\_\_\_ \_\_\_\_ \_\_\_\_ \_\_\_\_.

IQ1\_02. What is your main reason for participating in this study?

IQ1\_03. What do you care about most?

IQ1\_04. What gives you the most pleasure in your life?

IQ1\_05. What are your greatest worries?



Please list three personal goals you have for taking this mindfulness program:

PG1\_01. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

PG1\_02. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

PG1\_03. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## **Background Questions**

BQ1\_01. How many years old are you?

BQ1\_02. Are you Latino or Hispanic?

- ☐ No → *skip to B3*
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

B1\_02a. Which of the following represents your family's country of origin? (*check all that apply*)

- |  |   |
|--|---|
| <input type="checkbox"/> Cuba          | <input type="checkbox"/> Dominican Republic     |
| <input type="checkbox"/> Mexico        | <input type="checkbox"/> Other Central American |
| <input type="checkbox"/> Puerto Rico   | <input type="checkbox"/> Other: _____           |
| <input type="checkbox"/> Spain         | <input type="checkbox"/> I do not know          |
| <input type="checkbox"/> South America | <input type="checkbox"/> I prefer not to answer |
| <input type="checkbox"/> Columbia      |   |

BQ1\_03. If you were asked to put yourself into only one of these groups, in which one would you place yourself? (*select one only*):

- |   |   |
|---|---|
| <input type="checkbox"/> Asian                  | <input type="checkbox"/> Native American        |
| <input type="checkbox"/> Pacific Islander       | <input type="checkbox"/> Other : _____          |
| <input type="checkbox"/> African American/Black | <input type="checkbox"/> I do not know          |
| <input type="checkbox"/> Caucasian/White        | <input type="checkbox"/> I prefer not to answer |

BQ1\_04. Which of the following best describes your current work situation? (*select one only*)

- |   |  |
|---|--|
| <input type="checkbox"/> Working full-time                          | <input type="checkbox"/> Keeping house or raising children full-time |
| <input type="checkbox"/> Working part-time                          | <input type="checkbox"/> Military                                    |
| <input type="checkbox"/> Retired                                    | <input type="checkbox"/> Full-time student                           |
| <input type="checkbox"/> Unemployed: Looking for work               | <input type="checkbox"/> Other: _____                                |
| <input type="checkbox"/> Unemployed: Not currently looking for work | <input type="checkbox"/> I do not know                               |
| <input type="checkbox"/> Unemployed due to disability               | <input type="checkbox"/> I prefer not to answer                      |

BQ1\_05. What is the highest grade or level of regular school you have completed?

- ☐ Elementary School
- ☐ Junior High
- ☐ High School
- ☐ College
- ☐ Graduate School
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_06. What is the highest degree you earned? (*select one only*)

- ☐ Elementary school
- ☐ Some high school, but no GED
- ☐ GED
- ☐ High school
- ☐ Associate degree (Junior College)
- ☐ Bachelor's degree
- ☐ Master's degree
- ☐ Doctorate (PhD, EdD, etc)
- ☐ Professional (MD, JD, DDS, DVM, etc.)
- ☐ Other: \_\_\_\_\_
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_07. Did you ever attend any other school like a technical, vocational, or trade school?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_08. In total, about how many full-time years of education have you had, including 1<sup>st</sup> grade and all years of school after 1<sup>st</sup> grade?

\_\_\_\_\_ years

BQ1\_09a. Do you currently live alone?

- ☐ No
- ☐ Yes → skip to next section
- ☐ I do not know
- ☐ I prefer not to answer

Deleted: BQ\_10

BQ1\_09b. How many people currently live in your household, including yourself?

\_\_\_\_\_

BQ1\_09c. Of these people, how many are under 18?

\_\_\_\_\_

BQ1\_09d. Of the adults in your household (including yourself), how many bring income into the household?

\_\_\_\_\_

## **Physical Activity**

Physical activities are activities where you move and increase your heart rate above its resting rate, whether you do them for pleasure, work, or transportation. The following questions ask about the amount and intensity of physical activity you usually do. The intensity of the activity is related to *the amount of energy* you use doing these activities.

### **Examples of physical activity intensity levels:**

#### **Light activities**

Your heart beats slightly faster than normal  
You can talk and sing



Light exercise



Light stretching



Light vacuuming  
or yard work

#### **Moderate activities**

Your heart beats faster than normal  
You can talk but not sing



Brisk walking



Aerobics class



Strength training



Swim gently

#### **Vigorous activities**

Your heart rate increases a lot  
You can't talk, or your talking is broken  
up by large breaths



Aerobics classes



Jogging, Running,  
or Power Walking



Singles tennis,  
Racquetball, Pickle ball

## How physically active are you?

	YES	NO	I do not know	I prefer not to answer
PA1_01. I rarely or never do any physical activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_02. I do some light and/or moderate physical activities, but not every week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_03. I do some light physical activity every week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_04. I do moderate physical activity every week but less than 5 days per week or less than 30 minutes on those days.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_05. I do vigorous physical activities every week, but less than 3 days per week or less than 20 minutes on those days.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_06. I do 30 minutes or more per day of moderate physical activities 5 or more days per week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_07. I do 20 minutes or more per day of vigorous physical activities 3 or more days per week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_08. I do activities to increase muscle strength, such as lifting weights or calisthenics, once a week or more.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_09. I do activities to improve flexibility, such as stretching or yoga, once a week or more.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Deleted: Diet ¶

The secret to serving size is in your hand.



The first set of questions ask about foods you usually eat or drink. For each food, please place an X in the box (e.g. ☒) for the answer that best matches how often you eat or drink it. Remember to count fruit or vegetables that were part of another dish, like a banana on cereal or vegetables in a stew. Also, please pay attention to the serving sizes. For example, one serving size of bread is one slice, so a sandwich would contain 2 servings of bread. Please include all foods you eat, both at home and away from home. Enclosed are pictures of common serving sizes to assist you in filling out your questionnaire. ¶

### Deleted: How Often You Eat or Drink This Item

## **Eating Practices**

	Definitely True	Mostly True	Mostly False	Definitely False	I Do Not Know	I Prefer Not to Answer
EE1_01. I deliberately take small helpings to control my weight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_02. I start to eat when I feel anxious.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_03. Sometimes when I start eating, I just can't seem to stop.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_04. When I feel sad, I often eat too much.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_05. I don't eat some foods because they make me fat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_06. Being with someone who is eating, often makes me want to also eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_07. When I feel tense or "wound up", I often feel I need to eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_08. I often get so hungry that my stomach feels like a bottomless pit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_09. I'm always so hungry that it's hard for me to stop eating before finishing all of the food on my plate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_10. When I feel lonely, I console myself by eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_11. I consciously hold back on how much I eat at meals to keep from gaining weight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_12. When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating even if I've just finished a meal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_13. I'm always hungry enough to eat at any time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_14. If I feel nervous, I try to calm down by eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_15. When I see something that looks very delicious, I often get so hungry that I have to eat right away.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_16. When I feel depressed, I want to eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Seldom	Usually	Almost Always	I Do Not Know	I Prefer Not to Answer
EE1_17. How often do you avoid ‘stocking up’ on tempting foods?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Unlikely	A little likely	Somewhat likely	Very likely	I Do Not Know	I Prefer Not to Answer
EE1_18. How likely are you to make an effort to eat less than you want?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Rarely	Sometimes	At least once a week	I Do Not Know	I Prefer Not to Answer
EE1_19. Do you go on eating binges even though you’re not hungry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Only at mealtimes	Sometimes between meals	Often between meals	Almost always	I Do Not Know	I Prefer Not to Answer
EE1_20. How often do you feel hungry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	1	2	3	4	5	6	7	8	I Do Not Know	I Prefer Not to Answer
EE1_21. On a scale from 1 to 8, where 1 means no restraint in eating and 8 means total restraint, what number would you give yourself? Mark the number that best applies to you:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**Table Salt Use:**

**TS1\_01** Please report your average total use, during the past year, of “salt added at the table”.  
Would you say...

- Never ..... ☐
- Less than once per month..... ☐
- 1-3 shakes per month..... ☐
- 1 shake per week ..... ☐
- 2-4 shakes per week ..... ☐
- 5-6 shakes per week ..... ☐
- 1 shake per day ..... ☐
- 2-3 shakes per day ..... ☐
- 4-5 shakes per day ..... ☐
- 6+ shakes per day ..... ☐

## **Alcohol Consumption**

A drink of alcohol is defined as 1 can or bottle of beer, 1 glass of wine, 1 can or bottle of wine cooler, 1 cocktail, or 1 shot of liquor.

AC1\_01. During the past 30 days, how many days per week or per month did you have at least 1 drink of any alcoholic beverage? [if none, skip to next section]

Deleted: STOP

\_\_\_\_\_

AC1\_02. On the days when you drank, about how many drinks did you drink on average?

\_\_\_\_\_

AC1\_03. **Men:** Considering all types of alcoholic beverages, how many times during the past 30 days did you have 5 or more drinks on an occasion?

**Women:** Considering all types of alcoholic beverages, how many times during the past 30 days did you have 4 or more drinks on an occasion?

\_\_\_\_\_

## Smoking

SM1\_01. Have you smoked at least 100 cigarettes in your entire life?

- ☐ Yes
- ☐ No
- ☐ I Do Not Know
- ☐ Prefer not to answer

SM1\_02. Did you ever become a daily smoker (that is, smoke every day or nearly every day for two months or longer)?

- ☐ Yes
- ☐ No → *skip to next section*
- ☐ I Do Not Know
- ☐ Prefer not to answer

Deleted: SC1\_01

SM1\_03. How old were you when you last smoked daily?

Age \_\_\_\_\_ (in years)

- ☐ I Do Not Know
- ☐ Prefer not to answer
- ☐ Still smoking daily

SM1\_04. Do you smoke cigarettes now?

- ☐ Yes
- ☐ No → *skip to next section*
- ☐ I Do Not Know
- ☐ Prefer not to answer

SM1\_04a. How many cigarettes per day do you smoke? (One pack equals 20 cigarettes)

Number of cigarettes \_\_\_\_\_

- ☐ I Do Not Know
- ☐ Prefer not to answer

## About You

Please bring to mind a type of very tasty food that may contribute to hypertension through high salt intake or through eating too many calories (e.g., sweet sugary dessert, salty snack foods, etc.).

Think about the LAST WEEK you MOST WANTED this type of food. For each item, select a number (0 to 10) to indicate your rating.

At that time...	Not at All 0	1	2	3	4	5	6	7	8	9	Extremely 10
1. ...how much did you want it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ...how much did you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. ...how strong was the urge to have it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time, how vividly did you...											
4. ...picture it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. ...imagine its taste?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. ...imagine its smell?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. ...imagine what it would feel like in your mouth or throat?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. ...imagine how your body would feel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time...											
9. ...how hard were you trying not to think about it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. ...how intrusive were the thoughts?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. ...how hard was it to think about anything else?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please bring to mind any times in the LAST WEEK when you had a desire to do sedentary activities (e.g., read a book, watch a movie, be on the computer, etc.) instead of physical activities (e.g., walking, gardening, exercise).

Think about the LAST WEEK you MOST WANTED to do a sedentary activity. For each item, select a number (0 to 10) to indicate your rating.

At that time...	Not at All 0	1	2	3	4	5	6	7	8	9	Extremely 10
1. ...how much did you want it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ...how much did you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. ...how strong was the urge to have it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time, how vividly did you...											
4. ...picture it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. ...imagine how your body would feel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time...											
6. ...how hard were you trying not to think about it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. ...how intrusive were the thoughts?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. ...how hard was it to think about anything else?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please bring to mind any times in the LAST WEEK when you had a desire to drink alcohol, such as wine, beer or spirits.

Think about the LAST WEEK you MOST WANTED alcohol. For each item, select a number (0 to 10) to indicate your rating.

At that time...	Not at All 0	1	2	3	4	5	6	7	8	9	Extremely 10
1. ...how much did you want it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ...how much did you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. ...how strong was the urge to have it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time, how vividly did you...											
4. ...picture it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. ...imagine its taste?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. ...imagine its smell?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. ...imagine what it would feel like in your mouth or throat?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. ...imagine how your body would feel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time...											
9. ...how hard were you trying not to think about it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. ...how intrusive were the thoughts?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. ...how hard was it to think about anything else?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Using the scale provided, please indicate how much each of the following statements reflects how you typically are.

	Not at all	A little	Somewhat	Fair Amount	Very much	I do not know	I prefer not to answer
SC1_01. I am good at resisting temptation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_02. I have a hard time breaking bad habits.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_03. I am lazy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_04. I say inappropriate things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_05. I do certain things that are bad for me, if they are fun.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_06. I refuse things that are bad for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_07. I wish I had more self-discipline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_08. People would say that I have iron self-discipline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_09. Pleasure and fun sometimes keep me from getting work done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_10. I have trouble concentrating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_11. I am able to work effectively toward long-term goals.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_12. Sometimes I can't stop myself from doing something, even if I know it is wrong.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_13. I often act without thinking through all the alternatives.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The next few statements are about certain ways you may feel about your life. Please indicate how strongly you agree or disagree with each of the following statements: Strongly agree; Agree; Neutral, Disagree, or Strongly disagree

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	I Do Not Know	Prefer not to answer
SE1_01. I have little control over the things that happen to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SE1_02. There is really no way I can solve some of the problems I have.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SE1_03. There is little I can do to change many of the important things in my life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SE1_04. I often feel helpless in dealing with the problems of life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SE1_05. Sometimes I feel that I am being pushed around in life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SE1_06. What happens to me in the future mostly depends on me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SE1_07. I can do just about anything I really set my mind to do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

	Almost never	Not very often	Sometimes	Frequently	Almost always	I Do Not Know	Prefer not to answer
CO1_O1. When I fail at something important to me, I become consumed by feelings of inadequacy.							
CO1_O2. I try to be understanding and patient towards those aspects of my personality I don't like.							
CO1_O3. When something painful happens I try to take a balanced view of the situation.							
CO1_O4. When I'm feeling down, I tend to feel like most other people are probably happier than I am.							
CO1_O5. I try to see my failings as part of the human condition.							
CO1_O6. When I'm going through a very hard time, I give myself the caring and tenderness I need.							
CO1_O7. When something upsets me I try to keep my emotions in balance.							
CO1_O8. When I fail at something that's important to me, I tend to feel alone in my failure							
CO1_O9. When I'm feeling down I tend to obsess and fixate on everything that's wrong.							



	Almost never	<u>Not very often</u>	<u>Sometimes</u>	<u>Frequently</u>	Almost always	<u>I Do Not Know</u>	<u>Prefer not to answer</u>
CO1_10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.							
CO1_11. I'm disapproving and judgmental about my own flaws and inadequacies.							
CO1_12. I'm intolerant and impatient towards those aspects of my personality I don't like.							

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling how often you felt or thought a certain way.

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
PS1_01. In the last month, how often have you been upset because of something that happened unexpectedly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_02. In the last month, how often have you felt that you were unable to control the important things in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_03. In the last month, how often have you felt nervous and “stressed”?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_04. In the last month, how often have you felt confident about your ability to handle your personal problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_05. In the last month, how often have you felt that things were going your way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_06. In the last month, how often have you found that you could not cope with all the things that you had to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_07. In the last month, how often have you been able to control irritations in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_08. In the last month, how often have you felt that you were on top of things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_09. In the last month, how often have you been angered because of things that were outside of your control?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please indicate how often the following statements apply to you by checking the box that best describes your experience.

**Comment [D1]:** This section (ER1) was moved up in the questionnaire. None of the individual items have changed.

	Almost Never (0-10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_01. I am clear about my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_02. I pay attention to how I feel.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_03. I experience my emotions as overwhelming and out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_04. I have no idea how I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_05. I have difficulty making sense out of my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_06. I am attentive to my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_07. I know exactly how I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_08. I care about what I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_09. I am confused about how I feel.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_10. When I'm upset, I acknowledge my emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_11. When I'm upset, I become angry with myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_12. When I'm upset, I become embarrassed for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never (0-10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_13. When I'm upset, I have difficulty getting work done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_14. When I'm upset, I become out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_15. When I'm upset, I believe that I will remain that way for a long time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_16. When I'm upset, I believe that I will end up feeling very depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_17. When I'm upset, I believe that my feelings are valid and important.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_18. When I'm upset, I have difficulty focusing on other things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_19. When I'm upset, I feel out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_20. When I'm upset, I can still get things done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_21. When I'm upset, I feel ashamed at myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_22. When I'm upset, I know that I can find a way to eventually feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never (0- 10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_23. When I'm upset, I feel like I am weak.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_24. When I'm upset, I feel like I can remain in control of my behaviours.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_25. When I'm upset, I feel guilty for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_26. When I'm upset, I have difficulty concentrating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_27. When I'm upset, I have difficulty controlling my behaviours.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_28. When I'm upset, I believe there is nothing I can do to make myself feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_29. When I'm upset, I become irritated at myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_30. When I'm upset, I start to feel very bad about myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_31. When I'm upset, I believe that wallowing in it is all I can do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_32. When I'm upset, I lose control over my behaviour.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never (0- 10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_33. When I'm upset, I have difficulty thinking about anything else.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_34. When I'm upset I take time to figure out what I'm really feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_35. When I'm upset, it takes me a long time to feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_36. When I'm upset, my emotions feel overwhelming.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This scale is made up of a list of statements each of which may or may not be true about you. For each statement, select “definitely true” if you are sure it is true about you and “probably true” if you think it is true but are not absolutely certain. Similarly, you should select “definitely false” if you are sure the statement is false and “probably false” if you think it is false but are not absolutely certain.

**Comment [SF2]:** NEW section

	<u>Definitely False</u>	<u>Probably False</u>	<u>Probably True</u>	<u>Definitely True</u>	<u>I do not know</u>	<u>I prefer not to answer</u>
<u>IS1_01 If I wanted to go on a trip for a day (for example, to the country or mountains), I would have a hard time finding someone to go with me.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_02 I feel that there is no one I can share my most private worries and fears with.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_03 If I were sick, I could easily find someone to help me with my daily chores.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_04 There is someone I can turn to for advice about handling problems with my family.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_05 If I decide one afternoon that I would like to go to a movie that evening, I could easily find someone to go with me.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_06 When I need suggestions on how to deal with a personal problem, I know someone I can turn to.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_07 I don't often get invited to do things with others.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_08 If I had to go out of town for a few weeks, it would be difficult to find someone who would look after my house or apartment (the plants, pets, garden, etc.).</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_09 If I wanted to have lunch with someone, I could easily find someone to join me.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	<u>Definitely False</u>	<u>Probably False</u>	<u>Probably True</u>	<u>Definitely True</u>	<u>I do not know</u>	<u>I prefer not to answer</u>
<u>IS1_10 If I was stranded 10 miles from home, there is someone I could call who could come and get me.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_11 If a family crisis arose, it would be difficult to find someone who could give me good advice about how to handle it.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_12 If I needed some help in moving to a new house or apartment, I would have a hard time finding someone to help me.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Please indicate how often each of the statements below is descriptive of you.

**Comment [D3]:** This section (LS1) was moved here. None of the individual items have changed.

**Deleted:** INSTRUCTIONS: I

Statement	Never	Rarely	Sometimes	Often	I Do Not Know	Prefer not to answer
LS1_01. I feel in tune with the people around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	S
LS1_02. I lack companionship	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_03. There is no one I can turn to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_04. I do not feel alone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_05. I feel part of a group of friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_06. I have a lot in common with the people around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_07. I am no longer close to anyone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_08. My interests and ideas are not shared by those around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_09. I am an outgoing person	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_10. There are people I feel close to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_11. I feel left out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_12. My social relationships are superficial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_13. No one really knows me well	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_14. I feel isolated from others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_15. I can find companionship when I want it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_16. There are people who really understand me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_17. I am unhappy being so withdrawn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_18. People are around me but not with me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_19. There are people I can talk to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_20. There are people I can turn to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Below you will find a list of statements. Please indicate how often each statement applies to you generally in daily life.

**Comment [D4]:** The following three sections (IA1, RD1, and CR1) were moved here from later in the survey. None of the individual items have changed.

	0- Never	1	2	3	4	5 - Always
IA1_01. When I am tense I notice where the tension is located in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_02. I notice when I am uncomfortable in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_03. I notice where in my body I am comfortable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_04. I notice changes in my breathing, such as whether it slows down or speeds up.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_05. I do not notice (I ignore) physical tension or discomfort until they become more severe.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_06. I distract myself from sensations of discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_07. When I feel pain or discomfort, I try to power through it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_08. When I feel physical pain, I become upset.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_09. I start to worry that something is wrong if I feel any discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_10. I can notice an unpleasant body sensation without worrying about it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_11. I can pay attention to my breath without being distracted by things happening around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_12. I can maintain awareness of my inner bodily sensations even when there is a lot going on around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_13. When I am in conversation with someone, I can pay attention to my posture.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_14. I can return awareness to my body if I am distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_15. I can refocus my attention from thinking to sensing my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_16. I can maintain awareness of my whole body even when a part of me is in pain or discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_17. I am able to consciously focus on my body as a whole.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_18. I notice how my body changes when I am angry.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_19. When something is wrong in my life I can feel it in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_20. I notice that my body feels different after a peaceful experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_21. I notice that my breathing becomes free and easy when I feel comfortable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_22. I notice how my body changes when I feel happy / joyful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	0- Never	1	2	3	4	5 - Always
IA1_23. When I feel overwhelmed I can find a calm place inside.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_24. When I bring awareness to my body I feel a sense of calm.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_25. I can use my breath to reduce tension.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_26. When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_27. I listen for information from my body about my emotional state.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_28. When I am upset, I take time to explore how my body feels.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_29. I listen to my body to inform me about what to do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_30. I am at home in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_31. I feel my body is a safe place.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_32. I trust my body sensations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

We are interested in your recent experiences. Below is a list of things that people sometimes experience. Next to each item are five choices: “never”, “rarely”, “sometimes”, “often”, and “all the time”. Please choose one of these to indicate how much you currently have experiences similar to those described.

Deleted: darken

Please do not spend too long on each item—it is your first response that we are interested in. Please be sure to answer every item.

	Never	Rarely	Sometimes	Often	All the time
RD1_01. I think about what will happen in the future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_02. I remind myself that thoughts aren't facts.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_03. I am better able to accept myself as I am.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_04. I notice all sorts of little things and details in the world around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_05. I am kinder to myself when things go wrong.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_06. I can slow my thinking at times of stress.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_07. I wonder what kind of person I really am.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_08. I am not so easily carried away by my thoughts and feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_09. I notice that I don't take difficulties so personally.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_10. I can separate myself from my thoughts and feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_11. I analyze why things turn out the way they do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_12. I can take time to respond to difficulties.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_13. I think over and over again about what others have said to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_14. I can treat myself kindly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_15. I can observe unpleasant feelings without being drawn into them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_16. I have the sense that I am fully aware of what is going on around me and inside me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_17. I can actually see that I am not my thoughts.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_18. I am consciously aware of a sense of my body as a whole.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_19. I think about the ways in which I am different from other people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_20. I view things from a wider perspective.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**How do you cope with events?** Everyone gets confronted with negative or unpleasant events now and then and everyone responds to them in his or her own way. By the following questions you are asked to indicate what you generally think, when you experience negative or unpleasant events.

	(Almost) Never	Some- times	Regularly	Often	(Almost) Always
CR1_01. I think that I have to accept that this has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_02. I often think about how I feel about what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_03. I think I can learn something from the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_04. I feel that I am the one who is responsible for what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_05. I think that I have to accept the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_06. I am preoccupied with what I think and feel about what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_07. I think of pleasant things that have nothing to do with it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_08. I think that I can become a stronger person as a result of what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_09. I keep thinking about how terrible it is what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_10. I feel that others are responsible for what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_11. I think of something nice instead of what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_12. I think about how to change the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_13. I think that it hasn't been too bad compared to other things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_14. I think that basically the cause must lie within myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_15. I think about a plan of what I can do best.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_16. I tell myself that there are worse things in life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_17. I continually think how horrible the situation has been.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_18. I feel that basically the cause lies with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Instructions: Below is a collection of statements about your everyday experience. Using the scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what really reflects your experience rather than what you think your experience should be. Please treat each item separately from every other item.

***Please indicate the degree to which you agree with each of the following items using the scale below. Simply check your response to each item***

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never	I do not know	I prefer not to answer
MA1_01. I could be experiencing some emotion and not be conscious of it until some time later.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_02. I break or spill things because of carelessness, not paying attention, or thinking of something else.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_03. I find it difficult to stay focused on what's happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_04. I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_05. I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_06. I forget a person's name almost as soon as I've been told it for the first time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never	I do not know	I prefer not to answer
MA1_07. It seems I am “running on automatic” without much awareness of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_08. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_09. I get so focused on the goal I want to achieve that I lose touch with what I am doing right now to get there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_10. I do jobs or tasks automatically, without being aware of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_11. I find myself listening to someone with one ear, doing something else at the same time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_12. I drive places on “automatic pilot” and then wonder why I went there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_13. I find myself preoccupied with the future or the past.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_14. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_15. I snack without being aware that I’m eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes *your own opinion* of what is *generally true for you*.

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_01. When I'm walking, I deliberately notice the sensations of my body moving.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_02. I'm good at finding words to describe my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_03. I criticize myself for having irrational or inappropriate emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_04. I perceive my feelings and emotions without having to react to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_05. When I do things, my mind wanders off and I'm easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_06. When I take a shower or bath, I stay alert to the sensations of water on my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_07. I can easily put my beliefs, opinions, and expectations into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_08. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_09. I watch my feelings without getting lost in them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_10. I tell myself I shouldn't be feeling the way I'm feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_12. It's hard for me to find the words to describe what I'm thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_13. I am easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_15. I pay attention to sensations, such as the wind in my hair or sun on my face.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_16. I have trouble thinking of the right words to express how I feel about things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_17. I make judgments about whether my thoughts are good or bad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_18. I find it difficult to stay focused on what's happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_21. In difficult situations, I can pause without immediately reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_23. It seems I am "running on automatic" without much aware- ness of what I'm doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_24. When I have distressing thoughts or images, I feel calm soon after.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_25. I tell myself that I shouldn't be thinking the way I'm thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_26. I notice the smells and aromas of things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_27. Even when I'm feeling terribly upset, I can find a way to put it into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_28. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_29. When I have distressing thoughts or images, I am able just to notice them without reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_32. My natural tendency is to put my experiences into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_33. When I have distressing thoughts or images, I just notice them and let them go.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_34. I do jobs or tasks automatically without being aware of what I'm doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_35. When I have distressing thoughts or images, I judge myself as good or bad depending what the thought or image is about.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_36. I pay attention to how my emotions affect my thoughts and behavior.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_37. I can usually describe how I feel at the moment in considerable detail.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_38. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_39. I disapprove of myself when I have irrational ideas.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### This Week's Experiences

**Instructions:** Below is a collection of statements about how you find yourself reacting to unpleasant thoughts and feelings. Using the scale below, please indicate how frequently or infrequently you experienced each of the following reactions this week. **Please answer according to what *really reflects your experience this week* rather than what you think your experience should be.**

**This week, when I encountered an unpleasant thought or feeling,**

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always	I do not know	I prefer not to answer
MS1_01. I tried to think pleasant thoughts instead	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_02. I allowed myself to experience it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_03. I got angry or upset at myself for having the thought/emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_04. I felt the desire to make it better or make it go away	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_05. I wished I didn't feel or think that way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_06. I tried to let my thoughts just come and go without getting too entangled with them	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always	I do not know	I prefer not to answer
MS1_07. I thought the mood would never change	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_08. I explored the body sensations that accompanied the emotion.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_09. I named the emotion over and over as long as it lasted	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_10. I turned to work or other activities to take my mind off things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_11. I named the emotion and then redirected my attention to the present moment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_12. I thought "This mood, too, shall pass"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_13. I focused on my breathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_14. I took an active interest in how the experience changed over time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always	I do not know	I prefer not to answer
MS1_15. I explored my reactions to the thought or emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_16. I thought "my thinking is being distorted by my mood"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_17. Think "Why do I have problems that other people don't have?"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_18. I forgave myself for having the thought/emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_19. I challenged the thought's validity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_20. I asked myself questions about the experience in order to explore it better	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_21. I tried not to change it because I believe it is important to experience	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_22. I labelled my thoughts "images" or verbal "talk"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always	I do not know	I prefer not to answer
MS1_23. I thought "Why do I always react this way?"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_24. I adopted a welcoming stance toward the emotion/thought	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_25. I went somewhere alone to think about my feelings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_26. I sent out compassion to all people who struggle with this emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_27. I restrained myself from doing anything too quickly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_28. I became genuinely curious about the thought/emotion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_29. I laughed or kidded myself about the situation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Very Infrequently	Somewhat Infrequently	Somewhat Frequently	Very Frequently	Almost Always	I do not know	I prefer not to answer
MS1_30. I treated the repetitive thought like a “top ten radio tune” that's playing in the background	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_31. I talked to others about how I was feeling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_32. I tried to forget about it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_33. I thought "Why can't I handle things better"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_34. I tried to come up with a way to make it go away	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_35. I said to myself "thinking" or "this is just a thought"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_36. I thought about how much I disliked feeling that way	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_37. I reminded myself thoughts are not accurate reflections of reality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_38. I thought that that I must be headed into a downward spiral	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MS1_39. I thought "What I am doing to deserve this?"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### **Parent's Education**

CS1\_01. Please check the box beside the highest grade or degree that your BIOLOGICAL MOTHER completed.

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

CS1\_02. Please check the box beside the highest grade or degree that your BIOLOGICAL FATHER completed.

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>



Now please think of the two most important adults in your home between the time you were born and age 18 years. Please check the category below that best described their level of education during this time period.

Deleted: level

CS1\_03. First adult's highest level of education:

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

CS1\_04. Second adult's highest level of education

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

## **Your Childhood Experiences**

The following questions ask about some difficult experiences that you might have had as a child. These questions may be emotionally difficult to answer. Just as a reminder, you do not need answer any questions that you would prefer not to. Your answers to these questions, as with all questions, will remain confidential.

CE1\_01. Before you were 18 years old, did a parent or other adult in the household often or very often...

Swear at you, insult you, put you down, or humiliate you?

or

Act in a way that made you afraid that you might be physically hurt?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_02. Before you were 18 years old, did a parent or other adult in the household often or very often...

Push, grab, slap, or throw something at you?

or

Ever hit you so hard that you had marks or were injured?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_03. Before you were 18 years old, did an adult or person at least 5 years older than you ever...

Touch or fondle you or have you touch their body in a sexual way?

or

Attempt or actually have oral, anal, or vaginal intercourse with you?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_04.Before you were 18 years old, did you often or very often feel that ...

No one in your family loved you or thought you were important or special?

or

Your family didn't look out for each other, feel close to each other, or support each other?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_05.Before you were 18 years old, did you often or very often feel that ...

You didn't have enough to eat, had to wear dirty clothes, and had no one to protect you?

or

Your parents were too drunk or high to take care of you or take you to the doctor if you needed it?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_06.Before you were 18 years old, was a biological parent ever lost to you through divorce, abandonment, or other reason?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_07.Before you were 18 years old, was your mother or stepmother:

Often or very often pushed, grabbed, slapped, or had something thrown at her?

or

Sometimes, often, or very often kicked, bitten, hit with a fist, or hit with something hard?

or

Ever repeatedly hit over at least a few minutes or threatened with a gun or knife?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_08. Before you were 18 years old, did you live with anyone who was a problem drinker or alcoholic, or who used street drugs?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_09. Before you were 18 years old, was a household member depressed or mentally ill, or did a household member attempt suicide?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_10. Before you were 18 years old, did a household member go to prison?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

**Deleted:** SN1\_01. . How many close friends do you have? By close friends, we mean people that you feel at ease with, and that you can talk to about private matters.¶

¶  
- . . ☐ None → *skip to Y2* ¶

¶  
- . . \_\_\_\_\_ Number of close friends ¶

¶  
- . . ☐ I do not know ¶  
- . . ☐ I prefer not to answer ¶

¶  
- . . SN1\_01a. How many of these close friends do you see at least once a month? . ¶

¶  
- . . . . \_\_\_\_\_ Number of close friends (*if none, write zero*) ¶

¶  
- . . . . ☐ I do not know ¶  
- . . . . ☐ I prefer not to answer ¶

¶  
SN1\_02. . Thinking about your relatives, how many relatives do you feel at ease with, and feel that you can talk to about private matters? ¶

¶  
- . . ☐ None → *skip to Y3* ¶

¶  
- . . \_\_\_\_\_ Number of relatives ¶

¶  
- . . ☐ I do not know ¶  
- . . ☐ I prefer not to answer ¶

¶  
- . . SN1\_02a. How many of these relatives do you see at least once a month? . ¶

¶  
- . . . . \_\_\_\_\_ Number of relatives (*if none, write zero*) ¶

¶  
- . . . . ☐ I do not know ¶  
- . . . . ☐ I prefer not to answer ¶

¶  
¶  
¶  
SN1\_03. . About how often do you participate in groups or clubs, such as religious connected groups, self-help groups, charities, or a public service or community group.¶

¶  
- . . ☐ Never or almost never¶  
- . . ☐ A few times a year¶  
- . . ☐ Once or twice a month¶  
- . . ☐ Once a week¶  
- . . ☐ More than once a week¶  
- . . ☐ I do not know ¶  
- . . ☐ I prefer not to answer ¶

¶  
¶  
SN1\_04. . About how often do you go to religious meetings or services? ¶

¶  
- . . ☐ Never or almost never¶  
- . . ☐ A few times a year¶  
- . . ☐ Once or twice a month¶  
- . . ☐ Once a week¶  
- . . ☐ More than once a week¶

## Blood Pressure Medication Use

BM1\_01. Do you currently take medication for your blood pressure?

☐ Yes

☐ No (if responding "no", please skip to the next page).

	<u>Yes</u>	<u>No</u>
BM1_02. Do you sometimes forget to take your blood pressure pills?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_03. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_04. Have you ever cut back or stopped taking your blood pressure medicine without telling your doctor because you felt worse when you took it?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_05. When you travel or leave home, do you sometimes forget to bring along your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_06. Did you take all your blood pressure medicine yesterday?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_07. When you feel like your symptoms are under control, do you sometimes stop taking your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_08. Taking blood pressure medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	<input type="checkbox"/>	<input type="checkbox"/>

BM1\_09. How often do you have difficulty remembering to take all your blood pressure medicine?

☐ Never/rarely

☐ Once in a while

☐ Sometimes

☐ Usually

☐ All the time

## More About You

**Comment [SF6]:** New Section – readiness to change

Below are some modifiable factors that likely influence blood pressure. These may not all apply to you, as you may already have excellent levels of these factors.

### Physical activity:

The United States Office of Disease Prevention and Health Promotion 2008 Physical Activity Guidelines for Americans states that “Most health benefits occur with at least 150 minutes (2 hours and 30 minutes) a week of moderate intensity physical activity, such as brisk walking. Additional benefits occur with more physical activity. Both aerobic (endurance) and muscle-strengthening (resistance) physical activity are beneficial.”

RC1\_01. How motivated are you to make changes to your physical activity, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

Little intention of changing			Mixed feelings towards taking action				Motivated to take action		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_02. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your physical activity?

Not confident			Moderately confident				Confident		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Diet:

The Dietary Approaches to Stop Hypertension (DASH) diet eating plan is a diet rich in fruits, vegetables, low fat or nonfat dairy. It also includes mostly whole grains; lean meats, fish and poultry; nuts and beans. It is high fiber and low to moderate in fat. It is a plan that follows US guidelines for sodium content, along with vitamins and minerals. It can be considered to be an Americanized version of the Mediterranean diet.

RC1\_03. How motivated are you to make changes to your diet to be consistent with the DASH diet, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

Little intention of changing			Mixed feelings towards taking action				Motivated to take action		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_04. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your diet to be more consistent with the DASH diet?

Not confident			Moderately confident				Confident		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Salt Intake:

The 2010 Dietary Guidelines for Americans recommend that everyone age 2 years and up should consume less than 2,300 milligrams (mg) of sodium each day. Some groups of people should further limit sodium intake to 1,500 mg per day, including:

- Adults age 51 years or older.
- All African Americans.
- Anyone who has high blood pressure, diabetes, or chronic kidney disease.

RC1\_05. How motivated are you to make changes to your salt intake, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

<u>Little intention of changing</u>			<u>Mixed feelings towards taking action</u>				<u>Motivated to take action</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_06. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your salt intake?

<u>Not confident</u>			<u>Moderately confident</u>				<u>Confident</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Overweight/Obesity:

Extensive scientific evidence shows that being overweight or obese increases risk of having high blood pressure.

RC1\_07. How motivated are you to make changes to your body weight, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

<u>Little intention of changing</u>			<u>Mixed feelings towards taking action</u>				<u>Motivated to take action</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_08. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your body weight?

<u>Not confident</u>			<u>Moderately confident</u>				<u>Confident</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Stress, and Stress Response:

Several studies showed that stress, and being slower at emotionally recovering from stressful events, increase risk of hypertension.

RC1 09. How motivated are you to make changes to the amount of stress in your life, or your response to that stress, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

<u>Little intention of changing</u>			<u>Mixed feelings towards taking action</u>				<u>Motivated to take action</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1 10. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in the amount of stress in your life, or your response to that stress?

<u>Not confident</u>			<u>Moderately confident</u>				<u>Confident</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Alcohol Consumption:

Heavy and regular use of alcohol can increase blood pressure substantially. The American Heart Association recommends limiting alcohol consumption to no more than two drinks per day for men and one drink per day for women.

RC1 11. How motivated are you to make changes to the amount of alcohol you consume, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

<u>Little intention of changing</u>			<u>Mixed feelings towards taking action</u>				<u>Motivated to take action</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1 12. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in the amount of alcohol you consume?

<u>Not confident</u>			<u>Moderately confident</u>				<u>Confident</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**Blood Pressure (Antihypertensive) Medication Use:**

Blood pressure medication has been shown in many studies to be very effective at lowering blood pressure.

RC1 13. How motivated are you to make changes to your blood pressure medication use, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

<u>Little intention of changing</u>			<u>Mixed feelings towards taking action</u>				<u>Motivated to take action</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1 14. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes your blood pressure medication use?

<u>Not confident</u>			<u>Moderately confident</u>				<u>Confident</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Family History of Hypertension

Comment [SF7]: New section

FH1\_01. Did your biological mother ever have hypertension?

- ☐ No  
☐ Yes  
☐ I do not know  
☐ I prefer not to answer

FH1\_02. Did your biological father ever have hypertension?

- ☐ No  
☐ Yes  
☐ I do not know  
☐ I prefer not to answer

FH1\_03. How many full brothers and sisters do you have (*Please include any brothers or sisters who may have died, but do not include half or step brothers and sisters*).

- ☐ I do not have any brothers or sisters → *Skip to the page*  
                    brothers.                    sisters  
☐ I do not know  
☐ I prefer not to answer

FH1\_04. Of these brothers and sisters, how many have ever had hypertension?

- (*if none, write 0*)  
☐ I do not know  
☐ I prefer not to answer

## **Your Sleep**

**Comment [D8]:** This section (Sleep) was moved to the end of the survey. Several of the items were dropped to reduce participant burden.

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. ***Please answer all questions.***

SL1\_01. **During the past month**, what time have you usually gone to bed at night?

BED TIME \_\_\_\_\_ AM / PM

- ☐ I do not know
- ☐ I prefer not to answer

SL1\_02. **During the past month**, how long (in minutes) has it usually taken you to fall asleep each night?

NUMBER OF MINUTES \_\_\_\_\_

- ☐ I do not know
- ☐ I prefer not to answer

SL1\_03. **During the past month**, at what time have you usually gotten up in the morning?

GETTING UP TIME \_\_\_\_\_ AM / PM

- ☐ I do not know
- ☐ I prefer not to answer

SL1\_04. **During the past month**, how many hours of actual sleep did you get on average at night? (This may be different than the number of hours you spent in bed.)

AVERAGE HOURS OF SLEEP PER NIGHT \_\_\_\_\_

- ☐ I do not know
- ☐ I prefer not to answer

SL1\_15. **During the past month**, how would you rate your sleep quality overall?

- ☐ Very good
- ☐ Fairly good
- ☐ Fairly bad
- ☐ Very bad
- ☐ I do not know
- ☐ I prefer not to answer

**Deleted:** For each of the remaining questions, check the one best response. Please answer all questions.

**During the past month**, how often have you had trouble sleeping because you.....

SL1\_05. ....Could not get to sleep within 30 minutes?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_06. ....Woke up in the middle of the night or early morning?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_07. ....Had to get up to use the bathroom?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

**Deleted:** SL1\_16. **During the past month**, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_17. **During the past month**, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_18. **During the past month**, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

- ☐ No problem at all
- ☐ Somewhat of a problem
- ☐ A very big problem
- ☐ I do not know
- ☐ I prefer not to answer

Thank you for completing this survey!

Please note that these responses will not be seen immediately. Resources are shown below if you feel that you would like to talk with someone immediately for assistance.

National Suicide Prevention Lifeline: 1-800-273-8255

National Sexual Assault Hotline: 1-800-656-4673

Other options are to:

- Call your doctor's office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

# **Appendix 7: Revised In-Person Baseline Assessment with Track Changes**

*(v.1.4 – November 6, 2015)*

SECOND IN-PERSON VISIT SCREENING BASELINE  
QUESTIONNAIRE AND ASSESSMENT FORMS

PID. Participant ID # \_\_\_\_\_  
BA01. Staff ID # \_\_\_\_\_  
BA02. Today's date (MMDDYY): \_\_\_\_\_

Blood Pressure:

BA03a. Blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03b. Blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03c. Blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03d. Blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03e. Blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03f. Blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03g. Blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03h. Blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03i. Blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03j. Blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA04. Were the 4<sup>th</sup> and 5<sup>th</sup> systolic blood pressure readings within 20 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA05. Were the 4<sup>th</sup> and 5<sup>th</sup> diastolic blood pressure readings within 10 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA06a. Repeated blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06b. Repeated blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06c. Repeated blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06d. Repeated blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06e. Repeated blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06f. Repeated blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06g. Repeated blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06h. Repeated blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06i. Repeated blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06j. Repeated blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA07. Blood pressure cuff size used:    ☐ S    ☐ Reg    ☐ L    ☐ XL

BA08. Arm that cuff was placed on:    ☐ L    ☐ R



BA09. Height: \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

BA10. Weight: \_\_\_\_\_ . \_\_\_\_ kg (one decimal place)

Waist Circumference:

BA11a. Measurement 1 \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

BA11b. Measurement 2 \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

BA12. Is the difference between Measurement 1 and Measurement 2 greater than 1.0cm?

- ☐ Yes (**repeat measurements 3&4**)
- ☐ No

BA13a. Measurement 3 \_\_\_\_\_ . \_\_\_\_ cm

BA13b. Measurement 4 \_\_\_\_\_ . \_\_\_\_ cm

## Medications (ME)

Comment [SF1]: Moved here from In-Person Screener

ME01. Do you take any prescription medications or over-the-counter drugs?

- ☐ No → skip to end of medications questions
- ☐ Yes

- ☐ Don't know
- ☐ Prefer not to answer

ME02a. What is the name of the first prescription medication or over-the-counter drug that you take?

☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME02b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule
- ☐ Sublingual or orally-disintegrating tablet
- ☐ Liquid solution or suspension (drink, syrup)
- ☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment
- ☐ Ear drops (otic)
- ☐ Eye drops (ophthalmic)
- ☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME02c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month

☐ Don't know

☐ Prefer not to answer

ME02d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ %  
☐ mg  
☐ mcg  
☐ grams  
☐ I.U.

☐ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME02e. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ %  
☐ mg  
☐ mcg  
☐ grams  
☐ I.U.

☐ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME02f. Do you take it regularly or only as needed?

☐ Regularly  
☐ Only as needed

☐ Don't know  
☐ Prefer not to answer

ME02g. For how long have you been taking it?

☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME02h. What is the medication used for?

\_\_\_\_\_

ME02i. ***Interviewer comments:***

\_\_\_\_\_

ME02j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → ***skip to end of medications questions***  
☐ Yes

☐ Don't know  
☐ Prefer not to answer

ME03a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME03b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME03c. How frequently do you take it?

☐ times per day

☐ times per week

☐ times per month

☐ Don't know

☐ Prefer not to answer

ME03d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ %

☐ mg

☐ mcg

☐ grams

☐ I.U.

☐ Other unit:

☐ Don't know

☐ Prefer not to answer

ME03e. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ %

☐ Other unit: \_\_\_\_\_

☐ mg

☐ Don't know

☐ mcg

☐ Prefer not to answer

☐ grams

☐ I.U.

ME3f. Do you take it regularly or only as needed?

☐ Regularly

☐ Don't know

☐ Only as needed

☐ Prefer not to answer

ME03g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ years

☐ For \_\_\_\_\_ weeks

☐ Don't know

☐ For \_\_\_\_\_ months

☐ Prefer not to answer

ME03h. What is the medication used for?

\_\_\_\_\_

ME03i. *Interviewer comments:*

\_\_\_\_\_

ME03j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → ***skip to end of medications questions***

☐ Don't know

☐ Yes

☐ Prefer not to answer

ME04a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME04b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME04c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME04d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME04e. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit:  
\_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME04f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME04g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME04h. What is the medication used for?

\_\_\_\_\_

ME04i. ***Interviewer comments:***

\_\_\_\_\_

ME04j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → ***skip to end of medications section***

☐ Don't know

☐ Prefer not to answer

☐ Yes

ME05a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

☐ Don't know ☐ Prefer not to answer

ME05b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME05c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME05d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME05e. Total dosage **per day**. (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME05f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed
- ☐ Don't know  
☐ Prefer not to answer

ME05g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months
- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME05h. What is the medication used for?

ME05i. **Interviewer comments:**

ME05j. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of end of medications questions**  
☐ Yes
- ☐ Don't know  
☐ Prefer not to answer



ME06a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME06b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME06c. How frequently do you take it?

☐ times per day

☐ times per week

☐ times per month

☐ Don't know

☐ Prefer not to answer

ME06d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ %

☐ mg

☐ mcg

☐ grams

☐ I.U.

☐ Other unit:

☐ Don't know

☐ Prefer not to answer

ME06e. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- |                                      |  |
|--------------------------------------|--|
| <input type="checkbox"/> _____ %     | <input type="checkbox"/> _____ Other unit: _____ |
| <input type="checkbox"/> _____ mg    |  |
| <input type="checkbox"/> _____ mcg   | <input type="checkbox"/> Don't know              |
| <input type="checkbox"/> _____ grams | <input type="checkbox"/> Prefer not to answer    |
| <input type="checkbox"/> _____ I.U.  |  |

ME06f. Do you take it regularly or only as needed?

- |   |   |
|---|---|
| <input type="checkbox"/> Regularly      | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Only as needed | <input type="checkbox"/> Prefer not to answer |

ME06g. For how long have you been taking it?

- |   |   |
|---|---|
| <input type="checkbox"/> For _____ days   | <input type="checkbox"/> For _____ years      |
| <input type="checkbox"/> For _____ weeks  | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> For _____ months | <input type="checkbox"/> Prefer not to answer |

ME06h. What is the medication used for?

\_\_\_\_\_

ME06i. **Interviewer comments:**

\_\_\_\_\_

ME06i. Do you take any other prescription medications or over-the-counter drugs?

- |  |   |
|--|---|
| <input type="checkbox"/> No → <b><i>skip to end of medications questions</i></b> | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Yes   | <input type="checkbox"/> Prefer not to answer |

ME07a. What is the name of the next prescription medication or over-the-counter drug that you take?

- |   |
|---|
| <input type="checkbox"/> Label product name: _____  |
| <input type="checkbox"/> Label generic name: _____  |
| <input type="checkbox"/> Don't know _____           |
| <input type="checkbox"/> Prefer not to answer _____ |

ME07b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME07c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME07d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME07e. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME07f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME07g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME07h. What is the medication used for?

\_\_\_\_\_

ME07i. **Interviewer comments:**

\_\_\_\_\_

ME07j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications questions**

☐ Don't know

☐ Prefer not to answer

☐ Yes

ME08a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME08b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME08c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME08d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME08e. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME08f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed
- ☐ Don't know  
☐ Prefer not to answer

ME08g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months
- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME08h. What is the medication used for?

ME08i. **Interviewer comments:**

ME08j. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**  
☐ Yes
- ☐ Don't know  
☐ Prefer not to answer

ME09a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME09b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME09c. How frequently do you take it?

☐ times per day

☐ times per week

☐ times per month

☐ Don't know

☐ Prefer not to answer

ME09d. What is the strength? (Record strength of how it is actually taken, not how it is prescribed.)

☐ %

☐ mg

☐ mcg

☐ grams

☐ I.U.

☐ Other unit:

☐ Don't know

☐ Prefer not to answer

ME09e. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- |                                |   |
|--------------------------------|---|
| <input type="checkbox"/> %     | <input type="checkbox"/> Other unit: _____    |
| <input type="checkbox"/> mg    |   |
| <input type="checkbox"/> mcg   | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> grams | <input type="checkbox"/> Prefer not to answer |
| <input type="checkbox"/> I.U.  |   |

ME09f. Do you take it regularly or only as needed?

- |   |   |
|---|---|
| <input type="checkbox"/> Regularly      | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Only as needed | <input type="checkbox"/> Prefer not to answer |

ME09g. For how long have you been taking it?

- |   |   |
|---|---|
| <input type="checkbox"/> For _____ days   | <input type="checkbox"/> For _____ years      |
| <input type="checkbox"/> For _____ weeks  | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> For _____ months | <input type="checkbox"/> Prefer not to answer |

ME09h. What is the medication used for?

\_\_\_\_\_

ME09i. *Interviewer comments:*

\_\_\_\_\_

ME09j. Do you take any other prescription medications or over-the-counter drugs?

- |  |   |
|--|---|
| <input type="checkbox"/> No → <b><i>skip to end of medications questions</i></b> | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Yes   | <input type="checkbox"/> Prefer not to answer |

ME10a. What is the name of the next prescription medication or over-the-counter drug that you take?

- |  |   |
|--|---|
| <input type="checkbox"/> Label product name: | _____   |
| <input type="checkbox"/> Label generic name: | _____   |
| <input type="checkbox"/> Don't know          | <input type="checkbox"/> Prefer not to answer |

ME10b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME10c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME10d. What is the strength? (***Record strength of how it is actually taken, not how it is prescribed.***)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME10e. Total dosage **per day**. (***Record strength of how it is actually taken, not how it is prescribed.***)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME10f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed  
☐ Don't know  
☐ Prefer not to answer



ME10g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks
- ☐ For \_\_\_\_\_ months
- ☐ For \_\_\_\_\_ years
- ☐ Don't know
- ☐ Prefer not to answer

ME10h. What is the medication used for?

ME10i. **Interviewer comments:**

### **FOOD FREQUENCY QUESTIONNAIRE:**

*RA Script to be read to participants:* At this time, we are going to have you complete a few forms on your own. The first is a Food Frequency Questionnaire that will ask you about the types of foods and drinks that you consume. It should take around 20 minutes to complete. Please let me know if you have any questions.

**Comment [SF2]:** At this time, participants will be directed to complete the three page Harvard University Food Frequency Questionnaire (see proof included), known as the "80-out". It is designed to take around 20 minutes to complete and is self-administered with paper and pencil. Once completed, they will proceed to the next section of this assessment (DS\_1).



ID:        1. Do you currently take multi-vitamins? (Please report other individual vitamins in question 2.)☐ No ☐ Yes

→ If YES, a) How many do you take per week?

☐ 2 or less ☐ 3-5 ☐ 6-9 ☐ 10 or more

b) For how many years have you taken them?

☐ 0-1 ☐ 2-4 ☐ 5-9 ☐ 10 or more

c) What specific brand do you usually use? →

Specify exact brand and type

2. Not counting multi-vitamins, do you take any of the following preparations:

a) Vitamin A?

☐ No ☐ Yes, seasonal only  
☐ Yes, most months

→ If YES,

How many years?

☐ 0-1 yr. ☐ 2-4 years ☐ 5-9 years ☐ 10+ years ☐ Don't know

What dose per day?

☐ Less than 8,000 IU ☐ 8,000 to 12,000 IU ☐ 13,000 to 22,000 IU ☐ 23,000 IU or more ☐ Don't know

b) Vitamin C?

☐ No ☐ Yes, seasonal only  
☐ Yes, most months

→ If YES,

How many years?

☐ 0-1 yr. ☐ 2-4 years ☐ 5-9 years ☐ 10+ years ☐ Don't know

What dose per day?

☐ Less than 400 mg. ☐ 400 to 700 mg. ☐ 750 to 1250 mg. ☐ 1300 mg. or more ☐ Don't knowc) Vitamin B<sub>6</sub>?☐ No ☐ Yes

→ If YES,

How many years?

☐ 0-1 yr. ☐ 2-4 years ☐ 5-9 years ☐ 10+ years ☐ Don't know

What dose per day?

☐ Less than 10 mg. ☐ 10 to 39 mg. ☐ 40 to 79 mg. ☐ 80 mg. or more ☐ Don't know

d) Vitamin E?

☐ No ☐ Yes

→ If YES,

How many years?

☐ 0-1 yr. ☐ 2-4 years ☐ 5-9 years ☐ 10+ years ☐ Don't know

What dose per day?

☐ Less than 100 IU ☐ 100 to 250 IU ☐ 300 to 500 IU ☐ 600 IU or more ☐ Don't know

e) Selenium

☐ No ☐ Yes

→ If YES,

How many years?

☐ 0-1 yr. ☐ 2-4 years ☐ 5-9 years ☐ 10+ years ☐ Don't know

What dose per day?

☐ Less than 80 mcg. ☐ 80 to 130 mcg. ☐ 140 to 250 mcg. ☐ 260 mcg. or more ☐ Don't know

f) Iron?

☐ No ☐ Yes

→ If YES,

How many years?

☐ 0-1 yr. ☐ 2-4 years ☐ 5-9 years ☐ 10+ years ☐ Don't know

What dose per day?

☐ Less than 51 mg. ☐ 51 to 200 mg. ☐ 201 to 400 mg. ☐ 401 mg. or more ☐ Don't know

g) Zinc?

☐ No ☐ Yes

→ If YES,

How many years?

☐ 0-1 yr. ☐ 2-4 years ☐ 5-9 years ☐ 10+ years ☐ Don't know

What dose per day?

☐ Less than 25 mg. ☐ 25 to 74 mg. ☐ 75 to 100 mg. ☐ 101 mg. or more ☐ Don't know

h) Calcium? (Include Calcium in Dolomite and Tums, etc.)

☐ No ☐ Yes

→ If YES,

How many years?

☐ 0-1 yr. ☐ 2-4 years ☐ 5-9 years ☐ 10+ years ☐ Don't know

What dose per day?

☐ Less than 400 mg. ☐ 400 to 900 mg. ☐ 901 to 1300 mg. ☐ 1301 mg. or more ☐ Don't know

i) Are there other supplements that you take on a regular basis? Please mark if yes:

☐ Metamucil ☐ Cod liver oil ☐ Iodine ☐ Beta-carotene ☐ Other (please specify)  
☐ Vitamin D ☐ Folic acid ☐ Copper ☐ Niacin  
☐ B-Complex Vitamins ☐ Omega-3 fatty acids ☐ Brewer's yeast ☐ Magnesium

3. For each food listed, fill in the circle indicating how often on average you have used the amount specified during the past year.

## AVERAGE USE LAST YEAR

## DAIRY FOODS

	NEVER OR LESS THAN ONCE PER MONTH	1-3 PER MONTH	1 PER WEEK	2-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2-3 PER DAY	4-5 PER DAY	6+ PER DAY
Skim or low fat milk (8 oz. glass)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Whole milk (8 oz. glass)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Yogurt (1 cup)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ice Cream (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cottage or ricotta cheese (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other cheese, e.g. American, cheddar, etc., plain or as part of a dish (1 slice or 1 oz. serving)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Margarine (pat), added to food or bread; exclude use in cooking	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Butter (pat), added to food or bread; exclude use in cooking	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. What form of margarine do you usually use? →

☐ None ☐ Stick ☐ Tub ☐ Extra light  
☐ 'Lite' stick ☐ 'Lite' tub ☐ Squeeze

What specific brand and type (e.g., Parkay Corn Oil Spread)

PLEASE TURN TO PAGE 2



3. (Continued) Please fill in your average use, during the past year, of each specified food.

Please try to average your seasonal use of foods over the entire year. For example, if a food such as peaches are eaten 4 times a week during the approximate 3 months that it is in season, then the average use would be once per week.

FRUITS	NEVER OR LESS THAN ONCE PER MONTH	1-3 PER MONTH	1 PER WEEK	2-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2-3 PER DAY	4-5 PER DAY	6+ PER DAY
Fresh apples or pears (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oranges (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Orange juice or grapefruit juice (small glass)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peaches, apricots or plums (1 fresh, or 1/2 cup canned)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bananas (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other fruits, fresh, frozen, or canned (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

VEGETABLES	NEVER OR LESS THAN ONCE PER MONTH	1-3 PER MONTH	1 PER WEEK	2-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2-3 PER DAY	4-5 PER DAY	6+ PER DAY
Tomatoes (1) or Tomato juice (small glass)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
String beans (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Broccoli (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cabbage, cauliflower, or Brussels sprouts (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carrots, raw (1/2 carrot or 2-4 sticks)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carrots, cooked (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Corn (1 ear or 1/2 cup frozen or canned)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peas or lima beans (1/2 cup fresh, frozen, canned)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Yams or sweet potatoes (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Spinach or collard greens, cooked (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beans or lentils, baked or dried (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Yellow (winter) squash (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

MEAT, SWEETS, BAKED GOODS, CEREAL, MISC.	NEVER OR LESS THAN ONCE PER MONTH	1-3 PER MONTH	1 PER WEEK	2-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2-3 PER DAY	4-5 PER DAY	6+ PER DAY
Eggs (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chicken or turkey, with skin (4-6 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chicken or turkey, without skin (4-6 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bacon (2 slices)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hot dogs (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Processed meats, e.g. sausage, salami, bologna, etc. (piece or slice)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Liver (3-4 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hamburger (1 patty)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beef, pork, or lamb as a sandwich or mixed dish, e.g. stew, casserole, lasagna, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beef, pork, or lamb as a main dish, e.g., steak, roast, ham, etc. (4-6 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fish (3-5 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chocolate (1 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Candy without chocolate (1 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pie, homemade (slice)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pie, ready made (slice)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cake (slice)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cookies (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cold breakfast cereal (1 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
White bread (slice), including pita bread	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dark bread (slice), including wheat pita bread	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
French fried potatoes (4 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Potatoes, baked, boiled (1) or mashed (1 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Rice or Pasta, e.g., spaghetti, noodles, etc. (1 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Potato chips or corn chips (small bag or 1 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nuts (small packet or 1 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peanut butter (1 Tbs)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oil and vinegar dressing, e.g., Italian, (1 Tbs)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

PLEASE GO TO PAGE 3



4. (Continued) Please fill in your average use, during the past year, of each specified food.

## BEVERAGES

	NEVER OR LESS THAN ONCE PER MONTH	1-3 PER MONTH	1 PER WEEK	2-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2-3 PER DAY	4-5 PER DAY	6+ PER DAY	P
Coffee, <u>not</u> decaffeinated (1 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tea (1 cup), not herbal tea	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beer (1 glass, bottle, can)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wine (4 oz. glass)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Liquor, e.g. whiskey, gin, etc. (1 drink or shot)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Low calorie carbonated beverage, e.g., Diet Coke	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carbonated beverage with sugar, e.g., Coke, Pepsi	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hawaiian Punch, lemonade, or other fruit drinks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Consider the serving size as 1 glass, bottle or can for these fruit and carbonated beverages.

5. How many teaspoons of sugar do you add to your beverages or food each day? →

tsp.

0	1	2	3	4	5	6	7	8	9	5
0	1	2	3	4	5	6	7	8	9	
0	1	2	3	4	5	6	7	8	9	
0	1	2	3	4	5	6	7	8	9	6
0	1	2	3	4	5	6	7	8	9	a

6. Which cold breakfast cereal do you usually eat? →

☐ Don't eat cold breakfast cereal

Specify brand and type

0	1	2	3	4	5	6	7	8	9	
0	1	2	3	4	5	6	7	8	9	
0	1	2	3	4	5	6	7	8	9	6
0	1	2	3	4	5	6	7	8	9	a

7. How much of the visible fat on your beef, pork or lamb do you remove before eating?

☐ Remove all visible fat ☐ Remove most ☐ Remove small part of fat ☐ Remove none ☐ Don't eat meat

8. What kind of fat do you usually use for frying and sautéing at home? (Exclude "Pam"-type spray)

☐ Real butter ☐ Margarine ☐ Vegetable oil ☐ Vegetable shortening ☐ Lard

9. What kind of fat do you usually use for baking at home?

☐ Real butter ☐ Margarine ☐ Vegetable oil ☐ Vegetable shortening ☐ Lard

10. How often do you eat food that is fried at home? (Exclude "Pam"-type spray)

☐ Less than once a week ☐ 1-3 times per week ☐ 4-6 times per week ☐ Daily

11. How often do you eat fried food away from home? (e.g. french fries, fried chicken, fried fish)

☐ Less than once a week ☐ 1-3 times per week ☐ 4-6 times per week ☐ Daily

12. What type of cooking oil do you usually use at home (e.g. Mazola Corn Oil)? →

Specify brand and type

0	1	2	3	4	5	6	7	8	9	12
0	1	2	3	4	5	6	7	8	9	a

13. Do you use a microwave oven?

☐ Yes → If yes, for how many years? →

☐ No

Number of years using a microwave

0	1	2	3	4	5	6	7	8	9	12
0	1	2	3	4	5	6	7	8	9	a

14. Do you currently follow a physician-prescribed special diet?

☐ Yes → a) If yes, for how many years? →

☐ No

b) If yes, what kind of diet do you follow? (Select more than one if necessary.)

☐ Weight reduction (low calorie) ☐ Low cholesterol ☐ Low sodium  
☐ Diabetic ☐ Low fat ☐ Low triglyceride ☐ Ulcer ☐ High Potassium

Number of years on diet

0	1	2	3	4	5	6	7	8	9	14
0	1	2	3	4	5	6	7	8	9	a

0	1	2	3	4	5	6	7	8	9	b
0	1	2	3	4	5	6	7	8	9	

☐ Other →

Specify type of diet

15. How has your use of the following foods and beverages changed over the **PAST FIVE YEARS**?

FOOD	USE HAS DECREASED	USE ABOUT THE SAME	USE HAS INCREASED	15
a) Whole milk	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b) Butter	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c) Margarine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d) Eggs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e) Fish	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f) Red meat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g) Fruits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h) Vegetables	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i) Whole wheat bread	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j) Whole grains	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k) Sugar	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
l) Alcohol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



**Questions for Participants to Answer on Their Own In-Person on Paper:**

For each statement, please place a mark in the column that best describes how you have been feeling.

	Not at all or less than 1 day last week	1 or 2 days last week	3 to 4 days last week	5 to 7 days last week	Nearly every day for two weeks	I do not know	I prefer not to answer
DS_1. My appetite was poor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_2. I could not shake off the blues.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_3. I had trouble keeping my mind on what I was doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_4. I felt depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_5. My sleep was restless.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_6. I felt sad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_7. I could not get going.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_8. Nothing made me happy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C_9. I felt like a bad person.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_10. I lost interest in my usual activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_11. I slept much more than usual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_12. I felt like I was moving too slowly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_13. I felt fidgety.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_14. I wished I were dead.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_15. I wanted to hurt myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_16. I was tired all the time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_17. I did not like myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_18. I lost a lot of weight without trying to.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_19. I had a lot of trouble getting to sleep.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_20. I could not focus on the important things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past month, including today, by marking the box in the corresponding space in the column next to each symptom.

	Not At All	Mildly – it didn't bother me much	Moderately – it wasn't pleasant at all times	Severely – it bothered me a lot	I do not know	I prefer not to answer
BE_1. Numbness or tingling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_2. Feeling hot	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_3. Wobbliness in legs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_4. Unable to relax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_5. Fear of worst happening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_6. Dizzy or lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_7. Heart pounding/racing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_8. Unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_9. Terrified or afraid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_10. Nervous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_11. Feeling of choking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_12. Hands trembling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_13. Shaky/unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_14. Fear of losing control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_15. Difficulty in breathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_16. Fear of dying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_17. Scared	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_18. Indigestion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_19. Faint/lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_20. Face flushed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_21. Hot/cold sweats	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

After questionnaires are complete, participants will be asked to perform the following two computer-based tests:

### **Attention Control: Attention Network Test (20 minutes)**

Attention Network Test (ANT) is a brief computerized battery measuring three independent behavioral components of attention: Conflict resolution (ability to overcome distracting stimuli), spatial Orienting (the benefit of valid spatial pre-cues), and Alerting (the benefit of temporal pre-cues). Efficiency of orienting is examined by changes in RT that accompany cues indicating where the target will occur. The efficiency of the executive conflict resolution network is examined by requiring the subject to respond by pressing two keys indicating the direction (left or right) of a central arrow surrounded by congruent, incongruent or neutral flankers. Moderate to high reliabilities are found for all networks.



### **Sustained Attention to Response Task (15 minutes)**

The Sustained Attention to Response Task (SART) is a computerized test of sustained attention, response inhibition (executive function) and self-regulation. Subjects are instructed to press a key in response to rapidly displayed integers (1-9) and withhold response to a designated "no-go" integer. SART errors consist of summed commission errors (button press on no-go trial) and omission errors (button not pressed on "go" integers). SART performance is associated with prefrontal cortex functioning, has been found to increase with mindfulness training and is correlated with scores on mindfulness questionnaires (specifically, the Mindful Attention Awareness Scale).

## SAFETY PLAN

After the participant has completed the Beck Anxiety Inventory questionnaire and the Centers for Epidemiologic Studies Depressive Symptomatology questionnaire, ask the participant to wait for a few minutes while you check that all forms and assessments are completed. While the participant is waiting in a different room, check the scores according to the criteria below. If any scores trigger the safety plan, move forward with steps below as written.

### Beck Anxiety Inventory (BA)

If participant scores  $\geq 26$  on the Beck Anxiety Inventory, while having the participant wait, immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and your phone # will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, please leave a phone message for her with your contact information and provide her with the Beck Anxiety Inventory results on the message. If Dr. Flynn is not immediately reachable, or following participant release after consulting with Dr. Flynn, immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).

### Depressive Symptomatology (DS)

The CESD-R will be administered during the in-person assessment visits, and scores will be reviewed immediately upon completion of the in-person assessments.

1. Sadness (dysphoria): Question numbers 2, 4, 6
2. Loss of Interest (anhedonia): Question numbers 8, 10
3. Appetite: Question numbers 1, 18
4. Sleep: Question numbers 5, 11, 19
5. Thinking / concentration: Question numbers 3, 20
6. Guilt (worthlessness): Question numbers 9, 17
7. Tired (fatigue): Question numbers 7, 16
8. Movement (agitation): Question numbers 12, 13
9. Suicidal ideation: Question numbers 14, 15

Participants are considered to meet criteria for major depressive episode if they have anhedonia or dysphoria nearly every day for the past two weeks, plus symptoms in an additional 4 DSM symptom groups noted as occurring nearly every day for the past two weeks. If participants meet criteria for major depressive episode, while having the participant wait, immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and your phone # will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, please leave a phone message for her with your contact information and provide her with the Depressive Symptomatology results on the message. If Dr. Flynn is not immediately reachable, or following participant release after consulting with Dr. Flynn, immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).

If participants respond having any suicidal ideation (DS questions 14 or 15), perform the following 2 steps:

1. Immediately call 911 and Dr. Ellen Flynn.

**Specifically, while the participant is in the waiting room, call 911 immediately, and tell them:**

***“My name is \_\_\_\_\_. I am working on a research study at Brown University. I have a study participant in the waiting room who has shared that he/she is currently suicidal.” Please provide the participants’ name to the 911 operator, as requested.***

***Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.***

2. While speaking calmly with the participant, let them know that you have called 911 and Dr. Flynn, and why (i.e. because we are concerned about you). You can speak with participant to keep him/her in the waiting room if 911 has sent assistance, but the discussion should not be clinical in nature.

Examples of questions that could be asked in order to keep them in the waiting room:

- “Tell me what is going on.”
- “What’s happening right now?”
- Tell me more about why you are interesting in being part of this study.
- What are you hoping to get out of this study?

The following information can be provided to study participants.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020

E. Loucks responses to 12/4/15 email from Ita Irizarry – RE: "MINDFULNESS-BASED HYPERTENSION THERAPY PILOT STUDY," Amendment #4 submission.

**Questions/Requests:**

1. Regarding the request to add a control group, please confirm if this population will be identified, recruited, and consented with the same currently-approved procedures as the intervention group.

*Based on additional feedback from NCCIH on the study protocol, we have decided to hold off at this time on implementing the RCT. We have removed all language discussing the RCT and have attached an updated consent form (v.1.5) and Phone Screener. We will submit a new amendment to the IRB once the RCT is incorporated into the study protocol.*

2. Will the new \$100 compensation be provided to all participants who complete the study, both intervention and control groups? Will the compensation be given at the 1-year follow-up?

*Yes, all study participants will receive the \$100. It will be given out at the time of the 1-year follow-up. We will not be including a control group at this time.*

3. What is the rationale for adding the 1-year follow-up visit?

*There is early evidence in other mindfulness studies that have shown increases in effect by 1 year follow-up that were not present at 6 months. This longer follow-up time will allow us to determine longer term effectiveness of the intervention.*

4. What is the rationale for revising the screening and baseline assessments?

*The screening assessments were revised to reduce participant burden. We removed all assessments in the first in-person screening that do not influence if the person qualifies for the study or not. For the in-person baseline assessment, we included items moved from the first in-person screening, as well as added some additional measures that are central to the objectives of the recent NIH grant to evaluation impacts of the intervention on measures of self regulation.*

5. For the *In-Person Screening Assessment Form*, question BA2\_o8 (pg. 2) is marked as track-changed, but this was approved with Amendment #2. Was the question revised?

*No, it was not revised. It was marked in error.*

6. If you haven't already, please register your study on the [Clinical Trials website](#), per the terms of your NIH grant. Section 6 (pg. 254) states that the study must be registered within 21 days of the first participant enrollment.

*We will register the study on the Clinical Trials website within 21 days of the first participant enrollment for the NIH-funded study.*

### **Consent Document Revisions:**

1. The *Nature and Purpose of the Study* section (pg. 1, 3rd paragraph) only briefly mentions that participants may be randomized into the control group. To the *Explanation of Procedures* section, please add how that randomized will occur, and provide a further explanation of what participants in the control group will be asked to do at the baseline and 10-week visits.

*No longer applicable. We have decided to not implement the RCT at this time.*

2. Portions of the consent are marked as track-changed, although they were approved with Amendment #3. For example, the *Explanation of Procedures* section (pgs. 2-3, #3) and the procedure table (pg. 3, focus group) are marked. Were changes made to these sections?

*No, these two sections were not revised. They were marked in error. We have removed the track changes.*

3. To the *Discomforts and Risks* section (pg. 4, 3rd paragraph), please add an explanation of what will happen if a participant has a research-related injury.

*We have added the following language to the consent form (see v.1.5 attached):*

*"While physical and mental injury is always a possibility the potential for harm is limited. Note that a research injury is any physical or mental injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and potential added medical expenses, it is important to follow all study directions carefully. If you are covered by insurance and suffer a research injury, it is possible that some or all of the costs of treating your condition could appropriately be billed to your insurance company. If such costs are not covered your health insurance company, it is possible you would have to pay for these costs out of pocket. Brown University's policies do not cover payment for such things as lost wages, medical care expenses, or pain and suffering.*

*Precautions should be taken to avoid injuries. If you do become injured during the study, you should call your doctor immediately. You should also alert the study staff that you have been injured. Heart attack and sudden death related to heart problems have been known to occur in people while they are exercising. This is very rare, however. Estimates of sudden cardiac death range from 0 to 2 per 100,000 hours. However, the researchers cannot guarantee that no complications will happen to you."*

4. In the *Benefits* section (pg. 4), please remove the added compensation description. Compensation is not considered a benefit, and this information was already added to the *Nature and Purpose of the Study* section (pg. 1).

*This has been removed.*

5. As this is clinical trial, please add the required language regarding the Clinical Trials website: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time." This language must be added verbatim and cannot be changed, per NIH regulations.

*We have added this language to the last section of the consent.*

See below for a summary of changes made to the MBHT study documents since Amendment #4 was originally submitted. These changes were made per discussion with the Brown University IRB; some additional changes have been made in order to reduce participant burden. All modified documents have been included in this email.

#### **INFORMED CONSENT FORM**

- Removed language regarding the RCT
- Removed compensation description from the "Benefit" section
- Added language regarding research-related injuries
- Updated the IRB contact information
- Added the required language regarding clinical trials

#### **PHONE SCREENER**

- Removed language regarding the RCT

#### **IN-PERSON SCREENER**

- Removed the 4th and 5th Blood Pressure readings, such that BP will be taken three times in-person rather than five times.

#### **IN-PERSON BASELINE**

- Removed the 4th and 5th Blood Pressure readings, such that BP will be taken three times in-person rather than five times.
- Added the data entry variables for the Attention Network Test (see p.23). This data will be entered by the RA at the end of the test.

#### **HOME BASELINE**

- Removed all sleep questions *except for* SL1\_04
- Removed the sense of control scale (SE1)
- Removed the Mindfulness Skill Acquisition Scale (MS1)

## Agreement to Participate in a Research Study

### *Investigation of the Effects of Mindfulness on Blood Pressure and Well-Being*

You are being asked to take part in a Brown University research study about the effects of mindfulness and hypertension education on blood pressure and risk factors for hypertension. This form will explain the purpose of the study, how the study will be carried out and what you will be expected to do. It will also explain the possible risks and possible benefits of being in the study. If any part of the following description is not clear to you, you are encouraged to contact the researcher to answer any questions before you decide whether to take part in the study. If you decide to participate, please fill out and sign the last page of this form.

#### 1a. Nature and Purpose of the Study

The purpose of the study is to investigate the impact of mindfulness practices and health education on blood pressure. You have been selected for this study because you expressed interest in the project and because you met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program.

In order to assess the effects of these practices, you will be asked to complete some questionnaires and ~~a~~-laboratory assessments before and after learning the mindfulness practices. Assessments will be completed at: baseline, 10 weeks, 6 months and 1 year. If you complete the study, you will be given \$100 USD at the time of completion for your participation, to express our gratitude.

Participation in this study involves receiving training in mindfulness practices as well as health education on blood pressure.

#### 1b. Explanation of Procedures

If you agree to participate, you will be asked to consent to the following:

- 1) Participate in an interview in which you will be asked questions about past and present mental health, including depression and suicide.
- 2) Complete questionnaires about a wide range of topics, including your diet, physical activity, smoking, medication use, personality, emotions, attention and past experiences, including stressful or traumatic experiences. These questions will probe sensitive psychological areas, including physical, emotion and sexual abuse. These questionnaires may take up to 2-3 hours to complete. By completing the interviews and questionnaires, you are giving the researchers permission to use the information you have provided. You have the right not to answer any of the questions.
- 3) Directly assessed blood pressure, height, weight, waist circumference, hip circumference, physical activity, and antihypertensive (blood pressure) medication use at baseline and after the mindfulness course. Physical activity will be assessed for a week at a time using small actigraphy monitors that attach to your wrist and hip. If you take antihypertensive

medication, we will provide you with an electronic bottle cap that will automatically record when the pill bottle is opened during the study. This will help us measure how often the medication is used.

- 4) You will be asked to perform some cognitive tasks. ~~One~~ Some of these tasks may involve computer-based tests of attention or decision-making. Together these tests may take as long as 45 minutes.
- 5) You will participate in the mindfulness program, which consists of 9 weekly sessions of 2.5 hours each and will include one 8 hour weekend retreat. Daily homework assignments may take as long as one hour and consist of practicing mindfulness exercises with the aid of a guided audio CD and completing worksheets related to stress, thoughts, and common reactions to various types of events.
- 6) Class sessions will be audio taped so we can analyze the quality of the treatment you receive. The recordings will be transcribed so that we may analyze the text. The recordings will be identified by study number, will only be heard by study staff and will be destroyed after transcription.
- 7) You will be asked to complete a few short questionnaires each week during the 9 week condition.
- 8) After 9-10 weeks, you will be asked to complete questionnaires and return to the laboratory to repeat the same procedures for a second day of testing. You will also be invited to participate in a focus group to share any advice you may have on how to improve the intervention.
- 9) ~~Three-Six~~ months and one year after ~~the end of the 9 week condition~~ the beginning of the study, you will be asked to return to the laboratory to repeat the same testing procedures.



**Table Summarizing Activities and Time Commitment for this Study.**

<b>Activity</b>	<b>Time Commitment</b>
First blood pressure screen	30 minutes
Second blood pressure screen	30 minutes
Baseline health assessments, such as questionnaires, height, weight and waist circumference.	<del>2 hours</del> <u>3 hours</u>
Mindfulness course <u>In-person</u>	9 sessions that are 2.5 hours each. 1 retreat day on a Saturday that will be 8 hours <i>Total course time: 30.5 hours</i>
Home <del>mindfulness</del> -practices assigned during <u>mindfulness</u> course.	1 hour per day, 6 days per week, for 8 weeks. <i>Total practice time: 48 hours</i>
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that take place <i>immediately after course completion</i> .	<del>2 hours</del> <u>3 hours</u>
Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that <u>begin take place that take place 3-6 months after baseline course completion</u> .	<del>2 hours</del> <u>3 hours</u>
<u>Health assessments, such as questionnaires, blood pressure, height, weight and waist circumference, that begin 1 year after baseline.</u>	<u>3 hours</u>
Participate in focus group after intervention completion to share any advice you may have on how to improve the intervention.	1.5 hours
<b>TOTAL TIME COMMITMENT FOR STUDY</b>	<del>87.0 hours</del> <u>93.0 hours</u>

#### Feedback:

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing % change (increase or decrease) on scales of attention, stress, mood, health behaviours, weight, and blood pressure across the study.

#### 2. Discomforts and Risks

The risks to you in this study are small. The questionnaires used in the study are routine, standardized forms for epidemiologic research. Certain questions may be upsetting as they may probe sensitive psychological areas and inquire about upsetting or traumatic events, including physical, sexual or emotional abuse and/or current psychiatric symptoms. Since your participation is voluntary, you have the right to skip any questions that make you uncomfortable.

Meditation-based interventions may results in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable feelings with increased attention to them.

It is possible that injuries could be sustained during the study either from the gentle mindful movements (i.e., yoga), or from physical activities that participants engage in as a way to reduce blood pressure. To help limit this, you will receive a handout showing the yoga poses that will be offered during the course that you can show your health care provider so that they can advise on which poses to do, and which to avoid. Modifications of poses will be available as needed. None of the poses (or the yoga as a whole) are mandatory to be done. You will also be encouraged to explore physical activities that promote strength and conditioning as a way to reduce blood pressure. You will be encouraged to not go beyond any physical limits of your body, and will be encouraged to ask your healthcare provider about advised physical activities and mindful movements if you have any physical limitations.

While physical and mental injury is always a possibility the potential for harm is limited. Note that a research injury is any physical or mental injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and potential added medical expenses, it is important to follow all study directions carefully. If you are covered by insurance and suffer a research injury, it is possible that some or all of the costs of treating your condition could appropriately be billed to your insurance company. If such costs are not covered your health insurance company, it is possible you would have to pay for these costs out of pocket. Brown University's policies do not cover payment for such things as lost wages, medical care expenses, or pain and suffering.

Precautions should be taken to avoid injuries. If you do become injured during the study, you should call your doctor immediately. You should also alert the study staff that you have been injured. Heart attack and sudden death related to heart problems have been known to occur in people while they are exercising. This is very rare, however. Estimates of sudden cardiac death range from 0 to 2 per 100,000 hours. However, the researchers cannot guarantee that no complications will happen to you.

### 3. Benefits

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) receiving information about your psychological and physical functioning.

### 4. Alternative Therapies

A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

### 5. Confidentiality

Your responses for this study will be kept confidential. All data that we collect will be linked to a study ID# instead of your name. All questionnaires in this study will be filled out through an

online survey or a paper version of the survey if you prefer. All of these questionnaires will be linked solely to your study ID#, so that your identity is protected and your answers are confidential. Although these measures have been taken to protect your personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet.

While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then a collaborator (Dr. Ellen Flynn) who is a licensed psychiatrist, may contact you to discuss your responses and possible referral to a treatment provider. Questionnaire items that may warrant follow-up include endorsements of statements about hurting yourself, any high scores in depression, anxiety, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires researchers to report abuse or neglect of people age 60 and older to the Division of Elderly Affairs.

The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a unique code number and initials. All study records and specimens will be stored in a secure storage area.

*Keeping study records:* The Principal Investigator for this study will keep your research records indefinitely for research purposes.

## 6. Refusal/Withdrawal

Participation is voluntary, and you may decide to opt out or refuse any part of participation, including not answering certain questions. If you decide now to participate, you can change your mind later and quit the study. The decision to not participate or to withdraw from the study will not adversely affect current or future interactions with Brown University. The decision to not participate or to withdraw from the study will also not adversely affect your relationship with your physician.

If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

## 7. Contact Information

If you have questions about study procedures at any time you may contact the researchers: Dr. Eric B. Loucks, email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu), telephone (401) 863-6283. If you would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Brown University Human Research Protection Office Program, telephone number 1-866-309-2095 or 401-863-3050.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**CONSENT FORM:**  
**Please sign and return.**

Please read the following agreement and sign to consent to participating.

**I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY.**

\_\_\_\_\_  
PRINT NAME

\_\_\_\_\_  
Signature of participant

\_\_\_\_\_  
Date

**CONTACT INFORMATION**

Name (print): \_\_\_\_\_

Permanent Address: \_\_\_\_\_

Email(s): \_\_\_\_\_

Telephone: \_\_\_\_\_ (cell) \_\_\_\_\_ (other)

# PHONE-DELIVERED SCREENING QUESTIONNAIRE

## PHONE SCREENING QUESTIONNAIRE PART 1

The script is shown below in **bold italics**.

PID. Participant ID: \_\_\_\_\_

SQ01. Staff ID: \_\_\_\_\_

SQ02. Today's Date (MMDDYY): \_\_\_\_\_

SQ03. Current Time (24 hour time, e.g. 14:45): \_\_\_\_\_

Please now call the participant.

SQ04. Was the participant reached? YES NO

***Hello, my name is \_\_\_\_\_. I am calling from the Brown University School of Public Health because (name of participant) expressed interest in participating in our mindfulness blood pressure study. Is he/she available to talk at this time?***

***I would like to do a 10-15 minute phone interview with you to determine if you are a good match for this particular study.***

SQ05. ***Is now a good time to speak?***

*[If yes, proceed to SQ05 script below]*

If no... ***When would be a good time to talk?***

SQ06. Day to call back (DDMMYY) \_\_\_\_\_

SQ07. Time to call back \_\_\_\_\_ AM/PM

***OK, great. How about I give a quick overview of the study, and can then answer any questions you may have to see if it is a good fit for you. We will then go through a screening questionnaire to see if you qualify for the study. Does this sound OK?***

***In this study, we are looking to see if mindfulness practices improve blood pressure, and if education about hypertension risk factors may also improve blood pressure. If eligible, we will provide you with training in meditation, mindful movements, and the roles of things like diet, physical activity and medication in reducing blood pressure. You will be taught by a very experienced teacher who is an expert in these fields. The course is free and will take place over a 9-week period, where you come to a class once each week for 2.5 hours each time. There is also a one-day retreat on a Saturday that will be 8 hours long. As part of the project, we will also ask you to participate in health assessments before and after the study. Health assessments include measures such as blood pressure, height and weight, and questionnaires about your health and experiences. At the end of the study, you will be given \$100 USD to express our gratitude.***

Deleted: A basic overview of the study is that it is

Deleted: Specifically

Deleted: Y

Deleted: s

Deleted: Also, w

**Do you have any questions about the study?** [answer questions]

Deleted: Can I answer any questions about the study that you may have

SQ08. **Does this study sound like something you would be interested in doing?** Yes No

[If yes, proceed to next statement below. If no, politely thank the participant for considering being in this study, and end the call].

**Great. There are a few things that I would like to make clear before we start the interview. First of all, some of the questions that I will ask now to figure out if you are eligible to be in this study will be of personal nature, including asking about your mental health and life's experiences.**

SQ09. **Are you in a private place to talk?**

[If yes, proceed to text below. If no, reschedule meeting using variables **SQ06** and **SQ07** above].

Deleted: SQ04

Deleted: SQ05

**Because this interview is of a personal nature, it is important that you understand that everything you say will be kept strictly confidential. No one outside of our project will ever be able to see your answers, and we will not keep your name in the same place as any of your answers. If you are not eligible after the phone screen, we will destroy your information. If you like, though, we can keep your information on file for future studies.**

SQ10. Participant's First Name: \_\_\_\_\_

SQ11. Participant's Last Name: \_\_\_\_\_

Participant's Address (in case we need to send any study materials to you):

SQ12a. Street address: \_\_\_\_\_

SQ12b. City: \_\_\_\_\_

SQ12c. State: \_\_\_\_\_

SQ12d. Zip Code: \_\_\_\_\_

SQ13a. Participant's Phone number #1 (in case we need to contact you by phone)

\_\_\_\_\_

SQ13b. Participant's Phone number #2 \_\_\_\_\_

SQ14. Participant's email address (or mailing address if no email): \_\_\_\_\_

SQ15. Notes from interviewer related to participants' contact information (if any):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



## PHONE SCREENING QUESTIONNAIRE PART 2

PID. Participant ID #: \_\_\_\_\_

INCLUSION CRITERIA: All answers in 3<sup>rd</sup> column must be YES. If an answer is NO, immediately proceed to question SQ40.

			Comments
SQ26.	<b>What is your age?</b> [Is age at least 18 years?]	YES NO	
SQ27.	<b>Can you read and write in English?</b>	YES NO	

EXCLUSION CRITERIA: All answers in 3<sup>rd</sup> column must be NO with the exception of SQ32a and SQ33a. If an answer (other than SQ32a and SQ33a) is YES, then immediately proceed to question SQ40.

			Comments
<b>I will now start to ask some questions about your mental health.</b>			
SQ28.	<b>Has anyone ever told you that you have bipolar disorder or manic depression?</b>	YES NO	
SQ29.	<b>Has anyone ever used the word "Borderline" to describe you?</b>	YES NO	
SQ30a.	<b>Have you ever had a hallucination or seen things that other people can't see, or hear things other people can't hear?</b>	YES NO	
SQ30b.	<b>Have you ever been diagnosed with schizophrenia or psychosis?</b>	YES NO	
SQ31_1	<b>Have you ever taken any of the following medications that I am about to read to you?</b>		
SQ31_2	<b>Lithium</b>	YES NO DK	
SQ31_3	<b>Seroquel (quetiapine)</b>	YES NO DK	
SQ31_4	<b>Abilify (aripiprazole)</b>	YES NO DK	
SQ31_5	<b>Zyprexa (olanzapine)</b>	YES NO DK	
SQ31_6	<b>Clozaril (clozapine)</b>	YES NO DK	
SQ31_7	<b>Haldol/Haloperidol</b>	YES NO DK	
SQ31_8	<b>Geodon (ziprasidone)</b>	YES NO DK	
SQ31_8	<b>Risperdal (risperidone)</b>	YES NO DK	
SQ32a	<b>Have you ever had a suicide attempt?</b>	YES NO	
SQ32b	<b>[If yes, ask...] Have you considered killing yourself during the past month?</b>	YES NO	
SQ32c	<b>[If yes, ask...] Are you currently suicidal?</b>	YES NO	
	<b>[If yes, keep participant on the phone, and follow suicide safety plan below]</b>		
SQ32d	<b>[If no, ask...] Are you getting any help for that? If not, then provide list of resources from Safety Plan including Gateway, Anchor and The Providence Center] Not urgent, but inform Dr. Flynn about what was discussed.</b>	YES NO	

EXCLUSION CRITERIA: All answers in 3 <sup>rd</sup> column must be NO with the exception of SQ32a and SQ33a. If an answer (other than SQ32a and SQ33a) is YES, then immediately proceed to question SQ40.			
SQ33a	<b>Would you say you have a trauma history?</b>	YES NO	
SQ33b	<b>[If yes...]</b>	YES NO	
SQ33c	<b>In the past month, have you had any problems with dissociation (memory loss)?</b>	YES NO	
	<b>In the past month, have you had any flashbacks (i.e. sudden and disturbing vivid memory) about the trauma?</b>	YES NO	
SQ34a	<b>In the past month, have you had any problems with obsessions or compulsions, such as washing your hands or checking the oven over and over again?</b>	YES NO	
SQ34b	<b>[If yes...] Has anyone diagnosed you with obsessive compulsive disorder?</b>	YES NO	
SQ35	<b>In the past month, have you had a panic attack (i.e. sweating, heart palpitations, nausea, trouble breathing, fear of dying/choking/going crazy)?</b>	YES NO	
SQ36	<b>Have you had any problems with alcoholism or drug use in the past year?</b>	YES NO	
SQ37	<b>In the past year, have you had an eating disorder, such as starving, binge eating, or vomiting?</b>	YES NO	
SQ38a	<b>Do you currently have a mindfulness practice, such as meditation or yoga?</b>	YES NO	
SQ38b	<b>Please tell me more about your mindfulness practice, including how often you practice per week.</b>	Fill in response in comments section to the right	
SQ38c	<b>Do you currently practice meditation more than once per week? (yoga does not count as meditation in this context)</b>	YES NO	
SQ39	<b>This class will take place at Brown University in-person. Do you have any medical or mobility issues that would affect you being able to attend class?</b>	YES NO	
SQ40	Participant qualifies for next step of study (next step is 1 <sup>st</sup> blood pressure screening)	YES NO  If YES go to SQ41.  If NO, go to SQ42.	

SQ41a. **Thank you for taking the time to answer these questions. You qualify for the next stage of screening, which is to take your blood pressure at our office. If you're still interested, we'd like to schedule a time to have you come in to complete the in-person screener. It will only take 30 minutes or less and will involve taking your blood pressure 3-5 times. Is there a day or time that works best for you? [Schedule the In-Person Screening visit now].**

SQ41b. **As I mentioned earlier, there is a mindfulness intervention that is part of this study. If you are eligible based on the In-Person screening, you will then be invited to take part in a 9 week Mindfulness Course. We will be scheduling the mindfulness intervention at a time that works best with most of the participants. What days and times of the week typically work best with your schedule? Please keep in mind that the sessions are 2.5 hours long, and take place once per week for 9 weeks.**

**[Record participant's availability for Intervention and then proceed with the script]**

**Thank you for your time and interest in this study. We look forward to meeting you in person on [DATE / TIME]. Do you have any questions before we end this call?**

**IF INELIGIBLE:**

SQ42a. **Thank you for taking the time to answer these questions. According to the survey, you do not qualify for the study at this time. There may be other studies you qualify for.**

SQ42b. **Would you like me to keep your information to pass on to these studies? YES / NO**

SQ42c. [If yes...] **OK, thank you. We will keep this information for future studies you may qualify for. Thank you for taking the time to talk with me today. Can I answer any questions before hanging up?**

SQ42d. [If no...] **OK, our copy of this information will be destroyed. Thank you for taking the time to talk with me today. Can I answer any questions before hanging up?**

Deleted: **at two different times at least a week apart from each other. Let's book the in-person screening sessions** [Book both sessions. We can cancel the second session if they do not qualify].

Deleted:

## SAFETY PLAN

Enter details below on paper during screening (These variables should also be entered in the survey via questions SQ10-SQ13). Destroy this paper after screening is complete.

Participant's First Name: \_\_\_\_\_

Participant's Last Name: \_\_\_\_\_

Participant's Address:

Street address: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Zip Code: \_\_\_\_\_

Participant's Phone number #1: \_\_\_\_\_

Participant's Phone number #2: \_\_\_\_\_

During the phone-based screening, if participants respond yes to "Are you currently suicidal?", the interviewer should perform the following 2 steps:

1. Immediately have 911 and Dr. Ellen Flynn called by a colleague who has been informed beforehand that this is a possibility.

**Specifically, while keeping the participant on the phone, show the text below in the box to a colleague.**

***I have a study participant on the phone who is currently suicidal. Please call 911 immediately, and tell them:***

***"I am calling on behalf of [my name] who is performing a research study at Brown University. He has a participant on the phone who says they are currently suicidal." Please provide the participants' contact information to the 911 operator (i.e. name, address, phone #, email address) as requested. This information is shown above.***

***Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.***

2. While speaking calmly with the participant, let them know what you are doing. Specifically, let them know we are calling our study's psychiatrist Dr. Flynn and 911, and why you are doing that (i.e. because we are concerned about you). You can speak with participant to keep him/her on the phone, but the discussion should not be clinical in nature.

Examples of questions that could be asked in order to keep them on the phone:

- “Tell me what is going on.”
- “What’s happening right now?”
- Tell me more about why you are interesting in being part of this study.
- What are you hoping to get out of this study?

The following information can be provided to study participants if they state they have had considered killing themselves in the past month. If they are currently suicidal, the main priority is to keep them on the phone while 911 and Dr. Flynn are being contacted.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020

IN-PERSON SCREENING  
ASSESSMENT FORM

Deleted: FIRST

Deleted: VISIT

PID. Participant ID # \_\_\_\_\_  
BA2\_01. Staff ID # \_\_\_\_\_  
BA2\_02. Today's date (MMDDYY): \_\_\_\_\_

**Blood Pressure:**

BA2\_03a. Blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03b. Blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03c. Blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03d. Blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03e. Blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_03f. Blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA2\_04. Were the 2<sup>nd</sup> and 3<sup>rd</sup> systolic blood pressure readings within 20 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA2\_05. Were the 2<sup>nd</sup> and 3<sup>rd</sup> diastolic blood pressure readings within 10 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA2\_06a. Repeated blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06b. Repeated blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06c. Repeated blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06d. Repeated blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06e. Repeated blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA2\_06f. Repeated blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA2\_07. Blood pressure cuff size used: ☐ S ☐ Reg ☐ L ☐ XL

BA2\_08. Arm that cuff was placed on: ☐ L ☐ R

**Deleted:** BA2\_03g. Blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg¶

BA2\_03h. Blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg¶

BA2\_03i. Blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg¶  
BA2\_03j. Blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg¶

**Deleted:** 4<sup>th</sup> and 5<sup>th</sup>

**Deleted:** 4<sup>th</sup> and 5<sup>th</sup>

**Deleted:** BA2\_06g. Repeated blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg¶

BA2\_06h. Repeated blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg¶

BA2\_06i. Repeated blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg¶

BA2\_06j. Repeated blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg¶

**Comment [SF1]:** In order to reduce participant burden, Medication Use has been moved to the In-Person baseline assessment since it is not part of the eligibility criteria.

**Deleted:** Medications (ME)

**Deleted:** ¶

¶  
ME01. Do you take any prescription medications or over-the-counter drugs?¶  
<#>Section Break (Continuous)</#>

<#>No → **skip to end of medications questions**¶

<#>Yes¶

<#>Don't know¶

<#>Prefer not to answer

Section Break (Continuous)

Section Break (Continuous)

¶  
ME02a. What is the name of the first prescription medication or over-the-counter drug that you take?¶

¶  
☐ Label product name:

\_\_\_\_\_¶

¶  
☐ Label generic name:

\_\_\_\_\_¶

¶  
☐ Don't know . . . ☐ Prefer not to answer¶

¶  
ME02b. What is the dosage form?¶ (... [1])

**IN-PERSON BASELINE**  
QUESTIONNAIRE AND ASSESSMENT FORMS

Deleted: SECOND  
Deleted: VISIT SCREENING



PID. Participant ID # \_\_\_\_\_  
BA01. Staff ID # \_\_\_\_\_  
BA02. Today's date (MMDDYY): \_\_\_\_\_

Blood Pressure:

BA03a. Blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03b. Blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03c. Blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03d. Blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03e. Blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03f. Blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA04. Were the 2<sup>nd</sup> and 3<sup>rd</sup> systolic blood pressure readings within 20 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA05. Were the 2<sup>nd</sup> and 3<sup>rd</sup> diastolic blood pressure readings within 10 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA06a. Repeated blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06b. Repeated blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06c. Repeated blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06d. Repeated blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06e. Repeated blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06f. Repeated blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA07. Blood pressure cuff size used: ☐ S ☐ Reg ☐ L ☐ XL

BA08. Arm that cuff was placed on: ☐ L ☐ R

**Deleted:** BA03g. Blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA03h. Blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA03i. Blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA03j. Blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

**Deleted:** 4<sup>th</sup> and 5<sup>th</sup>

**Deleted:** 4<sup>th</sup> and 5<sup>th</sup>

**Deleted:** BA06g. Repeated blood pressure 4<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA06h. Repeated blood pressure 4<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA06i. Repeated blood pressure 5<sup>th</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA06j. Repeated blood pressure 5<sup>th</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA09. Height: \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

BA10. Weight: \_\_\_\_\_ . \_\_\_\_ kg (one decimal place)

Waist Circumference:

BA11a. Measurement 1 \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

BA11b. Measurement 2 \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

BA12. Is the difference between Measurement 1 and Measurement 2 greater than 1.0cm?

☐ Yes (***repeat measurements 3&4***)

☐ No

BA13a. Measurement 3 \_\_\_\_\_ . \_\_\_\_ cm

BA13b. Measurement 4 \_\_\_\_\_ . \_\_\_\_ cm

## Medications (ME)

**Comment [SF1]:** Moved here from In-Person Screener

ME01. Do you take any prescription medications or over-the-counter drugs?

☐ No → ***skip to end of medications questions***

☐ Don't know

☐ Yes

☐ Prefer not to answer

ME02a. What is the name of the first prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME02b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME02c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

☐ \_\_\_\_\_ times per month

☐ Don't know

☐ Prefer not to answer

ME02d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- |                                      |  |
|--------------------------------------|--|
| <input type="checkbox"/> _____ %     | <input type="checkbox"/> _____ Other unit: _____ |
| <input type="checkbox"/> _____ mg    | <input type="checkbox"/> Don't know              |
| <input type="checkbox"/> _____ mcg   | <input type="checkbox"/> Prefer not to answer    |
| <input type="checkbox"/> _____ grams |  |
| <input type="checkbox"/> _____ I.U.  |  |

ME02e. Total dosage **per day**. (**Record strength of how it is actually taken, not how it is prescribed.**)

- |                                      |  |
|--------------------------------------|--|
| <input type="checkbox"/> _____ %     | <input type="checkbox"/> _____ Other unit: _____ |
| <input type="checkbox"/> _____ mg    | <input type="checkbox"/> Don't know              |
| <input type="checkbox"/> _____ mcg   | <input type="checkbox"/> Prefer not to answer    |
| <input type="checkbox"/> _____ grams |  |
| <input type="checkbox"/> _____ I.U.  |  |

ME02f. Do you take it regularly or only as needed?

- |   |   |
|---|---|
| <input type="checkbox"/> Regularly      | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Only as needed | <input type="checkbox"/> Prefer not to answer |

ME02g. For how long have you been taking it?

- |   |   |
|---|---|
| <input type="checkbox"/> For _____ days   | <input type="checkbox"/> For _____ years      |
| <input type="checkbox"/> For _____ weeks  | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> For _____ months | <input type="checkbox"/> Prefer not to answer |

ME02h. What is the medication used for?

\_\_\_\_\_

ME02i. **Interviewer comments:**

\_\_\_\_\_

ME02j. Do you take any other prescription medications or over-the-counter drugs?

- |  |   |
|--|---|
| <input type="checkbox"/> No → <b><u>skip to end of medications questions</u></b> | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Yes   | <input type="checkbox"/> Prefer not to answer |

ME03a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know ☐ Prefer not to answer

ME03b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME03c. How frequently do you take it?

☐ times per day

☐ times per week

☐ times per month

☐ Don't know

☐ Prefer not to answer

ME03d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ %

☐ mg

☐ mcg

☐ grams

☐ I.U.

☐ Other unit:

☐ Don't know

☐ Prefer not to answer

ME03e. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

<input type="checkbox"/> _____ %	<input type="checkbox"/> _____ Other unit: _____
<input type="checkbox"/> _____ mg	<input type="checkbox"/> Don't know
<input type="checkbox"/> _____ mcg	<input type="checkbox"/> Prefer not to answer
<input type="checkbox"/> _____ grams	
<input type="checkbox"/> _____ I.U.	

ME3f. Do you take it regularly or only as needed?

<input type="checkbox"/> Regularly	<input type="checkbox"/> Don't know
<input type="checkbox"/> Only as needed	<input type="checkbox"/> Prefer not to answer

ME03g. For how long have you been taking it?

<input type="checkbox"/> For _____ days	<input type="checkbox"/> For _____ years
<input type="checkbox"/> For _____ weeks	<input type="checkbox"/> Don't know
<input type="checkbox"/> For _____ months	<input type="checkbox"/> Prefer not to answer

ME03h. What is the medication used for?

\_\_\_\_\_

ME03i. ***Interviewer comments:***

\_\_\_\_\_

ME03j. Do you take any other prescription medications or over-the-counter drugs?

<input type="checkbox"/> No → <b><i>skip to end of medications questions</i></b>	<input type="checkbox"/> Don't know
<input type="checkbox"/> Yes	<input type="checkbox"/> Prefer not to answer

ME04a. What is the name of the next prescription medication or over-the-counter drug that you take?

<input type="checkbox"/> Label product name: _____
<input type="checkbox"/> Label generic name: _____
<input type="checkbox"/> Don't know <input type="checkbox"/> Prefer not to answer

ME04b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME04c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME04d. What is the strength? (Record strength of how it is actually taken, not how it is prescribed.)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME04e. Total dosage per day. (Record strength of how it is actually taken, not how it is prescribed.)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME04f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME04g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME04h. What is the medication used for?

\_\_\_\_\_

ME04i. **Interviewer comments:**

\_\_\_\_\_

ME04j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications section**

☐ Don't know

☐ Prefer not to answer

☐ Yes

ME05a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME05b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer



ME05c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME05d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME05e. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME05f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed
- ☐ Don't know  
☐ Prefer not to answer

ME05g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months
- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME05h. What is the medication used for?

ME05i. *Interviewer comments:*

ME05j. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → ***skip to end of end of medications questions***  
☐ Yes
- ☐ Don't know  
☐ Prefer not to answer

ME06a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME06b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME06c. How frequently do you take it?

☐ times per day

☐ times per week

☐ times per month

☐ Don't know

☐ Prefer not to answer

ME06d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ %

☐ mg

☐ mcg

☐ grams

☐ I.U.

☐ Other unit:

☐ Don't know

☐ Prefer not to answer

ME06e. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- |                                      |  |
|--------------------------------------|--|
| <input type="checkbox"/> _____ %     | <input type="checkbox"/> _____ Other unit: _____ |
| <input type="checkbox"/> _____ mg    | <input type="checkbox"/> Don't know              |
| <input type="checkbox"/> _____ mcg   | <input type="checkbox"/> Prefer not to answer    |
| <input type="checkbox"/> _____ grams |  |
| <input type="checkbox"/> _____ I.U.  |  |

ME06f. Do you take it regularly or only as needed?

- |   |   |
|---|---|
| <input type="checkbox"/> Regularly      | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Only as needed | <input type="checkbox"/> Prefer not to answer |

ME06g. For how long have you been taking it?

- |   |   |
|---|---|
| <input type="checkbox"/> For _____ days   | <input type="checkbox"/> For _____ years      |
| <input type="checkbox"/> For _____ weeks  | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> For _____ months | <input type="checkbox"/> Prefer not to answer |

ME06h. What is the medication used for?

\_\_\_\_\_

ME06i. *Interviewer comments:*

\_\_\_\_\_

ME06i. Do you take any other prescription medications or over-the-counter drugs?

- |  |   |
|--|---|
| <input type="checkbox"/> No → <b><i>skip to end of medications questions</i></b> | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Yes   | <input type="checkbox"/> Prefer not to answer |

ME07a. What is the name of the next prescription medication or over-the-counter drug that you take?

- |   |
|---|
| <input type="checkbox"/> Label product name: _____  |
| <input type="checkbox"/> Label generic name: _____  |
| <input type="checkbox"/> Don't know _____           |
| <input type="checkbox"/> Prefer not to answer _____ |

ME07b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME07c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME07d. What is the strength? (Record strength of how it is actually taken, not how it is prescribed.)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME07e. Total dosage per day. (Record strength of how it is actually taken, not how it is prescribed.)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME07f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME07g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME07h. What is the medication used for?

ME07i. **Interviewer comments:**

ME07j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications questions**

☐ Yes

☐ Don't know

☐ Prefer not to answer

ME08a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME08b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME08c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME08d. What is the strength? (Record strength of how it is actually taken, not how it is prescribed.)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME08e. Total dosage per day. (Record strength of how it is actually taken, not how it is prescribed.)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME08f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed
- ☐ Don't know  
☐ Prefer not to answer

ME08g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months
- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME08h. What is the medication used for?

ME08i. **Interviewer comments:**

ME08j. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**  
☐ Yes
- ☐ Don't know  
☐ Prefer not to answer

ME09a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know ☐ Prefer not to answer

ME09b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME09c. How frequently do you take it?

☐ times per day

☐ times per week

☐ times per month

☐ Don't know

☐ Prefer not to answer

ME09d. What is the strength? (Record strength of how it is actually taken, not how it is prescribed.)

☐ %

☐ mg

☐ mcg

☐ grams

☐ I.U.

☐ Other unit:

☐ Don't know

☐ Prefer not to answer

ME09e. Total dosage **per day**. (*Record strength of how it is actually taken, not how it is prescribed.*)

- |                                      |  |
|--------------------------------------|--|
| <input type="checkbox"/> _____ %     | <input type="checkbox"/> _____ Other unit: _____ |
| <input type="checkbox"/> _____ mg    | <input type="checkbox"/> Don't know              |
| <input type="checkbox"/> _____ mcg   | <input type="checkbox"/> Prefer not to answer    |
| <input type="checkbox"/> _____ grams |  |
| <input type="checkbox"/> _____ I.U.  |  |

ME09f. Do you take it regularly or only as needed?

- |   |   |
|---|---|
| <input type="checkbox"/> Regularly      | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Only as needed | <input type="checkbox"/> Prefer not to answer |

ME09g. For how long have you been taking it?

- |   |   |
|---|---|
| <input type="checkbox"/> For _____ days   | <input type="checkbox"/> For _____ years      |
| <input type="checkbox"/> For _____ weeks  | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> For _____ months | <input type="checkbox"/> Prefer not to answer |

ME09h. What is the medication used for?

\_\_\_\_\_

ME09i. ***Interviewer comments:***

\_\_\_\_\_

ME09j. Do you take any other prescription medications or over-the-counter drugs?

- |  |   |
|--|---|
| <input type="checkbox"/> No → <b><i>skip to end of medications questions</i></b> | <input type="checkbox"/> Don't know           |
| <input type="checkbox"/> Yes   | <input type="checkbox"/> Prefer not to answer |

ME10a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name: \_\_\_\_\_

☐ Label generic name: \_\_\_\_\_

☐ Don't know      ☐ Prefer not to answer



**ME10b. What is the dosage form?**

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

**ME10c. How frequently do you take it?**

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

**ME10d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)**

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

**ME10e. Total dosage per day. (*Record strength of how it is actually taken, not how it is prescribed.*)**

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

**ME10f. Do you take it regularly or only as needed?**

- ☐ Regularly  
☐ Only as needed  
☐ Don't know  
☐ Prefer not to answer

ME10g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks
- ☐ For \_\_\_\_\_ months
- ☐ For \_\_\_\_\_ years
- ☐ Don't know
- ☐ Prefer not to answer

ME10h. What is the medication used for?

ME10i. *Interviewer comments:*

**FOOD FREQUENCY QUESTIONNAIRE:**

RA Script to be read to participants: At this time, we are going to have you complete a few forms on your own. The first is a Food Frequency Questionnaire that will ask you about the types of foods and drinks that you consume. It should take around 20 minutes to complete. Please let me know if you have any questions.

**Comment [SF2]:** At this time, participants will be directed to complete the three page Harvard University Food Frequency Questionnaire (see proof included), known as the "80-out". It is designed to take around 20 minutes to complete and is self-administered with paper and pencil. Once completed, they will proceed to the next section of this assessment (DS\_1).

**Questions for Participants to Answer on Their Own In-Person on Paper:**

For each statement, please place a mark in the column that best describes how you have been feeling.

	Not at all or less than 1 day last week	1 or 2 days last week	3 to 4 days last week	5 to 7 days last week	Nearly every day for two weeks	I do not know	I prefer not to answer
DS_1. My appetite was poor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_2. I could not shake off the blues.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_3. I had trouble keeping my mind on what I was doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_4. I felt depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_5. My sleep was restless.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_6. I felt sad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_7. I could not get going.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_8. Nothing made me happy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C_9. I felt like a bad person.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_10. I lost interest in my usual activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_11. I slept much more than usual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_12. I felt like I was moving too slowly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_13. I felt fidgety.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_14. I wished I were dead.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_15. I wanted to hurt myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_16. I was tired all the time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_17. I did not like myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_18. I lost a lot of weight without trying to.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_19. I had a lot of trouble getting to sleep.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_20. I could not focus on the important things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past month, including today, by marking the box in the corresponding space in the column next to each symptom.

	Not At All	Mildly – it didn't bother me much	Moderately – it wasn't pleasant at all times	Severely – it bothered me a lot	I do not know	I prefer not to answer
BE_1. Numbness or tingling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_2. Feeling hot	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_3. Wobbliness in legs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_4. Unable to relax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_5. Fear of worst happening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_6. Dizzy or lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_7. Heart pounding/racing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_8. Unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_9. Terrified or afraid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_10. Nervous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_11. Feeling of choking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_12. Hands trembling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_13. Shaky/unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_14. Fear of losing control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_15. Difficulty in breathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_16. Fear of dying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_17. Scared	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_18. Indigestion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_19. Faint/lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_20. Face flushed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_21. Hot/cold sweats	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

After questionnaires are complete, participants will be asked to perform the following two computer-based tests:

### **Attention Control: Attention Network Test (20 minutes)**

Attention Network Test (ANT) is a brief computerized battery measuring three independent behavioral components of attention: Conflict resolution (ability to overcome distracting stimuli), spatial Orienting (the benefit of valid spatial pre-cues), and Alerting (the benefit of temporal pre-cues). Efficiency of orienting is examined by changes in RT that accompany cues indicating where the target will occur. The efficiency of the executive conflict resolution network is examined by requiring the subject to respond by pressing two keys indicating the direction (left or right) of a central arrow surrounded by congruent, incongruent or neutral flankers. Moderate to high reliabilities are found for all networks.

#### **ANT data to be entered by RA prior to ANT:**

PPT Age: \_\_\_\_\_

PPT Sex: Male / Female

Category: Normal

Diagonal of "subject info" window: 10"

Press "distance between eyes and screen" button to calculate. Should be 23.2.

#### **ANT data to be entered by RA after ANT:**

PPT Age: \_\_\_\_\_

Alerting effect (ms): \_\_\_\_\_

Orienting effect (ms): \_\_\_\_\_

Conflict effect (ms): \_\_\_\_\_

Mean RT for correct trials (ms): \_\_\_\_\_

Mean accuracy (%): \_\_\_\_\_

### **Sustained Attention to Response Task (15 minutes)**

Deleted: \_\_\_\_\_ Page Break \_\_\_\_\_

The Sustained Attention to Response Task (SART) is a computerized test of sustained attention, response inhibition (executive function) and self-regulation. Subjects are instructed to press a key in response to rapidly displayed integers (1-9) and withhold response to a designated "no-go" integer. SART errors consist of summed commission errors (button press on no-go trial) and omission errors (button not pressed on "go" integers). SART performance is associated with prefrontal cortex functioning, has been found to increase with mindfulness training and is correlated with scores on mindfulness questionnaires (specifically, the Mindful Attention Awareness Scale).

## SAFETY PLAN

After the participant has completed the Beck Anxiety Inventory questionnaire and the Centers for Epidemiologic Studies Depressive Symptomatology questionnaire, ask the participant to wait for a few minutes while you check that all forms and assessments are completed. While the participant is waiting in a different room, check the scores according to the criteria below. If any scores trigger the safety plan, move forward with steps below as written.

### Beck Anxiety Inventory (BA)

If participant scores  $\geq 26$  on the Beck Anxiety Inventory, while having the participant wait, immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and your phone # will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, please leave a phone message for her with your contact information and provide her with the Beck Anxiety Inventory results on the message. If Dr. Flynn is not immediately reachable, or following participant release after consulting with Dr. Flynn, immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).

### Depressive Symptomatology (DS)

The CESD-R will be administered during the in-person assessment visits, and scores will be reviewed immediately upon completion of the in-person assessments.

1. Sadness (dysphoria): Question numbers 2, 4, 6
2. Loss of Interest (anhedonia): Question numbers 8, 10
3. Appetite: Question numbers 1, 18
4. Sleep: Question numbers 5, 11, 19
5. Thinking / concentration: Question numbers 3, 20
6. Guilt (worthlessness): Question numbers 9, 17
7. Tired (fatigue): Question numbers 7, 16
8. Movement (agitation): Question numbers 12, 13
9. Suicidal ideation: Question numbers 14, 15

Participants are considered to meet criteria for major depressive episode if they have anhedonia or dysphoria nearly every day for the past two weeks, plus symptoms in an additional 4 DSM symptom groups noted as occurring nearly every day for the past two weeks. If participants meet criteria for major depressive episode, while having the participant wait, immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and your phone # will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, please leave a phone message for her with your contact information and provide her with the Depressive Symptomatology results on the message. If Dr. Flynn is not immediately reachable, or following participant release after consulting with Dr. Flynn, immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).

If participants respond having any suicidal ideation (DS questions 14 or 15), perform the following 2 steps:

1. Immediately call 911 and Dr. Ellen Flynn.

**Specifically, while the participant is in the waiting room, call 911 immediately, and tell them:**

***“My name is \_\_\_\_\_. I am working on a research study at Brown University. I have a study participant in the waiting room who has shared that he/she is currently suicidal.” Please provide the participants’ name to the 911 operator, as requested.***

***Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.***

2. While speaking calmly with the participant, let them know that you have called 911 and Dr. Flynn, and why (i.e. because we are concerned about you). You can speak with participant to keep him/her in the waiting room if 911 has sent assistance, but the discussion should not be clinical in nature.

Examples of questions that could be asked in order to keep them in the waiting room:

- “Tell me what is going on.”
- “What’s happening right now?”
- Tell me more about why you are interesting in being part of this study.
- What are you hoping to get out of this study?

The following information can be provided to study participants.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020



# **HOME BASELINE ASSESSMENT**

QUESTIONNAIRES ANSWERED BY PARTICIPANTS  
AT BASELINE (VIA ONLINE OR PAPER FORM)

## Questionnaire Table of Contents

<u>Introductory Questions.....</u>	<u>3</u>
<u>Background Questions.....</u>	<u>5</u>
<u>Physical Activity.....</u>	<u>8</u>
<u>Eating Practices.....</u>	<u>10</u>
<u>Alcohol Consumption.....</u>	<u>13</u>
<u>Smoking.....</u>	<u>14</u>
<u>About You.....</u>	<u>15</u>
<u>Parent's Education.....</u>	<u>37</u>
<u>Your Childhood Experiences.....</u>	<u>39</u>
<u>Blood Pressure Medication Use.....</u>	<u>42</u>
<u>More About You.....</u>	<u>43</u>
<u>Family History of Hypertension.....</u>	<u>47</u>
<u>Your Sleep.....</u>	<u>48</u>
<u>END SCRIPT.....</u>	<u>48</u>

### **Introduction**

We appreciate you taking the time to participate in this research study. These questionnaires will ask a series of questions on various aspects of your health, health behaviours, family, and other life circumstances. It should take approximately one hour. Please keep in mind that you can refuse to answer any questions that you are not comfortable with.

### **Introductory Questions**

IQ1\_01. Please enter the 4-digit ID number you were given.    \_\_\_\_    \_\_\_\_    \_\_\_\_    \_\_\_\_.

IQ1\_02. What is your main reason for participating in this study?

IQ1\_03. What do you care about most?

IQ1\_04. What gives you the most pleasure in your life?

IQ1\_05. What are your greatest worries?

Please list three personal goals you have for taking this mindfulness program:

PG1\_01. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

PG1\_02. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

PG1\_03. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## **Background Questions**

BQ1\_01. How many years old are you?

BQ1\_02. Are you Latino or Hispanic?

- ☐ No → **skip to B3**
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

B1\_02a. Which of the following represents your family's country of origin? (**check all that apply**)

- |  |   |
|--|---|
| <input type="checkbox"/> Cuba          | <input type="checkbox"/> Dominican Republic     |
| <input type="checkbox"/> Mexico        | <input type="checkbox"/> Other Central American |
| <input type="checkbox"/> Puerto Rico   | <input type="checkbox"/> Other: _____           |
| <input type="checkbox"/> Spain         | <input type="checkbox"/> I do not know          |
| <input type="checkbox"/> South America | <input type="checkbox"/> I prefer not to answer |
| <input type="checkbox"/> Columbia      |   |

BQ1\_03. If you were asked to put yourself into only one of these groups, in which one would you place yourself? (**select one only**):

- |   |   |
|---|---|
| <input type="checkbox"/> Asian                  | <input type="checkbox"/> Native American        |
| <input type="checkbox"/> Pacific Islander       | <input type="checkbox"/> Other : _____          |
| <input type="checkbox"/> African American/Black | <input type="checkbox"/> I do not know          |
| <input type="checkbox"/> Caucasian/White        | <input type="checkbox"/> I prefer not to answer |

BQ1\_04. Which of the following best describes your current work situation? (**select one only**)

- |   |  |
|---|--|
| <input type="checkbox"/> Working full-time                          | <input type="checkbox"/> Keeping house or raising children full-time |
| <input type="checkbox"/> Working part-time                          | <input type="checkbox"/> Military                                    |
| <input type="checkbox"/> Retired                                    | <input type="checkbox"/> Full-time student                           |
| <input type="checkbox"/> Unemployed: Looking for work               | <input type="checkbox"/> Other: _____                                |
| <input type="checkbox"/> Unemployed: Not currently looking for work | <input type="checkbox"/> I do not know                               |
| <input type="checkbox"/> Unemployed due to disability               | <input type="checkbox"/> I prefer not to answer                      |

BQ1\_05. What is the highest grade or level of regular school you have completed?

- ☐ Elementary School
- ☐ Junior High
- ☐ High School
- ☐ College
- ☐ Graduate School
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_06. What is the highest degree you earned? (*select one only*)

- ☐ Elementary school
- ☐ Some high school, but no GED
- ☐ GED
- ☐ High school
- ☐ Associate degree (Junior College)
- ☐ Bachelor's degree
- ☐ Master's degree
- ☐ Doctorate (PhD, EdD, etc)
- ☐ Professional (MD, JD, DDS, DVM, etc.)
- ☐ Other: \_\_\_\_\_
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_07. Did you ever attend any other school like a technical, vocational, or trade school?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_08. In total, about how many full-time years of education have you had, including 1<sup>st</sup> grade and all years of school after 1<sup>st</sup> grade?

\_\_\_\_\_ years

BQ1\_09a. Do you currently live alone?

- ☐ No
- ☐ Yes → *skip to next section*
- ☐ I do not know
- ☐ I prefer not to answer

Deleted: BQ\_10

BQ1\_09b. How many people currently live in your household, including yourself?

\_\_\_\_\_

BQ1\_09c. Of these people, how many are under 18?

\_\_\_\_\_

BQ1\_09d. Of the adults in your household (including yourself), how many bring income into the household?

\_\_\_\_\_

## **Physical Activity**

Physical activities are activities where you move and increase your heart rate above its resting rate, whether you do them for pleasure, work, or transportation. The following questions ask about the amount and intensity of physical activity you usually do. The intensity of the activity is related to *the amount of energy* you use doing these activities.

### **Examples of physical activity intensity levels:**

#### **Light activities**

Your heart beats slightly faster than normal  
You can talk and sing



Light exercise



Light stretching



Light vacuuming  
or yard work

#### **Moderate activities**

Your heart beats faster than normal  
You can talk but not sing



Brisk walking



Aerobics class



Strength training



Swim gently

#### **Vigorous activities**

Your heart rate increases a lot  
You can't talk, or your talking is broken  
up by large breaths



Aerobics classes



Jogging, Running,  
or Power Walking



Singles tennis,  
Racquetball, Pickle ball



## How physically active are you?

	YES	NO	I do not know	I prefer not to answer
PA1_01. I rarely or never do any physical activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_02. I do some light and/or moderate physical activities, but not every week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_03. I do some light physical activity every week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_04. I do moderate physical activity every week but less than 5 days per week or less than 30 minutes on those days.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_05. I do vigorous physical activities every week, but less than 3 days per week or less than 20 minutes on those days.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_06. I do 30 minutes or more per day of moderate physical activities 5 or more days per week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_07. I do 20 minutes or more per day of vigorous physical activities 3 or more days per week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_08. I do activities to increase muscle strength, such as lifting weights or calisthenics, once a week or more.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_09. I do activities to improve flexibility, such as stretching or yoga, once a week or more.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Deleted: Diet ¶

The secret to serving size is in your hand.



The first set of questions ask about foods you usually eat or drink. For each food, please place an X in the box (e.g. ☒) for the answer that best matches how often you eat or drink it. Remember to count fruit or vegetables that were part of another dish, like a banana on cereal or vegetables in a stew. Also, please pay attention to the serving sizes. For example, one serving size of bread is one slice, so a sandwich would contain 2 servings of bread. Please include all foods you eat, both at home and away from home. Enclosed are pictures of common serving sizes to assist you in filling out your questionnaire. ¶

Deleted: How Often You Eat or Drink This Item

... [1]

## **Eating Practices**

	Definitely True	Mostly True	Mostly False	Definitely False	I Do Not Know	I Prefer Not to Answer
EE1_01. I deliberately take small helpings to control my weight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_02. I start to eat when I feel anxious.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_03. Sometimes when I start eating, I just can't seem to stop.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_04. When I feel sad, I often eat too much.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_05. I don't eat some foods because they make me fat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_06. Being with someone who is eating, often makes me want to also eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_07. When I feel tense or "wound up", I often feel I need to eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_08. I often get so hungry that my stomach feels like a bottomless pit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_09. I'm always so hungry that it's hard for me to stop eating before finishing all of the food on my plate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_10. When I feel lonely, I console myself by eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_11. I consciously hold back on how much I eat at meals to keep from gaining weight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_12. When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating even if I've just finished a meal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_13. I'm always hungry enough to eat at any time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_14. If I feel nervous, I try to calm down by eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_15. When I see something that looks very delicious, I often get so hungry that I have to eat right away.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_16. When I feel depressed, I want to eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never	Seldom	Usually	Almost Always	I Do Not Know	I Prefer Not to Answer
EE1_17. How often do you avoid ‘stocking up’ on tempting foods?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Unlikely	A little likely	Somewhat likely	Very likely	I Do Not Know	I Prefer Not to Answer
EE1_18. How likely are you to make an effort to eat less than you want?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Rarely	Sometimes	At least once a week	I Do Not Know	I Prefer Not to Answer
EE1_19. Do you go on eating binges even though you’re not hungry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Only at mealtimes	Sometimes between meals	Often between meals	Almost always	I Do Not Know	I Prefer Not to Answer
EE1_20. How often do you feel hungry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	1	2	3	4	5	6	7	8	I Do Not Know	I Prefer Not to Answer
EE1_21. On a scale from 1 to 8, where 1 means no restraint in eating and 8 means total restraint, what number would you give yourself? Mark the number that best applies to you:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Table Salt Use:**

**TS1 01** Please report your average total use, during the past year, of “salt added at the table”.  
Would you say...

- Never ..... ☐
- Less than once per month ..... ☐
- 1-3 shakes per month..... ☐
- 1 shake per week ..... ☐
- 2-4 shakes per week ..... ☐
- 5-6 shakes per week ..... ☐
- 1 shake per day ..... ☐
- 2-3 shakes per day ..... ☐
- 4-5 shakes per day ..... ☐
- 6+ shakes per day ..... ☐

## **Alcohol Consumption**

A drink of alcohol is defined as 1 can or bottle of beer, 1 glass of wine, 1 can or bottle of wine cooler, 1 cocktail, or 1 shot of liquor.

AC1\_01. During the past 30 days, how many days per week or per month did you have at least 1 drink of any alcoholic beverage? [if none, **skip to next section**]

Deleted: STOP

---

AC1\_02. On the days when you drank, about how many drinks did you drink on average?

---

AC1\_03. **Men:** Considering all types of alcoholic beverages, how many times during the past 30 days did you have **5** or more drinks on an occasion?

**Women:** Considering all types of alcoholic beverages, how many times during the past 30 days did you have **4** or more drinks on an occasion?

---

## **Smoking**

SM1\_01. Have you smoked at least 100 cigarettes in your entire life?

- ☐ Yes
- ☐ No
- ☐ I Do Not Know
- ☐ Prefer not to answer

SM1\_02. Did you ever become a daily smoker (that is, smoke every day or nearly every day for two months or longer)?

- ☐ Yes
- ☐ No → *skip to next section*
- ☐ I Do Not Know
- ☐ Prefer not to answer

Deleted: SC1\_01

SM1\_03. How old were you when you last smoked daily?

Age \_\_\_\_\_ (in years)

- ☐ I Do Not Know
- ☐ Prefer not to answer
- ☐ Still smoking daily

SM1\_04. Do you smoke cigarettes now?

- ☐ Yes
- ☐ No → *skip to next section*
- ☐ I Do Not Know
- ☐ Prefer not to answer

SM1\_04a. How many cigarettes per day do you smoke? (One pack equals 20 cigarettes)

Number of cigarettes \_\_\_\_\_

- ☐ I Do Not Know
- ☐ Prefer not to answer

## **About You**

Please bring to mind a type of very tasty food that may contribute to hypertension through high salt intake or through eating too many calories (e.g., sweet sugary dessert, salty snack foods, etc.).

Think about the LAST WEEK you MOST WANTED this type of food. For each item, select a number (0 to 10) to indicate your rating.

<u>At that time...</u>	<u>Not at All</u> <u>0</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>Extremely</u> <u>10</u>
1. ...how much did you want it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ...how much did you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. ...how strong was the urge to have it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>At that time, how vividly did you...</u>											
4. ...picture it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. ...imagine its taste?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. ...imagine its smell?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. ...imagine what it would feel like in your mouth or throat?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. ...imagine how your body would feel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>At that time...</u>											
9. ...how hard were you trying not to think about it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. ...how intrusive were the thoughts?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. ...how hard was it to think about anything else?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please bring to mind any times in the LAST WEEK when you had a desire to do sedentary activities (e.g., read a book, watch a movie, be on the computer, etc.) instead of physical activities (e.g., walking, gardening, exercise).

Think about the LAST WEEK you MOST WANTED to do a sedentary activity. For each item, select a number (0 to 10) to indicate your rating.

At that time...	Not at All 0	1	2	3	4	5	6	7	8	9	Extremely 10
1. ...how much did you want it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ...how much did you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. ...how strong was the urge to have it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time, how vividly did you...											
4. ...picture it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. ...imagine how your body would feel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time...											
6. ...how hard were you trying not to think about it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. ...how intrusive were the thoughts?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. ...how hard was it to think about anything else?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please bring to mind any times in the LAST WEEK when you had a desire to drink alcohol, such as wine, beer or spirits.

Think about the LAST WEEK you MOST WANTED alcohol. For each item, select a number (0 to 10) to indicate your rating.

At that time...	Not at All 0	1	2	3	4	5	6	7	8	9	Extremely 10
1. ...how much did you want it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ...how much did you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. ...how strong was the urge to have it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time, how vividly did you...											
4. ...picture it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. ...imagine its taste?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. ...imagine its smell?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. ...imagine what it would feel like in your mouth or throat?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. ...imagine how your body would feel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time...											
9. ...how hard were you trying not to think about it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. ...how intrusive were the thoughts?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. ...how hard was it to think about anything else?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Using the scale provided, please indicate how much each of the following statements reflects how you typically are.

	Not at all	A little	Somewhat	Fair Amount	Very much	I do not know	I prefer not to answer
SC1_01. I am good at resisting temptation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_02. I have a hard time breaking bad habits.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_03. I am lazy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_04. I say inappropriate things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_05. I do certain things that are bad for me, if they are fun.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_06. I refuse things that are bad for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_07. I wish I had more self-discipline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_08. People would say that I have iron self-discipline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_09. Pleasure and fun sometimes keep me from getting work done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_10. I have trouble concentrating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_11. I am able to work effectively toward long-term goals.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_12. Sometimes I can't stop myself from doing something, even if I know it is wrong.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_13. I often act without thinking through all the alternatives.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

	Almost never	Not very often	Sometimes	Frequently	Almost always	I Do Not Know	Prefer not to answer
CO1_O1. When I fail at something important to me, I become consumed by feelings of inadequacy.							
CO1_O2. I try to be understanding and patient towards those aspects of my personality I don't like.							
CO1_O3. When something painful happens I try to take a balanced view of the situation.							
CO1_O4. When I'm feeling down, I tend to feel like most other people are probably happier than I am.							
CO1_O5. I try to see my failings as part of the human condition.							
CO1_O6. When I'm going through a very hard time, I give myself the caring and tenderness I need.							
CO1_O7. When something upsets me I try to keep my emotions in balance.							
CO1_O8. When I fail at something that's important to me, I tend to feel alone in my failure							
CO1_O9. When I'm feeling down I tend to obsess and fixate on everything that's wrong.							

	Almost never	<u>Not very often</u>	<u>Sometimes</u>	<u>Frequently</u>	Almost always	<u>I Do Not Know</u>	<u>Prefer not to answer</u>
CO1_10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.							
CO1_11. I'm disapproving and judgmental about my own flaws and inadequacies.							
CO1_12. I'm intolerant and impatient towards those aspects of my personality I don't like.							

The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling how often you felt or thought a certain way.

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
PS1_01. In the last month, how often have you been upset because of something that happened unexpectedly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_02. In the last month, how often have you felt that you were unable to control the important things in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_03. In the last month, how often have you felt nervous and “stressed”?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_04. In the last month, how often have you felt confident about your ability to handle your personal problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_05. In the last month, how often have you felt that things were going your way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_06. In the last month, how often have you found that you could not cope with all the things that you had to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_07. In the last month, how often have you been able to control irritations in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_08. In the last month, how often have you felt that you were on top of things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_09. In the last month, how often have you been angered because of things that were outside of your control?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please indicate how often the following statements apply to you by checking the box that best describes your experience.

**Comment [D1]:** This section (ER1) was moved up in the questionnaire. None of the individual items have changed.

	Almost Never (0-10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_01. I am clear about my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_02. I pay attention to how I feel.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_03. I experience my emotions as overwhelming and out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_04. I have no idea how I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_05. I have difficulty making sense out of my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_06. I am attentive to my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_07. I know exactly how I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_08. I care about what I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_09. I am confused about how I feel.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_10. When I'm upset, I acknowledge my emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_11. When I'm upset, I become angry with myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_12. When I'm upset, I become embarrassed for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never (0-10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_13. When I'm upset, I have difficulty getting work done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_14. When I'm upset, I become out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_15. When I'm upset, I believe that I will remain that way for a long time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_16. When I'm upset, I believe that I will end up feeling very depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_17. When I'm upset, I believe that my feelings are valid and important.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_18. When I'm upset, I have difficulty focusing on other things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_19. When I'm upset, I feel out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_20. When I'm upset, I can still get things done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_21. When I'm upset, I feel ashamed at myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_22. When I'm upset, I know that I can find a way to eventually feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never (0- 10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_23. When I'm upset, I feel like I am weak.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_24. When I'm upset, I feel like I can remain in control of my behaviours.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_25. When I'm upset, I feel guilty for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_26. When I'm upset, I have difficulty concentrating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_27. When I'm upset, I have difficulty controlling my behaviours.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_28. When I'm upset, I believe there is nothing I can do to make myself feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_29. When I'm upset, I become irritated at myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_30. When I'm upset, I start to feel very bad about myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_31. When I'm upset, I believe that wallowing in it is all I can do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_32. When I'm upset, I lose control over my behaviour.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost Never (0- 10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_33. When I'm upset, I have difficulty thinking about anything else.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_34. When I'm upset I take time to figure out what I'm really feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_35. When I'm upset, it takes me a long time to feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_36. When I'm upset, my emotions feel overwhelming.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



This scale is made up of a list of statements each of which may or may not be true about you. For each statement, select “definitely true” if you are sure it is true about you and “probably true” if you think it is true but are not absolutely certain. Similarly, you should select “definitely false” if you are sure the statement is false and “probably false” if you think it is false but are not absolutely certain.

Comment [SF2]: NEW section

	Definitely False	Probably False	Probably True	Definitely True	I do not know	I prefer not to answer
<b>IS1_01</b> If I wanted to go on a trip for a day (for example, to the country or mountains), I would have a hard time finding someone to go with me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_02</b> I feel that there is no one I can share my most private worries and fears with.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_03</b> If I were sick, I could easily find someone to help me with my daily chores.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_04</b> There is someone I can turn to for advice about handling problems with my family.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_05</b> If I decide one afternoon that I would like to go to a movie that evening, I could easily find someone to go with me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_06</b> When I need suggestions on how to deal with a personal problem, I know someone I can turn to.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_07</b> I don't often get invited to do things with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_08</b> If I had to go out of town for a few weeks, it would be difficult to find someone who would look after my house or apartment (the plants, pets, garden, etc.).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_09</b> If I wanted to have lunch with someone, I could easily find someone to join me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	<u>Definitely False</u>	<u>Probably False</u>	<u>Probably True</u>	<u>Definitely True</u>	<u>I do not know</u>	<u>I prefer not to answer</u>
<u>IS1_10 If I was stranded 10 miles from home, there is someone I could call who could come and get me.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_11 If a family crisis arose, it would be difficult to find someone who could give me good advice about how to handle it.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>IS1_12 If I needed some help in moving to a new house or apartment, I would have a hard time finding someone to help me.</u>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please indicate how often each of the statements below is descriptive of you.

**Comment [D3]:** This section (LS1) was moved here. None of the individual items have changed.

**Deleted:** INSTRUCTIONS: I

Statement	Never	Rarely	Sometimes	Often	I Do Not Know	Prefer not to answer
LS1_01. I feel in tune with the people around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	S
LS1_02. I lack companionship	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_03. There is no one I can turn to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_04. I do not feel alone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_05. I feel part of a group of friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_06. I have a lot in common with the people around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_07. I am no longer close to anyone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_08. My interests and ideas are not shared by those around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_09. I am an outgoing person	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_10. There are people I feel close to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_11. I feel left out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_12. My social relationships are superficial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_13. No one really knows me well	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_14. I feel isolated from others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_15. I can find companionship when I want it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_16. There are people who really understand me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_17. I am unhappy being so withdrawn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_18. People are around me but not with me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_19. There are people I can talk to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_20. There are people I can turn to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Below you will find a list of statements. Please indicate how often each statement applies to you generally in daily life.

**Comment [D4]:** The following three sections (IA1, RD1, and CR1) were moved here from later in the survey. None of the individual items have changed.

	0- Never	1	2	3	4	5 - Always
IA1_01. When I am tense I notice where the tension is located in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_02. I notice when I am uncomfortable in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_03. I notice where in my body I am comfortable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_04. I notice changes in my breathing, such as whether it slows down or speeds up.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_05. I do not notice (I ignore) physical tension or discomfort until they become more severe.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_06. I distract myself from sensations of discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_07. When I feel pain or discomfort, I try to power through it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_08. When I feel physical pain, I become upset.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_09. I start to worry that something is wrong if I feel any discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_10. I can notice an unpleasant body sensation without worrying about it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_11. I can pay attention to my breath without being distracted by things happening around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_12. I can maintain awareness of my inner bodily sensations even when there is a lot going on around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_13. When I am in conversation with someone, I can pay attention to my posture.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_14. I can return awareness to my body if I am distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_15. I can refocus my attention from thinking to sensing my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_16. I can maintain awareness of my whole body even when a part of me is in pain or discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_17. I am able to consciously focus on my body as a whole.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_18. I notice how my body changes when I am angry.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_19. When something is wrong in my life I can feel it in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_20. I notice that my body feels different after a peaceful experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_21. I notice that my breathing becomes free and easy when I feel comfortable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_22. I notice how my body changes when I feel happy / joyful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	0- Never	1	2	3	4	5 - Always
IA1_23. When I feel overwhelmed I can find a calm place inside.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_24. When I bring awareness to my body I feel a sense of calm.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_25. I can use my breath to reduce tension.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_26. When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_27. I listen for information from my body about my emotional state.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_28. When I am upset, I take time to explore how my body feels.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_29. I listen to my body to inform me about what to do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_30. I am at home in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_31. I feel my body is a safe place.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_32. I trust my body sensations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

We are interested in your recent experiences. Below is a list of things that people sometimes experience. Next to each item are five choices: “never”, “rarely”, “sometimes”, “often”, and “all the time”. Please choose one of these to indicate how much you currently have experiences similar to those described.

Deleted: darken

Please do not spend too long on each item—it is your first response that we are interested in. Please be sure to answer every item.

	Never	Rarely	Sometimes	Often	All the time
RD1_01. I think about what will happen in the future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_02. I remind myself that thoughts aren't facts.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_03. I am better able to accept myself as I am.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_04. I notice all sorts of little things and details in the world around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_05. I am kinder to myself when things go wrong.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_06. I can slow my thinking at times of stress.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_07. I wonder what kind of person I really am.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_08. I am not so easily carried away by my thoughts and feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_09. I notice that I don't take difficulties so personally.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_10. I can separate myself from my thoughts and feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_11. I analyze why things turn out the way they do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_12. I can take time to respond to difficulties.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_13. I think over and over again about what others have said to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_14. I can treat myself kindly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_15. I can observe unpleasant feelings without being drawn into them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_16. I have the sense that I am fully aware of what is going on around me and inside me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_17. I can actually see that I am not my thoughts.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_18. I am consciously aware of a sense of my body as a whole.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_19. I think about the ways in which I am different from other people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_20. I view things from a wider perspective.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**How do you cope with events?** Everyone gets confronted with negative or unpleasant events now and then and everyone responds to them in his or her own way. By the following questions you are asked to indicate what you generally think, when you experience negative or unpleasant events.

	(Almost) Never	Some- times	Regularly	Often	(Almost) Always
CR1_01. I think that I have to accept that this has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_02. I often think about how I feel about what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_03. I think I can learn something from the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_04. I feel that I am the one who is responsible for what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_05. I think that I have to accept the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_06. I am preoccupied with what I think and feel about what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_07. I think of pleasant things that have nothing to do with it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_08. I think that I can become a stronger person as a result of what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_09. I keep thinking about how terrible it is what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_10. I feel that others are responsible for what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_11. I think of something nice instead of what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_12. I think about how to change the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_13. I think that it hasn't been too bad compared to other things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_14. I think that basically the cause must lie within myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_15. I think about a plan of what I can do best.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_16. I tell myself that there are worse things in life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_17. I continually think how horrible the situation has been.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_18. I feel that basically the cause lies with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Instructions: Below is a collection of statements about your everyday experience. Using the scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what really reflects your experience rather than what you think your experience should be. Please treat each item separately from every other item.

***Please indicate the degree to which you agree with each of the following items using the scale below. Simply check your response to each item***

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never	I do not know	I prefer not to answer
MA1_01. I could be experiencing some emotion and not be conscious of it until some time later.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_02. I break or spill things because of carelessness, not paying attention, or thinking of something else.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_03. I find it difficult to stay focused on what's happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_04. I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_05. I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_06. I forget a person's name almost as soon as I've been told it for the first time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never	I do not know	I prefer not to answer
MA1_07. It seems I am “running on automatic” without much awareness of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_08. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_09. I get so focused on the goal I want to achieve that I lose touch with what I am doing right now to get there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_10. I do jobs or tasks automatically, without being aware of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_11. I find myself listening to someone with one ear, doing something else at the same time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_12. I drive places on “automatic pilot” and then wonder why I went there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_13. I find myself preoccupied with the future or the past.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_14. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_15. I snack without being aware that I’m eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes *your own opinion* of what is *generally true for you*.

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_01. When I'm walking, I deliberately notice the sensations of my body moving.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_02. I'm good at finding words to describe my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_03. I criticize myself for having irrational or inappropriate emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_04. I perceive my feelings and emotions without having to react to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_05. When I do things, my mind wanders off and I'm easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_06. When I take a shower or bath, I stay alert to the sensations of water on my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_07. I can easily put my beliefs, opinions, and expectations into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_08. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_09. I watch my feelings without getting lost in them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_10. I tell myself I shouldn't be feeling the way I'm feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_12. It's hard for me to find the words to describe what I'm thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_13. I am easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_15. I pay attention to sensations, such as the wind in my hair or sun on my face.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_16. I have trouble thinking of the right words to express how I feel about things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_17. I make judgments about whether my thoughts are good or bad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_18. I find it difficult to stay focused on what's happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_21. In difficult situations, I can pause without immediately reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_23. It seems I am "running on automatic" without much aware- ness of what I'm doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_24. When I have distressing thoughts or images, I feel calm soon after.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_25. I tell myself that I shouldn't be thinking the way I'm thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_26. I notice the smells and aromas of things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_27. Even when I'm feeling terribly upset, I can find a way to put it into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_28. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_29. When I have distressing thoughts or images, I am able just to notice them without reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_32. My natural tendency is to put my experiences into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_33. When I have distressing thoughts or images, I just notice them and let them go.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_34. I do jobs or tasks automatically without being aware of what I'm doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_35. When I have distressing thoughts or images, I judge myself as good or bad depending what the thought or image is about.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_36. I pay attention to how my emotions affect my thoughts and behavior.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_37. I can usually describe how I feel at the moment in consider- able detail.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_38. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_39. I disapprove of myself when I have irrational ideas.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### **Parent's Education**

CS1\_01. Please check the box beside the highest grade or degree that your BIOLOGICAL MOTHER completed.

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

CS1\_02. Please check the box beside the highest grade or degree that your BIOLOGICAL FATHER completed.

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

Now please think of the two most important adults in your home between the time you were born and age 18 years. Please check the category below that best described their level of education during this time period.

Deleted: level

CS1\_03. First adult's highest level of education:

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

CS1\_04. Second adult's highest level of education

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

## **Your Childhood Experiences**

The following questions ask about some difficult experiences that you might have had as a child. These questions may be emotionally difficult to answer. Just as a reminder, you do not need answer any questions that you would prefer not to. Your answers to these questions, as with all questions, will remain confidential.

CE1\_01. Before you were 18 years old, did a parent or other adult in the household often or very often...

Swear at you, insult you, put you down, or humiliate you?

or

Act in a way that made you afraid that you might be physically hurt?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_02. Before you were 18 years old, did a parent or other adult in the household often or very often...

Push, grab, slap, or throw something at you?

or

Ever hit you so hard that you had marks or were injured?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_03. Before you were 18 years old, did an adult or person at least 5 years older than you ever...

Touch or fondle you or have you touch their body in a sexual way?

or

Attempt or actually have oral, anal, or vaginal intercourse with you?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_04. Before you were 18 years old, did you often or very often feel that ...

No one in your family loved you or thought you were important or special?

or

Your family didn't look out for each other, feel close to each other, or support each other?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_05. Before you were 18 years old, did you often or very often feel that ...

You didn't have enough to eat, had to wear dirty clothes, and had no one to protect you?

or

Your parents were too drunk or high to take care of you or take you to the doctor if you needed it?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_06. Before you were 18 years old, was a biological parent ever lost to you through divorce, abandonment, or other reason?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_07. Before you were 18 years old, was your mother or stepmother:

Often or very often pushed, grabbed, slapped, or had something thrown at her?

or

Sometimes, often, or very often kicked, bitten, hit with a fist, or hit with something hard?

or

Ever repeatedly hit over at least a few minutes or threatened with a gun or knife?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer



CE1\_08. Before you were 18 years old, did you live with anyone who was a problem drinker or alcoholic, or who used street drugs?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_09. Before you were 18 years old, was a household member depressed or mentally ill, or did a household member attempt suicide?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_10. Before you were 18 years old, did a household member go to prison?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

**Deleted:** SN1\_01. . How many close friends do you have? By close friends, we mean people that you feel at ease with, and that you can talk to about private matters.¶

¶ ☐ None → *skip to Y2* ¶

¶ . . . Number of close friends ¶

¶ ☐ I do not know ¶

¶ ☐ I prefer not to answer ¶

¶ . . SN1\_01a. How many of these close friends do you see at least once a month? . . ¶

¶ . . . . . Number of close friends (*if none, write zero*) ¶

¶ ☐ I do not know ¶

¶ ☐ I prefer not to answer ¶

¶ SN1\_02. Thinking about your relatives, how many relatives do you feel at ease with, and feel that . . you can talk to about private matters? ¶

¶ ☐ None → *skip to Y3* ¶

¶ . . . Number of relatives ¶

¶ ☐ I do not know ¶

¶ ☐ I prefer not to answer ¶

¶ . . SN1\_02a. How many of these relatives do you see at least once a month? . . ¶

¶ . . . . . Number of relatives (*if none, write zero*) ¶

¶ ☐ I do not know ¶

¶ ☐ I prefer not to answer ¶

¶ SN1\_03. . About how often do you participate in groups or clubs, such as religious connected groups, self-help groups, charities, or a public service or community group.¶

¶ ☐ Never or almost never¶

¶ ☐ A few times a year¶

¶ ☐ Once or twice a month¶

¶ ☐ Once a week¶

¶ ☐ More than once a week¶

¶ ☐ I do not know ¶

¶ ☐ I prefer not to answer ¶

¶ SN1\_04. . About how often do you go to religious meetings or services? ¶

¶ ☐ Never or almost never¶

¶ ☐ A few times a year¶

¶ ☐ Once or twice a month¶

¶ ☐ Once a week¶

¶ ☐ More than once a week¶

... [2]

## Blood Pressure Medication Use

BM1\_01. Do you currently take medication for your blood pressure?

☐ Yes

☐ No (if responding “no”, please skip to the next page).

	<u>Yes</u>	<u>No</u>
BM1_02. Do you sometimes forget to take your blood pressure pills?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_03. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_04. Have you ever cut back or stopped taking your blood pressure medicine without telling your doctor because you felt worse when you took it?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_05. When you travel or leave home, do you sometimes forget to bring along your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_06. Did you take all your blood pressure medicine yesterday?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_07. When you feel like your symptoms are under control, do you sometimes stop taking your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_08. Taking blood pressure medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	<input type="checkbox"/>	<input type="checkbox"/>

BM1\_09. How often do you have difficulty remembering to take all your blood pressure medicine?

☐ Never/rarely

☐ Once in a while

☐ Sometimes

☐ Usually

☐ All the time

## More About You

Below are some modifiable factors that likely influence blood pressure. These may not all apply to you, as you may already have excellent levels of these factors.

### Physical activity:

The United States Office of Disease Prevention and Health Promotion 2008 Physical Activity Guidelines for Americans states that “Most health benefits occur with at least 150 minutes (2 hours and 30 minutes) a week of moderate intensity physical activity, such as brisk walking. Additional benefits occur with more physical activity. Both aerobic (endurance) and muscle-strengthening (resistance) physical activity are beneficial.”

RC1\_01. How motivated are you to make changes to your physical activity, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

Little intention of changing			Mixed feelings towards taking action				Motivated to take action		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_02. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your physical activity?

Not confident			Moderately confident				Confident		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Diet:

The Dietary Approaches to Stop Hypertension (DASH) diet eating plan is a diet rich in fruits, vegetables, low fat or nonfat dairy. It also includes mostly whole grains; lean meats, fish and poultry; nuts and beans. It is high fiber and low to moderate in fat. It is a plan that follows US guidelines for sodium content, along with vitamins and minerals. It can be considered to be an Americanized version of the Mediterranean diet.

RC1\_03. How motivated are you to make changes to your diet to be consistent with the DASH diet, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

Little intention of changing			Mixed feelings towards taking action				Motivated to take action		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_04. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your diet to be more consistent with the DASH diet?

Not confident			Moderately confident				Confident		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Comment [SF6]:** New Section – readiness to change

### Salt Intake:

The 2010 Dietary Guidelines for Americans recommend that everyone age 2 years and up should consume less than 2,300 milligrams (mg) of sodium each day. Some groups of people should further limit sodium intake to 1,500 mg per day, including:

- Adults age 51 years or older.
- All African Americans.
- Anyone who has high blood pressure, diabetes, or chronic kidney disease.

RC1\_05. How motivated are you to make changes to your salt intake, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

<u>Little intention of changing</u>			<u>Mixed feelings towards taking action</u>				<u>Motivated to take action</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_06. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your salt intake?

<u>Not confident</u>			<u>Moderately confident</u>				<u>Confident</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Overweight/Obesity:

Extensive scientific evidence shows that being overweight or obese increases risk of having high blood pressure.

RC1\_07. How motivated are you to make changes to your body weight, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

<u>Little intention of changing</u>			<u>Mixed feelings towards taking action</u>				<u>Motivated to take action</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_08. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your body weight?

<u>Not confident</u>			<u>Moderately confident</u>				<u>Confident</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Stress, and Stress Response:

Several studies showed that stress, and being slower at emotionally recovering from stressful events, increase risk of hypertension.

RC1\_09. How motivated are you to make changes to the amount of stress in your life, or your response to that stress, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

<u>Little intention of changing</u>			<u>Mixed feelings towards taking action</u>				<u>Motivated to take action</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_10. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in the amount of stress in your life, or your response to that stress?

<u>Not confident</u>			<u>Moderately confident</u>				<u>Confident</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Alcohol Consumption:

Heavy and regular use of alcohol can increase blood pressure substantially. The American Heart Association recommends limiting alcohol consumption to no more than two drinks per day for men and one drink per day for women.

RC1\_11. How motivated are you to make changes to the amount of alcohol you consume, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

<u>Little intention of changing</u>			<u>Mixed feelings towards taking action</u>				<u>Motivated to take action</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_12. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in the amount of alcohol you consume?

<u>Not confident</u>			<u>Moderately confident</u>				<u>Confident</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Blood Pressure (Antihypertensive) Medication Use:**

Blood pressure medication has been shown in many studies to be very effective at lowering blood pressure.

RC1 13. How motivated are you to make changes to your blood pressure medication use, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

<u>Little intention of changing</u>			<u>Mixed feelings towards taking action</u>				<u>Motivated to take action</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1 14. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes your blood pressure medication use?

<u>Not confident</u>			<u>Moderately confident</u>				<u>Confident</u>		
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Family History of Hypertension

Comment [SF7]: New section

FH1\_01. Did your biological mother ever have hypertension?

- ☐ No  
☐ Yes  
☐ I do not know  
☐ I prefer not to answer

FH1\_02. Did your biological father ever have hypertension?

- ☐ No  
☐ Yes  
☐ I do not know  
☐ I prefer not to answer

FH1\_03. How many full brothers and sisters do you have (*Please include any brothers or sisters who may have died, but do not include half or step brothers and sisters*).

- ☐ I do not have any brothers or sisters → *Skip to the page*  
\_\_\_\_\_ brothers, \_\_\_\_\_ sisters  
☐ I do not know  
☐ I prefer not to answer

FH1\_04. Of these brothers and sisters, how many have ever had hypertension?

- \_\_\_\_\_ (*if none, write 0*)  
☐ I do not know  
☐ I prefer not to answer

## **Your Sleep**

The following question relates to your usual sleep habits during the past month only. Your answer should indicate the most accurate reply for the majority of days and nights in the past month.

SL1\_04. **During the past month**, how many hours of actual sleep did you get on average at night? (This may be different than the number of hours you spent in bed.)

AVERAGE HOURS OF SL1\_EEP PER NIGHT \_\_\_\_\_

- ☐ I do not know  
☐ I prefer not to answer

## **END SCRIPT**

Thank you for completing this survey!

Please note that these responses will not be seen immediately. Resources are shown below if you feel that you would like to talk with someone immediately for assistance.

National Suicide Prevention Lifeline: 1-800-273-8255

National Sexual Assault Hotline: 1-800-656-4673

Other options are to:

- Call your doctor's office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

**Comment [D8]:** This section (Sleep) was moved to the end of the survey. Several of the items were dropped to reduce participant burden.

**Deleted:** For each of the remaining questions, check the one best response. Please answer all questions.¶

¶ **During the past month**, how often have you had trouble sleeping because you.....¶

¶ SL1\_05. ....Could not get to sleep within 30 minutes?¶

- ☐ Not during the past month¶  
☐ Less than once a week ¶  
☐ Once or twice a week¶  
☐ Three or more times a week ¶  
☐ I do not know¶  
☐ I prefer not to answer¶

¶ SL1\_06. ....Woke up in the middle of the night or early morning?¶

- ☐ Not during the past month¶  
☐ Less than once a week ¶  
☐ Once or twice a week¶  
☐ Three or more times a week ¶  
☐ I do not know¶  
☐ I prefer not to answer ¶

¶ SL1\_07. ....Had to get up to use the bathroom?¶

- ☐ Not during the past month¶  
☐ Less than once a week ¶  
☐ Once or twice a week¶  
☐ Three or more times a week ¶  
☐ I do not know¶  
☐ I prefer not to answer ¶

¶ SL1\_08. ....Could not breathe comfortably?¶

- ☐ Not during the past month¶  
☐ Less than once a week ¶  
☐ Once or twice a week¶  
☐ Three or more times a week ¶  
☐ I do not know¶  
☐ I prefer not to answer ¶

... [3]

**Deleted:** SL1\_16. **During the past month**, how often have you taken medicine to help you sleep (prescribed or "over the counter")?¶

- ☐ Not during the past month¶  
☐ Less than once a week ¶  
☐ Once or twice a week¶  
☐ Three or more times a week ¶  
☐ I do not know¶  
☐ I prefer not to answer ¶

¶ SL1\_17. **During the past month**, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?¶

- ☐ Not during the past month¶  
☐ Less than once a week ¶  
☐ Once or twice a week¶  
☐ Three or more times a week ¶  
☐ I do not know¶  
☐ I prefer not to answer ¶

... [4]



**How Often You Eat or Drink This Item**

[illegible]

### How Often You Eat or Drink This Item

[illegible]

## How Often You Eat or Drink This Item

[illegible]

### How Often You Eat or Drink This Item

	Never or less than 1 per month	1-3 per month	1 per week	2-4 per week	5-6 per week	1 per day	2-3 per day	4-5 per day	More than 5 per day	I do not know	I prefer not to answer
<b>DT1_24.</b> Regular soft drinks (including caffeine free, but NOT including diet colas) (consider the serving size as 1 glass, bottle or can)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>DT1_25.</b> Coffee (regular or decaf) (1 cup)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Page 41: [2] Deleted**

**Saadeh, Frances**

**10/28/2015 11:57:00 AM**

SN1\_01. How many close friends do you have? By close friends, we mean people that you feel at ease with, and that you can talk to about private matters.

☐ None → *skip to Y2*

\_\_\_\_\_ Number of close friends

☐ I do not know

☐ I prefer not to answer

SN1\_01a. How many of these close friends do you see at least once a month?

\_\_\_\_\_ Number of close friends (*if none, write zero*)

☐ I do not know

☐ I prefer not to answer

SN1\_02. Thinking about your relatives, how many relatives do you feel at ease with, and feel that you can talk to about private matters?

☐ None → *skip to Y3*

\_\_\_\_\_ Number of relatives

☐ I do not know

☐ I prefer not to answer

SN1\_02a. How many of these relatives do you see at least once a month?

\_\_\_\_\_ Number of relatives (*if none, write zero*)

- ☐ I do not know
- ☐ I prefer not to answer

SN1\_03. About how often do you participate in groups or clubs, such as religious connected groups, self-help groups, charities, or a public service or community group.

- ☐ Never or almost never
- ☐ A few times a year
- ☐ Once or twice a month
- ☐ Once a week
- ☐ More than once a week
- ☐ I do not know
- ☐ I prefer not to answer

SN1\_04. About how often do you go to religious meetings or services?

- ☐ Never or almost never
- ☐ A few times a year
- ☐ Once or twice a month
- ☐ Once a week
- ☐ More than once a week
- ☐ I do not know
- ☐ I prefer not to answer

*For each of the remaining questions, check the one best response. Please answer all questions.*

**During the past month**, how often have you had trouble sleeping because you.....

SL1\_05. ....Could not get to sleep within 30 minutes?

- ☐ Not during the past month

- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_06. ....Woke up in the middle of the night or early morning?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_07. ....Had to get up to use the bathroom?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_08. ....Could not breathe comfortably?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_09. ....Coughed or snored loudly?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know

☐ I prefer not to answer

SL1\_10. ....Felt too cold?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_11. ....Felt too hot?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_12. ....Had bad dreams?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_13. ....Had pain?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_14a. Other reason(s), **please describe:** \_\_\_\_\_

SL1\_14b. How often during the past month have you had trouble sleeping because of this?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_16. **During the past month**, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_17. **During the past month**, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ I do not know
- ☐ I prefer not to answer

SL1\_18. **During the past month**, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

- ☐ No problem at all
- ☐ Somewhat of a problem
- ☐ A very big problem
- ☐ I do not know
- ☐ I prefer not to answer



SL1\_19. Do you have a bed partner or a room-mate in the same room ?

- ☐ No bed partner or roommate in the same room → *skip to next survey section:*
- ☐ Partner in same bed
  - ☐ Room-mate in the same room
  - ☐ I do not know
  - ☐ I prefer not to answer

If you have a roommate or bed partner, ask him/her how often in the past month you have had .....

SL1\_20. ....Loud snoring

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

SL1\_21. ....Long pauses between breaths while asleep

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

SL1\_22. ....Legs twitching or jerking while you sleep

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

SL1\_23. ....Episodes of disorientation or confusion during sleep

- ☐ Not during the past month
- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

SL1\_24a. ....Other restlessness while you sleep; ***please describe:***

---

SL1\_24b.    ☐ Not during the past month

- ☐ Less than once a week
- ☐ Once or twice a week
- ☐ Three or more times a week
- ☐ Unable to ask him/her
- ☐ he/she does not know
- ☐ he/she prefers not to answer

**Brown University**  
Research Protections Office  
Institutional Review Board  
**Modification Request**

**Date of Request:** 2/26/16 **Investigator's Name and Title:** Eric Loucks, PhD, Assistant Professor

**Study Title:** Mindfulness-based Hypertension Therapy Pilot Study (#1412001171)

**Original Type of Review:** ☐ Exempt ☐ Expedited ☒ Full Board

- 1) Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project. (Attach summary to this form)**

See attached summary

- 2) Provide a detailed description of the changes being requested (Use additional pages, if necessary):**

We are requesting permission to allow study participants the option to participate in the MBHT Intervention (i.e., 9-week MBHT course) via online video conferencing tool (e.g., Skype, Zoom, etc.) in situations when they are not able to attend class in-person.

- 3.) State the reason (justification) for the requested modification. (Use additional pages, if necessary):**

We would like to be able to allow participants, who are not able to physically come to the study site on a given day (a maximum of 2 classes), the option to participate in the study intervention via online video conferencing tool (e.g., Skype, Zoom, etc.). None of the video footage would be recorded and participation via video conferencing would be optional. Video conferencing would only take place with video software that establishes unique connections, such as via Skype names, or Zoom conference call ID numbers. This disallows anyone to join the call other than those who are specifically invited by the study staff. Study participants who choose to decline this option would still be allowed to continue with the broader study.

- 4.) What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

We do not anticipate this amendment will greatly affect the overall risk/benefit ratio of the study. If anything, it will allow participants additional flexibility in how they participate and will potentially reduce the number of classes missed, thus allowing participants, who otherwise might have missed classes, to get more out of the course.

- 5.) Does the requested modification require new documents or changes to the approved consent form or other documents?**

- ☐ Consent/assent documents (attach revised version with changes highlighted)  
☐ New/revised instruments (attach - if revised, highlight changes)

☐ New/revised advertising materials (attach - if revised, highlight changes)

Do you have a conflict of interest on this project according to Brown's policy? ☐ YES ☒ NO

If YES, has this conflict been previously disclosed to the IRB? ☐ YES ☐ NO

PI signature: \_\_\_\_\_



Date: \_\_\_\_\_

2/26/16

Date of IRB Review: \_\_\_\_\_

IRB

Determination: \_\_\_\_\_

Signature of IRB Chair or Designate \_\_\_\_\_

**1. Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project.**

The World Health Organization reported that suboptimal blood pressure (BP) is responsible for more than half of cardiovascular disease mortality world-wide. Furthermore, greater than half of those with hypertension have uncontrolled BP. A 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.” Evidence-based mindfulness interventions, including Mindfulness-Based Stress Reduction, may have some effects on blood pressure, where a recent meta-analysis and systematic review of 4 randomized controlled trials demonstrated significant effects, but evidence of heterogeneity in effect sizes. The methodologically highest quality studies had the smallest effect sizes (range 0-5 mmHg). Mindfulness-Based Stress Reduction (MBSR) has been customized to a number of disease processes, such as Mindfulness-Based Cognitive Therapy for patients with recurrent depression, and Mindfulness-Based Relapse Prevention for patients with substance use addictions. Effect sizes have been increased by customizing mindfulness interventions to diseases of interest. The same may be true for hypertension, however mindfulness interventions customized for prehypertensive/hypertensive patients have never been investigated. Until methodologically rigorous studies to evaluate customized interventions for hypertension are performed, we will not know if the observed preliminary effects of general mindfulness interventions on blood pressure reduction could be much more effective with a tailored approach. Consequently, we propose to conduct a stage I behavioral therapy intervention study to evaluate whether MBSR customized to prehypertensive and hypertensive patients has the potential to provide clinically relevant reductions in BP. Consequently the specific aims are:

**Stage 1a: Therapy Development/Manual Writing**

1. To outline and evaluate key novel elements of mindfulness-based hypertension therapy (MBHT), customized from the evidence-based MBSR. *We hypothesize that the most important novel element will be generation of mindfulness skills specifically applied to hypertension risk factors such as diet, physical activity, obesity, alcohol consumption and antihypertensive medication adherence.* This aim will be achieved using (1) focus groups of participants undergoing the MBHT behavioral intervention, (2) discussion with experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) prior to, and following pilot testing of MBHT in participants, and (3) clinical judgment of the investigators performing the intervention.
2. To determine effectiveness of MBHT on primary outcomes (systolic blood pressure, retention rates, recruitment rates, and adverse effects) and secondary outcomes (hypertension risk factors such as diet, physical activity, obesity, and antihypertensive medication adherence) in hypertension subgroups, specifically participants with (1) prehypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. Initial decisions about the targeted sample based on hypertension status will be made.
3. To develop an MBHT therapist manual and training program, including procedures for training, supervising, and evaluating therapists. Furthermore, acceptable therapist characteristics will be developed. The manual and training program will include themes such as specification of unique and common elements of MBHT vs. other interventions, description of interventions excluded from MBHT, and specification of key treatment parameters such as frequency and duration of treatment, session length, topics addressed, sequence of sessions, as well as therapist adherence and competency

measures. The MBHT training will consist of a therapist manual, a formal didactic training seminar, and at least one closely supervised training session.

*Stage Ib: Pilot Trial*

4. To determine whether a mindfulness-based hypertension therapy (MBHT) intervention, customized from the evidence-based MBSR, has promise to be an effective behavioral therapy for participants with hypertension and/or prehypertension. We will perform a randomized controlled pilot trial for MBHT vs. enhanced usual care control. *We hypothesize that MBHT will have adequate recruitment rates ( $\geq 10\%$  of prehypertensive/hypertensive participants invited from physicians' offices), fairly low drop out rates ( $< 15\%$ ), and medium effect sizes (e.g. 5-10 mmHg systolic BP) for reduction in blood pressure.*

These findings will provide publishable pilot data that will inform future randomized clinical trials that evaluate effects of MBHT on long-term changes in blood pressure vs. usual care and active control groups. *If proven effective, MBHT could be offered as a complementary program in the prehypertensive/hypertensive patient population that contributes to over half of the cardiovascular disease mortality world-wide.*

**Brown University**  
Research Protections Office  
Institutional Review Board  
**Modification Request**

**Date of Request:** 4/25/16   **Investigator's Name and Title:** Eric Loucks, PhD, Assistant Professor  
**Study Title:** Mindfulness-based Hypertension Therapy Pilot Study (#1412001171)

**Original Type of Review:**      ☐ Exempt                      ☐ Expedited                      ☒ Full Board

- 1) **Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project.** (Attach summary to this form)

See attached summary

- 2) **Provide a detailed description of the changes being requested** (Use additional pages, if necessary):

See attached summary

- 3.) **State the reason (justification) for the requested modification.** (Use additional pages, if necessary):

See attached summary

- 4.) **What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

See attached summary

- 5.) **Does the requested modification require new documents or changes to the approved consent form or other documents?**

☐ Consent/assent documents (attach revised version with changes highlighted)

☒ New/revised instruments (attach - if revised, highlight changes)

☒ New/revised advertising materials (attach - if revised, highlight changes)

**Do you have a conflict of interest on this project according to Brown's policy?**   ☐ YES   ☒ NO

**If YES, has this conflict been previously disclosed to the IRB?**                      ☐ YES   ☐ NO

PI signature: \_\_\_\_\_



Date: 4/25/16

**1. Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project.**

The World Health Organization reported that suboptimal blood pressure (BP) is responsible for more than half of cardiovascular disease mortality world-wide. Furthermore, greater than half of those with hypertension have uncontrolled BP. A 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.” Evidence-based mindfulness interventions, including Mindfulness-Based Stress Reduction, may have some effects on blood pressure, where a recent meta-analysis and systematic review of 4 randomized controlled trials demonstrated significant effects, but evidence of heterogeneity in effect sizes. The methodologically highest quality studies had the smallest effect sizes (range 0-5 mmHg). Mindfulness-Based Stress Reduction (MBSR) has been customized to a number of disease processes, such as Mindfulness-Based Cognitive Therapy for patients with recurrent depression, and Mindfulness-Based Relapse Prevention for patients with substance use addictions. Effect sizes have been increased by customizing mindfulness interventions to diseases of interest. The same may be true for hypertension, however mindfulness interventions customized for prehypertensive/hypertensive patients have never been investigated. Until methodologically rigorous studies to evaluate customized interventions for hypertension are performed, we will not know if the observed preliminary effects of general mindfulness interventions on blood pressure reduction could be much more effective with a tailored approach. Consequently, we propose to conduct a stage I behavioral therapy intervention study to evaluate whether MBSR customized to prehypertensive and hypertensive patients has the potential to provide clinically relevant reductions in BP. Consequently the specific aims are:

**Stage 1a: Therapy Development/Manual Writing**

1. To outline and evaluate key novel elements of mindfulness-based hypertension therapy (MBHT), customized from the evidence-based MBSR. *We hypothesize that the most important novel element will be generation of mindfulness skills specifically applied to hypertension risk factors such as diet, physical activity, obesity, alcohol consumption and antihypertensive medication adherence.* This aim will be achieved using (1) focus groups of participants undergoing the MBHT behavioral intervention, (2) discussion with experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) prior to, and following pilot testing of MBHT in participants, and (3) clinical judgment of the investigators performing the intervention.
2. To determine effectiveness of MBHT on primary outcomes (systolic blood pressure, retention rates, recruitment rates, and adverse effects) and secondary outcomes (hypertension risk factors such as diet, physical activity, obesity, and antihypertensive medication adherence) in hypertension subgroups, specifically participants with (1) prehypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. Initial decisions about the targeted sample based on hypertension status will be made.
3. To develop an MBHT therapist manual and training program, including procedures for training, supervising, and evaluating therapists. Furthermore, acceptable therapist characteristics will be developed. The manual and training program will include themes such as specification of unique and common elements of MBHT vs. other interventions, description of interventions excluded from MBHT, and specification of key treatment parameters such as frequency and duration of treatment, session length, topics addressed, sequence of sessions, as well as therapist adherence and competency



measures. The MBHT training will consist of a therapist manual, a formal didactic training seminar, and at least one closely supervised training session.

*Stage Ib: Pilot Trial*

4. To determine whether a mindfulness-based hypertension therapy (MBHT) intervention, customized from the evidence-based MBSR, has promise to be an effective behavioral therapy for participants with hypertension and/or prehypertension. We will perform a randomized controlled pilot trial for MBHT vs. enhanced usual care control. *We hypothesize that MBHT will have adequate recruitment rates ( $\geq 10\%$  of prehypertensive/hypertensive participants invited from physicians' offices), fairly low drop out rates ( $< 15\%$ ), and medium effect sizes (e.g. 5-10 mmHg systolic BP) for reduction in blood pressure.*

These findings will provide publishable pilot data that will inform future randomized clinical trials that evaluate effects of MBHT on long-term changes in blood pressure vs. usual care and active control groups. *If proven effective, MBHT could be offered as a complementary program in the prehypertensive/hypertensive patient population that contributes to over half of the cardiovascular disease mortality world-wide.*

## 2. Provide a detailed description of the changes being requested (Use additional pages, if necessary):

We would like to update the IRB on the following changes made to the overall study protocol, recruitment materials, and participant assessments...

- **Change in Study Name** – We have changed the study name from: “*The Mindfulness-based Hypertension Therapy Pilot Study (MBHT)*” to “*The Mindfulness-Based Blood Pressure Reduction Study (MB-BP)*”. The rationale behind this change is that the original study title was not completely accurate since the program is not exactly “therapy”, as much as it is a tailored intervention to see if participant’s blood pressure can be reduced over time. The revision also reflects the fact that we are not only recruiting individuals with hypertension but those with prehypertension as well.
- **Revised NCCIH Safety Monitoring Protocol** – the formal Safety Monitoring Protocol submitted to the NCCIH (a division of the NIH) was revised back on November 26, 2015. We have attached the updated version 1.3 here to be included as part of the study protocol (see Appendix 1). Under the NIH Safety Monitoring Protocol, we are required to check in with study participants regularly (at four week intervals) to assess if they have sustained any physical injuries. Please see p.9-10 of Appendix 1 for complete details on this process. We have copied and pasted the most relevant text below.

Monitoring of Physical Injuries: All patients will be monitored by study staff at weekly intervals in person or by telephone and assessed every four weeks with questionnaires about physical injuries, specifically the following questions:

1. Have you sustained any physical injuries during the past four weeks?

If yes,

- (a) Please describe the injury.
- (b) Please describe what happened to cause the injury.
- (c) Did this injury include:
  - i. Broken bone(s)? yes/no
  - ii. Lacerations requiring stitches? yes/no
  - iii. Concussion? yes/no

If injuries include any of the above (i – iii), it will be reported to Data Safety Monitoring Committee member Dr. Hank Wu, MD, who is a practicing physician and researcher. He will advise on any follow-up needed. It will also be reported to the chair of the Data Safety Monitoring Board.

- **Baseline and Follow up Assessments (split into two visits)** – Instead of having participants come into the office once for their baseline and follow up assessments, we would like to have them come in on two separate occasions at about one week apart. The reason behind this request is two-fold. First, participants will be asked to wear a Fitbit device, which will monitor their physical activity and sleep. The device will be worn for one week and will need to be returned to the office at the end of the week in order for the data to be synced and uploaded.

By having participants return to the office, it will ensure that the Fitbit tracker is returned and that the data are properly uploaded. The second reason for the return visit will be to allow the participant time to meet with the course instructor. This one-on-one meeting is already part of the mindfulness intervention. It is important to note that, apart from participant travel to and from the office, we are not adding any additional time to the length of the baseline and follow up assessments but rather the assessment content has been divided across two separate visits. If a participant indicates that he/she is unable to come into the office for the second visit, we can allow the participant the option of mailing his/her Fitbit tracker back to the office with a prepaid envelope.

- **Change in Data Collection Mode for Daily Practice Forms and other Class questionnaires** – we would like to change the mode of administration by which our mindfulness-course practice forms and questionnaires are able to be completed by participants. Currently, participants are asked to complete these forms on paper. Moving forward we would like to allow participants the option to complete the course assignments online in Qualtrics. We would still allow participants the option to complete on paper if preferred.
- **Revised Study Recruitment Materials and Protocol** – we have made revisions to our study advertisement material and protocol. Below are details regarding these changes:

Revised Flyers and Advertisement Cards – we have revised our study advertisement card and flyer. See Appendix 2 for revisions noted with track changes. Note that the content of both the card and the flyer are the same, but that the print format is different (Appendix 3 contains a clean version of each). A summary of the changes as well as the justification for the revisions are below:

Per feedback from a Graphic Designer at RISD, we have made the following modifications to our study advertisement materials: (1) Moved "Research Study" from title to explanatory paragraph to make more visually appealing. (2) Changed study phone number from PI's personal cell phone to a study cell phone paid for by the grant and indicated that texting as well as calling is permissible. (3) Modified the descriptive language used to describe the study so that it is easier to read and is more specific and accurate.

Facebook Page and Advertisements – we have created a study Facebook page and would like to begin using Facebook to recruit for the study. See Appendix 4 for screenshots from the study page. Note that we will wait for IRB approval before making this page public.

Twitter Page – we have created a study twitter page, on which we can tweet about upcoming events (e.g., mindfulness courses). See Appendix 5 for a screenshots of our twitter account page (that can be made public once IRB approval has been received).

Craigslist Advertisement – see Appendix 6 for craigslist advertisement content. Note that the content is the same as that used for the advertisement cards.

- **NEW Study Webpage** – we have created two new MB-BP study webpages, which are found on the broader Mindfulness and Cardiovascular Health Lab websites. The Mindfulness and Cardiovascular Health Lab is located at the Brown University School of Public Health's Center for Population Health and Clinical Epidemiology and is directed by Dr. Eric Loucks. There are two websites for the Mindfulness and Cardiovascular Health Lab. One is hosted through Brown's domain and the other through an external website platform known as Weebly. The MB-BP study is featured on both websites. See Appendix 7 for screenshots and content from each of the websites. Note that these websites will not be publically launched until IRB approval has been received.

Website URL's are below:

*Brown University Site:* <https://www.brown.edu/research/projects/blood-pressure-reduction/home>

*Weebly webpage:* <http://mindfulnesscvlab.weebly.com/>

**Revisions to the in-class worksheets and assessments** – the following revisions have been made to the mindfulness course worksheets / assignments:

*Weeks 4 and 5: Goal Related to Diet, Alcohol Consumption, Physical Activity, or Stress Reaction/Response (v.1.1, Appendix 8)* – there were errors in the question variable names found in the tables on p.3-5. This was likely due to a cut and paste error. This has since been corrected. We have included a track changed version of Week 4 (Appendix 7). Week 5 is the same exact questions, so we did not include that version here. We can send upon request.

**MB-BP Questionnaire Revisions** - we have made changes to several of the individual assessments. See below for details as well as Appendices 9-12 for revised assessments with track changes)

Phone Screener: (v.1.5, See Appendix 9)

- Modified the language slightly to improve survey flow, ease of administration and to be more clear and concise about study involvement.
- For other revisions - see individual comments in attached screener document for detailed rationale on revisions

In-Person Screening: (v.1.5, See Appendix 10)

- Added in the Blood Pressure Safety Protocol, which is also reported to the NCCIH as part of the Data Safety Monitoring Plan.
- For other revisions - see individual comments in attached in-person screener document for detailed rationale on revisions

In-Person Baseline Assessment (v.1.5, See Appendix 11)

- Added in the Blood Pressure Safety Protocol, which is also reported to the NCCIH as part of the Data Safety Monitoring Plan.
- To reduce participant burden we have dropped several of the variables collected on the Food Frequency Questionnaire. See marked up FFQ found within Appendix 10 for details on variables dropped.

- We switched the order of administration for the ANT and SART. The SART is a better measure of attention, so it is important that it is completed first, in case the first measure has an effect on the outcome of the second measure completed.
- For other revisions - see individual comments in attached in-person baseline assessment for detailed rationale on revisions

Home Baseline Assessment: (v.1.5, See Appendix 12) - The only revision to this assessment is the addition of a scale known as the “self-efficacy for managing chronic disease questionnaire”. See the track changes document for details.

Follow-Up Assessments – Follow-up assessments will take place at 10 weeks, 6 months, and 1 year post baseline. The follow-up assessments will be identical to those administered at baseline (Home and In-Person), with the exception that any variables that are not expected to change over time (e.g., race-ethnicity), will be removed in order to reduce participant burden. We have listed the question items below that will NOT be included in the follow up assessments. The only additional measure during follow-up assessments is recording the amount of formal and informal mindfulness practices that participants are doing (see Appendix 13).

**In-Person Assessment** – The in-person assessment used at baseline will be the same assessment used for all of the follow-ups.

**Home Assessment** – The variables found in the Home Baseline Questionnaire that will NOT be included in the follow up assessments are:

PG1_01-03	Personal goals
BQ1_01-03	Age, Race and Ethnicity
BQ1_05-08	Education, degree earned, technical/vocation schooling
CS1_01-04	Parents’ education
CE1_01-10	Childhood experiences
FH1_01-04	Family history of hypertension

**Measurement of Mindfulness Practices** – see Appendix 13 for questions that will be asked during the follow up assessments in order to record the amount of formal and informal mindfulness practices that participants are doing:

### 3. State the reason (justification) for the requested amendment:

Please see justifications in Section 2 above.

#### **4. What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

The changes we have made in this amendment affect the risk/benefit ratio in small ways, and if anything, we anticipate the revisions will decrease participant burden. We modified the study name to be more concise about the purpose of the study. We moved around some of the questions in an attempt to improve the overall survey flow and spread out the overall time/effort burden on participants. And although some new question items have been added to the assessments, we have also removed some items. We estimate, that the overall assessment time has not changed.

The revisions to the formalized Safety Monitoring protocol help reduce participant risk by predicting potential areas of concern and by outlining clear procedures with how to manage incidents that may come up.

#### **5. Does the requested amendment require new documents or changes to the approved consent form or other documents?**

Yes. Please see **Appendices 1-13**.

Appendix 1	NCCIH Safety Monitoring Protocol (v.1.3)
Appendix 2	Revised MB-BP Recruitment Card – <i>with track changes</i>
Appendix 3	Revised MB-BP Recruitment Card and Flyer – <i>clean copy</i>
Appendix 4	MB-BP Study Facebook page screenshots
Appendix 5	MB-BP Study Twitter account screenshots
Appendix 6	MB-BP Study Craigslist advertisement screenshots
Appendix 7	MB-BP Study webpage screenshots
Appendix 8	Week 4: Goal Related to Diet, Alcohol Consumption, Physical Activity, or Stress Reaction/Response (v.1.1) – <i>with track changes</i>
Appendix 9	Phone Screener (v.1.5) – <i>with track changes</i>
Appendix 10	In-person Screener (v.1.5) – <i>with track changes</i>
Appendix 11	In-Person Baseline Assessment (v.1.5) – <i>with track changes</i>
Appendix 12	Home Baseline Assessment (v.1.5) – <i>with track changes</i>
Appendix 13	Measurement of formal and informal mindfulness practice at time of follow ups - NEW

## **References**

<sup>1</sup> Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care. 1986;24 (1):67-74.

# **Appendix 1:**

## **Safety Monitoring Protocol**

*(Formal protocol submitted to the NCCIH – revised on November 26, 2015)*

# PROTECTION OF HUMAN SUBJECTS

## MINDFULNESS-BASED HYPERTENSION THERAPY

NIH Grant #: 1UH2AT009145-01

### 1. Risks to Human Subjects

#### 1.1 Human Subjects Involvement, Characteristics, and Design

##### 1.1.1 Involvement:

Participants will be recruited in part through cardiology and family practices via established relationships with physicians in Rhode Island and Massachusetts, such as Cathleen Hood MD, Sam Dudley MD, Charles Eaton MD and Hank Wu MD, amongst others. Furthermore, advertisements will be posted throughout Rhode Island, and distributed via social media, inviting participants interested in lowering their blood pressure to enroll

*MBHT Intervention Description:* This study proposes to customize MBSR to participants with prehypertension/hypertension creating an intervention called Mindfulness-Based Hypertension Therapy (MBHT). Specifically, MBHT is based on the standardized MBSR intervention described elsewhere,<sup>153-156</sup> and will consist of nine 2.5-hour weekly group sessions and an 8-hour one-day session, initially led by Dr. Loucks until further instructors are certified in MBHT if initial findings suggest an effect. Dr. Loucks is an expert in cardiovascular physiology, cardiovascular epidemiology, and social epidemiology. He completed MBSR instructor training at UMass Medical School, and has almost 20 years of mindfulness meditation experience, including teaching and mentoring community members, as well as a recent publication record investigating associations of mindfulness with cardiovascular health.<sup>164,183,184</sup> The unique areas of MBHT are expected to be education on hypertension risk factors, hypertension health effects, and specific mindfulness modules focused on awareness of diet, physical activity, medication adherence, alcohol consumption, stress, and social support for behavior change. A preliminary manual has been created based on the standardized MBSR manual developed at UMass Medical School (**Appendix A**), and will be further developed through the approaches described above, and sequentially revised based on participant feedback and preliminary findings.<sup>155,156</sup> MBHT sessions contain instruction and practice in mindfulness meditation, and conversations about stress and coping. Students learn a range of mindfulness skills including body scan exercises, meditation and yoga. Homework consists of practicing skills for ≥45 min/day, 6 days/week.

MBHT builds a foundation of mindfulness skills (e.g. meditation, self-awareness, etc.) through the MBSR curriculum. MBHT then directs attention towards hypertension risk factors. Early in the MBHT, the importance of hypertension for health and mortality is described, along with hypertension risk factors. Participants will have their blood pressure and hypertension risk factors assessed at baseline, and be provided with this information during the first in-person MBHT session. This phase aims to engage participants' interest in hypertension risk factors, and increase motivation for behavior change. MBHT encourages participants to explore personal readiness for change in the different hypertension risk factors, and explore utilizing mindfulness practices to engage with those risk factors that they choose to. Each week, focus is provided on different hypertension risk factors. However, common themes exist across all hypertension risk factors including (1) awareness of thoughts, emotions and physical sensations particularly surrounding hypertension risk factors such as overconsumption of palatable foods, sedentary activities, alcohol consumption, medication adherence; (2) craving, particularly for hypertension risk factors such as overconsumption of palatable foods, sedentary activities, and alcohol consumption; (3) the impact of bringing mindfulness to every moment, particularly in relation to hypertension risk factors. For example, when consuming highly palatable food, bringing awareness to the emotions, thoughts and physical sensations prior to eating it, during eating it, along with the many minutes, if not hours, afterwards. Participants are trained to bring non-judgmental attention to the often short-term pleasure of overconsumption of foods, sedentary activities, heavy alcohol consumption, or not taking medications, and bring non-judgmental attention to the longer term suffering associations with these activities. Through this process, participants are encouraged to reflect on if behavioral choices provide more benefit or harm to their well-being, and to choose the behaviors that bring benefit. (4) Self-care: as awareness of thoughts, emotions and physical sensations increases, and self-regulation will likely increase as a result of the meditation practices, the curriculum will emphasize to participants that it is common for people to start caring for themselves more. It is a way of better knowing ourselves, and through knowing ourselves in each



moment, we often want to care for ourselves in each moment. This may mean taking medication that will help our health, or being more physical active, eating more healthily, or consuming more moderate amounts of alcohol. The intervention can be modified to change the dose of any of these 4 components, for example via (1) Increased use of specific meditations focused on health behaviors such as diet and physical activity. (2) Increased use of meditations focused on craving. Participants will be trained to notice craving arising, and fading away in relation to hypertension risk factors such as palatable high caloric foods, sedentary activities, and alcohol consumption. (3) Increased use of mindfulness practices related to long term experiences of health behaviors such as alcohol consumption, diet, physical activity and medication use on thoughts, emotions, physical sensations and well-being. (4) Self-care: Increased use of modules that show how mindfulness practice increased self-awareness and in doing so can increase people's desire to care for themselves. The potential use of loving kindness meditation will be considered.

**MBSR Intervention Group:** MBSR consists of eight 2.5-hour weekly group sessions, led by a certified instructor.<sup>153,154</sup> These sessions contain instruction and practice in mindfulness meditation, as well as conversations of stress, coping, and homework assignments. Students learn a range of mindfulness skills including body scan exercises, sitting meditation, and yoga. Homework consists of practicing these skills for at least 45 minutes per day, 6 days per week, in addition to practicing mindfulness skills during group meetings. The program concludes with an 8-hour intensive mindfulness retreat with the instructor. During and after the program, students are encouraged to pay mindful, nonjudgmental attention to daily activities like walking, eating and talking. One goal is for participants to see that most sensations, emotions, and thoughts are transient events that do not need to be acted upon. Towards the end of the program, participants are provided materials and encouragement to find existing groups in their communities to continue their practice with, such as meditation and yoga centers. The MBSR intervention will be performed by certified MBSR instructors with at least 500 hours of MBSR teaching experience, detailed further in Section 4.1.4.2 of the Research Strategy. There are over 80 instructors in New England. Participants will be enrolled in MBSR courses taking place close to their home or workplace. Having participants take part in standard MBSR courses will improve generalizability of these findings compared to if only a small number of instructors were selected to teach MBSR to participants. MBSR instructor competency and treatment fidelity are further described below.

**MBHT and MBSR Competency and Treatment Fidelity:** Treatment fidelity strategies will be performed in accordance with recommendations of the NIH Behavior Change consortium, specifically ensuring treatment fidelity in the following five areas: study design, training providers, delivery of treatment, receipt of treatment and enactment of treatment skills,<sup>240</sup> as follows. **Study design:** The study will provide the same treatment dose for each participant enrolled in the MBSR and MBHT interventions, including fixed length and number of frequency of contact sessions for all MBSR and MBHT sessions. All session durations will be recorded, and evaluated monthly by research staff to ensure consistency. Any deviations from the planned duration will be recorded. All class sessions will be audiotaped. Dr. Willoughby Britton and her team will review treatment audiotapes for one of out four sessions, using classes and sessions selected at random. Dr. Britton and her team will conduct competency ratings on these tapes using validated adherence scales (MBCT Adherence Scale, where items 1-11 in the scale are for MBSR, MBHT and MBCT<sup>241</sup>), and provide detailed feedback to treatment providers. We will ensure equivalent dose across conditions, including meditation, yoga and stress reduction training, through tracking the audio recordings. Possible setbacks in implementation of treatment will be addressed, including having a large pool of MBSR and MBHT instructors in the event that specific instructors no longer teach classes. Instructor attrition will be tracked.

**Provider training:** MBSR and MBHT will be performed by certified instructors. MBSR teacher certification is fairly extensive, and accreditation occurs through the University of Massachusetts Medical School Center for Mindfulness in Medicine, Health Care and Society, detailed elsewhere.<sup>242</sup> Examples of criteria for becoming a certified MBSR teaching include (i) completion of an eight-week MBSR course as a participant, (ii) completion of several multi-day residential training courses in mindfulness based stress reduction practice and teaching, (iii) substantial experience in teaching MBSR, (iv) strong references letters from colleagues and participants who have taken your MBSR courses, (v) completion of several multi-day mindfulness meditation retreats, (vi) have a graduate degree in a field connected to MBSR (e.g. education, psychology, medicine) or demonstration of equivalent understanding through work experience in a related field. There are 89 registered MBSR programs in Massachusetts (60), RI (9) and CT (20) that offer year-round program including the Center for Mindfulness where MBSR originated. Eligible programs must be 8 weeks and the instructors must have completed the MBSR Instructor certification training to participate in the study. **Delivery of treatment:** We will assess participants' perceptions of provider warmth and credibility using brief measures based on the validated

Working Alliance Inventory,<sup>243</sup> and Empathy Scale<sup>244</sup> at Weeks 4 and 8 of the intervention. Feedback will be provided to the interventionist, and measures of warmth and credibility will be adjusted for in sensitivity analyses, to evaluate if results differ when these measures are included vs. excluded. *Receipt of treatment and enactment of treatment skills:* These will be assessed using the Mindfulness Skill Acquisition Scale,<sup>245</sup> which assesses: (i) the frequency of how often participants apply strategies in their lives taught during MBSR and MBHT classes, and (ii) frequency by which participants refrain from using harmful coping strategies, such as mental/behavioral disengagement, substance use (e.g. smoking) and overeating.<sup>245</sup> Participants' meditation diaries, described in Section 5.4, will assess regularity of meditation practice.

*Phone-Based Screening:* For people who indicate interest in the study, this screening will take place by phone using trained research assistants to assess the exclusion criteria described above, with the exception of blood pressure which will be assessed in-person

*In-Person Screening:* If participants remain eligible after the phone-based screening, they will attend an in-person screening for blood pressure and medication assessment. If mean blood pressure shows hypertension/prehypertension ( $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure or taking antihypertensive medication), participants will be invited to return for a second blood pressure reading. At that time, if the mean blood pressure across both assessment times is  $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure, they will be invited to participate in the study.

#### *Baseline Assessments:*

- (1) *Demographics:* age, race/ethnicity, socioeconomic status (education).
- (2) *Family History of Hypertension (FH):* Assesses biological parents' history of having hypertension, based on questions from New England Family Study LEAP Project.
- (3) *Childhood socioeconomic status:* retrospective reporting of parents' education, based on standardized questionnaires used in the Atherosclerosis Risk in Communities (ARIC) study.
- (4) *Adverse Childhood Experiences:* Measured using the standardized Adverse Childhood Experiences (ACE) questionnaire developed by Vincent Felitti et al.<sup>185,186</sup>
- (5) *Depressive symptomatology:* Assessed using Center for Epidemiologic Studies Depression Scale Revised (CESD-R). The CESD survey has been used extensively in the epidemiologic literature to assess depressive symptomatology.<sup>187</sup> The scale was updated to the CESD-R by Van Dam *et al.*, which allows diagnosable criteria similar to Diagnostic and Statistical Manual (DSM) of Mental Disorders.<sup>188</sup>
- (6) *Anxiety:* Assessed using the validated Beck Anxiety Inventory.<sup>189-195</sup>
- (7) *Medication use:* Assessed directly from participants' medication bottles and self-report using standardized forms, including medication name, dose, frequency of use, and reason of use.
- (8) *Antihypertensive medication adherence:* Measured using (a) electronic medication bottle caps, and (b) the validated Morisky 8-item questionnaire.<sup>196</sup>
- (9) *Systolic and diastolic blood pressure:* Blood pressure will be measured using a calibrated Omron HEM907XL Intellisense automated BP monitor with established validity,<sup>197</sup> following American Heart Association and Joint National Committee (JNC) guidelines.<sup>178,198</sup>
- (10) *Anthropometry:* height, weight and waist circumference directly assessed using standard epidemiologic methods.<sup>172</sup>
- (11) *Physical activity:* (a) MET minutes per week, assessed using actigraphy. We will use two accelerometers, one (the Actical) worn round the waist, and one (the Actiwatch-64) worn on the wrist (Philips Respironics, Andover, MA),<sup>173,174</sup> that have become the gold standard for such assessment.<sup>175-177</sup> (b) Rapid Assessment Physical Activity Scale. This scale was chosen because it is validated and responsive to behavioral changes including the types (e.g. yoga) introduced in MBHT and MBSR.<sup>199,200</sup>
- (12) *Diet:* assessed utilizing the validated Food Frequency that allows for calculation of hypertension-related dietary factors, including salt intake, alcohol consumption, total caloric consumption, fruit and vegetable consumption, and Dietary Approaches to Stop Hypertension (DASH) eating pattern score.<sup>180</sup>
- (13) *Cigarette smoking:* current smoking assessed using self-report standardized questions from the New England Family Study.
- (14) *Sleep duration:* Sleep duration is assessed using actigraphy devices described above for assessing physical activity.
- (15) *Mindfulness:* Assessed using the validated Mindfulness Attention Awareness Scale<sup>204,205</sup> and Five Facet Mindfulness Questionnaire.<sup>205</sup>
- (16) *Emotional eating:* measured using the Three Factor Eating Questionnaire Revised 21-item (TFEQ-R21).<sup>207,208</sup>

- (17) *Self-control*: assessed using the validated Self-Control Scale short form.<sup>209,210</sup>
- (18) *Self-compassion*: Assessed using the validated Self-Compassion Scale (SCS).<sup>113</sup>
- (19) *Perceived stress*: Assessed using the validated 10-item Perceived Stress Scale.<sup>212,213</sup>
- (20) *Emotion regulation*: Measured using (a) the validated Difficulties in Emotion Regulation Scale,<sup>214</sup> and (b) positive reappraisal using the validated Cognitive Emotion Regulation Scale.<sup>215-217</sup>
- (21) *Interoception*: Used the validated Multidimensional Assessment of Interoceptive Awareness (MAIA).<sup>218-220</sup>
- (22) *Decentering*: Assessed using the validated Experiences Questionnaire.<sup>221,222</sup>
- (23) *Attention control*: Assessed using (a) the Attention Network Test (ANT), which is a brief validated computerized battery measuring three independent behavioral components of attention: conflict resolution, spatial orienting, and alerting.<sup>223</sup>, and (b) the Sustained Attention to Response Task (SART). The SART is a validated computerized test of sustained attention, response inhibition (executive function) and self-regulation.<sup>224-226 227-229</sup>
- (24) *Craving*: craving for hypertension risk factors, including palatable foods, alcohol, and sedentary activities will be assessed using the validated Craving Experiences Questionnaire.<sup>230</sup>
- (25) *Social integration*: Measured using the validated 12-item Interpersonal Support Evaluation List (ISEL-12) measure of social support.<sup>231</sup>
- (26) *Loneliness*: Assessed using the validated R-UCLA Loneliness Scale.<sup>232</sup>
- (27) *Readiness to change for hypertension risk factors*: Assessed using questionnaire on readiness to change for hypertension risk factors including physical activity, DASH diet, salt intake, overweight/obesity, stress and stress response, antihypertensive medication use, based on the Transtheoretical Model for stages of change.<sup>233,234</sup>
- (28) *Functional Magnetic Resonance Imaging (fMRI)*: In the UH3 phase only, if secondary data analyses during the UH2 phase indicate evidence of neuroimaging-based measures of self-regulation being important mechanisms, participants in the UH3 phase will undergo an MRI scanning session for approximately 30 minutes at baseline and 10 weeks follow-up. Scans will be acquired with a 3T scanner while the subject is in the resting state. Sample size will be 24 per group. Participants will undergo a separate consent form for fMRI imaging, so that they can be in the MBHT study without imaging if they prefer.

*Follow-Up Assessments at 10 Weeks and 6 Months Follow-Up*: Questionnaires and assessments administered at 10 weeks and 6 months follow-up are identical to those administered at the first in-person screening assessment and at baseline, with the exception that questionnaires for which the answers should not change or be informative (age, race/ethnicity, education, adverse childhood experiences, family history of hypertension) are not given at follow-ups. In addition adverse events are monitored at both the 10 week and 6 month follow-up period. We are also exploring performing a 1-year follow-up to enhance understanding of longer term target engagement. However due to the relatively brief period of time for the UH2 phase, the 6 month follow-up time is the primary endpoint for decisions on target engagement. In addition adverse events are monitored at all follow-up assessments.

*Focus Groups*: Focus group assessments of experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) will occur prior to, and following pilot testing of MBHT in participants. Focus groups of participants undergoing the MBHT behavioral intervention will take place following the final week of class. The goal of the focus groups will be to adapt MBHT to the unique needs of this population. Adaptions may include, for example, types of specific mindfulness exercises, sequence in which modules are introduced, relative emphasis on different types of modules (e.g. mindfulness practices customized to prehypertension/hypertension risk factors vs. general mindfulness practices), and class duration. Focus groups will be facilitated by Dr. Melissa Clark, who is an experienced focus group moderator, along with another team member present to assist and take notes. The groups will be held in comfortable and convenient meeting rooms at the Brown University School of Public Health.

We will follow study procedures similar to those performed during previous epidemiologic studies by our group. In-person screenings will take place at the Brown University Center for Population Health and Clinical Epidemiology, described in Sections 2.7.1 and 2.7.2 at baseline, completion of the 8-week MBHT course and at 6-months follow-up. Major assessment variables are shown in **Table 1**. Qualitative interviews (focus groups) will evaluate participants' experiences such as usefulness of specific modules, duration of sessions, time burden, and overall intervention effectiveness. Interviewer training includes high standards for selection of interviewers who are at ease with strangers, are culturally-sensitive and able to readily establish professional

rapport. Interviewers will be thoroughly trained in the administration of the structured interview, anthropometry, and blood pressure assessments. Routine quality control procedures will be in place regarding calibration of scales and blood pressure instruments. Clinical exams will be supervised by Dr. Loucks to at least monthly to evaluate accuracy of technique, particularly for anthropometry and blood pressure assessment. Re-training will be implemented if needed. Data will be entered and cleaned in an ongoing matter to facilitate quality control and preliminary analyses.

### 1.1.2 Inclusion/exclusion criteria:

#### *Inclusion Criteria:*

Hypertension/prehypertension ( $\geq 120$  mmHg systolic,  $\geq 80$  mmHg diastolic pressure or taking antihypertensive medication). Able to speak, read, and write in English. All adults ( $\geq 18$  years of age), genders and racial/ethnic groups are eligible to be included.

*Exclusion Criteria:* Exclusion criteria follow standard guidelines and recommendations:<sup>3</sup> (a) current regular meditation practice ( $> \text{once/week}$ ); (b) serious medical illness precluding regular class attendance; (c) current substance abuse, suicidal ideation or eating disorder, (d) history of bipolar or psychotic disorders or self-injurious behaviors. These participants are excluded because they may disrupt group participation, require additional or specialized treatment, or are already participating in practices similar to the intervention.

### 1.1.3 Vulnerable populations:

There are no participants in the study we are aware of who are considered part of a vulnerable population.

### 1.1.4 Collaborating sites:

There are no other collaborating sites that will assess participants during this study.

### 1.1.5 Data management:

The clinical data will be de-identified but linked. Private information such as name date of birth, next of kin, address for recontacting will be kept in a password protected, encrypted database on a different disk than the clinical data. Only the principal investigators for the purposes of patient safety or monitoring by the NIH, data safety monitoring boards or HIPPA compliance officer approved agents will be given access to identifiable personal information.

### 1.1.6 Equipoise

Clinical equipoise, defined as “no consensus within the expert clinical community about the comparative merits of the alternative [trial arms] to be tested”<sup>138</sup> applies to this study, and it will be designed in a way that the findings should disrupt clinical equipoise. The study will be described to potential participants as a

**Table 1.** Variables measured and assessment times in the Mindfulness-Based Hypertension Therapy Study.

Variables Measured	Assessment Times		
	Baseline	10 weeks	6 months
Demographics	x		
Family history of hypertension	x		
Childhood socioeconomic status	x		
Adverse childhood experiences	x		
Depressive symptomatology	x	x	x
Anxiety	x	x	x
Medication use	x	x	x
Antihypertensive medication adherence	x	x	x
Anthropometry	x	x	x
Physical activity	x	x	x
Diet	x	x	x
Cigarette smoking	x	x	x
Sleep duration	x	x	x
Mindfulness	x	x	x
Emotional eating	x	x	x
Self-control	x	x	x
Self-compassion	x	x	x
Perceived stress	x	x	x
Emotion regulation	x	x	x
Interoception	x	x	x
Decentering	x	x	x
Attention control	x	x	x
Craving for hypertension risk factors	x	x	x
Social integration	x	x	x
Loneliness	x	x	x
Readiness to change for hypertension risk factors	x	x	x

randomized controlled trial that will evaluate the impact of a stress reduction program on risk for cardiovascular disease. The statements in the study description and consent forms will show equipoise (i.e. “a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial”<sup>138</sup>), where the state of the research does not know conclusively whether the stress-reduction program will have an effect on subclinical cardiovascular disease (hence we are performing the trial). For example, the consent form will describe that is not currently known whether the stress reduction intervention we are testing reduces cardiovascular disease risk. Similarly, all study personnel including the PI will be instructed to demonstrate equipoise to the best of their ability, regardless of personal biases (in either direction – favoring treatment or control), so that any types of biases on treatment effects will not be communicated to study participants. Instruction will be provided for all study personnel on the importance of demonstrating equipoise. Further instruction will be provided on ways to distinguish appropriately among (1) validated knowledge accepted by the clinical community, (2) data on treatments that are promising but are not generally convincing, and (3) mere hunches, including how these principles apply to the current study.<sup>138</sup>

## 1.2 Sources of Materials

### 1.2.1 Research material obtained from living individuals

#### 1.2.1.1 Outcomes

##### *Primary Outcomes*

Self-regulation will be assessed using targets identified in the UH2 phase. A list shown above in the Baseline Assessments section. Examples include emotional eating (measured using the Three Factor Eating Questionnaire),<sup>207,208</sup> self-control (assessed using the validated Self-Control Scale short form.<sup>209,210</sup>), self-compassion (Assessed using the validated Self-Compassion Scale (SCS).<sup>113</sup>), emotion regulation (measured using the validated Difficulties in Emotion Regulation Scale,<sup>214</sup> and positive reappraisal using the validated Cognitive Emotion Regulation Scale.<sup>215-217</sup>), interoception (using the validated Multidimensional Assessment of Interoceptive Awareness<sup>218-220</sup>), decentering (assessed using the validated Experiences Questionnaire.<sup>221,222</sup>), attention control (assessed using the validated Attention Network Test,<sup>223</sup> and the Sustained Attention to Response Task<sup>224-226 227-229</sup>), and craving for hypertension risk factors, including palatable foods, alcohol, and sedentary activities will be assessed using the validated Craving Experiences Questionnaire.<sup>230</sup>

##### *Secondary Outcome*

##### *Prehypertension/Hypertension Medical Regimen Adherence Outcomes Assessment Methods: (1)*

Electronically-Measured Antihypertensive Medication Adherence: measured continuously using electronic medication bottle caps. (2) Body Mass Index: height and weight directly assessed using standard epidemiologic methods.<sup>172</sup> (3) Physical activity: MET minutes per week, assessed using actigraphy. We will use two accelerometers, one (the Actical) worn round the waist, and one (the Actiwatch-64) worn on the wrist (Philips Respironics, Andover, MA),<sup>173,174</sup> that have become the gold standard for such assessment.<sup>175-177</sup> Adherence to Joint National Commission-7 (JNC-7) guidelines is 30 min aerobic physical activity  $\geq 4$  days per week.<sup>178</sup> (4) Diet: assessed utilizing Dietary Approaches to Stop Hypertension (DASH) eating pattern score,<sup>179</sup> measured via diet history food frequency questionnaire.<sup>180</sup> Adherence to JNC-7 guidelines DASH eating pattern score (range 0-8).<sup>178,179</sup> (5) Alcohol consumption: Amount and frequency of alcohol consumption, will be assessed via self-report utilizing standard questions from the behavioral Risk Factor Surveillance Survey. JNC-7-stated cut-point of healthy alcohol intake is  $\leq 2$  drinks (e.g. 24 oz. beer, 10 oz. wine, or 3 oz. 80-proof whiskey) per day in men and  $\leq 1$  drink per day in women.<sup>178</sup> Medical regimen adherence will be defined as adherence to JNC-7-recommended behavioral and medication treatment of hypertension.<sup>178</sup> Specifically, analyses will assess changes in mean Z-scores of health behaviors or medication adherence in 6 domains, being (1) Physical activity assessed via MET scores. (2) Electronically-measured antihypertensive medication adherence measured continuously using electronic medication bottle caps, where medication adherence is calculated as the percent of days during which medication was taken as prescribed. For multi-day dosings, participants will receive points for the proportion of actual over expected dosings. (3) Body Mass Index (kg/m<sup>2</sup>), (4) Diet via Dietary Approaches to Stop Hypertension (DASH) eating pattern score<sup>179</sup> (5) Alcohol consumption (number of drinks per day).

### **1.2.2 Who will have access to individually identifiable private information about human subjects.**

Only the principal investigators for the purposes of patient safety or monitoring by the NIH, data safety monitoring boards or HIPPA compliance officer approved agents will be given access to identifiable personal information.

### **1.2.3 How the specimens, records, and/or data are collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed research project.**

Questionnaire data will typically be collected using Qualtrics, LLC (Provo, UT, USA) survey instruments, so that participants can complete questionnaires on their own time at home, using their computers or smart phones. Exceptions to this include the phone screening questionnaire, and the baseline and follow-up questions on depression and anxiety to allow for a safety protocol to be followed if there are high levels of depression, anxiety or suicidal ideation.

Assessments of blood pressure, height, weight, waist circumferences and medication use are assessed in-person by trained research assistants blinded to treatment allocation.

*Confidentiality of Patient Records:* The clinical data will be de-identified but linked. Private information such as name, date of birth, and address for recontacting will be kept in a password protected, encrypted database on a different disk than the clinical data. Only the principal investigator for the purposes of patient safety or monitoring by the NIH, data safety monitoring boards or HIPPA compliance officer approved agents will be given access to identifiable personal information.

Data management will be performed by downloading data at minimum every 2 weeks during data collection periods, and assessing data for missingness and errors. Data will be maintained in password-protected Microsoft Excel Spreadsheets, and then exported using .csv functions for analysis in SAS software.

## **1.3 Potential Risks and Minimization of Risk**

### **1.3.1 Expected Risks**

The following is a statement from NCCIH about the potential risks of meditation practice: "Meditation is considered to be safe for healthy people. There have been rare reports that meditation could cause or worsen symptoms in people who have certain psychiatric problems, but this question has not been fully researched. People with physical limitations may not be able to participate in certain meditative practices involving physical movement. Individuals with existing mental or physical health conditions should speak with their health care providers prior to starting a meditative practice and make their meditation instructor aware of their condition."<sup>235</sup>

*Discomfort during meditation:* Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable emotions with increased attention to them. In order to minimize risk, instructors encourage participants to be aware of their discomfort and to set their own limitations. Participants are encouraged to alter their postures, including standing, sitting in chairs, lying down, as needed in order to be comfortable. In addition, the curriculum of the training program is specifically geared towards addressing such discomfort.

*Psychological distress:* Research subjects participating in this study may have feelings of loss of privacy from being contacted about participating in the study, and possible psychological distress caused by questions on the diagnostic interview that bring up painful memories or feelings. However, the resulting potential for injury to research subjects is judged to be minimal. We have already contacted and clinically evaluated thousands of participants from other studies such as the New England Family and Women's Health Initiative using similar assessment procedures to this study, with good responses from the participants. With regard to psychological distress from taking part in the MBSR or MBHT intervention, given that screening questions will exclude participants with substantial mental illness, and given the NCCIH statement above that "Meditation is considered to be safe for healthy people."<sup>235</sup> we expect that risk of psychological distress will be low. The risk of increased psychological distress from meditation will be clearly outlined in the consent form and participants will be encouraged to consult with both the course instructor and study staff in the case of any increased distress. Dr. Ellen Flynn, a licensed psychiatrist, will be available to advise on any psychological events that occur, and provide referrals for treatment if needed.

*Loss of confidentiality:* Likelihood: rare. Minimization: Confidentiality will be maintained by numerically coding all data, by disguising identifying information, and by keeping all data in locked file drawers. All information obtained from participants will be accessible only to research staff.

*Injury due to physical activities:* It is possible that injuries could be sustained from (1) the gentle mindful movements (yoga), or (2) physical activities that participants engage in as a result of the intervention

encouraging exploration of physical activity as a way to reduce blood pressure. (1) *Mindful movements*: Participants receive a handout during the orientation showing the yoga poses that will be offered during the course. They are encouraged to explore limits in their body related to movement, but not to go beyond those limits. Participants are asked to listen to what their body is telling them more closely than what the mindful movement instructor is telling them. Modifications of poses are available, including for those limited to chairs or wheelchairs. Participants are encouraged to bring the handout of poses to their health care providers if they have any physical limitations, so that the providers can advise on which poses to do, and which to avoid. (2) *Physical activities*: Participants are encouraged to explore physical activities that promote strength and conditioning as a way to reduce blood pressure. As with the mindful movements, they are encouraged to explore limits in their body related to movement, but not to go beyond those limits. Participants are asked to listen to what their body is telling them more closely than what the mindful movement instructor is telling them. Furthermore, they are encouraged to ask their healthcare provider about advised physical activities if they have any physical limitations.

*Risks associated with fMRI*: This study will be conducted in a 3T MR scanner at UMass Medical School, which has been approved for research and clinical studies in children and adults by the FDA. Magnetic resonance (MR) technology does not use X-rays, it uses strong magnetic fields and radio waves. Subjects will be asked whether they have devices that can be affected by MRI, and if so, they will not be able to participate in this study. Significant risks also can arise if ferromagnetic materials are brought into the high magnetic field environment of the scanner and immediate vicinity, as they can become hazardous projectiles. These types of items are not permitted in the scanning area. The MR exams are painless, and except for the pulsating sounds, subjects will not be aware that MR scanning is taking place. With proper safety precautions in terms of the avoidance of metal objects, there are no known health risks associated with MRI. The safety of MRI is reflected in the fact that it is used in standard medical practice without the requirement for informed patient consent. Most people experience no ill effects from the magnetic field, but some report claustrophobia, dizziness, mild nausea, headaches, a metallic taste in their mouth, double vision, or a sensation of flashing lights. These symptoms are transient and resolve quickly after the subject exits the scanner. The technologist will be able to hear subjects at all times and subjects are free to end the procedure at any time. In rare cases, a very slight, uncomfortable tingling of the back due to the rapid switching of the magnetic field has been reported during certain types of scans. Subjects are asked to report this immediately so the scan can be changed to avoid this. Although these precautions will avoid all known risks associated with MR, this procedure may involve risks that are currently unknown. The scanner is noisy, but does not harm hearing. For comfort, subjects will be given earplugs to muffle the noise.

*Risk of adverse events during the study*: It is possible that some patients will have an adverse event during the study, including increased stress or anxiety. Participants with major mental health conditions, such as bipolar depression, suicidal ideation, borderline personality disorder, post-traumatic stress disorder, and obsessive compulsive disorder, are ineligible for the study. We expect risk of adverse events to be very low.

*Impact statement*: These risks are considered to be minimal and are addressed in the protocol and consent form.

## **Adverse Events**

*Mental Health Deterioration and Suicidality*: Participants assigned to any treatment group may experience mental health or suicidal ideation. All patients will be monitored by study staff at weekly intervals in person or by telephone and assessed every four weeks with questionnaires about anxiety, depression and suicidal ideation, specifically the Beck Anxiety Inventory and the Center for Epidemiology Study Depression Scale Revised (CESD-R). Dr. Flynn is a licensed psychiatrist and has extensive experience evaluating research participants for clinical deterioration or suicidality.

*Beck Anxiety Inventory (BA)*: If participant scores  $\geq 26$  on the Beck Anxiety Inventory, while having the participant wait, immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and your phone # will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, please leave a phone message for her with your contact information and provide her with the Beck Anxiety Inventory results on the message. If Dr. Flynn is not

immediately reachable, or following participant release after consulting with Dr. Flynn, immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).

*Depressive Symptomatology:* The CESD-R will be administered during the in-person assessment visits, and scores will be reviewed immediately upon completion of the in-person assessments.

1. Sadness (dysphoria): Question numbers 2, 4, 6
2. Loss of Interest (anhedonia): Question numbers 8, 10
3. Appetite: Question numbers 1, 18
4. Sleep: Question numbers 5, 11, 19
5. Thinking / concentration: Question numbers 3, 20
6. Guilt (worthlessness): Question numbers 9, 17
7. Tired (fatigue): Question numbers 7, 16
8. Movement (agitation): Question numbers 12, 13
9. Suicidal ideation: Question numbers 14, 15

Participants are considered to meet criteria for major depressive episode if they have anhedonia or dysphoria nearly every day for the past two weeks, plus symptoms in an additional 4 DSM symptom groups noted as occurring nearly every day for the past two weeks. If participants meet criteria for major depressive episode, while having the participant wait, staff will immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and the staff's phone #'s will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, staff will leave a phone message for her with their contact information and provide her with the Depressive Symptomatology results on the message. If Dr. Flynn is not immediately reachable, or following participant release after consulting with Dr. Flynn, staff will immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).

If participants respond having any suicidal ideation (CES-D questions 14 or 15), staff will perform the following 2 steps:

1. Immediately call 911 and Dr. Ellen Flynn. Specifically, while the participant is in the waiting room, staff will call 911 immediately, and tell them about the situation. This will be followed by a call to Dr. Flynn.
2. While speaking calmly with the participant, staff will let them know that he/she called 911 and Dr. Flynn, and why (i.e. because we are concerned about them). Staff can speak with participant to keep him/her in the waiting room if 911 has sent assistance, but the discussion should not be clinical in nature.

The following information can be provided to study participants.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor's office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020

*Injury due to physical activities:* It is possible that injuries could be sustained from (1) the gentle mindful movements (yoga), or (2) physical activities that participants engage in as a result of the intervention encouraging exploration of physical activity as a way to reduce blood pressure.



- (1) Mindful movements: Participants receive a handout during the orientation showing the yoga poses that will be offered during the course. They are encouraged to explore limits in their body related to movement, but not to go beyond those limits. Participants are asked to listen to what their body is telling them more closely than what the mindful movement instructor is telling them. Modifications of poses are available, including for those limited to chairs or wheelchairs. Participants are encouraged to bring the handout of poses to their health care providers if they have any physical limitations, so that the providers can advise on which poses to do, and which to avoid.
- (2) Physical activities: Participants are encouraged to explore physical activities that promote strength and conditioning as a way to reduce blood pressure. As with the mindful movements, they are encouraged to explore limits in their body related to movement, but not to go beyond those limits. Participants are asked to listen to what their body is telling them more closely than what the mindful movement instructor is telling them. Furthermore, they are encouraged to ask their healthcare provider about advised physical activities if they have any physical limitations.

All patients will be monitored by study staff at weekly intervals in person or by telephone and assessed every four weeks with questionnaires about physical injuries, specifically the following questions:

1. Have you sustained any physical injuries during the past four weeks?

If yes,

- (a) please describe the injury
- (b) please describe what happened to cause the injury.
- (c) did this injury include
  - i. Broken bone(s) yes/no
  - ii. Lacerations requiring stitches yes/no
  - iii. Concussion yes/no

If injuries include any of the following, it will be reported to Data Safety Monitoring Committee member Dr. Hank Wu, MD, who is a practicing physician and researcher. He will advise on any follow-up needed. It will also be reported to the chair of the Data Safety Monitoring Board.

- a. Broken bone(s)
- b. Lacerations requiring stitches
- c. Concussion

*Non-Response to Treatment:* The possibility that the treatment will not yield benefit is another possible risk and will be explained during informed consent procedures. Non-responders (identified as minimal change in medical regimen adherence from baseline assessment) will be provided with referrals to other treatment, if desired.

#### **1.4 Safety Monitoring**

Oversight of internal monitoring of the participants' safety will be conducted by the PIs, Dr. Eric Loucks and Dr. Willoughby Britton. Oversight of the external Data and Safety Monitoring Committee will be conducted by the chair (Dr. Edmondson). The Data and Safety Monitoring Committee will include experts in cardiology, psychology/psychiatry, epidemiology, and biostatistics.

##### *Entities Conducting Monitoring*

The Institutional Review Board (IRBs) at Brown University will review all research procedures, and will provide oversight. Internal monitoring will be done by the Brown University principal investigators (Dr. Loucks and Dr. Britton) and the Brown University IRB. The Data Safety Monitoring Committee will provide external monitoring, and will meet every six months by phone or in-person. They will be provided data every six months to evaluate potential effects of the RCT on major outcomes (e.g. medical regimen adherence). Any serious adverse effects will be immediately reported to the principal investigators (Loucks, Britton) and the committee chair.

### *What is Monitored*

Monitoring is done of all procedures to ensure that they conform to the approved protocol; of unforeseen circumstances that might arise and affect safety; of all reports of serious adverse events as defined in US Department of Health and Human Services regulations for the protection of human research subjects 45 CFR Part 46, and the FDA 312.32 (death, life-threatening experience, new or prolonged hospitalization, persistent or significant disability/incapacity); of other significant adverse events (adverse events that lead to drop out by participant or termination by the investigator); of unexpected adverse events resulting from the study; and of expected adverse events.

Monitoring is done of all study inclusion and exclusion criteria. During this clinical trial, we will notify officials, as mandated by law, if a participant reports intentions to harm him/herself or others, or reports child abuse or abuse of an elder. Dr. Ellen Flynn, a licensed psychiatrist, will be available to advise on any psychological events that occur, and provide referrals for treatment if needed.

### *Frequency of Monitoring*

All adverse events will be continuously monitored by the PI. Participants will be given contact information so that they can inform us of events that occur in between study visits. Dr. Loucks will conduct daily oversight of participant safety. He will meet weekly with staff to review participant progress and their experiences with the experimental procedures, including adverse events. Any adverse events that are observed and/or reported will be immediately reported to Dr. Loucks, Dr. Britton, and the Data Safety Monitoring Committee chair. The Investigators and Data Safety Monitoring Committee will be available to meet outside of the regularly scheduled meetings (scheduled semiannually), if necessary, due to concerns regarding a particular participant or any problems that may arise for participants. If necessary, they will make appropriate recommendations for changes in protocol, or terminate the study. The Brown University IRB conducts the monitoring at the continuing reviews as scheduled, whenever modification requests are considered, and upon receiving reports of serious adverse events from the PI or anyone else.

### *Reporting Plan*

Any serious adverse events that are observed and/or reported will be immediately reported to Dr. Loucks and the Data Safety Monitoring Committee Chair. Serious adverse events are then reported to the Brown University IRB and to NIH. Brown's IRB requires fatalities related to the study be reported within 24 hours. All serious adverse events related to this study will be reported to the Brown University IRB immediately by telephone and by written report within 48 hours of our receipt of information regarding the event. All other adverse events related to the study will be reported at the continuing review. Serious adverse events will also be reported in writing to the NIH Project Officer within 48 hours. All serious adverse events related to the study will be reported annually in the Progress Report sent to the NIH Project Officer.

Any actions taken by the IRB, other than acceptance of the adverse event report, will be reported to the NIH along with any changes or amendments to the protocol requested by the IRB in response to these reports. Proposed changes or amendments to the protocol in general must be requested first in writing to the Brown and IRB, which will then grant or deny permission to make the requested change or amendment in protocol. NIH will subsequently be informed of any substantive changes or amendments in approved protocol.

## **2 Adequacy of Protection Against Risks**

### **2.1 Recruitment and Informed Consent**

#### **2.1.1 Recruitment:**

Participants will be recruited in part through cardiology and family practices via established relationships with physicians in Rhode Island and Massachusetts, such as Cathleen Hood MD, Sam Dudley MD, Charles Eaton MD and Hank Wu MD, amongst others. Furthermore, advertisements will be posted throughout Rhode Island, and distributed via social media, inviting participants interested in lowering their blood pressure to enroll.

#### **2.1.2 Informed Consent:**

All informed consent forms and protocols have been reviewed and approved by the Brown University IRB. Each potential participant will be fully informed about the nature of the study, its risks and benefits, and

Version 1.3 November 26, 2015

about his/her rights as a research subject. The participant will sign and receive a copy of the document stating that he/she has given his/her informed consent to participate before interviewing is begun. In every instance, project personnel will verbally review the content of the consent form before participants sign.

## **2.2 Protections Against Risk**

Please refer to Section 1.3 above.

## **3 Potential Benefits of the Proposed Research to Human Subjects and Others**

There may be no direct benefits from participating in this study. The risks to participants are minimal. The potential benefits of participating in the proposed study include improved knowledge on stress reduction techniques and risk factors for cardiovascular disease. Each participant will also be contributing to an important study which will answer questions on whether mindfulness-based stress reduction may influence health.

## **4 Importance of the Knowledge to be Gained**

There is great interest in understanding the impact of mindfulness-based interventions on risk for cardiovascular disease, however the vast majority of studies to date have had substantial methodological limitations, leading at 2007 government report on "Meditation Practices for Health: State of the Research" to conclude that "as a whole, firm conclusions on the effects of meditation practices in healthcare cannot be drawn based on the available evidence."<sup>36</sup> This study proposes to fill a substantial gap in knowledge, and rigorously evaluate the effects of a mindfulness-based intervention on risk for hypertension and cardiovascular disease. Expected outcomes are to inform recommendations on whether mindfulness-based stress reduction has long-term impacts on subclinical cardiovascular disease and cardiovascular disease risk factors. Findings will further inform health care providers, communities, workplaces and individuals, who are currently grappling with whether to include mindfulness practices as part of approaches to reduce risk for cardiovascular disease.

## **5 Data and Safety Monitoring Plan**

Please see Section 1.4 above for Safety Monitoring details.

### *Data Safety Monitoring Board:*

Oversight of internal monitoring of the participants' safety will be conducted by the PIs, Dr. Eric Loucks and Dr. Willoughby Britton. Investigators on this application have extensive experience with clinical trials for mindfulness-based interventions and cardiovascular outcomes. Oversight of the external Data and Safety Monitoring Committee will be conducted by the chair, Dr. Donald Edmondson, PhD, is Assistant Professor of Behavioral Medicine at Columbia University Medical Center. He is a Psychologist, and has extensive research experience in evaluating effects of stress and psychosocial factors on cardiovascular disease outcomes.<sup>246-264</sup>

The Data and Safety Monitoring committee will also include Dr. Wen-Chih (Hank) Wu and Dr. Tao Liu. Dr. Wu, MD, is Associate Professor of Medicine and Associate Professor of Epidemiology at Brown University. He is a practicing clinical cardiologist with research in preventive cardiology,<sup>265-272</sup> and will be able to advise on clinical outcomes and any cardiovascular complications arising from the study, in addition to methodological concerns. Dr. Liu, PhD, is an Assistant Professor of Biostatistics at Brown University, experienced in clinical trials.<sup>273,274</sup> He will receive all preliminary analyses from the primary statistician, and will have access to all data from the study, to evaluate any evidence of serious adverse effects or other concerns.

### *Entities Conducting Monitoring*

The Institutional Review Board (IRBs) at Brown University will review all research procedures, and will provide oversight. Internal monitoring will be done by the principal investigators (Dr. Loucks and Dr. Britton) and the Brown University IRB. The Data Safety Monitoring Committee will provide external monitoring, and will meet every six months by phone or in-person. During the randomized-controlled trial phase (phase 4), they will be provided data every six months to evaluate potential effects of the RCT on the primary outcome (i.e. medical regimen adherence). Any serious adverse effects will be immediately reported to the principal investigator (Loucks) and the committee chair (Edmondson).

### **5.1 Entities Conducting Monitoring**

The Institutional Review Board (IRBs) at Brown University will review all research procedures, and will provide oversight. Internal monitoring will be done by the Brown University principal investigators (Dr. Loucks

and Dr. Britton) and the Brown University IRB. Dr. The Data Safety Monitoring Committee will provide external monitoring, and will meet every six months by phone or in-person. They will be provided data every six months to evaluate potential effects of the RCT on major outcomes (e.g. medical regimen adherence). Any serious adverse effects will be immediately reported to the principal investigators (Loucks, Britton) and the committee chair.

## **5.2 What is Monitored**

Monitoring is done of all procedures to ensure that they conform to the approved protocol; of unforeseen circumstances that might arise and affect safety; of all reports of serious adverse events as defined in US Department of Health and Human Services regulations for the protection of human research subjects 45 CFR Part 46, and the FDA 312.32 (death, life-threatening experience, new or prolonged hospitalization, persistent or significant disability/incapacity); of other significant adverse events (adverse events that lead to drop out by participant or termination by the investigator); of unexpected adverse events resulting from the study; and of expected adverse events.

Monitoring is done of all study inclusion and exclusion criteria. During this clinical trial, we will notify officials, as mandated by law, if a participant reports intentions to harm him/herself or others, or reports child abuse or abuse of an elder. Co-investigator Dr. Willoughby Britton is a clinical psychologist, who will be available on call in case of any psychological adverse events.

## **5.3 Frequency of Monitoring**

All adverse events will be continuously monitored by the PI. Participants will be given contact information so that they can inform us of events that occur in between study visits. Dr. Loucks will conduct daily oversight of participant safety. He will meet weekly with staff to review participant progress and their experiences with the experimental procedures, including adverse events. Any adverse events that are observed and/or reported will be immediately reported to Dr. Loucks, Dr. Britton, and the Data Safety Monitoring Committee chair. The Investigators and Data Safety Monitoring Committee will be available to meet outside of the regularly scheduled meetings (scheduled semiannually), if necessary, due to concerns regarding a particular participant or any problems that may arise for participants. If necessary, they will make appropriate recommendations for changes in protocol, or terminate the study. The Brown University IRB conducts the monitoring at the continuing reviews as scheduled, whenever modification requests are considered, and upon receiving reports of serious adverse events from the PI or anyone else.

## **5.4 Reporting Plan**

All adverse events will be continuously monitored by the PI. Participants will be given contact information so that they can inform us of events that occur in between study visits. Dr. Loucks will conduct daily oversight of participant safety. He will meet weekly with staff to review participant progress and their experiences with the experimental procedures, including adverse events. Any adverse events that are observed and/or reported will be immediately reported to Dr. Loucks, Dr. Britton, and the Data Safety Monitoring Committee chair. The Investigators and Data Safety Monitoring Committee will be available to meet outside of the regularly scheduled meetings (scheduled semiannually), if necessary, due to concerns regarding a particular participant or any problems that may arise for participants. If necessary, they will make appropriate recommendations for changes in protocol, or terminate the study. The Brown University IRB conducts the monitoring at the continuing reviews as scheduled, whenever modification requests are considered, and upon receiving reports of serious adverse events from the PI or anyone else.

Any actions taken by the IRB, other than acceptance of the adverse event report, will be reported to the NIH along with any changes or amendments to the protocol requested by the IRB in response to these reports. Proposed changes or amendments to the protocol in general must be requested first in writing to the Brown and IRB, which will then grant or deny permission to make the requested change or amendment in protocol. NIH will subsequently be informed of any substantive changes or amendments in approved protocol.

## **5.5 Data Quality Assurance and Confidentiality**

Several procedures currently in practice in our laboratory will also be utilized for this study to guarantee the validity, integrity, accuracy, and completeness of the data. It will be made clear to all participants that all information obtained during assessments is confidential.

*Procedures to guarantee the accuracy and completeness of the data during data collection, transmission, and analysis:* The data manager (Saadeh) will review each file within 2 weeks of data collection for


completeness, accuracy, and validity of responses. Data files are accessible only to project personnel and are password protected. Ms. Saadeh will review the distributions of all raw data to ensure that data are within range and to check missing data with the hard copy of the data. The project database is password protected and accessible only to the project's data managers, the biostatistician, and the PI.

*Procedures to maintain confidentiality:* Study staff will maintain strict confidentiality regarding all aspects of a subject's participation in this study. Any individual information gathered in the course of the study will not be discussed with anyone who is not directly involved with this study. For each stage of the research, participant names and contact information will be maintained in a recruitment/enrollment database during the course of the study. Once individuals enroll in the study, names will be linked to participant ID number in this database, which will be kept in a restricted access folder on a secure server. This file will be assigned a code name unrelated to the name of the study. Signed consent forms will be kept in a locked file cabinet, separate from any other project data. Once data collection is completed, the corresponding recruitment/enrollment database will be deleted as it is unnecessary to maintain the link between participant identity and study data. All information collected as part of this study will be accessible only to research staff who have completed mandatory training in the protection of human subjects.

## **6 ClinicalTrials.gov Requirements**

The RCT will be registered, and results reported, at ClinicalTrials.gov in accordance with NIH recommendations. Registration in ClinicalTrials.gov will occur no later than 21 days after the first subject is enrolled. Reporting of results (including adverse events) will occur no later than 1 year after completion date.

## APPENDICES

*A. MBHT Curriculum Guide* 

*B. CVs of Data Safety Monitoring Board Members*

## **Curriculum Vitae**

Prepared 10.6.2014

### **Personal Data**

Name: Donald Edmondson  
Birthdate: 12.12.1979  
Birthplace: Wynne, AR  
Citizenship: U.S.

### **Education**

2013 M.P.H., Effectiveness and Outcomes Research; Mailman School of Public Health, Columbia University, New York, New York  
2009 Ph.D., Personality Psychology; University of Connecticut, Storrs, CT;  
Dissertation: **Edmondson, D.**, et al. From shattered assumptions to weakened worldviews: Trauma symptoms signal anxiety buffer disruption. *Journal of Loss and Trauma*. 2011, 16, 358-85. (Crystal L. Park, Ph.D., Dissertation Chair).  
2007 M.A., Clinical Psychology; University of Connecticut, Storrs, CT  
2001 B.A., History; Union University, Jackson, TN.

### **Postdoctoral Training**

2009-2010 Postdoctoral Research Scientist, Center for Behavioral Cardiovascular Health, Columbia University Medical Center, New York, NY

### **Hospital Appointment**

2010-2011 Associate Research Scientist, Center for Behavioral Cardiovascular Health, Columbia University Medical Center, New York, NY

### **Academic Appointment**

2011-present Assistant Professor of Medicine (Departments of Medicine and Psychiatry), Center for Behavioral Cardiovascular Health, Columbia University Medical Center, New York, NY

### **Professional Organizations and Societies**

American Psychological Association	American Psychosomatic Society
Association for Psychological Science	Society for Personality and Social Psychology
Society of Behavioral Medicine	

### **Honors**

2014 Neal E. Miller Young Investigator award, Academy for Behavioral Medicine Research  
2014 Grant reviewer, Israel Science Foundation  
2013 Invited to join Social Psychology, Personality, and Interpersonal Processes (SPIP) study section as a permanent member  
2011 NIH Early Career Reviewer, Social Psychology, Personality, and Interpersonal Processes (SPIP) study section  
2011 Columbia Summer Research Institute selection  
2010-present NIH Loan Repayment Grant recipient  
2007 & 2008 Highest Distinction in Undergraduate Instruction, University of Connecticut  
2006 Sydney Jourard Award for best paper, Division 32 of the Am Psych Assoc

2003 Psi Chi (psychology honors society), University of Memphis  
 1997-2001 Scholars of Excellence Provost's Scholar Award, Union University

**Current Grants and Contracts:**

<u>Title of Project and Source</u>	<u>Dates</u>
R01 HL117832 ( <b>Edmondson</b> , PI) <b>NIH/NHLBI</b> Impact of Social-Interpersonal Factors in the ER on PTSD/Cardiac Outcomes	2013-2018
Loan Repayment Grant ( <b>Edmondson</b> ) <b>NIH/NHLBI</b> PTSD Due to Acute Coronary Syndromes Role: Awardee	2011-2014
P01 HL088117 (Davidson, PI) <b>NIH/NHLBI</b> Depression, Biobehavioral Mechanisms & CHD/Mortality Outcomes Role: Co-Investigator (in-kind support)	2008-2013
P01 HL47540 (J Schwartz, PI) <b>NIH/NHLBI</b> Psychosocial Factors and Cardiovascular Disease Role: Co-Investigator (in-kind support)	1993-2014
<i>ECRIP</i> -HPR iSCRIPT Center (Davidson, PI) <b>New York State Department of Health</b> Innovative Strategies to decrease Readmissions through Improving Patient & System Stress & behavior Role: Training Director	2014-2016
<u>Completed</u>	
KM1 CA156709 (Begg, PI) <b>NIH/NCI</b> Comparative Effectiveness Research Career Development Award Role: Funded trainee	2011-2013
Seed Grant (Edmondson, PI) <b>American Psychological Association</b> Religious Struggle, PTSD, and Terror Management	2007-2008

**Teaching Experience and Responsibilities**

Instructor

2014	Course Instructor, P8112 Systematic Review and Metaanalysis, Columbia University Mailman School of Public Health
2013	Statistics Lectures, Epidemiology and Clinical Epidemiology Course, College of



- Physicians and Surgeons, Columbia University (David Lederer and Steven Shea, Unit Directors)
- 2008 Structural Equation Modeling (with Tessa V. West), Yale University, graduate level
- 2006-2009 Theories of Personality, University of Connecticut, undergraduate; enrollment=100
- Abnormal Psychology, University of Connecticut, undergraduate; enrollment=100

#### Precepting and Invited Lectures

- 2012-2013 Epidemiology and Clinical Epidemiology Course, College of Physicians and Surgeons, Columbia University (David Lederer and Steven Shea, Unit Directors)
- 2012 Meta-analysis; N9653 Advanced Research Methods, Columbia University School of Nursing (Arlene Smaldone and Patricia Stone, Unit Directors) enrollment=30

#### Teaching Assistant

- 2008 Structural Equation Modeling (David Kenny, Instructor), University of Connecticut, graduate; enrollment= 45
- 2006-2009 Multivariate Statistics [Eric Lundquist (2 sections), Brian Connelly, Instructors], University of Connecticut, graduate; enrollment= 85
- 2004-2006 General Psychology I: Introductory, University of Connecticut; enrollment= 100
- Honors General Psychology II: Enhanced, University of Connecticut, undergraduate, enrollment= 100

#### **Thesis/Dissertation Sponsorship**

<u>Student Name</u>	<u>Level of Learner</u>	<u>Date of Training</u>	<u>Nature of Responsibility</u>
Laura Goorin	Ph.D.	2010	Dissertation Committee Member (TC)
Aurelie Athan	Ph.D.	2010	Dissertation Committee Member (TC)

#### **Other Professional Activities**

##### University Committees

Clinical/Epidemiological Research Task Force (Elizabeth Shane, leader)

##### Mailman School of Public Health student research practicum supervisor

2012- Safiya Richardson, M.D.: The influence of stress on cardiovascular events

##### BEST Diversity Program mentor; Biostatistics

2012- Introduce biostatistics to under-represented minority, economically disadvantaged, and disabled undergraduates, with special emphasis on cardiovascular and pulmonary research.

##### Co-editor (with Karina Davidson)

2012-*Progress in Cardiovascular Diseases* special issue: "Psychosocial factors and cardiovascular disease"

##### Ad hoc reviewer:

Ageing and Society  
Anxiety, Stress, and Coping  
Biological Psychology  
Cleveland Clinic Journal of Medicine  
European Heart Journal  
International J for the Psych of Religion

Annals of Behavioral Medicine  
Biological Psychiatry  
Circulation  
General Hospital Psychiatry  
Health Psychology  
Journal of Applied Social Psychology

Journal of Behavioral Medicine  
Journal of Psychosomatic Research  
J of Traumatic Stress  
Personality and Individual Differences  
Trials

J of Personality and Social Psychology  
J of the American College of Cardiology  
Metabolism  
Psychosomatic Medicine  
World Journal of Biological Psychiatry

## **Publications**

### **A. Original, Peer Reviewed Articles**

1. Wasson, L. T., Shaffer, J., Alcantara, C., Schwartz, J. E., & **Edmondson, D.** (2014). The association of posttraumatic stress disorder and quality of life during the first year after acute coronary syndrome. *International Journal of Cardiology*. Aug 13 [Epub ahead of print]
2. Alcántara, C., **Edmondson, D.**, Moise, N., Oyola, D., Hiti, D., & Kronish, I. M. (2014). Anxiety Sensitivity and Medication Nonadherence in Patients with Uncontrolled Hypertension. *Journal of Psychosomatic Research*, 77(4), 283-286.
3. Davidson KW, Peacock J, Kronish IM, **Edmondson D.** (2014). Personalizing behavior change interventions through single-patient (N-of-1) randomized controlled trials. *Social and Personality Psychology Compass*, 8(8), 408-421.
4. **Edmondson D**, Green P, Ye S, Halazun H, Davidson KW (2014). Psychological stress and 30-day all-cause hospital readmission in acute coronary syndrome patients: An observational cohort study. *PLoS ONE*, 9(3): e91477. PMCID: PMC3951368
5. **Edmondson D**, Kronish IM, Wasson LT, Giglio J, Davidson KW, Whang W. (2014). A test of the diathesis-stress model in the emergency department: Who develops PTSD after an acute coronary syndrome? *Journal of Psychiatric Research*, 53:8-13. PMCID: PMC4023688 [Available on 2015/6/1].
6. Shaffer JA, Diaz K, Alcantara C, **Edmondson D**, Krupka DJ, Chaplin WF, Davidson KW. (2014). An inexpensive device for monitoring patients' weights via automated hovering. *International Journal of Cardiology*, 172(2): e263-4. PMCID: PMC3984000 [Available on 2015/3/15]
7. Shaffer JA, **Edmondson D**, Wasson LT, Falzon L, Homma K, Ezeokoli N, Li P, Davidson KW (2014). Vitamin D Supplementation for Depressive Symptoms: A Systematic Review and Meta-analysis of Randomized Controlled Trials. *Psychosomatic Medicine*, 2014, 76(3), 190-196. PMCID: PMC4008710 [Available on 2015/4/1]
8. Alcantara C, Peacock J, Hiti D, Davidson KW, **Edmondson D.** The association of short sleep after acute coronary syndrome with recurrent cardiac events and mortality. *International Journal of Cardiology*, 2014, 171(2):e11-2. PMCID: PMC3947905 [Available on 2015/2/1]
9. **Edmondson D.** (2014). An enduring somatic threat model of posttraumatic stress disorder due to acute life-threatening medical events. *Social and Personality Psychology Compass*, 8(3), 118-134. PMCID: PMC4048720 [Available on 2015/3/15]
10. Kronish IM, Lin JJ, Cohen BE, Voils CI, **Edmondson D.** (2014). Posttraumatic Stress Disorder increases risk for non-adherence to medications in patients with uncontrolled hypertension. *JAMA Internal Medicine*, 174(3), 468-470. PMCID: PMC3999520
11. **Edmondson, D.** & Cohen, B. (2013). Posttraumatic stress disorder and cardiovascular disease. *Progress in Cardiovascular Diseases*, 55, 548-56. PMCID: PMC3639489

12. Burg, MM, **Edmondson, D**, Whang, W, Shaffer, JA, Kronish, IM, Alacántara, C, Schwartz, JE, Muntner, P, Shimbo, D., Davidson, KW. (2013). The 'Perfect Storm' that leads to acute coronary syndrome: Do psychosocial factors play a role? *Progress in Cardiovascular Diseases*, 55, 601-610. PMID:PMC3652628
13. **Edmondson, D.**, Gamboa, C., Cohen, A., Hyre Anderson, A., Kutner, N., Kronish, I. M., Mills, M.A. & Muntner, P. (2013). Association of posttraumatic stress disorder and depression with all-cause and cardiovascular disease mortality and hospitalization among Hurricane Katrina survivors with end-stage renal disease. *American Journal of Public Health*, 2013;103:e130-137. PMID: PMC3673270
14. **Edmondson, D.**, Horowitz, C. R., Goldfinger, J. Z., Fei, K., Kronish, I M. (2013). Concerns about medications mediate the association of posttraumatic stress disorder with adherence to medication in stroke survivors. *British Journal of Health Psychology*, 18:799-813. PMID: PMC3760991
15. **Edmondson D**, Kronish IM, Shaffer JA, Falzon L, Burg MM (2013). Posttraumatic stress disorder and risk for coronary heart disease: A meta-analytic review. *American Heart Journal*, 166, 806-814. PMID:PMC3815706 [Available on 2014/11/1]
16. **Edmondson, D.**, Newman, J. D., Whang, W., & Davidson, K.W. (2013). Emotional triggers of acute myocardial infarction: Do they matter? *European Heart Journal*, 34, 300-6. PMID:PMC3549526
17. **Edmondson D**, Richardson S, Fausett JK, Falzon L, Howard VJ, Kronish I. Prevalence of posttraumatic stress disorder in stroke survivors: A meta-analytic review. *PLoS ONE*. 2013;8:e66435. PMID: PMC3686746
18. **Edmondson D**, Shaffer JA, Chaplin WF, Burg MM, Stone AA, Schwartz JE. Trait anxiety and trait anger measured by ecological momentary assessment and their correspondence with traditional trait questionnaires. *Journal of Research in Personality*, 2013;47:843-852. PMID: PMC3815708
19. **Edmondson, D.**, Shimbo, D., Ye, S., Wyer, P., & Davidson, K.W. (2013). The association of emergency department crowding during treatment for acute coronary syndrome with subsequent posttraumatic stress disorder symptoms. *JAMA Internal Medicine*, 2013;173:472-475. PMID: PMC3973030  
**Editorial commentary:** O'Malley PG. The environment of health care: Primum non nocere comment on "the association of emergency department crowding during treatment for acute coronary syndrome with subsequent posttraumatic stress disorder symptoms". *JAMA Internal Medicine*, 2013;173:474-474.
20. Goldfinger JZ, **Edmondson D**, Kronish IM, Fei K, Balakrishnan R, Tuhim S, Horowitz CR (2013). Correlates of posttraumatic stress disorder in stroke survivors. *Journal of Stroke and Cerebrovascular Diseases*, Oct 19 [Epub ahead of print]. PMID: PMC3992186 [Available on 2015/4/19]
21. Kronish IM, Diefenbach M, **Edmondson D**, Phillips LA, Fei K, Horowitz CR (2013). Key barriers to medication adherence in survivors of strokes and transient ischemic attacks. *Journal of General Internal Medicine*, 28, 675-682. PMID: PMC3631079
22. Shaffer JA, Kronish IM, Burg M, Clemow L, **Edmondson D** (2013). Association of acute coronary syndrome-induced posttraumatic stress disorder symptoms with self-reported sleep.

*Annals of Behavioral Medicine*, 46, 349-357. PMID: PMC3800234 [Available on 2014/11/30].

23. **Edmondson, D.**, Newman, J. D., Chang, M. J., Wyer, P., & Davidson, K.W. (2012). Depression is associated with longer emergency department length of stay in acute coronary syndrome patients. *BMC Emergency Medicine*, 12:14 (5 November 2012). PMID: PMC3546889.
24. **Edmondson, D.**, Richardson, S., Falzon, L., Davidson, K.W., Mills, M.A., & Neria, Y. (2012). Posttraumatic stress disorder prevalence and risk of recurrence in acute coronary syndrome patients: A meta-analytic review. *PLoS ONE*. PMID: PMC3380054
25. **Edmondson D**, Shaffer JA, Denton EG, Shimbo D and Clemow L (2012). Posttraumatic stress and myocardial infarction risk perceptions in hospitalized acute coronary syndrome patients. *Frontiers in Psychology* 3:144. doi: 10.3389/fpsyg.2012.00144. PMID: PMC3350942
26. Hale-Smith A, Park CL, **Edmondson D**. Measuring beliefs about suffering: Development of the views of suffering scale. *Psychol Assess*. 2012;24:855-866. PMID: PMC3695743
27. Kronish, I. M., **Edmondson, D.**, Li, Y., Cohen, B. (2012). Posttraumatic stress disorder and medication adherence: Results from the Mind Your Heart study. *Journal of Psychiatric Research*, 43, 2192-7. PMID: PMC3485414
28. Kronish, I., **Edmondson, D.**, Goldfinger, J., & Horowitz, C. (2012). Posttraumatic stress disorder and adherence to medications in survivors of strokes and transient ischemic attacks. *Stroke*, 43, 2192-7. PMID: PMC3404197
29. Kronish IM, Rieckmann N, Burg MM, **Edmondson D**, Schwartz JE, Davidson KW. (2012). The Effect of Enhanced Depression Care on Adherence to Risk Reducing Behaviors after Acute Coronary Syndromes: Findings from the COPEs Trial. *American Heart Journal*, 164, 524-9. PMID: PMC3549526
30. Park, C.L., **Edmondson, D.**, & Lee, J. (2012). Development of self-regulation abilities as predictors of psychological adjustment across the first year of college. *Journal of Adult Development*, 19, 40-49.
31. Park, C.L., Mills, M. A., & **Edmondson, D.** (2012). PTSD as meaning violation: Testing a cognitive worldview perspective. *Psychological Trauma: Theory, Research, Practice, Policy*, 4, 66-73. PMID: PMC4029350
32. Park, C. L., Sacco, S., & **Edmondson, D.** (2012). Expanding coping goodness of fit: Religious coping, health locus of control and depressed affect in heart failure patients. *Anxiety, Stress, and Coping*, 25, 137-53.
33. Richardson, S., Shaffer, J.A., Falzon, L., Davidson, K.W., Krupka, D., & **Edmondson, D.** (2012). Meta-analysis of perceived stress and its association with incident coronary heart disease. *American Journal of Cardiology*, 110, 1711-16. PMID: PMC3511594
34. Wortmann, J.H., Park, C.L., Swenson, E., & **Edmondson, D.** (2012). Spiritual struggle and adjustment to loss in college students: Moderation by denomination. *International Journal for the Psychology of Religion*, 22, 303-20.
35. **Edmondson, D.**, Chaudoir, S. C., Mills, M. A., Park, C. L., Holub, J., & Bartkowiak, J. M. (2011). From shattered assumptions to weakened worldviews: Trauma symptoms signal anxiety buffer disruption. *Journal of Loss and Trauma*, 16, 358-85. PMID: PMC3783359

36. **Edmondson, D.**, Rieckmann, N., Shaffer, J. A., Schwartz, J. E., Burg, M. M., Davidson, K. W., Clemow, L., Shimbo, D., & Kronish, I. M. (2011). Posttraumatic stress due to an acute coronary syndrome increases risk of 42-month major adverse cardiac events and all-cause mortality. *Journal of Psychiatric Research*, 45, 1621-26. PMCID: PMC3210372
37. Ishikawa, J., Ishikawa, Y., **Edmondson, D.**, Pickering, T. G., & Schwartz, J. E. (2011). Age and the difference in awake ambulatory blood pressure and clinic blood pressure: A meta-analysis. *Blood Pressure Monitoring*, 16, 159-67. PMCID: PMC3839085
38. Newman JD, Muntner P, Shimbo D, Davidson KW, Shaffer JA, & **Edmondson D.** (2011). Post-traumatic stress disorder (PTSD) symptoms predict delay to hospital in patients with acute coronary syndrome. *PLoS One*, 2011, 6, e27640. PMCID: PMC3214073
39. Park, C. L., Wortmann, J.H., & **Edmondson, D.** (2011). Religious struggle as a predictor of subsequent mental and physical well-being in advanced heart failure patients. *Journal of Behavioral Medicine*, 34, 426-36.
40. Shaffer, J. A., **Edmondson, D.**, Chaplin, W. F., Schwartz, J. E., Iyer, P., Burg, M. M., Rieckmann, N., Shimbo, D., & Davidson, K. W. (2011). Directionality of the relationship between depression symptom dimensions and C-reactive protein among patients with acute coronary syndromes. *Psychosomatic Medicine*, 73, 370-77. PMCID: PMC3110525
41. Wortmann, J. H., Park, C. L., & **Edmondson, D.** (2011). Trauma and PTSD symptoms: Does spiritual struggle mediate the link? *Psychological Trauma: Theory, Research, Practice, Policy*, 3, 442-52. PMCID: PMC3269830
42. **Edmondson, D.**, Mills, M. A., & Park, C. L. (2010). Factor structure of the Acute Stress Disorder Scale in Hurricane Katrina evacuees. *Psychological Assessment*, 22, 269-278. PMCID: PMC2883796
43. **Edmondson, D.**, & Park, C. L. (2009). Shifting foundations: Religious belief change and adjustment in college students. *Mental Health, Religion, and Culture*, 12, 289-302.
44. Park, C. L., **Edmondson, D.**, & Blank, T. O. (2009). Religious and non-religious pathways to stress-related growth in cancer survivors. *Applied Psychology: Health and Well-Being*, 1, 321-335.
45. Park, C. L., **Edmondson, D.**, Blank, T. O., & Hale Smith, A. (2009). Religiousness/spirituality and health behaviors in younger adult cancer survivors: Does faith promote a healthier lifestyle? *Journal of Behavioral Medicine*, 32, 582-591
46. Penner, L. A., Dovidio, J. F., **Edmondson, D.**, Albrecht, T. L., Dailey, R. K., & Markova, T. (2009). The experience of discrimination and Black-White health disparities in medical care. *Journal of Black Psychology*, 35, 180-203. PMCID: PMC3862356
47. Sullivan, T. P., Cavanaugh, C. E., Buckner, J. D., & **Edmondson, D.** (2009). Testing posttraumatic stress as a mediator of physical, sexual, and psychological intimate partner violence and substance problems among women. *Journal of Traumatic Stress*, 22, 575-584. PMCID: PMC3012603
48. Yanez, B., **Edmondson, D.**, Stanton, A. L., Park, C. L., Kwan, L., Ganz, P., & Blank, T. O. (2009). Facets of spirituality as predictors of adjustment to cancer: Relative contributions of having faith and finding meaning. *Journal of Consulting and Clinical Psychology*, 77, 730-741. PMCID: PMC2825181

49. **Edmondson, D.**, Park, C. L., Chaudoir, S. R., & Wortmann, J. (2008). Death without God: Religious struggle, death concerns, and depression in the terminally ill. *Psychological Science*, 19, 628-632.
50. **Edmondson, D.**, Park, C. L., Blank, T. O., Fenster, J., & Mills, M. A. (2008). Deconstructing spiritual well-being: Existential well-being and HRQOL in cancer survivors. *Psycho-Oncology*, 17, 161-169.
51. Park, C. L., **Edmondson, D.**, Blank, T. O., & Fenster, J. R. (2008). Meaning making and psychological adjustment following cancer: The mediating roles of growth, life meaning, and restored just world beliefs. *Journal of Consulting and Clinical Psychology*, 76, 863-875.
52. Park, C. L., **Edmondson, D.**, Fenster, J. R., & Blank, T. O. (2008). Positive and negative health behavior changes in cancer survivors: A stress and coping perspective. *Journal of Health Psychology*, 13, 1198-1206.
53. Mills, M. A., **Edmondson, D.**, & Park, C. L. (2007). Trauma and stress response in Katrina's evacuees. *American Journal of Public Health*, 97, S116-123. PMID: PMC1854990

#### B. Case Reports

n/a

#### C. Reviews, Chapters and Editorials

1. **Edmondson D**, Davidson KW. Introduction to the special issue on psychosocial factors in cardiovascular disease. *Prog Cardiovasc Dis*. 2013; 55:509-510
2. Park, C. L., **Edmondson, D.**, & Hale Smith, A. Why religion? Meaning as the motivation. In K. I. Pargament (Ed.), *APA Handbook of Psychology, Religion, and Spirituality*. Washington, D.C., APA. 2013.
3. **Edmondson D**, Hiti D, Kronish IM. Posttraumatic stress disorder and cardiovascular disease. In *Cardiovascular Prevention: A Global Challenge*, Donna K. Arnett, ed. In press.
4. Park, C. L. & **Edmondson, D.** Religion as a source of meaning. In Mikulincer, M. & Shaver, P. (Eds.), *Meaning, Mortality, and Choice: The Social Psychology of Existential Concerns*. Washington, D.C., APA. 2012.
5. Park, C. L., **Edmondson, D.**, & Mills, M. A. Religious worldviews and stressful encounters: Reciprocal influence from a meaning making perspective. In T. W. Miller (Ed.), *Handbook of stressful transitions across the lifespan*. New York, Springer. 2009, 485-502.
6. **Edmondson, D.** & Mills, M. A. Research in New Orleans: Through the eyes of the victims of Hurricane Katrina. *The Society for the Psychological Study of Social Issues: The Rookie*. 2005, November.

#### D. Patents

n/a

#### E. Abstracts

1. Brondolo E, Wasson L, Alcantara C, **Edmondson D**. Posttraumatic stress disorder and smoking in year after an acute coronary syndrome event. Paper presented at American Psychosomatic Society, San Francisco, CA. March 2014.
2. Kronish I, Lin J, Cohen B, Voils C, Olamiju B, **Edmondson D**. PTSD and medication nonadherence in patients with uncontrolled hypertension. Paper presented at American Psychosomatic Society, San Francisco, CA. March 2014.
3. **Edmondson D**, Green P, Ye S, Halazun H, Davidson KW (2013). Psychological Stress And

30-day Readmission In Acute Coronary Syndrome Patients. Poster presented at the American Heart Association Scientific Sessions, Dallas.

4. **Edmondson D**, Richardson S, Fausett JK, Falzon L, Howard, VJ, Kronish, IK. (2013). Prevalence of PTSD in Stroke Survivors: A Meta-analytic Review. Poster presented at the American Heart Association Epidemiology and Prevention Scientific Sessions, New Orleans.
5. **Edmondson D**, Kronish, IK, Shaffer JA, Falzon L, Burg MM. (2013). Posttraumatic Stress Disorder and Risk for Coronary Heart Disease: A Meta-analytic Review of Prospective Studies Poster presented at the American Heart Association Epidemiology and Prevention Scientific Sessions, New Orleans.
6. Halazun H, Kronish I, **Edmondson D**, Davidson KW, Ye S (2013). The Impact of Patient Comorbidity on Risk of 30-day Readmission Following Hospitalization for Acute Coronary Syndromes. Poster presented at the American Heart Association Scientific Sessions, Dallas.
7. Happy, S., Morales, R., & **Edmondson, D.** (2013). Lifetime history of PTSD predicts nonadherence to medications after acute coronary syndrome. Poster presented at the 25th Annual Association for Psychological Science Convention, May 23-26, 2013.
8. Goldfinger JZ, Fei K, Balakrishnan R, Diefenbach MA, **Edmondson D**, Kronish IM, Tuhim S, Horowitz CR. (2012, February). Prevalence and Correlates of PTSD After Stroke. Poster presented at the AHA/ASA International Stroke Conference, New Orleans, LA.
9. **Edmondson, D.**, Newman, J., Chang, M., Wyer, P., & Davidson, K.W. (2012, April). Patients with suspected NSTEMI or unstable angina who are depressed wait longer in emergency departments than non-depressed patients. Poster presented at the 33rd Annual Meeting & Scientific Sessions of the Society of Behavioral Medicine, New Orleans.
10. **Edmondson, D.**, Richardson, S., Falzon, L., Davidson, K. D., Mary Alice Mills, Ph.D., & Neria, Y. (2012, March). Acute coronary syndrome-induced posttraumatic stress disorder: A meta-analytic review of prevalence, association with clinical outcomes, and intervention effects. Poster presented at the Annual Meeting of the American Psychosomatic Society, Athens, Greece.
11. **Edmondson, D.**, Ye, S., Schulman, J., & Davidson, K. D. (2012, March). Cost-effectiveness of enhanced depression treatment in acute coronary syndrome patients. Paper presented at the Annual Meeting of the American Psychosomatic Society, Athens, Greece.
12. **Edmondson, D.**, Parsons, F., Shaffer, J. A., & Davidson, K. D. (2012, March). Wait, who are we missing? Demographic predictors of refusal to participate in a randomized controlled trial of depression treatment. Poster presented at the Annual Meeting of the American Psychosomatic Society, Athens, Greece.
13. **Edmondson, D.**, Shaffer, J. A., Denton, E., Shimbo, D., & Clemow, L. P. (2011, March). PTSD and Recurrence Risk Perceptions in Acute Coronary Syndrome Patients. Paper presented at the Annual Meeting of the American Psychosomatic Society, San Antonio, TX.
14. Perez, S. A. (**student**), Duer-Hefel, J. T., Davidson, K. W., & **Edmondson, D.** (2011, November). Posttraumatic stress disorder symptoms and poor sleep quality in acute coronary syndrome patients. Paper presented at the American Heart Association Scientific Sessions, Orlando, FL.
15. Moran, M. D. (**student**), Duer-Hefel, J. T., Davidson, K. W., & **Edmondson, D.** (2011, November). Female patients with suspected NSTEMI or unstable angina wait longer in emergency department than male patients. Paper presented at the American Heart Association Scientific Sessions, Orlando, FL.
16. Shaffer, J. A., **Edmondson, D.**, Chaplin, W., Schwartz, J. E., & Stone A. A. (2010, March).

Anxiety and anger in daily life: Contributions of the person and situation in momentary assessments of elicited states. Poster presented at the annual meeting of the American Psychosomatic Society, Portland.

17. **Edmondson, D.**, Ishikawa, J., Yurgel, T., Burg, M. M., & Schwartz, J. E. (2010, March). Comparison of blood pressure assessment methods using CFA. Poster presented at the annual meeting of the American Psychosomatic Society, Portland.
18. Park, C. L. & **Edmondson, D.** (2010, May). Advances in the measurement of meaning making and meanings made. In C. L. Park (Chair), Innovations in meaning making research: Conceptual and methodological advances. Symposium conducted at the annual Association for Psychological Science Convention, Boston, MA.
19. **Edmondson, D.** & Schwartz, J. E. (2010, May). Potentially Traumatic Events Increase Resting Heart Rate in Civilians Assessed with ABPM. Poster presented at the annual meeting of the Association for Psychological Science, Boston.
20. Shaffer, J. A., **Edmondson, D.**, Chaplin, W. F., Schwartz, J. E., Burg, M. M., Reickmann, N., & Davidson, K. W. (2010, August). Somatic and Cognitive Symptoms of Depression Predict Changes in C-Reactive Protein (CRP) in Patients with Acute Coronary Syndrome (ACS). Poster presented at the annual International Congress of Behavioral Medicine, Washington, D.C.
21. **Edmondson, D.**, Kronish, I., Harlapur, M., Shaffer, J. A., Davidson, K. W., Schwartz, J. E., Burg, M. M., Iyer, P., Shimbo, D., Clemow, L., & Rieckmann, N. (2010, November). Posttraumatic Stress Disorder (PTSD) Symptoms Predict Worse Long-term Cardiovascular Prognosis in Post-Acute Coronary Syndrome (ACS) Patients. Paper presented at the American Heart Association Scientific Sessions, Chicago, IL.
22. **Edmondson, D.**, Chaudoir, S. C., Bartkowiak, J., & Bestrom, P. (2009, February). Terror management and PTSD: Shattered assumptions or damaged worldview? Poster presented at the annual Society for Personality and Social Psychology Convention, Tampa, FL.
23. Park, C. L., **Edmondson, D.**, & Blank, T. O. (2009, April). Religious and non-religious pathways to stress-related growth in younger adult cancer survivors. Paper presented at the 29<sup>th</sup> annual meeting of the Society of Behavioral Medicine, Montreal.
24. Mills, M. A., Park, C. L., & **Edmondson, D.** (2009, November). Shattered assumptions? A prospective study: The impact of trauma on global beliefs. Paper presented at the International Society for Traumatic Stress Studies, Atlanta.
25. Ishikawa, J., Ishikawa, Y., **Edmondson, D.**, Schwartz, J. E., & Pickering, T. G. (2009, November). Age and the difference in awake ambulatory blood pressure and clinic blood pressure: A meta-analysis. Paper presented at the American Heart Association Scientific Sessions, Orlando.
26. **Edmondson, D.**, Chaudoir, S. C., Holub, J., & Park, C. L. (2008, August). Weakened, but not shattered: Evidence of worldview dysfunction in PTSD. In D. Edmondson (Chair), The causes and psychological consequences of cultural worldview breach. Symposium conducted at the annual American Psychological Association Convention, Boston, MA.
27. **Edmondson, D.**, Holub, J., Chaudoir, S. C., Gavitt, C., Bestrom, P., & Park, C. L. (2008, March). Religious struggle as adaptive meaning making in the service of terror management. In C. L. Park (Chair), Religious meaning systems in action: Stress appraisals, terror management, and restoration of global religious beliefs. Symposium conducted at the Annual Mid-Year Research Conference on Religion and Spirituality, Columbia, MD.



28. Sullivan, T. P., Cavanaugh, C. E., Buckner, J. D., & **Edmondson, D.** (2008, July). Intimate partner violence (IPV) and drug and alcohol use problems among community women: The roles of physical, sexual, and psychological IPV and PTSD. Paper presented at the International Family Violence and Child Victimization Research Conference, Portsmouth, New Hampshire.
29. Wortmann, J.H., Park, C.L., **Edmondson, D.**, & Swenson, E. (2008, August). Denominational Differences in Religious Comfort and Struggle and Adjustment After Loss. Paper presented at the annual Convention of the American Psychological Association, Boston.
30. **Edmondson, D.**, Park, C. L., Blank, T. O., & Smith, Hale Smith, A. (2008, August). Religion/Spirituality and Health Behaviors in Younger Adult Cancer Survivors. Poster presented at the annual American Psychological Association Convention, Boston, MA.
31. **Edmondson, D.**, Park, C. L., & Blank, T. O. (2007, March). Change in existential well-being influences HRQOL in cancer survivors. Paper presented at the 28<sup>th</sup> annual meeting of the Society of Behavioral Medicine, Washington, DC.
32. **Edmondson, D.** (2007, March). Religious meaning influences the cognitive response to cancer, and vice versa. In M. Koltko-Rivera (Discussant), Trauma and spirituality: The recursive nature of spiritual meaning and meaning making. Symposium conducted at the annual Mid-Year Research Conference on Religion and Spirituality, Columbia, MD.
33. **Edmondson, D.**, Park, C. L., Blank, T. O., & Fenster, J. R. (2007, August). The process and products of meaning making in cancer survivorship. Poster presented at the annual American Psychological Association Convention, San Francisco.
34. Mills, M. A., Park, C. L., & **Edmondson, D.** (2007, November). The immediate aftermath: Stress, coping, and distress in Hurricane Katrina's evacuees. Paper presented at the 23rd annual meeting of the International Society for Traumatic Stress Studies, Baltimore, MD.
35. Fenster, J., Park, C. L., **Edmondson, D.**, & Blank, T. O. (2007, November). Relationship Between Previous Life Trauma, Resolution of Trauma, and Adjustment in Young Cancer Survivors. Poster presented at the International Society for Traumatic Stress Studies, Baltimore, MD.
36. **Edmondson, D.**, Park, C. L., & Mills, M. A. (2006, March). A terror management model of religious engagement in older adults. In C. L. Park (Chair), Religion and death-related phenomena. Symposium conducted at the annual Mid-Year Research Conference on Religion and Spirituality, Columbia, MD.
37. **Edmondson, D.**, & Mills, M. A. (2006, March). The role of religious coping in the cognitive processing of trauma. Paper presented at the annual Mid-Year Research Conference on Religion and Spirituality, Columbia, MD.
38. **Edmondson, D.**, Park, C.L., Blank, T. O., Mills, M. A., & Fenster, J. (2006, March). Existential well-being and health related quality of life in cancer survivors. Paper presented at the 27<sup>th</sup> annual meeting of the Society of Behavioral Medicine, San Francisco.
39. Park, C. L., Blank, T. O., Fenster, J. R., & **Edmondson, D.** (2006, July). Spirituality, Meaning, and Well-being in Young to Middle Aged Cancer Survivors. Paper presented in Symposium, Meaning, Spirituality and Approaches to Decrease Distress (D. Pyritz, Chair) at the UICC World Cancer Congress. Washington, DC.
40. Park, C. L., Blank, T. O., Fenster, J. R., & **Edmondson, D.** (2006, July). Meaning Making Processes and Adjustment to Cancer Survivorship. Poster presented at the UICC World Cancer Congress, Washington, DC.

41. **Edmondson, D.**, Wortmann, J., Ayotte, K., & Park, C. L. (2006, August). Model of religious struggle and depression in CHF (congestive heart failure) patients. Poster presented at the annual American Psychological Association Convention, New Orleans, LA.
42. **Edmondson, D.** (2006, August). Cancer survivorship as mortality salience: Terror management and wellbeing. Paper presented at the annual American Psychological Association Convention, New Orleans, LA.
43. **Edmondson, D.**, & Park, C. L. (2005, April). Terror management perspectives on religion and adjustment to cancer. Paper presented in Symposium, Religion and Death-Related Adjustment (C. L. Park, Chair), at the Annual Midwinter Meeting of Division 36 (Psychology of Religion), American Psychological Association, Baltimore.
44. **Edmondson, D.**, Parizeau, L., & Park, C. L. (2005, April). Religious and spiritual dimensions as determinants of health behaviors in college students. Paper presented at the annual Mid-Year Research Conference on Religion and Spirituality, Columbia, MD.
45. **Edmondson, D.**, & Park, C. L. (2005, August). Religious belief change in college students. Paper presented at the American Psychological Association Convention, Washington, DC.

### **Invited Presentations**

1. **Edmondson, D.** (2013, February). *PTSD and Cardiovascular Disease*. Invited presentation to New York University Department of Psychiatry.
2. **Edmondson, D.** (2011, April). *Religion and Meaning*. Presented at the Fourth Annual Herzliya Symposium on Social and Personality Psychology, Interdisciplinary Center, Herzliya, Israel.
3. **Edmondson, D.** (2010, April). *PTSD after acute coronary syndrome as an independent risk factor for MACE/ACM recurrence*. Presented at Division of General Medicine Spring Conference, Columbia University Medical Center, NY.
4. **Edmondson, D.** (2006, March). *Meaning and mortality in health research*. Presented at the University of Connecticut Center for Health Intervention and Prevention, "Sex, Drugs, and Health Behaviors II", Storrs, CT.
5. **Edmondson, D.**, & Mills, M.A. (2006, March). *Acute Stress Disorder in Katrina's evacuees: Prevalence and predictors*. Presented at the University of Connecticut Economics Department Graduate Student Seminar series, Storrs, CT.

### F. Media

#### **2013**

For: **Edmondson, D.**, Shimbo, D., Ye, S., Wyer, P., & Davidson, K.W. (2013). The association of emergency department crowding during treatment for acute coronary syndrome with subsequent posttraumatic stress disorder symptoms. *JAMA Intern Med.* 2013;173:472-475. NIHMS453931

#### **1. Chicago Tribune**

##### [Overcrowded ERs, PTSD signs tied in heart patients](#)

Being treated for a heart attack in a crowded emergency department may be linked to developing symptoms of a stress disorder, according to a new study.

For: **Edmondson D**, Richardson S, Fausett JK, Falzon L, Howard VJ, Kronish I. Prevalence of posttraumatic stress disorder in stroke survivors: A meta-analytic review. *PLoS ONE*. 2013;8:e66435

## 1. CBS THIS MORNING

### [PTSD can be triggered by serious medical events](#)

June 29, 2013

Post-Traumatic Stress Disorder - PTSD - is often associated with military combat veterans, but a new study found that it can also be triggered by serious health events. **Donald Edmondson** and **Dr. Ian Kronish**, the co-authors of the study, talk to the "CBS This Morning: Saturday" co-hosts about their findings.

## 2. WALL STREET JOURNAL LIVE

### [PTSD: Not Just for Soldiers Anymore](#)

July 24, 2013

A new study finds that one in four stroke patients are developing post traumatic stress disorder within a year of the stroke. And the odds of a psychological recovery are worse for younger patients. Sumathi Reddy and the study's lead author **Dr. Donald Edmondson** have details.

## 3. Also: CNN; USA Today; LA Times; WCBS; Medscape; HHS Healthbeat

## 2012

For **Edmondson, D.**, Richardson, S., Falzon, L., Davidson, K.W., Mills, M.A., & Neria, Y. (2012). Posttraumatic stress disorder prevalence and risk of recurrence in acute coronary syndrome patients: A meta-analytic review. *PLoS ONE*. PMID: PMC3380054

## 1. JAMA

Voelker R. Study: Acute coronary events linked with PTSD: JAMA. 2012 Jul 11;308(2):121.

## 2. American Psychiatric Association

Sinclair L. PTSD Often Overlooked in Treating Cardiac Patients. *Psychiatric News*. 2012;Sect. 22-5.

## 3. NEW YORK TIMES

[Heart Attack Survivors May Develop P.T.S.D.](#) By Tara Parker-Pope; June 20, 2012

## 4. TIME

[Heart Attacks Can Trigger Post-Traumatic Stress](#) By Amanda Macmillan; June 21, 2012

5. **ABC NEWS/ World News with Diane Sawyer**  
[Heart Attacks and PTSD: A Vicious Cycle](#) By Dr. Jenniffer Mahand; June 20, 2012
6. **FOX NEWS**  
[PTSD prevalent among heart attack patients, study finds](#) By Alex Crees; June 21, 2012
7. **CNN**  
[PTSD strikes one in eight heart attack patients](#)
8. **US News and World Report**  
Doheny, K. (2012), PTSD symptoms common after heart attack: Study. *U.S. News & World Report*.
9. **PBS NewsHour** for June 21, 2012

## **2011**

For: **Edmondson, D.**, Rieckmann, N., Shaffer, J. A., Schwartz, J. E., Burg, M. M., Davidson, K. W., Clemow, L., Shimbo, D., & Kronish, I. M. (2011). Posttraumatic stress due to an acute coronary syndrome increases risk of 42-month major adverse cardiac events and all-cause mortality. *Journal of Psychiatric Research*, 45, 1621-26. PMCID: PMC3210372

1. **Journal Watch Psychiatry**  
PTSD Affects Medical Outcomes After Acute Coronary Syndromes (2011, September 19). *Journal Watch Psychiatry*. <http://psychiatry.jwatch.org>.  
*Internal Medicine News*
2. **Internal Medicine News**  
PTSD Linked to Risk for Coronary Disease, Death (2010, December 10). *Internal Medicine News*. <http://www.internalmedicine.com/news/mental-health/single-article/ptsd-linked-to-risk-for-coronary-disease-death/60996e5568.html>.

## **2009**

1. **UConn Magazine**  
Surviving the Ph.D. Process (2009, Fall/Winter). *UConn Magazine*  
<http://uconnmagazine.uconn.edu/fwin2009/feature2.html>.

Revised 5/1/2015

**CURRICULUM VITAE  
WEN-CHIH HANK WU, M.D., M.P.H.**

**Business address:** 830 Chalkstone Ave, Providence, RI 02908

**Business Tel:** (401) 273-7100 ext. 2426

**Business Fax:** (401) 457-3311

**E-mail:** [Wen-chih.wu@va.gov](mailto:Wen-chih.wu@va.gov)  
[Wen-Chih\\_Wu@brown.edu](mailto:Wen-Chih_Wu@brown.edu)

**Education:**

B.S., M.D. University of Costa Rica School of Medicine  
San Jose, Costa Rica, 1989-1995  
Full-tuition Honor Scholarship 1990-1995  
Honor Graduation 1995

M.P.H. Brown University, June 2010  
M.A. Brown University, July 2010 (*ad eundem gradum*)

**Postgraduate Training:**

1996-1997 Internship, Primary Care Internal Medicine  
University of Connecticut School of Medicine  
Farmington, CT

1997-1999 Residency, Primary Care Internal Medicine  
University of Connecticut School of Medicine  
Farmington, CT

1999-2002 Fellowship, Cardiovascular Diseases  
Brown University Medical School  
Providence, RI

2008 Level 2 Training, Cardiac Computed Tomography  
Angiography; The Christ Hospital, Cincinnati, Ohio

**Postgraduate Honors and Awards**

1999 Medical Resident of the Year  
University of Connecticut School of Medicine

2001-2003 Dean's Teaching Excellence Awards  
Brown Medical School

2002 – 2005 Teacher of the Year Award

	Cardiology Fellowship, Brown Medical School
2010	Beckwith Family Award for Outstanding Teaching Dept. of Medicine, Alpert Medical School, Brown Univ.

**Professional Licensure and Board Certification**

1999-2011	Connecticut Medical License
1999-	ABIM- Internal Medicine
2001-	Rhode Island medical license
2002-	ABIM - Cardiology

**Academic Appointments**

2002 - 2010	Assistant Professor of Medicine (Cardiology) Brown University Alpert Medical School
2010 –	Associate Professor of Medicine (Research), Brown University Alpert Medical School
2012 -	Associate Professor of Epidemiology, Brown University School of Public Health

**Hospital Appointments**

July, 2002-	Staff Cardiologist Providence VA Medical Center
July 2004 - 2014	Medical Director, Cardiovascular Risk Reduction Clinic, Providence VA Medical Center
July 2008 – July 2010	Medical Director, Heart Failure Clinic, Providence VA Medical Center
July 2011 – September 2014	Medical Director, Intravenous Diuretic Clinic, Providence VA Medical Center
July 2012 – current	Medical Director Shared-medical-appointment Clinics in Heart Failure, Providence VA Medical Center
March 2013 – current	Chief of Cardiology (Acting), Providence VA Medical Center
October 2014 -	Director of the Cardiovascular Wellness and Prevention Center at Miriam, Newport, and Rhode Island Hospitals

**Other Appointments**

1995-1996	General Practitioner Orotina / San Mateo Division, Ministry of Health of Costa Rica
2007-	Faculty, NHLBI R25HL088992-01, Short-Term Training Program to Increase Diversity in Health-Related Research
2008-2013	Faculty, NHLBI T32HL094300-01, Brown CardioPulmonary Research Training Program
2009-	Faculty, T35HL094308-01, Alpert Medical School Summer Research Program (AMSSRP) in Molecular Pathobiology and Health Services/Outcomes research in cardiopulmonary diseases
2012-	Core investigator, Providence VAMC Center of Innovation (COIN) for Long Term Support and Services
2012-2015	Core investigator, CHF QUERI, Palo Alto, CA
2012-2015	Core investigator, DM QUERI, Ann Arbor, MI

### **Editorial Positions**

2008-2013	Section Editor, <i>Ferri's Clinical Advisor</i> , Ferri, FF [ed], Elsevier, St. Louis.
April 2014 - present	Academic Editor, PLoS One
April 2015 – present	Editorial Board: Alzheimer's & Dementia: Diagnosis, Assessment & Disease Monitoring (DADM) - a journal of the Alzheimer's Association

Ad Hoc Reviewer for *JAMA*

Ad Hoc Reviewer for *Chest*

Ad Hoc Reviewer for *American Journal of Medicine*

Ad Hoc Reviewer for *Cardiovascular Reviews and Reports*

Ad Hoc Reviewer for *Journal of the American Society of Echocardiography*

Ad Hoc Reviewer for *American Journal of Cardiology*

Ad Hoc Reviewer for *International Journal of Impotence Research*

Ad Hoc Reviewer for *Journal of Sexual Medicine*

Ad Hoc Reviewer for *Diabetes Care*

### **Study Section/Review Group**

2008 Ad Hoc Reviewer for VA Cooperative Studies Program

2009 - 2010 NIH Special Emphasis Panel/Scientific Review Group 2009/10 ZRG1 HDM-P(58) R

2010 - present VA HSR&D Scientific Merit Review HSR1 Group

2010 – 2013 VA VISN 1 Career Development Award Program (V1CDA)

2011 – 2014 VA QUERI Rapid Response Projects review board

2012/08 Special Emphasis Panel/Scientific Review Group HQ2 R (CREATE review board)

2013 – 2015 VA Quality Enhancement Research Initiative (QUERI) Service Directed Project (SDP)

Proposal Review Section

### **Hospital Committees**

2003-present

IRB Committee

2005-2010

Chair, Radiation Safety Committee

2006- 2010

Member, VA Advanced Clinic Access Committee

2006- 2010

Member, VA (VISN-1) Laboratory Utilization Council

2010-present

Member, Radiation Safety Committee

2012-present

Member, Education Leadership Committee

### **University Committees**

2004 - 2007

Medical Faculty Executive Committee, Brown Univ.

### **Membership in Societies**

1996-

Member, American College of Physicians

1999-

Member, American College of Cardiology

1999-

Member, American Heart Association

2003-

Interdisciplinary Working Group on Quality of Care & Outcomes Research, AHA

2005-

Fellow, American College of Cardiology



2007-	Member, Minority Members Committee, American Heart Association
2008-	Member, American Society of Preventive Cardiology
2008-	Member, Society of Cardiovascular Computed Tomography
2008-	Fellow, American Heart Association

### **Original Peer Reviewed Publications**

1. **Wu WC**, Rathore SS, Wang Y, Radford MJ, Krumholz HM. Effectiveness of blood transfusion in elderly patients with acute myocardial infarction. *N Eng J Med* 2001; 345(17): 1230-6.
2. Shahi C, Rathore SS, Wang Y, Thakur R, **Wu WC**, Lewis JM, Petrillo MK, Radford MJ, Krumholz HM. Quality of care among elderly patients hospitalized with unstable Angina. *Am Heart J* 2001;142(2):263-70.
3. **Wu WC**, Tilkemeier PL. Significance of right ventricular visualization on stress sestamibi in a patient with dyspnea after atrial-septal-defect repair. *J Nucl Cardiol* 2002;9(2):236-7.
4. Sebastian CC, **Wu WC**, Shafer M, Choudhary G, Patel PM. Pneumopericardium and pneumothorax after permanent pacemaker implantation. *PACE* 2005; 28:1–3.
5. **Wu WC**, Sharma SC, Choudhary G, Coulter L, Coccio E, Eaton CB. Flow Mediated Vasodilation Predicts the Presence and Extent of Coronary Disease Assessed by Stress Thallium Imaging. *J Nucl Cardiol* 2005; 12(5):538-44.
6. Taveira TH, **Wu WC**, Martin OJ, Schleinitz MD, Friedmann P, Sharma SC. Pharmacist-led cardiac risk reduction model. *Prev Cardiol* 2006; 9(4):202-8.
7. Martin OJ, **Wu WC**, Taveira TH, Eaton CB, Sharma SC. Multidisciplinary Group Behavioral and Pharmacologic Intervention for Cardiac Risk Reduction in Diabetes-a Pilot Study. *Diabetes Educator* 2007; 33(1):118-27.
8. **Wu WC**, Schiffter TL, Henderson WG, Eaton CB, Poses RM, Uttley G, Sharma SC, Vezeridis M, Khuri SF, Friedmann PD. Levels of Preoperative Hematocrit Predict Postoperative Cardiovascular and Fatal Outcomes in Elderly Patients Undergoing Major Non-Cardiac Surgery. *J.A.M.A.* 2007; 297(22): 2481-8.\*(selected publication submitted)
9. Pirraglia PA, Taveira TH, Cohen LB, **Wu WC**. The moderating effect of depression diagnosis on the effectiveness of a multi-factorial cardiovascular risk reduction clinic. *Preventing Chronic Disease* 2008; 5(4): A127 pp1-7
10. Khatana SAM, Taveira TH, Miner M, Eaton CB, **Wu WC**. Does Cardiovascular Risk Reduction Alleviate Erectile Dysfunction in Men with Type 2 Diabetes Mellitus? *Int J Impot Res.* 2008; 20(5): 501-6.

11. Taveira TH, Pirraglia PA, Cohen LB, **Wu WC**. Efficacy of a Pharmacist-led Cardiovascular Risk Reduction Clinic for Diabetic Patients with and without Mental Health Conditions. *Prev Cardiol* 2008; 11(4):195-200.
12. Khatana SA, Taveira TH, Choudhary G, Eaton CB, **Wu WC**. Change in Hemoglobin A1C and C-Reactive Protein Levels in Patients with Diabetes Mellitus. *J Cardiometa Synd* 2009;4:1-5.
13. Pirraglia PA, Taveira TH, Cohen LB, Dooley A, **Wu WC**. Maintenance of Cardiovascular Risk Goals in Veterans with Diabetes after Discharge from a Cardiovascular Risk Reduction Clinic. *Prev Cardiol* 2009;12(1):3-8.
14. Taveira TH, Friedmann PD, Cohen LB, Dooley AG, Khatana SAM, Pirraglia PA, **Wu WC**. Pharmacist-led Group Medical Appointment Model in Type 2 Diabetes. *Diabetes Educator* 2009; Dec 4 [Epub ahead of print], doi:10.1177/0145721709352383.
15. Choudhary G, Shin V, Punjani S, Ritter N, Sharma SC, **Wu WC**. The Role of Calcium Score and CT Angiography in the medical management of patients with normal myocardial perfusion imaging. *J Nuc Cardiol* 2009; Nov 21[Epub ahead of print]. doi:10.1007/s12350-009-9158-x.
16. Chen CK, Tseng VL, **Wu WC**, Greenberg PB. A Survey of the Current Role of Manual Extracapsular Cataract Extraction. *Journal of Cataract and Refractive Surgery* 2010; 36(4):692-3.
17. **Wu WC**, Smith TS, Henderson WG, Eaton CB, Poses RM, Uttley G, Mor V, Sharma SC, Vezeridis M, Khuri SF, Friedmann PD. Operative Blood Loss, Blood Transfusion and 30-day Mortality in Older Patients after Major Noncardiac Surgery. *Annals of Surgery* 2010 252(1):11-7.
18. Chen CK, Tseng VL, **Wu WC**, Scott IU, Greenberg PB. A Survey on the Use of General Anesthesia for Cataract Surgery. *Graefes Arch Clin Exp Ophthalmol*. 2010;248(7):1051-2.
19. Jankowich MD, Taveira TH, **Wu WC**. Decreased lung function is associated with increased arterial stiffness as measured by peripheral pulse pressure: data from NHANES III. *Am J Hypertension* 2010 23(6):614-9.
20. Cohen LB, Taveira TH, **Wu WC**, Pirraglia PA. Maintenance of risk factor control in patients with diabetes after discharge from a cardiovascular risk reduction clinic in patients with and without mental health conditions. *Annals of Pharmacotherapy* 2010; [Epub ahead of print], DOI 10.1345/aph.1P034.
21. Greenberg PB, Tseng VL, **Wu WC**, Liu J, Jiang L, Chen CK, Scott IU, Friedmann PD. Prevalence and Predictors of Ocular Complications Associated with Cataract Surgery in United States Veterans. *Ophthalmology* 2010 Oct 28. [Epub ahead of print].
22. Greenberg PB, Liu J, **Wu WC**, Jiang L, Tseng VL, Scott IU, Friedmann PD. Predictors of Mortality Within 90 Days of Cataract Surgery. *Ophthalmology* 2010 117(10):1894-9.

23. Khatana SAM, Taveira TH, Dooley AG, **Wu WC**. The Association between C-Reactive Protein Levels and Insulin Therapy in Obese vs. Non-Obese Veterans with Type 2 Diabetes Mellitus. *J Clin Hypertens* 2010;12(6):462-8.
24. Chen CK, Tseng VL, **Wu WC**, Scott IU, Greenberg PB. A Survey of the Management of Antithrombotic Therapy in Cataract Surgery Patients. *J Cataract Refract Surg*. 2010;36(7):1239-40.
25. Choudhary G, Atalay MK, Ritter N, Shin V, Grand D, Pearson C, Kirchner RM, **Wu WC**. Interobserver Reliability In The Assessment Of Coronary Stenoses By Multi-Detector Computed Tomography. *J Comput Assist Tomogr* 2011;35: 126-134.
26. Tseng VL, Greenberg PB, **Wu WC**, Jiang L, Li E, Kang JM, Scott IU, Friedmann PD. Cataract Surgery Complications in Nonagenarians. *Ophthalmology*. 2011 Mar 7. [Epub ahead of print]
27. Punjani S, **Wu WC**, Cohen S, Sharma SC, Choudhary G. Echocardiographic indices of diastolic function relate to functional capacity and quality of life in ambulatory men with atrial fibrillation. *Journal of the American Society of Echocardiography* 2011;24(5): 533-540.
28. Greenberg PB, Tseng VL, Jiang L, **Wu WC**. Cataract Surgery in the very ill. *J Cataract Refract Surg* 2011, 37(5):970-1.
29. **Wu WC**, Waring ME, Lessard D, Yarzebski J, Gore J, Goldberg RJ. 6-Month Mortality and Cardiac Catheterization in Non-ST Elevation Myocardial Infarction Patients with Anemia. *Coronary Artery Disease* 2011, 22:317–323.
30. Khatana SAM, Kane J, Taveira TH, Bauer MS, **Wu WC**. Monitoring and Prevalence Rates of Metabolic Syndrome in Veterans with Major Mental Illness. *PLOS One* 2011, 6(4): e19298.
31. Jankowich M, Choudhary G, Taveira TH, **Wu WC**. Age-, Race-, and Gender-Specific Prevalence of Diabetes among Smokers. *Diabetes Research and Clinical Practice* 2011, doi:10.1016/j.diabres.2011.05.029 (Epub ahead of print).
32. Taveira TH, Dooley AG, Cohen LB, Khatana SAM, **Wu WC**. Pharmacist-led Group Medical Appointments for the Management of Type 2 Diabetes with Co-Morbid Depression in Older Adults. *Annals of Pharmacotherapy* 2011; DOI: 10.1345/aph.1Q212 (Epub ahead of print).
33. Cohen LB, Taveira TH, Khatana SAM, Dooley AG, Pirraglia PA, **Wu WC**. Pharmacist-led Shared Medical Appointments for Multiple Cardiovascular Risk Reduction in Patients with Type 2 Diabetes. *Diabetes Educator* 2011; 37(6): 785-95. [DOI 10.1177/0145721711423980](https://doi.org/10.1177/0145721711423980)
34. Malandrino N, **Wu WC**, Taveira TH, Whitlatch H, Smith RJ. Association between Red Blood Cell Distribution Width and Macrovascular and Microvascular Complications in Diabetes. *Diabetologia* 2011; 55(1):226-35.
35. **Wu WC**, Trivedi A, Friedmann PD, Henderson WG, Smith TS, Poses RM, Uttley G, Vezeridis M, Eaton CB, Mor V. Association between Hospital Intraoperative Blood Transfusion Practices for Surgical Blood Loss and Hospital Surgical Mortality Rates. *Ann Surg*. 2012 Feb 24. [Epub ahead of print]

36. Pirraglia PA, Rowland E, **Wu WC**, Taveira TH, Cohen LB, Friedmann PD, O'Toole TP. The benefits of a primary care clinic co-located and integrated in the mental health setting for veterans with serious mental illness. *Preventing Chronic Disease* 2012;9:E51. [Epub Feb 2]
37. Li E, Greenberg PB, Tseng V, Caffrey AR, **Wu WC**, Friedmann PD, LaPlante KL. In vitro coagulation effects of ophthalmic doses of bevacizumab. *Journal of Ocular Pharmacology* 2012, Feb 3. [Epub ahead of print].
38. Kapoor M, Schleinitz MD, Gemignani A, **Wu WC**. Outcomes of Patients with Chronic Heart Failure and Iron Deficiency Treated with Intravenous Iron: A Meta-analysis. *Cardiovasc Hematol Disord Drug Targets*. 2012 Sep 27. [Epub ahead of print]
39. Patel N, Taveira TH, Choudhary C, **Wu WC**. C-peptide Levels Predict Cardiovascular Mortality In Nondiabetic Adults. *J Am Heart Assoc*. 2012;1:e003152
40. Cohen S, Gaddam S, Gemignani A, **Wu WC**, Sharma S, Choudhary G. Right Ventricular Function Relates To Functional Capacity In Men With Atrial Fibrillation And Preserved Left Ventricular Ejection Fraction. *Echocardiography* 2013;0:1-9.
41. Kim J, Gaddam S, **Wu WC**, Behera V, Sharma S, Choudhary G. Stratified Reporting of High Sensitivity Troponin I Assay is Associated with Suboptimal Management of Patients with Acute Coronary Syndrome and Intermediate Troponin Elevation. *Journal of Clinical Laboratory Analysis* 2013 Sep;27(5):402-6. doi: 10.1002/jcla.21618. PubMed PMID: 24038227.
42. Sathya B, Davis R, Taveira T, Whitlatch H, **Wu WC**. Intensity of Peri-operative Glycemic Control and Postoperative Outcomes in Patients with Diabetes: A Meta-analysis. *Diabetes Research and Clinical Practice* 102 (2013), pp. 8-15. DOI information: 10.1016/j.diabres.2013.05.003
43. Chatterjee S, Kim J, Dahhan A, Choudhary G, Sharma S, **Wu WC**. Use of High-Sensitivity Troponin Assays Predicts Mortality in Patients with Normal Conventional Troponin Assays on Admission - Insights from a Meta-Analysis. *Clinical Cardiology* 2013. doi: 10.1002/clc.22196. [Epub ahead of print] PubMed PMID:24037966.
44. Khatana SAM, Jiang L, **Wu WC**. A comprehensive analysis of multidisciplinary management of dyslipidemia in a large health care system. *Journal of Evaluation in Clinical Practice* 2013. doi:10.1111/jep.12082. [Epub ahead of print] PubMed PMID: 24118549.
45. Sardar P; Chatterjee S; **Wu WC**; Lichstein E; Ghosh J; Aikat S; Mukherjee D. New Oral Anticoagulants are not Superior to Warfarin in Secondary Prevention of Stroke or Transient Ischemic Attacks, but Lower Risk of Intracranial Bleeding: Insights From a Meta- Analysis and Indirect Treatment Comparisons. *PLoS ONE* 2013; 8(10): e77694. doi:10.1371/journal.pone.0077694.
46. Taveira TH; **Wu WC**; Tschibelu E; Borsook D; Simonson D; Yamamoto R; Langleben DD; Swift R; Elman I. Naltrexone decreases body fat mass in olanzapine-treated schizophrenic or schizoaffective patients: a randomized double-blind placebo-controlled study. *Journal of Psychopharmacology* 2013. Nov 11. [Epub ahead of print] PMID: 24218048

47. Choudhary G, Jankowich M, **Wu WC**. Prevalence And Clinical Characteristics Associated With Pulmonary Hypertension In African-Americans. PLoS One. 2013;8(12):e84264. doi: 10.1371/journal.pone.0084264. PMID: 24358351.
48. Kirsh S, **Wu WC**, Edelman D, Aron DC. Research versus Quality Improvement: Distinct or a Distinction without a Difference? The Joint Commission Journal on Quality and Patient Safety 2014; 40(8): 365-75.
49. Taveira TH, **Wu WC**. Interventions to maintain cardiac risk control after discharge from a cardiovascular risk reduction clinic: A randomized controlled trial. Diabetes Res Clin Pract (2014), <http://dx.doi.org/10.1016/j.diabres.2014.05.013> PMID: 24969964
51. Choudhary G, Jankowich M, **Wu WC**. Elevated Pulmonary Artery Systolic Pressure Predicts Heart Failure Admissions in African Americans: Jackson Heart Study. Circ Heart Fail. 2014 Jun 5. pii: CIRCHEARTFAILURE.114.001366. [Epub ahead of print]. PMID: 24902739
52. **Wu WC**, Jiang L, Friedmann PD, Trivedi A. Association Between Process Quality Measures for Heart Failure and Mortality Among U.S. Veterans. Am Heart J 2014; 168(5): 713–720.e3.
53. Greenberg PB, Chen AJ, **Wu WC**. Sudden vision loss and cardiovascular risk factors in African Americans: the Jackson Heart Study. Ophthalmic Epidemiol. 2015; 22(2):116-22. doi: 10.3109/09286586.2015.1012273. PubMed PMID: 25777311.
54. Jones LG, Sin M-K, Hage FG, Kheirbek RE, Morgan CJ, Zile MR, **Wu WC**, Deedwania P, Fonarow GC, Aronow WS, Prabhu SD, Fletcher RD, Ahmed A, Allman RM. Characteristics and Outcomes of Patients with Advanced Chronic Systolic Heart Failure Receiving Care at the Veterans Affairs vs. Other Hospitals: Insights from the BEST Trial. Circ Heart Fail. 2015; DOI: 10.1161/CIRCHEARTFAILURE.114.001300.
55. Chan KHK, Chacko SA, Song Y, Cho M, Eaton CB, **Wu WC**, Liu S. Genetic Variations in Magnesium-Related Ion Channels May Affect Diabetes Risk among African American and Hispanic American Women J. Nutr. 2015 jn.114.203489; published online January 7, 2015.
56. Steiner J, **Wu WC**, Jankowich M, Maron BA, Sharma S, Choudhary G. Echocardiographic Predictors of Mortality in Patients with Pulmonary Hypertension and Cardiopulmonary Comorbidities. PLoS ONE 03/2015; 10(3):e0119277. DOI:10.1371/journal.pone.0119277
57. Lin X, Zhang X, Guo J, Roberts CK, McKenzie S, **Wu WC**, Liu S, Song Y. Effects of Exercise Training on Cardiorespiratory Fitness and Biomarkers of Cardio-metabolic Health: A Systematic Review and Meta-analysis of Randomized Controlled Trials. J Am Heart Assoc. 2015 (4:e002014 doi: 10.1161/JAHA.115.002014)
58. Salmoirago-Blotcher E, Wayne P, Bock BC, Dunsiger S, **Wu WC**, Stabile L, Yeh G. Design and methods of the Gentle Cardiac Rehabilitation Study - A behavioral study of tai chi exercise for patients not attending cardiac rehabilitation. Contemporary clinical trials 06/2015; DOI:10.1016/j.cct.2015.06.020
59. Chen A, Trivedi AN, Jiang L, Vezeridis M, Henderson WG, **Wu WC**. Hospital Blood Transfusion Patterns During Major Noncardiac Surgery and Surgical Mortality. Medicine 2015; 94(32):e1342. doi: 10.1097/MD.0000000000001342.

60. Wellenius G, Kingsley S, Eliot M, Whitsel E, Wang Y, Coull B, Hou L, Margolis H, Margolis K, Mu L, **Wu WC**, Johnson K, Allison M, Manson J, Eaton C. Residential proximity to major roadways and incident hypertension in post-menopausal women. *Environmental Research* 2015; 142:522–528.
61. Santos CY, Lim YY, **Wu WC**, Polynice S, Maruff P, Snyder PJ. Resting-State Cardiac Workload is Related to Both Increased Neocortical Aggregation of  $\beta$ -Amyloid Protein and Relative Impairments in Spatial Working Memory in Pre-Clinical Alzheimer's Disease. *Journal of Alzheimer's Disease* 2015 (in press)
62. Lacy ME, Wellenius GA, Carnethon MR, Loucks EB, Carson AP, Luo X, Kiefe CI, Gjelsvik A, Gunderson EP, Eaton CB, **Wu WC**. Racial differences in the performance of existing risk prediction models for incident type 2 diabetes: The CARDIA study. *Diabetes Care* 2015 (in press).
63. Dev S, Lacy ME, Masoudi FA, **Wu WC**. Temporal Trends and Hospital Variation in Mineralocorticoid Receptor Antagonist Use in Veterans Discharged with Heart Failure. *J Am Heart Assoc* 2015 (in press)

#### **Other Peer Reviewed Publications**

1. Sadaniantz A, Wu WC. Survival of renal transplant patients after first myocardial infarction: a look to the past and promises for the future. *Am J Kidney Dis* 2000;36:211-3.
2. Rathore SS, Wu WC, Krumholz HM. Transfusion in elderly patients with myocardial infarction. Correspondence: authors reply to editor. *N Eng J Med* 2002;346(10):780-1.
3. Wu WC, **Ireland LA\***, Sadaniantz A. Evaluation of aortic valve disorders using stress echocardiography. *Echocardiography* 2004;21:451-8.
4. Sadaniantz A, Katz A, Wu WC. Miscellaneous use of stress echocardiography in patients with chronic pulmonary disease or congenital heart defect. *Echocardiography* 2004;21:477-84.
5. Wu WC, **Aziz GF\***, Sadaniantz A. Evaluation of aortic valve disorders using stress echocardiography. *Echocardiography* 2004;21:459-66.
6. Wu WC, **Bhavsar JH\***, Sadaniantz A. An overview of stress echocardiography in the study of patients with dilated and hypertrophic cardiomyopathy. *Echocardiography* 2004;21:467-75.
7. Wu WC, Gordon PG. Invasive management of patients with ST elevation MI with >12 hour delay in presentation, the question remains unanswered. *Chest* 2004;126:2-4.
8. **Mehta SB\***, Wu WC. Management of coronary heart disease – stable angina, acute coronary syndrome, myocardial infarction. *Primary Care Clinics of North America* 2005; 32(4):1057-81.
9. **Patel PM\***, Wu WC. The electrocardiogram in the primary care office. *Primary Care Clinics of North America* 2005; 32(4):901-30.
10. Wu WC, Schiffter TL, Henderson WG. Preoperative Hematocrit Levels and Outcomes After Noncardiac Surgery *J.A.M.A.* 2007; 298(13): 1513-4.

11. **Karnik RS\***, Wu WC. Self assessment in Cardiology. Common Tachyarrhythmias: Review Questions. *Hospital Physician* 2007; 43(11): 33-6.
12. **Regnante R\***, Wu WC. Self-Assessment in Cardiology. Management of Chest Pain in the Emergency Department: Review Questions. *Hospital Physician* 2008; 44(11): 13-16.
13. Wu, WC. Does Blood Transfusion Increase Mortality Risk in Acute Myocardial Infarction? *Am J Cardiol* 2008; 102(8):1116-7 (Editorial letter).
14. **Leitner J\***, Wu WC. Self-Assessment in Cardiology. Management of Aortic Valve Disease: Review Questions. *Hospital Physician*; November/December 2009: 33-7.
15. Greenberg PB, Tseng VL, **Wu WC**, Margo CE. Creating a Feedback Loop to Improve Cataract Surgery Outcomes. *J Cataract Refract Surg* 2011, Oct 22nd. [Epub ahead of print].

#### **\*Fellow/Resident/Trainee**

#### **Books and Chapters**

1. Salas I, Chan K, Wu WC. *Pain relief in cancer patients*. San Jose: Editorial Universidad de Costa Rica 1996. 79 pp. (Spanish).
2. **Aziz GA\***, Wu WC. Hypertension. In: *Primary Care for Women*. 2<sup>nd</sup> ed. Leppert PC, Peippert JF [ed], Lippincott, Williams, & Wilkins: Philadelphia, 2004.
3. **Mehta, SB\***, Wu, WC. Atrial myxoma. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2007 (p.100).
4. **Mikaelian B\***, and Wu, WC. Carotid sinus syndrome. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2007 (p. 158).
5. Wu, WC. Tricuspid Regurgitation. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2006 (p. 860-861).
6. **Afshar M\***, and Wu, WC Tricuspid Stenosis. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2007 (p. 913).
7. **Cho Y\***, and Wu, WC. Ventricular Septal Defect. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2007 (pgs. 955-956).
8. **Patel PM\*** and Wu, WC. Aneurysm, abdominal aorta. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2006 (p. 59-60).
9. **Patel PM\*** and Wu, WC. Cardiac tamponade. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2006 (p. 155).
10. **Patel PM\*** and Wu, WC. Cor pulmonale. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2006 (p. 219-220).

11. **Mehta S\***, and Wu, WC. Tetralogy of Fallot. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2007 (pgs. 880-881).
12. **Cho Y\***, Wu, WC. Peripheral Vascular Disease. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2007 (pgs. 674-675).
13. Wu, WC. Temporomandibular Joint Syndrome. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2009 (pg. 916).
14. **Gemignani, AS\***; Ferri, FF; Wu, WC. Cardiomyopathy, hypertrophic. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 204-205).
15. **Gemignani, AS\***; Ferri, FF; Wu, WC. Cardiomyopathy, dilated. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 202-203).
16. **Gemignani, AS\***; Ferri, FF; Wu, WC. Cardiomyopathy, restrictive. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 206-207).
17. **Gemignani, AS\***; Ferri, FF; Wu, WC. Mitral regurgitation. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 685-686).
18. **Pacheco, R\***; Ferri, FF; Wu, WC. Mitral stenosis. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 687-688).
19. **Gemignani, AS\***; Ferri, FF; Wu, WC. Mitral valve prolapse. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 689).
20. **Cohen S\***; Ferri, FF; Wu, WC. Pericarditis. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 815-816).
21. **Punjani, S\***; Ferri, FF; Wu, WC. Hyperosmolar hyperglycemic syndrome. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 542).
22. **Punjani, S\***; Ferri, FF; Wu, WC. Diabetes mellitus. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 327-332).
23. **Punjani, S\***; Ferri, FF; Wu, WC. Diabetic ketoacidosis. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 333-335).
24. **Punjani, S\***; Wu, WC. Obesity. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 748-751).
25. **Punjani, S\***; Ferri, FF; Wu, WC. Hypertension. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 548-551).
26. **Brancato, S\***; Ferri, FF; Wu, WC. Heart block, second degree. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 472).
27. **Brancato, S\***; Ferri, FF; Wu, WC. Multifocal atrial tachycardia. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 696).



28. Wu, WC; Ferri, FF. Aortic regurgitation. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 92).
29. **Earl, T\***; Ferri, FF; Wu, WC. Heart block, complete. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 470-471).
30. **Brancato, S\***; Ferri, FF; Wu, WC. Paroxysmal Supraventricular Tachycardia. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 800).
31. **Brancato, S\***; Ferri, FF; Wu, WC. Sick sinus syndrome. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 1011).
32. **Cohen, S\***; Ferri, FF; Wu, WC. Atrial septal defect. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 128-129).
33. **Earl, T\***; Ferri, FF; Wu, WC. Atrial flutter. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 125-126).
34. **Earl, T\***; Ferri, FF; Wu, WC. Atrial fibrillation. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 122-124).
35. **Cohen, S\***; Ferri, FF; Wu, WC. Kawasaki disease. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 598-600).
36. **Pacheco, R\***; Ferri, FF; Wu, WC. Radiation exposure. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 926-928).
37. **Earl, T\***; Ferri, FF; Wu, WC. Long QT syndrome. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 628-629).
38. **Earl, T\***; Ferri, FF; Wu, WC. Wolff-Parkinson-White. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 1192-1193).
39. **Sayed, SM\***; Ferri, FF; Wu, WC. Congestive heart failure. In: *Ferri's Clinical Advisor*, Ferri, FF [ed], Elsevier, St. Louis, 2011 (pg. 273-275).
40. **Silverstein, JR**; Ferri, FF; Wu, WC. Atrial Fibrillation. In *Ferri's Clinical Advisor*, FF [ed], Elsevier, St. Louis, 2012 (pg. 120-121).
41. **Silverstein, JR**; Ferri, FF; Wu, WC. Atrial Flutter. In *Ferri's Clinical Advisor*, FF [ed], Elsevier, St. Louis, 2012 (pg. 122-123).
42. **Pacheco, R**; Ferri, FF; Wu, WC. Atrial Myxoma. In *Ferri's Clinical Advisor*, FF [ed], Elsevier, St. Louis, 2012 (pg. 124).
43. **Cohen, S; Abdulbaki, A**; Ferri, FF; Wu, WC. Atrial Septal Defect, In *Ferri's Clinical Advisor*, FF [ed], Elsevier, St. Louis, 2012 (pg. 125-126).
44. **Lee, P**; Wu, WC. Brugada Syndrome, In *Ferri's Clinical Advisor*, FF [ed], Elsevier, St. Louis, 2012 (pg. 176-177).

45. **Lee, P**; Wu, WC. Cardiomyopathy, Stress-Induced, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 197)
46. **Brancato, S**; Wu, WC. Carotid Syndrome. In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 198).
47. **Gemignani, A**; Ferri, FF; Wu, WC. Diabetes Mellitus, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 301-306).
48. **Gemignani, A**; Ferri, FF; Wu, WC. Diabetic Ketoacidosis, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 307-308).
49. **Earl, TJ**; Ferri, FF; Wu, WC. Heart Block, Complete, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 436).
50. **Silverstein, JR**; Ferri, FF; Wu, WC. Heart-Block, Second Degree, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 437).
51. **Kapoor, M**; Ferri, FF; Wu, WC. Heart Failure, In *Ferri's Clinical Advisor*, FF [ed], Elsevier, St. Louis, 2012 (pg. 438-441).
52. **Gemignani, A**; Ferri, FF; Wu, WC. Hyperosmolar, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 510).
53. **Gemignani, A**; Ferri, FF; Wu, WC. Hypertension, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 516-518)
54. **Abdulbaki, A**; Wu, WC. Kawasaki Disease, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 564-566).
55. **Silverstein, JR**; Ferri, FF; Wu, WC. Long QT Syndrome, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 596-597).
56. Wu, WC; Ferri, FF. Myocardial Infarction, In *Ferri's Clinical Advisor*, FF [ed], Elsevier, St. Louis, 2012 (pg. 675-678).
57. **Gemignani, A**; Ferri, FF; Wu, WC. Obesity, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 705-707)
58. **Truesdell, A**; Ferri, FF; Wu, WC. Sick Sinus Syndrome, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 936).
59. **Cohen, S**; Wu, WC.. Tetralogy of Fallot, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 1003-1004).
60. **Cohen, S; Abdulbaki, A**; Wu, WC. Ventricular Septal Defect, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 1077-1079).
61. **Silverstein, JR**; Ferri, FF; Wu, WC. Wolff-Parkinson-White Syndrome, In *Ferri's Clinical Advisor* , FF [ed], Elsevier, St. Louis, 2012 (pg. 1104-1005).

**\*Fellow/Resident/Trainee**

## **Abstracts**

1. Lai T, Ma L, **Wu WC**, Knibbs D, Waters D, Chen C. Recovery of myocyte hypertrophy and slippage associated with the left ventricular remodeling of myocardial hibernation. J Am Coll Cardiol 1998;31:15A.
2. Lai T, Ma L, Linfert D, **Wu WC**, Olatidoye A, Gillam L, Waters D, Tsongalis G, Chen C. Reperfusion prevents apoptosis in hibernating myocardium. J Am Coll Cardiol 1998;31:394A.
3. Shahi C, Wang Y, **Wu WC**, Wang Y, Chen YT, Lewis JM, Krumholz HM, Radford MJ. Variability in quality of care for elderly patients admitted with unstable angina in Connecticut. J Am Coll Cardiol 1999; 33:337A.
4. Shahi C, Wang Y, **Wu WC**, Wang Y, Chen YT, Radford MJ, Krumholz HM. Prognostic significance of abnormal creatine kinase MB fraction with normal total creatine kinase in patients with acute coronary ischemic syndrome. J Am Coll Cardiol 1999; 33:394A.
5. Wright RM, **Wu WC**, Hamdan N, Fan A, Erickson A. Case report of carotid sinus hypersensitivity in a patient with head and neck cancer. 2000 Rhode Island Chapter of American College of Physicians Annual Meeting.
6. **Wu WC**, Cannistra AJ, Leavitt JL. Transient Brugada pattern in EKG mimicking anteroseptal myocardial infarction. 2002 Rhode Island Chapter of American College of Physicians Annual Meeting.
7. Taveira TH, Martin OJ, Petropoulos PN, Patel P, Sharma SC, **Wu WC**. Effectiveness of interdisciplinary cardiovascular risk reduction clinic for patients with coronary disease or diabetes. Circulation 2003; 107(19):e131,P4.
8. Martin OJ, **Wu WC**, Schleinitz MD, Taveira TH, Anderson ML, Patel PM, Donofrio G, Sharma S. Effectiveness of pharmacist-coordinated care to reduce cardiovascular risk factors in patients with diabetes mellitus. Circulation 2004; 109(7):e71,P203.
9. Uttley G., **Wu WC**, Freeman N, Sharma SC, Vezeridis M. The relationship of preoperative hematocrit levels with post-operative 30-day mortality in older veterans undergoing surgery. National Surgical Quality Improvement Program Meeting 2004.
10. **Wu WC**, Martin OJ, Taveira TH, Schleinitz MD, Mor V, Sharma SC. Durability of guideline adherence in coronary disease and diabetic patients after discharge from a cardiovascular risk reduction clinic. Circulation 2004; 109(20):e285, P41.
11. Patel PM, **Wu WC**, Cheng J, Martin OJ, Taveira TH, Sharma SC. Pattern of care of outpatients with coronary artery disease in a VA hospital. Circulation 2004;109(20):e231, P184.
12. Misra B, Gopalakrishnan G, Martin O, **Wu WC**, Taveira T, Anderson M, Sharma SC. Cardiovascular risk reduction programs for patients with diabetes. Circulation 2005;111(14): e209, P80.

13. **Wu WC**, Schifftner TL, Henderson WG, Eaton CB, Poses RM, Uttley G, Sharma SC, Vezeridis M, Khuri SF, Friedmann PD. Levels of Preoperative Hematocrit Predict Postoperative Cardiovascular and Fatal Outcomes in Elderly Patients Undergoing Major Non-Cardiac Surgery. VA HSR&D 2007 National Meeting Abstract. Washington, D.C., Feb 2007.

14. Pirraglia PA, Taveira TH, Cohen LB, **Wu W**. Depression diagnosis impact on the effectiveness of a multidisciplinary diabetes and cardiovascular risk reduction clinic. *Journal of General Internal Medicine*, 22(Supplement 1):17, 2007.

15. Taveira TH, Pirraglia PA, Cohen LB, **Wu WC**. Pharmacist-led Cardiac Risk Reduction Clinic Reduces Framingham Risk Score in Patients with Diabetes and Mental Illness. American Psychosomatic Society 65th Annual Scientific Meeting. Budapest, Hungary March 10, 2007. *Psychosomatic Medicine* 2007;69 (Supplement 1:1585) A-81.

16. Taveira TH, Cohen LB, Pirraglia PA, Friedmann PD, **Wu WC**. Pharmacist-led Group Medical Visits for Cardiovascular Risk Reduction in Diabetes. VA National HSRD 2008. National Meeting Abstract, Baltimore, MD, Feb 2008.

17. Khatana S, Taveira TH, Choudhary G, Eaton CB, **Wu WC**. Change In Hemoglobin A1c And C-reactive Protein Levels In Patients With Diabetes Mellitus American Heart Association 48th Cardiovascular Disease Epidemiology and Prevention and Nutrition, Physical Activity and Metabolism Conference. Colorado Springs, Colorado, March 11 –15, 2008.

18. Taveira TH, Cohen LB, Pirraglia PA, Friedmann PD, **Wu WC**. Pharmacist-led Group Medical Visits for Cardiovascular Risk Reduction in Diabetes. American Heart Association 48th Cardiovascular Disease Epidemiology and Prevention and Nutrition, Physical Activity and Metabolism Conference. Colorado Springs, Colorado, March 11 –15, 2008.

19. Cohen LB, Taveira TH, **Wu WC**, Pirraglia P. The Impact of Mental Health Conditions on Maintenance of Risk Factor Control in Diabetic Patients After Discharge from a Cardiovascular Risk Reduction Clinic. Academy Health 25th Annual Research Meeting. Marriott Wardman Park, Washington, DC. June 8-10, 2008.

20. **Wu WC**, Smith TS, Henderson WG, Eaton CB, Poses RM, Uttley G, Sharma SC, Vezeridis M, Khuri SF, Friedmann PD. Preoperative Hematocrit Is Not Predictive of CNS Events in Elderly Patients After Major Non-Cardiac Surgery. VA National QUERI Meeting 2008, Phoenix, AZ.

21. **Wu WC**, Lessard D, Goldberg RJ. Underuse of, and Mortality Associated With, Cardiac Catheterization in Patients with Acute Myocardial Infarction According to Anemia Status. VA National HSR&D meeting. Baltimore Marriott Waterfront, Baltimore, MD. Feb 10-12, 2009.

22. Prachanronarong K, Khatana SAM, Taveira TH, Cohen LB, Dooley AG, Pirraglia PA, Friedmann PD, **Wu WC**. Pharmacist-led Group Medical Visits for Multiple Cardiovascular Risk Reduction in Patients with Type 2 Diabetes. VA National HSR&D meeting. Baltimore Marriott Waterfront, Baltimore, MD. Feb 10-12, 2009.

23. **Wu WC**, Jiang L, Pirraglia P, O'Toole T, Friedmann P. Multidisciplinary Service Utilization and Cholesterol Guideline Implementation for Patients with Coronary Disease or Diabetes. AHA American Heart Association 49th Cardiovascular Disease Epidemiology and

Prevention and Nutrition, Physical Activity and Metabolism Conference. Circulation 2009; 119: e353, P322.

24. Taveira TH, Cohen LB, Dooley AG, Pirraglia PA, Friedmann PD, **Wu WC**. Pharmacist-Led Group Medical Visits for Diabetes in Patients with Comorbid Depression. AHA Joint Conference - Cardiovascular Disease Epidemiology and Prevention and Nutrition, Physical Activity, and Metabolism. Circulation 2009; 119: e359.

25. **Wu WC**, Parker D, Taveira TH, Choudhary G, Eaton C. Prevalence of Diabetes Among Adult Smokers: Need for Early Screening? AHA National Meeting 2009; Orlando, FLA.

26. **Wu WC**, Lessard D, Yarzebski J, Gore J, Goldberg RJ. Anemia and Invasive Management Utilization in Acute Non-ST Elevation Myocardial Infarction. AHA National Meeting 2009; Orlando, FLA.

27. Chen CK; Tseng VL; **Wu WC**; Greenberg PB. Current Role of Manual Extracapsular Cataract Extraction in Veterans Health Administration. American Society of Cataract and Refractive Surgery (ASCRS) 2010; Boston, MA.

28. Tseng VL; Greenberg PB; **Wu WC**; Jiang L; Scott IU; Friedmann PD. Cataract Surgery Complications in Nonagenarians. Joint Meeting of the American Academy of Ophthalmology and the Middle East Africa Council of Ophthalmology, October 16-19 2010; Chicago, IL.

29. Trivedi AN, Jiang L, Friedmann PD, **Wu WC**. Adherence to Quality Measures and Mortality among Veterans with Congestive Heart Failure. 2011 VA National HSRD meeting, Washington DC, February 2011.

30. Taveira TH, Dooley AG, Cohen LB, Khatana SAM, **Wu WC**. Effectiveness of Different Strategies in Maintaining Target Goals of Cardiovascular Risk Factors in Patients Discharged from a Cardiovascular Risk Reduction Clinic. AHA CVD Epidemiology and Prevention Scientific sessions 2011, March 14-16, San Diego, CA.

31. Khatana SAM, Kane, J, Taveira TH, Bauer MS, **Wu WC**. Monitoring and prevalence rates of metabolic syndrome in veterans with major mental illness. AHA CVD Epidemiology and Prevention Scientific sessions 2011, March 14-16, San Diego, CA.

32. Patel N, Taveira TH, Choudhary C, **Wu WC**. C-peptide Levels Predict Cardiovascular And Diabetes Related Mortality In Nondiabetic Adults, American Heart Association Scientific Sessions 2011, Orlando, FLA; November 15<sup>th</sup>, 2011.

33. Gemignani A, Kapoor M, Cohen S, Sharma SC, Choudhary G, **Wu WC**. Preoperative Renin-Angiotensin System Inhibitor Use is Associated with Worse Clinical Outcomes Following Cardiovascular Surgery: Results of a Meta-Analysis. American Heart Association Scientific Sessions 2011, Orlando, FLA; November 15<sup>th</sup>, 2011.

34. Jankowich M, Choudhary G, Klinger J, **Wu WC**. Relationship Between Lung Function And Albuminuria: Data From The Third National Health And Nutrition Examination Survey (NHANES III). 2012 ATS International Conference in San Francisco, California.

35. Grebla RC; Wellenius GA; Eaton CB; Gatsonis C, **Wu WC**. Beta-Blocker Monotherapy is Inferior to Treatment with Angiotensin-Converting-Enzyme Inhibitor/Angiotensin-Receptor

Blocker or Combined Therapy after Hospital Discharge among Patients with Acute Decompensated Heart Failure with Reduced Ejection Fraction. *Circ Cardiovasc Qual Outcomes*. 2012; 5: A99.

36. Lacy ME, Wellenius G, Eaton CB, Loucks EB, Correa A, Gjelsvik A, Wu WC. Examining the Gender-specific Effect of Adding Hemoglobin A1c to Existing Diabetes Risk Prediction Models: the Jackson Heart Study. American Diabetes Association 74th Scientific Sessions. San Francisco, CA: June 13-17, 2014.

37. Dev S, Lacy ME, Masoudi F, Wu WC. Patient Characteristics Associated with Appropriate Use of Aldosterone Antagonists in a National Cohort of Veterans Hospitalized with Heart Failure. *Circ Cardiovasc Qual Outcomes*. 2014;7:A158

## **Invited Presentations**

### **Local**

1. Outpatient Management of Chronic Stable Angina. RI Chapter of American College of Cardiology's Symposium: "Second Annual Cardiology for the Primary Care Provider", September 24, 2003; Warwick, RI
2. "BNP and the management of CHF." Medical Grand Rounds, Roger Williams Hospital, Boston University School of Medicine. March, 2005; Providence, RI.
3. "NOVEL RISK FACTORS OF CARDIOVASCULAR DISEASE", *Cardiovascular Disease and Cancer Behavioral Medicine Seminar Series*. The Miriam Hospital and Brown University. October 9, 2007; Providence, RI.
4. "Pathophysiology of Cardiovascular Diseases", RI Dept. of Health Cardiovascular disease educator certification course; October 7<sup>th</sup>, 2009, Warwick Sheraton Hotel, RI.
5. "Anemia and Transfusions in the ICU", Pulmonary Research Seminar, October 19<sup>th</sup>, 2009, Rhode Island Hospital.
6. "Outpatient management of CHF exacerbation", Primary Care Retreat, September 29<sup>th</sup>, 2010, White's of Westport, Westport, MA.
7. "Group Medical Visits in Diabetes", Center for Primary Care and Prevention Grand Rounds, March 15<sup>th</sup>, 2011; Memorial Hospital of Rhode Island.
8. "Group Medical Visits in Diabetes", Medical Grand Rounds -General Internal Medicine Update, March 22, 2011; Rhode Island Hospital.
9. "Obesity, Insulin Resistance, Diabetes and Cardiovascular Disease", Alpert Medical School of Brown University. Adult and Pediatric Endocrine Grand Rounds, October 17, 2012; Rhode Island Hospital.
10. Obesity, Insulin Resistance, Diabetes and Cardiovascular Disease, Alpert Medical School of Brown University. Cardiology Grand Rounds, May 9<sup>th</sup>, 2014; Rhode Island Hospital.

11. Magnesium Intake or Supplementation and Heart failure, Center for Primary Care and Prevention, Brown University. Grand Rounds, September 10th, 2014; Memorial Hospital of Rhode Island.

12. Cardiac Rehabilitation, Weight Control and Diabetes Research Center, Miriam hospital, September 29th, 2015, CARDIOVASCULAR BEHAVIORAL MEDICINE lecture series.

### **Regional**

“Preoperative Risk Stratification for non-cardiac surgery”, Cardiology Grand Rounds. Rhode Island Hospital and Lifespan. November 2<sup>nd</sup>, 2007.

“Radiation Exposure in Cardiac Imaging”, at INVESTIGATION, INSTITUTIONAL COMMITTEES & INNOVATION Conference of the Massachusetts Medical Society, Waltham, MA. September 25, 2008

“Dyslipidemia in the Elderly, is it too late to help?”, at 2009 Senior Symposium by the Connecticut Chapter of the American Society of Consultant Pharmacists, Ledyard, CT.

“Anemia and Transfusions in the ICU”, at 2009 Update in Critical Care “Where are we now, and where are we going?” by Rhode Island Hospital, Providence, RI.

“Anemia and Acute Myocardial Infarction”, Quality Scholars Conference. Louis Stokes Cleveland Dept. of Veterans Affairs Medical Center. May 21st, 2009.

“Pharmacist-Led Group Medical Appointments for Cardiac Risk Reduction in Diabetes”, Medicine / Primary Care Noon Conference. Louis Stokes Cleveland Dept. of Veterans Affairs Medical Center. May 21st, 2009.

“Pharmacist-Led Group Medical Appointments for Cardiac Risk Reduction in Diabetes”, Medicine / Primary Care Noon Conference. Louis Stokes Cleveland Dept. of Veterans Affairs Medical Center. May 21st, 2009.

“NOVEL RISK FACTORS OF CARDIOVASCULAR DISEASE”, *Medicine Grand Rounds*, Honolulu VA Medical Center, February 24, 2010; Honolulu, HI.

“Interobserver Reliability in the Assessment of Coronary Stenoses by Multi-Detector Computed Tomography” West Roxbury VA Medical Center, October 22, 2010.

“Practical Approach to Group Visits or SMAs”, VISN 7 (VHA) Shared Medical Appointments (SMA) Mini-Collaborative, October 25-26, 2011 in Duluth, GA.

“Status of SMA Implementation”, VISN 7 (VHA) Shared Medical Appointments (SMA) Mini-Collaborative, April 24-25, 2012 in Duluth, GA.

Obesity, Insulin Resistance, Diabetes and Cardiovascular Disease. 44th Annual Samuel D. Plotkin Cardiovascular Symposium - April 28<sup>th</sup>, 2015, The Heart & Vascular Program at Baystate Medical Center, Springfield, MA.

## **National**

1. **Wu WC**. Blood Transfusion Use in AML. Society of Critical Care Medicine 33<sup>rd</sup> Critical Care Congress: "Transfusion Medicine Today – Blood Banking", February 23, 2004; Orlando, Florida.
2. **Wu WC**, Kirsh S, Edelman D. Workshop in "Inter-professional Diabetes Care: Research and Operational Issues of Group Appointments", 2008 VA HSR&D QUERI National Meeting, December 10-12, 2008; Phoenix, AZ.
3. **Wu WC**, Pascuzzi K, Taveira TH. "The Art & Science of Shared Medical Appointments: Lessons Learned", VA Employee Education System, May 31, 2011; National webcast.
4. **Wu WC**. "C-peptide Levels Predict Cardiovascular And Diabetes Related Mortality In Nondiabetic Adults", American Heart Association Scientific Sessions 2011, Orlando, FLA; November 15<sup>th</sup>, 2011.
5. **Wu WC**. "Adherence to Quality Measures and Mortality among Veterans with Congestive Heart Failure" CHF QUERI; March 14<sup>th</sup>, 2012; National webcast.
6. **Wu, WC**. "Group Medical Visits: System Redesign Practice to Enhance Patient Centered-Care" Specialty and Surgical Collaborative learning session; VA Employee Education System, September 21, 2012, National webcast
7. **Wu WC**. "Implementation of Transition of Care Model in CHF to Reduce Rehospitalization Rates" CHF QUERI; November 28<sup>th</sup>, 2012; National webcast.
8. **Wu WC**. "Group Visits" Specialty and Surgical Collaborative Practice Day (Learning Session #3), VA Employee Education System, January 9, 2014; VA National webcast

## **International**

1. **Wu WC**. "Reducing hospitalization and improving outcomes in heart failure" Dept. of Emergency Medicine; National Taiwan University Hospital, August 18<sup>th</sup>, 2014.

## **Grants**

2003-2005	Scios, Inc.	"The use of nesiritide for treatment of acute decompensated congestive heart failure complicated by acute renal insufficiency" Wu, PI \$20,000 Direct costs (no grant number)
2003- 2005	Merck, Inc.	"Effectiveness of different strategies in maintaining target of cardiovascular risk factors in patients discharged from cardiovascular risk reduction clinic" Wu, PI \$35,000 Direct costs (no grant number)
2004-2006	CVT-5131	"A Phase III, Randomized, Double-Blind Study of Intravenous CVT-3146 vs. Adenoscan® in Patients Undergoing Stress Myocardial



		Perfusion Imaging": Wu, site PI \$20,000 Direct (no grant number)
2005	RI Foundation	Multidisciplinary Behavioral and Pharmacological Intervention for Cardiac Risk Reduction in Diabetes. Wu, PI Initiator \$9,952 Direct costs (no grant number)
2005-2007	VA HSR&D	IIR- 04-313 "Variability in Surgical Blood transfusion Practices and Cardiovascular Outcome"; W. Wu, PI \$ 171,850 Direct costs
2006-2007	ACCP	"Pharmacist-led Group Intervention for Diabetes and Psychiatric Illness": Role: Mentor, Co-I Taveira: trainee PI, \$20,000 (no grant number)
2006-2008	ASHP	"Pharmacist-led Telehealth Disease Management in Patients with Diabetes and Depression": Role: Mentor, Co-I; Cohen, PI trainee), \$25,000 (no grant number)
2006-2008	Auxilium, Inc.	"Effect of Testosterone on flow-mediated vasodilation, small artery elasticity index, insulin resistance, and erectile dysfunction in men with hypogonadism": Wu, Co-investigator (PI = Miner), \$20,000 Direct. (no grant number)
2006-2008	Daugherty Foundation	"Multi-Targeted Cardiac Risk Intervention in Type 2 Diabetes", Wu, PI: \$50,000 Direct costs (no grant number)
2007-2009	VA HSRD	VISN-1 Patient Safety Center of Inquiry, "Clinical Trial of a Home Safety Intervention for Alzheimer's Disease" (NRH 05-056 PI: Horvath), "PROVIDENCE VAMC CHF Clinic" substudy, Wu, co-I: \$45,000 Direct costs
2008-2012	VA HSR&D	IAB – 06-269 "Group Intervention for DM Guideline Implementation", Wu, PI: \$ 900,000 Direct costs
2009-2011	VA HSR&D	Supplement to IAB-06-269: Implementation of Honolulu VAMC in group intervention for DM and feasibility of video-conferencing diabetes group intervention in American Samoa, Wu, PI: \$169,990.
2010-2011	VA QUERI - HSR&D	RRP 09-172 "Variations in Quality of Care and Outcomes for Veterans with Heart Failure", Wu, PI: \$100,000 direct
2010-2013	Dept. Med, Brown Univ.	Chairman's developmental research grant program

		<i>"Role of systemic vascular dysfunction in exercise tolerance rehabilitation in COPD" (Jankowich, PI, mentee); \$50,000. Role: Co-I, Mentor.</i>
2011	VA HSR&D	Supplement to IAB-06-269: Assessment of Patient Satisfaction in Group Intervention for DM, Wu, PI: \$41,500
2011-2012	VA QUERI - HSR&D	RRP 10-229 "Medical Center Implementation of PCMH in Acute CHF to Reduce Rehospitalization Rates", Wu, PI: \$100,000 direct
2012-2014	AHA Founder Affiliate	12CRP9840018 "Behavioral activation therapy for both depression and diabetes vs. diabetes alone delivered via group visits. Role: co-PI, mentor (Taveira, PI mentee); \$75,000
2012-2013	RI Foundation	#20113648 "Effect of cardiovascular risk reduction on systemic vascular function in diabetics with COPD." Role: co-I, mentor (Jankowich, PI mentee); \$13,790.
2012-2013	VA CHF QUERI	Heart Failure Shared-Medical-Appointment to provide early (<7 days) post-heart failure discharge follow-up. Role: PI; \$24,800.
2013-2014	VA DM QUERI	RRP 12-452 "Video-Conference Shared Medical Appointments to Improve Rural Diabetes Care." Role: PI, \$100,000
2013-2014	VA CHF QUERI	Pre-Implementation Study of Spironolactone Appropriateness and Safety Monitoring. Role: co-PI (Dev, PI); \$100,000.
2013 – 2015	VA HSRD DM QUERI SDP	1 I01 HX000869-01A1 "Implementation Study of the Peer-to-Peer Program for Patients with Diabetes". Role: co-I & site PI (PI: Heisler) \$335,000.
2013 – 2016	VA HSR&D	IIR 12-346 "Patient-experienced Integrated Care for Veterans with Multiple Chronic Conditions" Role: Co-I (PI: Meterko, M) \$1,048,073
2014 – 2016	R34 AT 007569	Development of A Tai-Chi Program To Overcome Barriers To Cardiac Rehabilitation Role: Co-I (PI: Salmoirago-Blotcher)
4/2013 – 4/2015	VA V1CDA2012-19	Process Quality and Outcomes in Cataract Surgery Role: Mentor (Mentee: Paul Greenberg, MD – study PI) \$245,000 (salary support).

6/2015 – 5/2017 1 F31 DK105791-01A1	The effect of sickle cell trait status on diabetes prediction in African Americans Role: Sponsor (Mentee: Mary E. Lacy, PhD Candidate)
2015-2016 5R01CA155381-04	Quit for Health study: Role: Co-I (PI: D Williams – Brown University, Subcontract 710-9852 TMH: S Dunsiger)
09/01/11-05/31/16 5 R01HL109116-04	“Efficacy of Exercise Videogames for Physical Activity Adoption and Maintenance” (B. Bock, PI) \$367,976 Role: Co-Investigator 0.6 Calendar
08/01/15 – 07/31/19 VA HSR&D IIR 14-293-2	“Group Medical Visits in Heart Failure for Post-Hospitalization Follow-Up” \$275,000 per yr Role: PI 3 CM

### **University Teaching Roles**

July, 2002 - 2009	Section co-leader: BI/0281 - Pathophysiology course Brown Medical School
July, 2003 - 2009	Lecturer Bio 281 – “Pharmacologic management of CHF” The Warren Alpert Medical School of Brown University
July 2003 -	VA Site director, Fellowship Program in Cardiovascular Diseases at Brown University
July 2003 - 2008	Lecturer “EKG course” for Medical Students, Providence VA Medical Center, Alpert Medical School of Brown University
April 2008	Leader, Epidemiology for Medical students, small group sessions, Dept. of Community Health, Brown University
August 2008-	Program Director, Fellowship Program in Preventive Cardiology at Brown University
2010-2012	Member, Doctoral Thesis Committee, Dept. of Epidemiology, Brown University
2012-	Research Mentor: Doctoral Student, Dept. of Epidemiology, School of Public Health, Brown University

### **Hospital Teaching Roles**

July, 2002-	Consult Service Attending in Cardiology and clinic preceptor, Brown Fellowship in Cardiovascular diseases
-------------	---

July, 2002-	Medical student inpatient preceptor, Alpert Medical School, Brown University
July 2003 – present	Lecturer, EKG course Internal Medicine Residency Program – Brown University
July 2005 – present	Lecturer, Preoperative cardiac evaluation, Brown Fellowship in Cardiovascular diseases
July 2008 – present	Lecturer, Syncope and CV pharmacology for Internal Medicine Residency Program – Brown University

## *Curriculum Vitae*

### **Tao Liu, Ph.D.**

Assistant Professor of Biostatistics (Research)  
Brown University School of Public Health

---

Department of Biostatistics  
Center for Statistical Sciences (CSS)  
Center for AIDS Research (CFAR)  
Alcohol Research Center on HIV (ARCH)  
American College of Radiology Imaging Network (ACRIN)  
The AMPATH Biostatistics and Data Program (AMPATH)

Tel: (401) 863-6480  
Fax: (401) 863-9182  
Email: tliu@stat.brown.edu  
Campus Addr: Box GS121-7  
Brown University  
Providence, RI 02912, US

## **PROFESSIONAL APPOINTMENTS**

### **A. Current Academic Positions**

#### **Assistant Professor of Biostatistics (Research)**

Department of Biostatistics, Brown University School of Public Health.

#### **Associate Director of the ARCH Data and Biostatistics Core**

Brown Alcohol Research Center on HIV (ARCH).

#### **Faculty Member**

Brown Center for Statistical Sciences (CSS).  
The Lifespan/Tuft/Brown Center for AIDS Research (CFAR).  
The American College of Radiology Imaging Network (ACRIN).  
Brown Alcohol Research Center on HIV (ARCH).

#### **Affiliated Faculty Member**

The AMPATH Biostatistics and Data Program (AMPATH), Kenya-USA.

### **B. Former Academic Appointments**

#### **Assistant Professor of Community Health (Research)** (Sep. 2008 – Sep. 2012)

Biostatistics Division, Department of Community Health, the Alpert Medical School of Brown University.

#### **Acting Co-Director of the CFAR Outcomes & Biostatistics Core** (Jan. – Jun. 2010)

The Lifespan/Tuft University/Brown Center for AIDS Research (CFAR).

#### **Postdoctoral Research Associate** (Oct. 2006 – Aug. 2008)

Biostatistics Division, Department of Community Health, the Alpert Medical School of Brown University.

#### **Graduate Teaching Assistant** (Sep. 2003 – Oct. 2006)

Department of Biostatistics, Center for Clinical Epidemiology and Biostatistics (CCEB), the University of Pennsylvania.

#### **Graduate Research Assistant / Consultant** (May 2004 – May 2005)

Department of Biostatistics, Center for Clinical Epidemiology and Biostatistics (CCEB), the University of Pennsylvania.

**Research Assistant / Graduate Instructor** (Aug. 2001 – Jun. 2003)

Department of Statistics, Iowa State University.

**Graduate Research Assistant** (Aug. 1999 – Aug. 2001)

Department of Civil Engineering, Iowa State University.

**Undergraduate Research Assistant** (Aug. 1998 – May 1999)

Department of Environmental Science and Engineering, State Key Center of Environmental Stimulation and Pollution Control, Tsinghua University, Beijing, China.

**C. Other Appointments****Research Fellow & Consultant** (Jan. 2005 – Sep. 2006)

Research Statistics Unit, GlaxoSmithKline (GSK) Corp., Collegeville, PA

**Summer Intern** (Summer, 2003)

Department of Biostatistics, Amgen Incorporation, Thousand Oaks, CA

**EDUCATION**

- |      |                                       |   |
|------|---------------------------------------|---|
| 2006 | <b>Ph.D. Biostatistics</b>            | <u>The University of Pennsylvania</u> , PA, US<br><i>PhD Dissertation: Measuring sensitivity to nonignorable censoring in nonparametric and semiparametric survival modeling.</i> |
| 2002 | <b>M.S. Statistics</b>                | <u>Iowa State University</u> , IA, US<br><i>Thesis: Improved Confidence Interval Estimation for Parameters in Nonlinear Models</i>  |
| 2002 | <b>M.S. Civil Engineering</b>         | <u>Iowa State University</u> , IA, US<br><i>Thesis: Ammonia Inhibition in Thermophilic Anaerobic Process</i>  |
| 1999 | <b>B.E. Environmental Engineering</b> | <u>Tsinghua University</u> , Beijing, China   |

**PUBLICATIONS****A. Book Chapter**

1. Fedorov, V.V. and **Liu, T.\*** (2007). "Enrichment Design." *Encyclopedia of Clinical Trials*. John Wiley & Son Press. (\*Authorship in alphabetical order)

**B. Journals Articles (Peer-reviewed)**

1. **Liu, T.** and Hogan, J. (2015). "Inference about ATE from observational studies with continuous outcome and unmeasured confounding." Under revision for *Statistics in Medicine*.
2. Kahler, C., **Liu, T.**, Cioe, P., Bryant, V., Pinkston, M., Kojic, E., Onen, N., Baker, J., Hammer, J., Brook, J. and Patel, P. (2015). "Direct and Indirect Effects of Heavy Alcohol Use on HIV and non-HIV Outcomes in a Longitudinal Study of HIV Patients Receiving ART." Under review in *Journal of AIDS*.

3. **Liu, T.**, Bazerman, L., Pinkston, M., Nunn, A., Rana, A. and Beckwith, C. (2015). "Co-occurring HIV risk behaviors among males entering jail." Invited revision for *Journal of AIDS & Clinical Research*.
4. Merchant RC, Baird JR, **Liu T**, and Nirenberg TD (2015). "Short-term efficacy of a brief intervention to reduce drug misuse and increase drug treatment utilization among adult emergency department patients." *Academic Emergency Medicine* (Accepted).
5. Stillman, A.E., Gatsonis, C., Lima, J.A.C., Black, W.C., Cormack, J., Gareen, I., Hoffmann, U., **Liu, T.**, Mavromatic, K., Schnall, M.D., Udelson, J.E., Wood, P. (2015). "Rationale and Design of the RESCUE (Randomized Evaluation of Patients with Stable Angina Comparing Utilization of Noninvasive Examinations) Trial." Under review in *the American Heart Journal*.
6. Merchant RC, DeLong AK, **Liu T**, Baird JB (2015). "The impact of time elapsed participating in a study on a brief intervention aimed to increase uptake of rapid HIV and Hepatitis C screening among drug misusing adult Emergency Department patients." *AIDS and Behavior*. (in press).
7. Bernardino VL, Baird JR, **Liu T**, and Merchant RC (2015). "Comparison of substance use prevalence among Rhode Island and The Miriam Hospital Emergency Department patients to state and national general population prevalence estimates." *Rhode Island Medical Journal*. (In press).
8. Beaudoin F; Baird JR; **Liu T**; Merchant RC (2015). "Gender differences in substance use among adult emergency department patients: prevalence, severity, and need for intervention." *Academic Emergency Medicine*. (In press).
9. Shao W, Guan W\*, Clark MA, **Liu T**, Santelices, C, Cortes, DE, and Merchant, RC (2015) "Does a video improve knowledge of HIV/AIDS and HIV testing among a global internet audience?" *International Journal of STD & AIDS*. (\*student advised; Accepted).
10. Shao W, Guan W\*, Clark MA, **Liu T**, Santelices C, Cortes DE, and Merchant RC (2015). "Variations in recruitment yield, costs, and speed and participant diversity across internet platforms in a global study of English- or Spanish-speaking Internet users." *Digital Culture & Education*, 7(1), 40-86. (\*student advised)
11. Merchant R.C., Clark, M.A., Santelices, C.A., **Liu, T.**, and Cortes, D. (2015). "Effectiveness of an HIV/AIDS and HIV testing informational video for Spanish-speaking Latinos in healthcare and non-healthcare settings". *AIDS and Behavior*. 19(3): 523—535. [PMID: 25179540].
12. Rana, A.I., **Liu, T.**, Gillani, F.S., Reece, R., Kojic, E.M., Zlotnick, C., and Wilson, I.B. (2014) "Multiple gaps in care common among newly diagnosed HIV patients." *AIDS Care*. 27(6): 679—687. [PMCID: PMC25634492] [PMCID: PMC4366312].
13. Tai, M.\*, **Liu, T.**, and Merchant, R.C. (2014). "HIV/AIDS-related hospitalizations in the United States short-stay hospitals, 1982-2010." *Journal of the International Association of Providers of AIDS Care*. (\*Advised student). (in press).
14. Merchant, R.C., Baird, J.R., **Liu, T.**, and Taylor, L.E. (2014). "HCV among the Miriam Hospital and Rhode Island Hospital adult emergency department patients." *Rhode Island Medical Journal*, 97(4): 35—39. [PMID: 24983020].
15. Merchant, R., Baird, J., **Liu, T.**, Taylor, L, Montague, B., and Nirenberg, T. (2014) "Brief intervention to increase emergency department uptake of combined rapid HIV and hepatic

- tis C screening among a drug misusing population." *Academic Emergency Medicine*. 21:752—767. [PMID: 25125271] [PMCID: PMC4135533]
16. Federov, V. and **Liu, T.\*** (2014). "Randomized discontinuation trials with binary outcomes." *The Journal of Statistical Theory and Practice*, 8:30—45. (\*Authorship in alphabetical order)
  17. **Liu, T.**, Hogan J.W., Wang, L., Zhang, S. and Kantor, R. (2013). "Optimal Allocation of Gold Standard Testing under Constrained Availability: Application to Assessment of HIV Treatment Failure." *Journal of the American Statistical Association (JASA)*, 108 (504): 1173—1188. [PMCID: PMC3963362].
  18. Trillo, A., Merchant, R., Baird, J., Ladd, G., **Liu, T.**, and Nirenberg, T. (2013). "Interrelationship of alcohol misuse, HIV sexual risk and HIV screening uptake among emergency department patients." *BMC Emergency Medicine*, 13:9-22. [PMID: 23721108] [PMCID: PMC3686630]
  19. Xu, H.\*, Short, S.E., and **Liu, T.** (2013). "Dynamic relations between fast-food restaurant and body weight status: A longitudinal and multilevel analysis of Chinese adults." *Journal of Epidemiology & Community Health*, 67:271-279. [PMID: 22923769]. (\*Advised student; Recipient of the 2009 Brown Global Health Scholarship).
  20. **Liu, T.** and Heitjan, D.F. (2012). "Sensitivity of the discrete-time Kaplan-Meier estimate to non-ignorable censoring: Application in a clinical trial". *Statistics in Medicine*, 31: 2998-3010. [PMID: 22806989].
  21. Trillo, A., Merchant, R.C., Baird, J.R., **Liu, T.**, and Nirenberg, T.D. (2012). "Sex differences in alcohol misuse and estimated blood alcohol concentrations among emergency department patients: Implications for brief interventions." *Academic Emergency Medicine*, 19(8): 924-33. [PMID: 22849748] [PMCID: PMC3424395].
  22. Wei, F., Zhou, J., Wei, X., Zhang, J., Fleming, B.C., Terek, R., Pei, M., Chen, Q., **Liu, T.**, and Wei, L. (2012). "Activation of Indian Hedgehog promotes chondrocyte hypertrophy and upregulation of MMP-13 in human osteoarthritic cartilage." *Osteoarthritis and Cartilage*, 20(7):755-63. [PMID: 22469853] [PMCID: PMC3374008].
  23. Anderson, A., Cindy, F., **Liu, T.**, Swarts, A., Siminya, M. and Cu-Uvin, S. (2012). "Effect of trichomoniasis therapy on genital HIV viral burden among African women." *Sexually Transmitted Diseases*. 39(8):638-642. [PMID: 22797689] [PMCID: PMC3398383].
  24. Loucks, E.B., Gilman, S.E., Rogers, M., **Liu, T.**, Kawachi, I., Martins, L., Kubzansky, L., Buka, S.L. (2012). "Education and coronary heart disease risk associations may be affected by early life common prior causes: A propensity matching analysis." *Annals of Epidemiology*, 22(4):221-232. [PMID: 22463841] [PMCID: PMC3327475].
  25. Merchant, R.C., Waxman, M.J., Maher, J.G., Clark, M.A., Celada, M.T., **Liu, T.**, Simmons, E.M., Beckwith, C.G. and Mayer, K.H. (2012). "Patient and clinician ethical perspectives on the 2006 Centers for Disease Control and Prevention HIV testing methods." *Public Health Reports*, 127(3):318- 329. [PMID: 22547863] [PMCID: PMC3314076].
  26. Rosen (Asnis)\*, L.M., **Liu, T.** and Merchant, R.C. (2012). "Efficiency of ICD-9 billing code searches to identify blood or body fluid exposure emergency department visits through a state-wide multi-center database." *Infection Control and Hospital Epidemiology*. 33(6): 581-588. [PMID: 22561713 ] (\*Advised student)
  27. Saffarini, C.M., Heger, N.E., Yamasaki, H., **Liu, T.**, Hall, S.J., and Boekelheide, K. (2012). "Induction and persistence of abnormal testicular cells following gestational exposure to di-



- (n-butyl) phthalate in p53-null mice.” *The Journal of Andrology*, 33(3):505-13. [PMID: 21868749].
28. Mabeya, H., Khozaim, K., **Liu, T.**, Orango, O., Chumba, D., Pisharodi, L., and Cu-Uvin, S. (2011). “Comparison of conventional cervical cytology versus visual inspection with acetic acid (VIA) among HIV-infected women in western Kenya.” *Journal of Lower Genital Tract Disease*. 16(2): 92. [PMID: 22126834] [PMCID: PMC3289722].
  29. Merchant, R.C., DePalo D.M., **Liu, T.**, Rich J.D., and Stein M.D. (2010). “Developing a system to predict laboratory-confirmed chlamydial and/or gonococcal urethritis in adult male emergency department patients.” *Postgraduate Medicine*. 22(1): 52–60. [PMID: 20107289] [PMCID: PMC3021915].
  30. Beckwith, C.G., **Liu, T.**, Bazerman, L.B., DeLong, A.K., Desjardins, S.F., Poshkus, M., Flanigan, T.P. (2010). “HIV risk behavior pre- and post-HIV testing in jail: A pilot study.” *Journal of Acquired Immune Deficiency Syndromes*, 53(4): 485–90. [PMID: 20035232] [PMCID: PMC2837107].
  31. Merchant R.C., Lau T.S., **Liu, T.**, Mayer K.H., and Becker B.M. (2009). “Adult sexual assault evaluations at Rhode Island emergency departments, 1995-2001.” *Journal of Urban Health*, 86(1): 43–53. [PMID: 18797994] [PMCID: PMC2629515].
  32. Phelan, S., **Liu, T.**, Gorin, A., Lowe, M., Hogan, J., Fava, J., Wing, R. (2009). “What distinguishes long-term weight loss maintainers from the treatment-seeking obese? Analysis of environmental, behavioral, and psychosocial variables in diverse patient populations.” *Annals of Behavioral Medicine*, 38: 94–104. [PMID: 19847584]
  33. Moreira C., Venkatesh, K.K., DeLong A.K., **Liu, T.**, Kurpewski J., Ingersoll J., Caliendo A.M., Cu-Uvin S. (2009). “Effect of treatment of asymptomatic bacterial vaginosis on HIV-1 shedding in the genital tract among women on antiretroviral therapy: Pilot study.” *Clinical Infectious Diseases*, 49: 991–992. [PMID: 19694541] [PMCID: PMC2730467].
  34. Hogan, J.W. and **Liu, T.** (2008). “Mediation analysis for intervention trial: Objectives, models and inference.” *Health Services and Outcomes Research Method*, 8: 77-79.
  35. Anderson B.L., Wang C.C., **Liu, T.**, DeLong A.K., Kojic E.M., Kurpewski J., Ingersoll J., Mayer K., Caliendo A., and Cu-Uvin S. (2008). “Genital tract leukocytes and shedding of genital HIV-1 RNA.” *Clinical Infectious Diseases*, 47(9): 1216–1221. [PMID: 18808359] [PMCID: PMC2714169].
  36. Merchant, R.C., Chee, K.J., **Liu, T.**, Mayer, K.H., and Becker, B.M. (2008). “Incidence of visits for health care worker blood and body fluid exposures and HIV post-exposure prophylaxis provision at Rhode Island Emergency Departments.” *Journal of AIDS*, 47: 358–368. [PMID: 18176321] [PMCID: PMC3180865].
  37. Sung, S. and **Liu, T.** (2003). “Ammonia inhibition on thermophilic methanogens.” *Chemosphere*, 53(1):43-52. [PMID: 12892665].
  38. **Liu, T.** and Sung, S. (2002). “Ammonia inhibition on thermophilic aceticlastic methanogens.” *Water Science and Technology*, 45(10):113–120. [PMID: 12188530].
  39. **Liu, T.** and Sung, S. (2001). “Effect of ammonia inhibition in thermophilic anaerobic process.” *Proceedings of the Water Environment Federation*, 2001(1): 1292-1306.

### C. Non-Refereed Articles

38. **Liu, T.**, DeLong, A., and Blossom, B. (2009) "Challenge to IDSA recommendations for late neurologic Lyme disease treatment and post Lyme syndrome: A statistical review of NIH-funded treatment studies." The International Lyme And Associated Diseases Society (IDSA) Lyme Panel Review Hearing ([http://www.ilads.org/lyme\\_disease/written\\_testimony/12%20Liu%20DeLong%20Blossom%20-%20Statistical%20Review.pdf](http://www.ilads.org/lyme_disease/written_testimony/12%20Liu%20DeLong%20Blossom%20-%20Statistical%20Review.pdf))
39. **Liu, T.** (2006). "Measuring sensitivity to nonignorable censoring in nonparametric and semiparametric survival modeling." *Doctoral Dissertation*. The University of Pennsylvania. (<http://repository.upenn.edu/dissertations/AAI3246193/>)
40. Fedorov, V. V. and **Liu, T.\*** (2005). "Randomized discontinuation trials: design and efficiency." GlaxoSmithKline Biomedical Data Science Technical Report, 3. (\*Authorship in Alphabetical order).
41. **Liu, T.** (2001). "Ammonia inhibition in thermophilic anaerobic process." Master thesis, Iowa State Univ. ([http://books.google.com/books?id=\\_XZfNwAACAAJ](http://books.google.com/books?id=_XZfNwAACAAJ))

#### **D. Manuscript in Progress**

42. Merchant, R.C., **Liu, T.**, and Baird, J. (2015) "Comparison of Priorities for Addressing Adult Emergency Department Patient Substance Misuse based on Simplified Screening Strategies versus Formal Substance Misuse Evaluations." Under revision.
43. **Liu T**, Huang R, Hogan J, and Kantor R. (2015) "Improved Viral Load Monitoring Capacity with Rank-Based Algorithms for Pooled Assays". Under revision.
44. Merchant R.C., **Liu, T.**, and Baird, J.R. (2015) "Priorities for substance misuse interventions among adult emergency department patients based on prevalence, recency of use, frequency and severity of use misuse screening strategies." Under preparation.
45. **Liu T**, Hogan J, Xu Y, DeLong Am and Kantor R. (2015) "Covariate-Assisted Pooled Nucleic Acid Testing to Identify Antiretroviral Treatment Failure During HIV Infection". Under revision.
46. Omenge, O., **Liu, T.**, Christoffersen-Deb A., Itsura, P., Mabeya, H., Washington, S., and Cu-Uvin, S. (2015) "A comparison of Visual Inspection with Acetic Acid (VIA), Pap smear and HPV typing for follow-up after VIA/Cryotherapy in HIV-infected women." [working title] Under preparation.
47. Jones, M.M, **Liu, T.** and Shenassa, E. (2015). "Differential secular trends in BMI in relation to region of childhood residence: A 25 year follow-up of a nationally representative sample". Under preparation.

#### **E. Abstracts / Conference Presentations**

48. **Liu T.** and Hogan J. (2015). "Coherence, Relevance, Transparency: The three requirements for sensitivity analysis in clinical trials." The Fourth ISBS/DIA Joint Symposium on Biopharmaceutical Statistics, June 29-July 1, Beijing, China.
49. Merchant RC, **Liu T**, Clark M, Rosenberger J, Bauermeister J and Mayer K (2015). "How do young adult social media-using black, Hispanic and white MSM differ in their interest in using fingerstick rapid HIV self-testing? Implications for encouraging testing among hard to reach populations." The 2015 International AIDS Society Meeting (late breaker). Vancouver, Canada. July 20-22. (Submitted)

50. Kuo I, Kurth A, **Liu T**, Trezza C, Bazerman L, Castonguay B, Olsen H, Patrick R, Abbott S, Cates A, Peterson J, Beckwith C. (2015) "Gender Disparities Among HIV-Positive Individuals Involved in the Criminal Justice System: The CARE+ Corrections Study in Washington, DC". The 2015 National HIV Prevention Conference. Atlanta, GA, December 6-9, 2015. (Submitted).
51. Merchant RC, **Liu T**, Melissa C, Bauermeister, J, Mayer K. (2015). "Incongruence between self-perceived HIV risk and reported sexual risk among social media-using Black, Hispanic and white MSM." The 2015 National HIV Prevention Conference. Atlanta, GA, December 6-9, 2015. (Submitted).
52. Merchant RC, **Liu T**, Melissa C, Bauermeister, J, Mayer K. (2015). "Low PrEP utilization among among social media-using young adult Black, Hispanic and white MSM at higher risk for HIV acquisition." The 2015 National HIV Prevention Conference. Atlanta, GA, December 6-9, 2015. (Submitted).
53. (*Invited presentation*) **Liu T** (2015) "Coherence, Relevance, Transparency: The three requirements for sensitivity analysis in clinical trials" The 4th International Symposium on Biopharmaceutical Statistics, Beijing, China, June 29 - July 1, 2015.
54. Merchant RC, DeLong AK, **Liu T** and Baird JR (2015) "Does a brief intervention among drug misusing adult emergency department patients increase uptake of rapid HIV/HCV screening?" The 2015 National Summit on HCV and HIV Diagnosis, Prevention and Access to Care, June 4-6, Arlington VA. (Submitted).
55. Kuo I, Kurth A, Cates A, Trezza C, Bazerman L, Castonguay B, Olsen H, Patrick R, **Liu T**, Peterson J, Abbott S, Beckwith C (2015). "HIV Risk and Clinical Characteristics Among HIV-Positive Individuals Involved in the Criminal Justice System: The CARE+ Corrections Trial in Washington, DC" The 2015 International AIDS Society Meeting. Vancouver, Canada. July 20-22. (Accepted).
56. Merchant RC, Baird JR, **Liu T**, and Nirenberg TD. "Does A Brief Intervention For Adult Emergency Department Patients Decrease Drug Misuse And Increase Drug Treatment Services Utilization?" [abstract] 2015 Society for Academic Emergency Medicine Annual Meeting, San Diego, CA, May 12-15, 2015. (Accepted).
57. Merchant RC, Shao W, Guan W\*, Clark MA, **Liu T**, Santelices C and Cortes DE (2015). "Variations in recruitment yield, costs, and speed and participant diversity across internet or social media platforms in a global study of HIV/AIDS and HIV testing knowledge". The 2015 International AIDS Society Meeting. Vancouver, Canada. July 20-22. (Accepted).
58. Merchant, R.C., Baird, J.R., **Liu T**, and Nirenberge, T.D. (2015). "Short-term efficacy of a brief intervention to reduce drug misuse and increase drug treatment utilization among adult emergency department patients". The 2015 Society for Academic Emergency Medicine (SAEM) Meeting. San Diego, CA. May 12-16, 2015. (Accepted).
59. Guan W\*, **Liu T**, Baird JR, and Merchant RC (2015) "Evaluation of a Brief Intervention to Reduce Negative Consequences of Drug Misuse among Adult Emergency Department Patients." Brown Public Health Research Day (Poster Presentation). April 16 2015, Brown University, Providence, RI. (\*Advised student)
60. Stillman, AE, Gatsonis, CG, Lima, J, Cormack, J, Gareen, I., Hoffmann, U, **Liu T.**, Mavromatis, K., Schnall, M., Udelson, J., Woodward, P., and RESCUE Investigators ACRIN. (2015). "Randomized Evaluation of Patients with Stable Angina Comparing Utilization of

- Noninvasive Examinations (RESCUE) Trial.” The 64th Annual Scientific Session & Expo of American College of Cardiology (ACC). San Diego, CA. March 14-16, 2015.
61. (*Invited lecture*) **Liu T** (2015) “Design of non-inferiority and equivalence clinical trials with time-to-event outcomes: The RESCUE study.” North Sichuan Medical College School of Public Health, March 3-4, Sichuan, China.
  62. **Liu, T.**, Hogan, J.W., Huang, R.\*, Kantor, R. (2015) “Improved viral load monitoring capacity with rank-based algorithms for pooled assays”. The 2015 Conference on Retroviruses and Opportunistic Infections (CROI). Seattle, WA. Feb 23-26, 2015. (\*advised student).
  63. (*Invited Poster Presentation*) **Liu T**, Hogan JW, and Kantor R (2014). “Optimal Allocation of Viral Load Testing Under Resource Constraints”. The 2014 CFAR National Meeting. Providence, RI. November 5-6, 2014.
  64. Merchant, R.C., Baird, J.R., **Liu, T.**, Beaudoin, F., and Nirenberg, T. (2014). “Severity of substance misuse and need for substance misuse interventions among adult emergency department patients.” [abstract 189] American College of Emergency Physicians Scientific Assembly. Chicago, IL, October 27. (Peer reviewed).
  65. Shao, W., Merchant, R., Clark, M., **Liu, T.**, Guan, W., Santelices, C, Cortes, D. (2014). “Does a Video Improve HIV/AIDS and HIV Testing Knowledge Among a Global Sample of Internet and Social Media Users?” [abstract 35819] National Conference on Health Communication, Marketing, and Media. Atlanta, GA, August 20. (Peer reviewed).
  66. (*Invited Presentation*) **Liu, T.**, Hogan, J.W., and Kantor, R. (2014). “Optimizing Diagnosis of HIV Treatment Failure with Selective Use of Gold Standard Test.” The 2014 New England Statistics Symposium. Harvard University School of Public Health, Boston, MA. April 25-26.
  67. Shao, W., Merchant, R., Clark, M., **Liu, T.**, Guan, W., Santelices, C, Cortes, D. (2014). “How Do Internet and Social Media Sites Compare in Achieving Optimal Completion Rates and Costs for an Internet-Based Research Study?” The 2014 CDC National Conference on Health Communication, Marketing, and Media. (August 19-21). (Peer reviewed).
  68. Omenge, E., **Liu, T.**, Itsura, P., Mabeya, H., Christofferson-deb, A., Washington, S., and Cu-Uvin, S. (2014) “Visual inspection with acetic acid is good for follow-up after cryotherapy in HIV-infected women.” The 2014 Conference on Retroviruses and Opportunistic Infections. March 3-6, 2014, Boston, MA. (Peer reviewed).
  69. Merchant RC, Baird JR, **Liu T.**, Taylor L, Montague B, and Nirenberg T. (2014). “Does a Brief Intervention Increase HIV/HCV Screening among Drug-using Emergency Department Patients?” [abstract #743] 2014 Society for Academic Emergency Medicine Annual Meeting, Dallas, TX, May 14, 2014. (Peer reviewed).
  70. **Liu, T.**, Hogan, J.W., Wang, L., Zhang, S. and Kantor, R. (2014) “Optimizing diagnostic accuracy of HIV treatment failure in resource-limited settings with selective use of viral load testing.” The 17th International Workshop on HIV Observational Databases. Cavtat, Croatia. March 2014. (Reference #17-185). (Peer reviewed).
  71. Jones, M.M, **Liu, T.**, and Shenassa, E.D. (2013) “Differential secular trends in BMI in relation to region of childhood residence: A 25 years follow-up of a nationally representative sample.” (Poster, Session 4362). The American Public Health Association (APHA) 141st Annual Meeting. Nov 2-6, 2013, Boston, MA. (Peer reviewed).

72. Thakore, R.\*, Pinkson, M., and **Liu, T.** (2013). "The effect of cocaine Use on the diet and metabolic status of HIV-infected individuals." Brown Public Health Research Day (Poster Presentation). April 18, Brown University, Providence, RI. (\*Advised student).
73. Tai, M.\*, **Liu, T.**, and Merchant, R.C. (2013). "HIV/AIDS-related hospitalization rates in US short-stay hospitals, 1982-2010." Brown Public Health Research Day (Poster Presentation). April 18, Brown University, Providence, RI. (\*Advised student)
74. Omenge, E., Itsura, P., **Liu, T.**, Mabeya, H., Christoffersen-Deb, A., Washington, S., and Cu-Uvin, S. (2013). "Six Months Follow-up of HIV-infected Women After Visual Inspection with Acetic Acid (VIA) and Immediate Cryotherapy in Western, Kenya." The 2013 Conference on Retroviruses and Opportunistic Infections (CROI). March 3-6, 2013; Poster. (Peer-reviewed).
75. Merchant RC, Clark MA, **Liu, T.**, Santelices C, and Cortes D. (2012). "Can a video substitute for an in-person discussion in delivering HIV pre-test information to Spanish-speaking Latinos and better serve those with lower health literacy?" [Paper #31945] 2012 National Conference on Health Communication, Marketing, and Media. Atlanta, GA, August 7-9, 2012. (Peer-reviewed).
76. Merchant R.C., Clark M.A., **Liu, T.**, Santelices C., and Cortes D. (2012) "Can a video substitute for an in-person discussion in delivering HIV pre-test information to Spanish-speaking Latinos?" The 2012 National Summit on HIV and Viral Hepatitis Diagnosis, Prevention and Access To Care. Poster #116. Washington DC. November 26-28, 2012. (Peer-reviewed).
77. Tai, M.\*, **Liu, T.**, and Merchant, R.C. (2013). "HIV/AIDS-related hospitalization rates in US short-stay hospitals, 1982-2010." The 2012 National Summit on HIV and Viral Hepatitis Diagnosis, Prevention and Access To Care. Abstract #80. Washington DC. November 26-28, 2012. (Peer-reviewed).
78. Kuo I., Kurth A., Bazerman L., Peterson J., Cates A., Azikiwe N., Wong J., **Liu, T.**, and Beckwith C. (2012). "CARE+ Corrections—Innovative use of technology in jails to support linkage and adherence to HIV care." The 2nd International Treatment as Prevention Workshop 2012, April, Vancouver, BC, Canada.
79. (*Invited Presentation*) **Liu, T.**, Hogan, J.W., Zhang, S., Kantor, R. (2012). "Using auxiliary biomarkers to improve pooling strategies for HIV viral load testing." The 2012 International Biometrics Society (IBS) ENAR Meeting, May, Washington DC.
80. (*Invited Presentation*) **Liu, T.** (2011). "Optimizing diagnosis of HIV viral failure with selective use of gold standard testing in resource limited settings." CFAR Research-in-Progress Lectureship Series, November 18, 2011. The Mariam Hospital, Providence, RI.
81. (*Invited Presentation*) **Liu, T.** (2011). "Instrumental variable method and principal stratification: An application to a CFAR study." ACRIN Working Group Meeting, Brown University, Oct 18, 2011, Providence, RI.
82. Baird J.R., Merchant R.C., Nirenberg T.D., **Liu, T.**, and Ladd G.T. (2011). "Increasing the uptake of testing for chlamydia and gonorrhea among young female Emergency Department patients." [Abstract: 244972] 139th American Public Health Association Annual Meeting, Nov 1, Washington, DC. (Peer-reviewed).
83. Trillo A., Merchant R.C., Baird J.R., **Liu, T.**, and Nirenberg, T.D. (2011). "Gender differences in alcohol misuse and estimated blood alcohol levels among emergency department patients: implications for brief interventions." [Abstract: 16] 8th Annual International Net-

- work on Brief Interventions for Alcohol & Other Drugs (INEBRIA) Conference, Sept 22, Boston, MA. (Peer-reviewed).
84. Merchant R.C., Baird J.R., Nirenberg T.D., **Liu, T.**, and Ladd G.T. (2011). "Does self-report of alcohol misuse and sexual risk-taking behavior motivate patients to be tested for HIV?" [Abstract: 1399] CDC 2011 National HIV Prevention Conference, Aug 14-17, Atlanta, GA. (Peer-reviewed).
  85. Merchant R.C., Baird J.R., Nirenberg T.D., **Liu, T.**, and Ladd G.T. (2011). "Increasing HIV sexual risk-taking as a function of alcohol misuse among emergency department patients." [Abstract: 1408] CDC 2011 National HIV Prevention Conference, Aug 14-17, Atlanta, GA. (Peer-reviewed).
  86. (*Invited Presentation*) **Liu, T.** (2011). "Optimizing diagnosis of HIV treatment failure with selective use of gold standard test." ACRIN Working Group Meeting, Brown University, July 27, 2011, Providence, RI.
  87. (*Invited Presentation*) **Liu, T.** (2011). "Comparison of positive predictive values in matched pairs clinical trials." Invited Lectureship Series of the 60th Anniversary of North Sichuan Medical College. June 7, 2011. Nanchong, Sichuan, China.
  88. Hogan, J., **Liu, T.**, Kantor, R., Wang, L., and Zhang, S. (2011). "Optimizing diagnosis of HIV viral failure with selective use of gold standard testing in resource limited settings." Workshop on Statistical Methods in HIV research. April 14-15, 2011, Montreal Canada. (By Invitation).
  89. **Liu, T.**, Hogan, J. and Kantor, R. (2011). "Optimal use of selective viral load testing for HIV treatment monitoring in resource limited settings." The 2011 International Biometrics Society (IBS) ENAR Meeting. March, Miami, FL.
  90. Anderson, A., Firnhaber C., **Liu, T.**, Swarts, A., Siminya, M. and Cu-Uvin, S. (2011). " " The International Conference on Retroviruses and Opportunistic Infections. Feb 27-Mar 2, Boston, MA. (Peer-reviewed).
  91. Anderson, B., Firnhaber, C., Swarts, A., Siminya, M., **Liu, T.**, and Cu-Uvin, S (2010). "Self-Collected Vaginal Swabs for Trichomoniasis Testing in HIV-infected Women in South Africa." The 34th Annual Scientific Meeting of Infectious Diseases Society for Obstetrics and Gynecology (IDSOG). Aug. 5-7. Santa Fe, NM. (Peer-reviewed).
  92. Guzman H., Merchant, R.C., Baird, J.R., Nirenberg, T.D., **Liu, T.**, Ladd, G.T. (2010) "How does hazardous and heavy episodic alcohol drinking relate to HIV sexual risk among emergency department patients?" *Annals of Emergency Medicine*, 56 (3), S22-S22. [PIL: S0196-0644(10)00690-6; doi:10.1016].
  93. Guzman, H., Merchant, R.C., Baird, J.R., Nirenberg, T.D., **Liu, T.**, and Ladd, G.T. (2010). "How does hazardous and heavy episodic alcohol drinking relate to HIV sexual risk among emergency department patients?" 2010 American College of Emergency Physicians Scientific Assembly Research Forum, Las Vegas, NV. (Peer-reviewed).
  94. Xu, H\*, and **Liu, T.** (2010). "Community Context and Obesity among Chinese Adults: A Longitudinal and Multilevel Analysis." Population Association of America 2010 Annual Meeting, Dallas, TX. (Peer-reviewed) (\*Advised student).
  95. Mabeya, H., Khozaim, K., **Liu, T.**, Orango, O., Chumba, D., Pisharodi, L., and Cu-Uvin, S. (2010). "Comparison of Conventional Pap Smear and Visual Inspection with Acetic Acid (VIA) in HIV Infected Women in Western Kenya." The International Conference on Retroviruses and Opportunistic Infections (CROI) 2010, San Francisco, CA. (Peer-reviewed).

96. **Liu, T.**, DeLong, A., and Blossom, B. (2009). "Challenge to IDSA recommendations for late neurologic Lyme disease treatment and post Lyme syndrome." The 2009 International Lyme and Associated Diseases Society (ILADS) Conference, Washington DC. 2010. (By invitation).
97. Merchant R.C., Waxman M.J., Clark M.A., Maher J.C., Celada M.T., Beckwith C.G., **Liu, T.**, Simmons E.A., and Mayer K.H. (2009). "Do patients and clinicians have ethical concerns about the 2006 CDC HIV testing recommendations?" The 2009 CDC National HIV Prevention Conference, Atlanta, GA. (Peer-reviewed).
98. Waxman M.J., Merchant R.C., Clark M.A., Maher J.G., Celada M.T., Beckwith C.G., **Liu, T.**, Simmons E.A., and Mayer K.H. (2009). "Will the 2006 CDC HIV testing recommendations reduce stigma and increase HIV testing?" The 2009 CDC National HIV Prevention Conference, Atlanta, GA. (Peer-reviewed).
99. Nijhawan A., McManus J., **Liu T.**, DeLong A.K., Chapman S., Rapoza K., Kurpewski J., Caliendo A. and Cu-Uvin S. (2009). "The effect of Acyclovir on CD4 count and CD4 percent slope in HIV-1/HSV-2 co-infected women taking highly active antiretroviral therapy (HAART)." The 47th IDSA Annual Meeting; Oct. 29-Nov. 1, 2009, Philadelphia, PA.
100. McManus J., Nijhawan A., **Liu T.**, DeLong A., Chapman S., Rapoza K., Kurpewski J., Caliendo A. and Cu-Uvin S. (2009). "The effect of Acyclovir on the prevalence of bacterial vaginosis on HIV-1/HSV-2 co-infected women taking highly active antiretroviral therapy (HAART)." 47th IDSA Annual Meeting; Oct. 29-Nov. 1, 2009, Philadelphia, PA.
101. Waxman, M.J., Merchant, R., Maher, J., Clark, M., Simmons, E., Celada, T., Beckwith, C., **Liu, T.** (2009). "Who prefers CDC-recommended streamlined methods for HIV testing?" The 2009 Society for Academic Emergency Medicine (SAEM) Annual Meeting, New Orleans, LA. (Peer-reviewed).
102. Beckwith, C.G., **Liu, T.**, Bazerman, L.B., DeLong, A.K., Pinkston, M., Nunn, A., and Flanigan, T.P. (2009). "Identification of multiple HIV risk factors among jail detainees." The 2009 CDC National HIV Prevention Conference, Atlanta, GA. (Peer-reviewed).
103. Waxman, M.J., Merchant, R.C., Maher, J.G., Clark, M.A., Simmons, E.A., Celada, M.T., Beckwith, C.G., **Liu, T.**, Mayer, K.H. (2008). "Do clinicians prefer the 2006 or 2001 CDC HIV testing recommendations?" The 2008 Forum for Collaborative HIV Research. Poster # 151. (Peer-reviewed).
104. Waxman, M.J., Clark, M.A., Maher, J.C., Simmons, E.A., Celada, M.T., Beckwith, C.G., **Liu, T.**, and Mayer, K.H. (2008). "Do patients and clinicians have ethical concerns about the 2006 CDC HIV testing recommendations?" The CDC National HIV Prevention Conference. (Peer-reviewed).
105. Beckwith, C., **Liu, T.**, Bazerman, L., DeLong, A.K., Desjardins, S., and Flanigan, T. (2008). "HIV risk behavior pre- and post-HIV testing and counseling in jail." The 2008 Infectious Diseases Society of America (IDSA) Annual Meeting, Washington DC. (Peer-reviewed).
106. Phelan, S., Gorin, A., **Liu, T.**, Hogan, J.W., Lowe, M., Fava, F., and Wing, R. (2008). "What distinguishes long-term weight loss maintainers from the treatment-seeking obese? Analysis of environmental, behavioral, and psychosocial variables." The 2008 Annual Scientific Meeting of the North American Association for the Study of Obesity (NAASO), Phoenix, AZ. (Peer-reviewed).

107. Moreira C., DeLong A.K., **Liu, T.**, Kurpewski J., Ingersoll J., Caliendo A., and Cu-Uvin S.C. (2008). "HIV-infected women on highly active antiretroviral therapy with asymptomatic bacterial vaginosis have low rates of genital tract HIV-1 RNA shedding." The 17th International AIDS Conference (IAS), Mexico. (Peer-reviewed).
108. Merchant R.C., DePalo D.M., **Liu, T.**, Rich J.D., and Stein M.D. (2008). "Predictors of a chlamydia and/or gonorrhea infection among adult male emergency department patients." The 2008 National Sexually Transmitted Diseases (STD) Prevention Conference, Chicago, IL. (Peer-reviewed).
109. Anderson B.L., **Liu, T.**, DeLong A.K., Ingersoll J., Wang C.C., Kurpewski J., Caliendo A., and Cu-Uvin S.C. (2007). "Genital tract shedding of HIV-1 RNA and lower genital tract infections may be linked by inflammation." The 45th Annual Meeting of the Infectious Diseases Society of America (IDSA), San Diego, CA. 2008 (Peer-reviewed).
110. Wang C.C., **Liu T.**, Anderson B.L., DeLong A.K., Chapman S., Kurpewski J., Ingersoll J., Caliendo A.M., Cu-Uvin S.C. (2008) "Association between genital tract HIV-1 RNA shedding and mucosal inflammation among women on effective ART with undetectable plasma viral load." Poster presentation. The 15th Annual Conference on Retroviruses and Opportunistic Infections (CROI), February, 2008, Boston, MA.
111. Anderson B.L., DeLong A.K., **Liu, T.**, Wang C.C., Kurpewski J., and Cu-Uvin S.C. (2007). "Association between genital tract white blood cells and viral shedding among HIV-infected women in the absence of genital infections." The 34th Annual Scientific Meeting of Infectious Diseases Society for Obstetrics and Gynecology (IDSOG), Boston, MA. (Peer-reviewed).
112. **Liu, T.**, Hogan, J.W., and DeLong, A.K. (2008). "Bounds of ATE and unmeasured confounding bias in observational studies with continuous outcome." The 2008 International Biometric Society (IBS) ENAR meeting, Arlington, VA.
113. **Liu, T.** and Heitjan, D.F. (2007). "Sensitivity of Cox regression to nonignorable censoring." The 2007 American Statistical Association (ASA) Joint Statistical meeting, Salt Lake City, UT.
114. (*Invited Presentation*) **Liu, T.** and Heitjan, D.F. (2006). "Sensitivity and Kaplan-Meier estimate to nonignorable censoring." Dana-Farber Cancer Institute (Harvard University), Department of Biostatistics and Computation Biology, Cambridge, MA.
115. (*Invited Presentation*) **Liu, T.** and Heitjan, D.F. (2006). "Sensitivity and Kaplan-Meier estimate to nonignorable censoring." Brown University, Center for Statistical Sciences, Department of Community Health, Providence, RI.
116. **Liu, T.** and Heitjan, D.F. (2006). "Sensitivity and Kaplan-Meier estimate to nonignorable censoring." The 2006 American Statistical Association (ASA) Joint Statistical Meeting, Seattle, WA.
117. **Liu, T.** and Gao, L. (2006). "Relationship assessment between PK and PD." The 2006 International Biometric Society (IBS) ENAR Meeting, Tampa, FL.
118. (*Invited Presentation; Distinguished Student Paper Award*) **Liu, T.** and Heitjan, D.F. (2006). "Sensitivity and Kaplan-Meier estimate to nonignorable censoring." The 2006 International Biometric Society (IBS) ENAR Meeting, Tampa, FL.
119. **Liu, T.** and Fedorov, V.V. (2006). "Randomized discontinuation trials." The 2006 International Biometric Society (IBS) ENAR Meeting, Tampa, FL.



## RESEARCH GRANTS

### A. Active Grants

#### 1. Facilitating HIV Testing Among Young Adult MSM Through Social Networking

My Role: Brown CSS sub-Award PI  
 Funding Agency: NIH/Rhode Island Hospital subcontract  
 PI: Merchant  
 Type: R21  
 Period: 4/15/2014-3-31/2016  
 Cost: \$91,042

This project assesses acceptance of a new rapid HIV self-test, as compared to current HIV testing approaches, as well as usage of a MSM social-networking website to facilitate HIV testing and dissemination. The entire study will be internet-based, in regards to recruitment, enrollment, follow-up, and acquisition of HIV tests, which is appropriate given the high level of familiarity, use and comfort with the internet among young adult MSM.

#### 2. Optimal HIV Treatment Monitoring Strategies under Resource Constraints

My Role: Co-Investigator  
 Funding Agency: NIH  
 PI: Hogan, Kantor  
 Type: R01  
 Period: 12/1/2014-11/31/2019  
 Cost: \$2,882,699 (Project total)

We propose to develop the statistical framework, theory and methods required to discover optimal diagnostic algorithms for monitoring treatment failure with limited or no VL availability; to use cohort data from both the US and Kenya to derive, calibrate and cross-validate the algorithms; to use extant blood samples from patients in a PEPFAR-funded HIV care program to design and cross-validate a new diagnostic algorithm that includes implementation of pooled assays; and to develop usable software that will enable programs to design their own protocols based on the characteristics of their patient population and local capacity for viral load testing.

#### 3. Facilitating HIV/AIDS and HIV Testing Literacy for Emergency Department Patients

My Role: Co-Investigator  
 Funding Agency: NIH  
 PI: Merchant  
 Type: RO1  
 Period: 7/23/2014-4/30/2019  
 Cost: pending

This project aims to address HIV/AIDS and HIV testing literacy deficits among emergency department patients. The video from the prior R21 study will be tested for efficacy as compared to a pictorial brochure in a multi-site, randomized, controlled, longitudinal study.

#### 4. AMPATH-Oncology Institute: HPV and Cervical Cancer in Kenyan Women with HIV/AIDS

My Role: Co-investigator and Lead Statistician  
 Funding Agency: NCI

Brown PI: Lehrer, Darron, Omenge  
 Type: U54  
 Period: 9/19/2014-8/31/2019  
 Cost: \$728,206 (Project total)

This project aims to assess the results of cryotherapy and LEEP among VIA positive HIV- and HIV+ women in western Kenya. Modifiable risk factors that lead to treatment failure and HPV types (persistence and alterations) also will be assessed.

5. "See and LEEP" Training for Kenyan Non-gynecologists

My Role: Brown sub-Award PI  
 Funding Agency: CFAR/PepFAR Supplement  
 PI: CuUvin  
 Type: P30  
 Period: 4/4/2014-3/31/2015  
 Cost: \$364,969 (Project total)

This project proposes to evaluate the feasibility of training Kenyan nurses to perform cervical cancer screening and LEEP treatment for HIV+ women in Western Kenya and to assess its safety. Findings of the study will provide important information to improve health outcomes among HIV-infected women needing treatment for cervical neoplasia.

6. Alcohol and HIV: Biobehavioral Interactions and Intervention

My Role: Investigator  
 Funding Agency: NIAAA  
 PI: Monti  
 Type: P01 AA019072  
 Period: 09/30/10-08/31/15 (renewal pending)  
 Cost: \$148,924

The goals of this alcohol research center are to study the effects of alcohol use on HIV disease progression and the effects of interventions to reduce alcohol use in HIV-infected populations. The center also fosters multidisciplinary collaborations and training in research on alcohol and HIV and dissemination of research findings to clinicians treating addictions and HIV.

7. CARE Corrections: A technology-based HIV and HCV tool

My Role: Brown sub-Award Principal Investigator  
 Funding Agency: NIDA/The Miriam Hospital subcontract  
 PI: Beckwith  
 Type: R01DA030747-01  
 Period: 07/01/10-06/30/15  
 Cost: \$18,806

It involves providing biostatistical expertise and collaboration in a project related to a new intervention to reduce substance abuse and hence reduce risks of HIV and HCV infections.

8. A Stage 2 Cognitive-Behavioral Trial: Reduce Alcohol First in Kenya Intervention

My Role: Co-Investigator  
 Funding Agency: NIAAA/Brown  
 PI: Papas  
 Type: R01 AA020805-01

Period: 09/15/11 – 08/31/16

Cost: \$429, 932

The major objectives of this stage 2 randomized clinical trial are to determine whether a para-professionally led group cognitive-behavioral therapy intervention is effective in reducing alcohol use among 336 HIV-infected Kenyan outpatients who report hazardous or binge drinking when compared against a group health education intervention

9. Evaluating the impact of patient-centric home health quality reports

My Role: Co-Investigator

Funding Agency: Healthcentric Advisors/AHRQ

Brown PI: Clark

Type: R21 HS021879-01

Period: 09/30/12-08/31/15

Cost: \$69,111

The specific aims are to: (1) determine how home health consumers (patients and care-givers) use the current reporting content and format, and what changes they recommend to increase its frequency of use and decision-making utility; (2) determine how hospital discharge planners use the current reporting content and format, and what changes do they recommend to increase its frequency of use and decision-making utility; (3) evaluate whether or not home health consumers and hospital discharge planners who view a revised, consumer-centric, web-based public report understand the information and how to use it; and (4) evaluate the extent to which home health consumers offered a new consumer-centric report prior to hospital discharge use the information to inform their home health choices, and how their use, satisfaction and outcomes compare to consumers offered the old format.

10. Center for AIDS Research (CFAR) Biostatistics Core

My Role: Investigator

Funding Agency: NIH/The Miriam Hospital contract

Brown PI: Hogan

Type: P30 A1 42853

Period: 09/01/12 - 06/30/16

Cost: \$100,966

The primary goal involves providing biostatistical expertise for the design and analysis of individual projects within CFAR; the core will also be responsible for implementation of data analyses and will participate in the preparation of reports and manuscripts.

**B. Grant Submitted (Disposition Pending)**

11. Mindfulness RCT for CVD Risk

My Role: Statistician

Funding Agency: NIH

PI: E. Loucks

Type: RO1 GRANT11597822

Cost: \$535,497 (Project Total)

Period: 9/1/2014 - 8/31/2019

The research objective is to conduct a methodologically rigorous randomized controlled trial that will provide information on whether mindfulness-based stress reduction has sus-

tained one-year impacts on CVD risk factors, with systolic blood pressure and smoking as the primary outcomes.

12. Computerized Intervention to Improve HIV Medication Adherence

My Role: Brown sub-Award PI  
 Funding Agency: NIMH  
 PI: Ramsey  
 Type: RO1

This project aims to promote HIV medication adherence using an innovative computerized intervention. A revised computerized medication adherence intervention (MAI) will be tested for effectiveness as compared to a general health control intervention (GHC) in a randomized, controlled, longitudinal study.

13. The influence of fetal growth on infant growth and obesity among Samoans

My Role: Investigator  
 Funding Agency: NIMHD  
 PI: McGarvey  
 Type: RO1

The research objective is to document the relationships between maternal obesity and related pregnancy conditions to fetal growth and directly relate temporal patterns of fetal growth to childhood obesity.

14. Behavioral Intervention to Prevent Child Overweight and Obesity in American Samoa

My Role: Investigator  
 Funding Agency: NIMHD  
 PI: McGarvey  
 Type: R01  
 Cost: \$1,250,000 (Project total)

The research objective is to conduct a randomized trial of family-based lifestyle intervention with conditional incentives on parents in order to prevent excessive weight gain among American Samoan children 7-12 years of age.

### C. Completed Grants

15. Brief Intervention for Drug Misuse in the Emergency Department (BIDMED)

My Role: Brown Principal Investigator  
 Funding Agency: NIDA/Rhode Island Hospital subcontract  
 PI: Merchant  
 Type: R01 DA026066  
 Period: 03/15/09-02/28/14  
 Cost: \$27,705

The primary goal involves providing biostatistical expertise and collaboration in a project related to a new intervention to reduce drug misuse in the Emergency Department.

16. Randomized Evaluation of Patients with Stable Angina Comparing Utilization of Noninvasive Examinations (RESCUE)

My Role: Protocol Statistician  
 Funding Agency: AHRQ  
 Brown PI: Gatsonis

Type: R01 HS019403  
 Period: 09/30/10-09/29/14  
 Cost: \$401,721

This research project involves organizing and operating the Biostatistics Center and the Outcomes and Economics Core Laboratory components of the RESCUE trial - a randomized, multi-center study designed to compare CCTA and SPECT for patients with symptoms of stable angina.

17. Cervical Cancer See and Treat: How Best to Follow-Up

My Role: Co-Investigator  
 Funding Agency: NIAID/The Miriam Hospital subcontract  
 PI: Cu-UVin  
 Type: P30 A142853  
 Period: 07/01/11 – 06/30/13  
 Cost: \$51,488

This proposal involves providing biostatistical expertise and collaboration in a project related to comparing three methods, visual inspection with acetic acid (VIA), pap smear and HPV typing, for diagnosing cervical neoplasia/cancer.

18. Methods to Optimize Use of Limited Resources for Monitoring Treatment of HIV/AIDS in the Developing World

My Role: Principal Investigator  
 Funding Agency: Center for AIDS Research  
 PI: Liu  
 Type: 5P30 AI042853-12  
 Period: 1/01/10-12/31/11  
 Cost: \$40,000

This project involves developing a clinical algorithm that will make optimal use of viral load assays when they are available on a limited basis.

19. Increasing Viral Testing in the Emergency Department (InVITED)

My Role: Brown sub-Award Principal Investigator  
 Funding Agency: NIDA/Rhode Island Hospital subcontract  
 PI: Merchant  
 Type: R21 DA028645  
 Period: 3/04/10 – 2/28/2012  
 Cost: \$15,000

This project involves providing biostatistical expertise and collaboration in a project related to a new intervention to reduce substance abuse.

20. Video-Based Delivery of HIV Test Information for Spanish-Speaking Latinos

My Role: Investigator  
 Funding Agency: DHHS/ Rhode Island Hospital subcontract  
 PI: Merchant  
 Type: R21 NR011997  
 Period: 03/04/11-02/29/13  
 Cost: \$18,806

This research project involves comparing the effects of video delivery of HIV testing information for Spanish-Speaking Latinos.

## 21. New Approaches to Mediation Analysis using Causal Inference Methods

My Role: Co-Investigator  
 Funding Agency: NIAAA (stimulus)  
 PI: Hogan  
 Type: 1RC1AA019186-01  
 Period: 10/01/09-09/30/11  
 Cost: \$327,201 (Project total)

The proposed research will develop statistical approaches for discovering pathways and mechanisms of behavioral interventions targeted at alcohol abuse. Knowledge of mechanistic pathways allows deeper understanding of how and why certain interventions work, and opens the door to customizing interventions based on person-specific characteristics.

## 22. Shaping Long-Term Care in America

My Role: Statistician  
 Funding Agency: NIH/NIA  
 PI: Mor  
 Type: P01 AG027296  
 Cost: \$1,390,110 (Project total)  
 Period: 09/01/08-06/30/10

The overall objectives of the program project are to (1) Build a long term care data and policy repository and analysis infrastructure as the basis for currently proposed and future examining the nations long term care" system;" (2) Implement a survey of states policies and a national sample of nursing homes, integrating them with secondary data to serve the proposed research projects within an overall administrative structure; (3) integrate economic and organizational theory to develop measures and to propose testable hypothesis in the proposed projects focusing on provides responses to market and policy changes; and (4) systematically catalogue and broadly disseminate to numerous audiences project findings.

## 23. Analyzing Complex Longitudinal Data in Behavior Sciences

My Role: Lead Statistician  
 Funding Agency: NIH  
 Brown PI: Hogan  
 Type: RO1 HL079457  
 Cost: \$249,500 (Project total)  
 Period: Aug., 1, 04 --- July, 31, 08

This project will develop innovative approaches to the analysis of longitudinal data specifically for behavioral medicine trials. The first two components of the project will develop latent class and latent variable models for classifying patterns of behavior change in smoking cessation and weight change. The third aim of the study addresses the issue of informative missing data, presenting a unifying and coherent framework for pattern-mixture modeling and associated sensitivity analyses. All of the methods will be developed on and applied to data from recently completed or ongoing trials in behavioral medicine, particularly in smoking cessation and weight change.

## 24. Secondhand Tobacco Smoke Exposure, Maternal Stress, and Adverse Birth Outcomes

My Role: Lead Statistician  
 Funding Agency: Flight Attendants Medical Research Institute

PI: Shenassa  
 Type: FAMRI 032069  
 Cost: \$623,239 (Project total)  
 Period: Sept. 1, 08 --- Dec. 31, 08

This is a study to elucidate mechanisms explaining the heightened susceptibility to adverse health effects of secondhand tobacco smoke exposure observed among people of low SES by examining the exacerbating role of stress as measured by Allostatic Load.

## ACADEMIC SERVICES

### A. Department and University Services

1. Search Committee for Assistant or Associate Professor, Teaching Scholar. 2015.
2. Biostatistics PhD Student Admission Committee. 2011— 2013, 2014 — 15.
3. The 2014 Atlantic Causal Inference Conference (ACIC) Organizing Committee. 2014.
4. Best Thesis Award Committee. 2013 — 2014
5. Biostatistics Master Student Admission Committee. 2014.
6. Biostatistics Curriculum Committee. 2012 — 2014.
7. The 2014 Scholarship for Overseas Chinese Students Evaluation Committee 2014.
8. Search Committee for Research Assistant Professor of Biostatistics. 2013.
9. Biostatistics PhD Qualifying Exam Committee. 2008 — 11, 2012 — 13
10. Biostatistics Graduate Program Committee. 2011 — 2013.
11. Epidemiology MPH Qualifying Exam Committee. 2010 — 2011.

### B. Editorial Services

#### Journal Reviewer

*Journal of the American Statistical Association (JASA); Annals of Applied Statistics; Annals of Epidemiology; Biometrics; Biostatistics; Statistics in Medicine; Statistical Science; Statistics and Probability Letters; Statistical Modelling; Journal of Computational and Graphical Statistics (JCGS); Health Services and Outcomes Research Methodology (HSOR); The American Journal of Epidemiology (AJE); BMC Infectious Diseases; Emerging Themes in Epidemiology; Epidemiology; Clinical Infectious Diseases (CID); International Journal of Epidemiology & Infection; Journal of AIDS & Clinical Research; Journal of Clinical Epidemiology (JCE).*

#### Book Reviewer

1. Chapman & Hall/CRC Press.

#### Journal Editorial Board

1. 2010 – Present Journal of Clinical Research & Bioethics (JCRB).
2. 2012 – Present International Journal of Clinical Therapeutics and Diagnosis.
3. 2013 – Present Annals of Biometrics & Biostatistics (ABB).
4. 2010 – Present International Journal of Epidemiology & Infection

### C. Grant Reviewer

1. 2015 Ad-Hoc reviewer for Beijing Natural Science Foundation & Shanyuan Joint Research Projects: *Infectious Diseases and Epidemiology*.
2. 2014 Ad-Hoc reviewer for the National Science Foundation (NSF): *Panel of Methodology, Measurement, and Statistics*.
2. 2013 Scientific expert reviewer for the French National Research Agency (ANR): *Basic Research on Networks of Trials*.

### D. Other Academic Services

1. 2015 Judge of the Best Student Poster Awards, Brown Public Health Research Day, April 16th 2015.
2. 2011-2012 Chair of the 2011-12 Starr Lectureship Series on “Comparative Effective Research and Causal Inference”. Brown University.
3. 2011-2012 Chair of the Biostatistics Seminar Series. Department of Biostatistics, Center for Statistical Sciences, Brown University.
4. August 2009. Chair of “Biometrics Section” (No.570). The American Statistical Association Joint Statistical Meeting (JSM). Washington D.C.

## HONORS & AWARDS

1. 2010 The Lifespan/Tuft/Brown CFAR Developmental Award.
2. 2006 The Biometric Society ENAR Distinguished Student Paper Award.
3. 2004 Jonathan Raz Award for the Best Doctoral Qualifying Exam.
4. 1999-2002 Iowa State University Graduate Scholarship.
5. 1994-1998 Tsinghua University Undergraduate Scholarships.
6. 1994 Outstanding Freshmen Award at Tsinghua University.
7. 1993 Second Prize, National Physics Olympiad (High School).

## TEACHING

### A. Brown University (Instructor):

1. Spring 2012 PHP 2511 Applied Regression Analysis. (student enrollment: 18).
2. Fall 2009 PHP 2510 Principles of Biostatistics and Data Analysis. (27).
3. Spring 2008 PHP 2603 Analysis of Longitudinal Data (with Prof. Hogan). (15).



4. Fall 2008                      PHP 2601    Linear and Generalized Linear Models. (11).

**B. University of Pennsylvania (Graduate Teaching Assistant/Instructor):**

5. Spring 2006                  BSTA 771    Applied Bayesian Analysis. (7).
6. Fall 2005                    BSTA 630    Statistical Methods and Data Analysis. (26).
7. Spring 2004                EPI 520     Introductory Biostatistics. (32).

**C. Iowa State University (Graduate Instructor):**

8. Summer. 2002            STAT 402    Statistical Methods for Research Workers. (43).

**G. Invited/Guest Lectures**

1. Fall 2013                    “Clinical Trials Methodology”  
Brown University, School of Public Health
2. Summer 2012              “Causality 101 Workshop: Recent Mediation Analysis Methods”  
Brown University, School of Public Health
3. Fall 2010                    “Design of Clinical Trials with Survival Outcomes”  
Brown University, School of Public Health
4. Fall 2010                    “Statistical Methods in Biology”  
Brown University, Department of Molecular Biology
4. Fall 2009                    “Statistical Methods in Biology”  
Brown University, Department of Molecular Biology

**ADVISING/CONSULTING**

**A. Thesis Advisor/Reader**

1. Ran Wei,                      Sc.M. (Biostatistics)                  2016 (Expected).  
Thesis: To be decided.  
My role: Thesis Advisor.
1. Wentao Guan,                Sc.M. (Biostatistics)                  2015.  
Thesis: Evaluation of a Brief Intervention to Reduce Negative Consequences of Drug Mis-  
use among Adult Emergency Department Patients.  
My role: Thesis Advisor.
2. Jay Jia Xu,                    B.S. (Statistics)                          2015.  
Thesis: A Comparison of INLA and JAGS When Applied To Multiple Imputation with the  
Penalized Spline of Propensity Prediction Method  
My role: Thesis reader.
3. Renxia Huang,                Sc.M. (Biostatistics)                  2014.  
Thesis: Combining Routine Clinical Markers and Pooled Viral Load Strategy to Monitor  
Antiretroviral Treatment Failure in Resource Poor Settings.

My role: Thesis Advisor.

***Winner of the 2014 Best Thesis Award of Public Health***

4. Andrea Austin, Ph.D. (Biostatistics) 2013.  
Thesis: Methods for prediction and inference on social networks with extensions to bimolecular pathways.  
My role: Committee member.
5. Miao Tai, Sc.M. (Biostatistics) 2013  
Thesis: HIV/AIDS-related hospitalizations in United States short-stay hospitals, 1982-2010  
My role: Thesis Advisor.
6. Rachel Thakore, B.S. (Community Health) 2013  
Honors Thesis: The effect of cocaine use on the diet and metabolic status of HIV-infected individuals.  
My role: Committee member
7. Xuan Deng, Sc.M. (Biostatistics) 2013  
Thesis: Mediation effects of behavioral and psychological factors in maintaining weight loss.  
My role: Committee member.
8. Edwin Sang, Sc.M. (Biostatistics) 2013  
Thesis: Causal effect of HIV serostatus disclosure on mortality and loss to follow-up after HAART initiation using propensity score.  
My role: Committee member

***Winner of the 2013 Best Master Thesis Award of Public Health***

9. Ann Mwangi, Ph.D. (Biostatistics) 2011  
Thesis: Addressing selection bias in observational event history data, with application to HIV in Western Kenya.  
My role: Committee member.
10. Jing Zhang, Ph.D. (Biostatistics) 2011  
Thesis: Causal Inference for Mediation Effects.  
My role: Committee member.
11. Raymond Ng, Sc.M. (Biostatistics) 2011  
Thesis: Analysis of repeated FDG-PET scans in the National Oncology PET Registry (NOPR).  
My role: Committee member.
12. Patricia S. Fox, Sc.M. (Biostatistics) 2009  
Thesis: Transition within states of lung function: A multinomial logistic approach using two-year follow-up data from bacteriologically cured tuberculosis patients.  
My role: Committee member.
13. Lisa tai (Asnis), Sc.M. (Biostatistics) 2009  
Thesis: Evaluating the utilization and efficiency of ICD-9 codes to identify visits for blood or body fluid exposures in 11 Rhode Island emergency departments.  
My role: Thesis advisor.

**C. Graduate Academic Advisor**

1. Ran Wei,	Sc.M. (Biostatistics)	2016 (expected)
2. Jin Shi,	Sc.M. (Biostatistics)	2016 (expected)
3. Wuntao Guan	M.S. (Biostatistics)	2015
4. Lisa Wang,	M.S. (Biostatistics)	2013
5. Nuo Xu,	M.A. (Biostatistics)	2012
6. Junchao Shangguan,	M.A. (Biostatistics)	2011
7. Dong-Hyun Ahn,	M.A. (Biostatistics)	2010

#### **D. Other Teaching and Advising Roles**

1. C Yuan, Brown master student (Biostatistics). 2013 Summer Intern at Press Ganey. My role: Curriculum Practical Training Advisor.
2. J Shangguan, Brown master student (Biostatistics). 2010 Summer Intern at Fidelity Co. My role: Curriculum Practical Training Advisor.
3. Alina Kung, Brown undergraduate student (International Relationships). Awardee of International Scholars Program Scholarship 2010. "Evaluating the Effectiveness of American Healthcare NGOs in China." My role: Research Advisor.
4. Hongwei Xu, Brown PhD student (Sociology). Awardee of Brown University Global Health Scholarship 2009. "A Longitudinal Study of the Coexistence of Underweight and Overweight Persons within Household in China: 1997-2006." My role: Research Advisor.

#### **E. Junior Faculty Mentoring and Medical Consulting**

1. Ed Wing, M.D. and Rena Wing, Ph.D. (2014). CFAR Developmental Grant: "An Internet-based Behavioral Weight Programs for HIV+ patients". My role: Consultant.
2. Elizabeth M. Goldberg, M.D. (2014). UEMF Research Development Grant: "Is Emergency Department Hypertension Predictive of Future Hypertension?" My role: Mentor.
3. Gary Wessel, Ph.D. (MCBB) (2013). CFAR Developmental Grant: "Metagenomic Analysis of the Gut Microbiome in the HIV Infected Patients: Prospects for Therapy." My role: Mentor.
4. Francesca Beaudoin, M.D. (2013). NIDA Emergency Medicine Foundation. "Prescription opioid use and misuse in older emergency department patients." My role: Mentor.
5. Francesca Beaudoin, M.D. (2013). NIH RO3: "Chronic Opioid Use, Pain Sensitivity and Acute Pain in the Emergency Department." My role: Consultant.
6. Elkanah Omenge Orango, M.D. (2013). CFAR Supplement: "Cryotherapy and HIV Genital Shedding." My role: Mentor.
7. Nick Zaller, Ph.D. (2013). CFAR Supplement: "HIV treatment cascade among HIV+ person in community corrections (tentative title)." My role: Consultant.
8. Elkanah Orango, MD. (2013). International CFAR Developmental Award: "Outcome of excisional treatment for cervical neoplasia in HIV infected and uninfected women in Western Kenya." My role: Consultant.

9. Kevin Dushay, M.D. (2012). CFAR Developmental Grant: "The prevalence of obstructive airway disease and the burden of chronic respiratory symptoms in HIV subjects enrolled in care in Kenya." My role: Consultant.
10. Rana Aadia, M.D. (2012). K-23 Award: "Improving Retention in Care Among Postpartum HIV-infected Women in Mississippi." My role: Mentor.
11. Willoughby Britton, Ph.D. (2012). K-Award (NCCAM): "Dismantling Mindfulness: Contributions of Attention vs. Acceptance." My role: Consultant.
12. Becky Genberg, PhD. (2012). K-Award: "Linkage to care following home-based counseling and testing for HIV in western Kenya." My role: Consultant.
13. Michelle Mellion, MD. (2011). CFAR Developmental Award: "The effect of alcohol on CSF cytokine concentrations in patients with HIV and its association with neuro-cognitive disturbances." My role: Consultant.
14. Philips Chan, MD. (2011). K-Award: "Molecular Epidemiology of HIV Transmission Networks". My role: Consultant.
15. Adrian Garder, MD. (2011). CFAR Developmental Award: "Implementation of GeneXpert® for evaluation of HIV positive TB suspects previously treated for TB in Western Kenya." My role: Consultant.
16. Ammy Nunn, PhD. (2010). K-Award: "Exploring Patterns of Sexual Concurrency Among Urban African Americans." My role: Consultant.
17. Rosemarie Martin, PhD (2010). Developmental Award: "Contingency Management for Drug Use in HIV+ Adults after Prison or Jail Release". My role: Consultant.
18. Philips Chan, MD. (2010). Burroughs Wellness Grant: "Association of human leukocyte antigen and the development of antiretroviral drug resistance in HIV-1 infection". My role: Consultant
19. Erna Kojic, MD (2009). K-Award: "HPV and related diseases in HIV infected women". My role: Consultant.
20. Michael Waxman, MD (Assistant Professor of Emergency Medicine) (2007). The Brown Department of Emergency Medicine Junior Faculty Research Award. My role: Consultant.
21. Brenna Anderson, MD (Assistant Professor of Obstetrics & Gynecology) (2007). Developmental Award: "Effect of trichomoniasis therapy on genital HIV viral burden among African women". My role: Consultant.

## **SOFTWARES**

1. R-package: TVLT (Targeted testing under cost constraints); alpha-version.

## **PROFESSIONAL SOCIETIES**

1. The American Association for the Advancement of Science (AAAS).
2. International Biometric Society
3. American Statistics Association (ASA).
4. The Tau Beta Pi Honor Society.

## **HOBBIES**

Soccer; beekeeping; carpentry; organic gardening.

**Appendix 2:**  
**Revised MB-BP Recruitment Card**  
**with track changes**

# **~~RESEARCH STUDY:~~**

## **MINDFULNESS-BASED INTERVENTION**

### **FOR BLOOD PRESSURE REDUCTION**



**Free to qualified participants**

For more information [on our research study](#), or to see if you qualify, [call-contact](#) the Brown University Mindfulness & Cardiovascular Health Lab at 401-~~369-0443~~[400-4768](#) ([call or text](#)), or email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu).

**Brown University  
School of Public Health**



This is a 9-week program that includes mindfulness meditation, mindful movements, education about hypertension, and support for reducing hypertension risk factors. The study is testing whether this intervention lowers blood pressure. The [program-course](#) consists of nine weekly sessions that are 2.5 hours, [and as well as](#) an all-day weekend retreat. People who have a current [regulation-regular](#) meditation practice (i.e. meditate more than once per week) are not eligible.

Research participation includes interviews, questionnaires and [health](#) measurements, [such as](#) of blood pressure, height, [and](#) weight, [and waist circumference](#), [completed both](#) before and after the meditation program.

**Contact:** For more information, or to see if you qualify, [call-contact](#) the Brown University Mindfulness & Cardiovascular Health Lab at [401-369-0443](#) [401-400-4768](#) (call or text) or [email at mindfulness@brown.edu](mailto:mindfulness@brown.edu).



**Appendix 3:**  
**Revised MB-BP Recruitment**  
**Card and Flyer - *clean copies***

# **MINDFULNESS-BASED INTERVENTION FOR BLOOD PRESSURE REDUCTION**



**Free to qualified participants**

For more information on our research study, or to see if you qualify, contact the Brown University Mindfulness & Cardiovascular Health Lab at 401-400-4768 (call or text), or email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu).

**Brown University  
School of Public Health**



**BROWN**

This is a 9-week program that includes free training in mindfulness meditation, mindful movements, education about hypertension, and support for reducing hypertension risk factors. The study is testing whether this intervention lowers blood pressure. The course consists of nine weekly sessions that are 2.5 hours, as well as an all-day weekend retreat. People who have a current regular meditation practice (i.e. meditate more than once per week) are not eligible.

Research participation includes interviews, questionnaires and health measurements, such as blood pressure, height, and weight, completed both before and after the meditation program.

**Contact:** For more information, or to see if you qualify, contact the Brown University Mindfulness & Cardiovascular Health Lab at 401-400-4768 (call or text) or email at [mindfulness@brown.edu](mailto:mindfulness@brown.edu).

# MINDFULNESS-BASED INTERVENTION FOR BLOOD PRESSURE REDUCTION



## Free to qualified participants

This is a 9-week program that includes free training in mindfulness meditation, mindful movements, education about hypertension, and support for reducing hypertension risk factors. The research study is testing whether this intervention lowers blood pressure. The course consists of nine weekly sessions that are 2.5 hours, as well as an all-day weekend retreat. People who have a current regular meditation practice (i.e. meditate more than once per week) are not eligible.

Research participation includes interviews, questionnaires and health measurements, such as blood pressure, height, and weight, completed both before and after the meditation program.

**Contact:** For more information, or to see if you qualify, contact the Brown University Mindfulness & Cardiovascular Health Lab at: 401-400-4768 (call or text) or email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu).

**Brown University**  
**School of Public Health** BROWN



Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Mindfulness Blood Pressure Study  
Call/Text: 401-400-4768  
Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

**Appendix 4:**  
**MB-BP Study Facebook**  
**Page Screenshots**



# Mindfulness-Based Intervention for Blood Pressure Reduction

Medical Research · Alternative & Holistic Health



Add Action Button

Like

Message

...

- Timeline
- About
- Services
- Reviews
- More

Search for posts on this Page

See Pages Feed  
Posts from Pages you've liked as your Page

- Status
- Photo / Video
- 31 Event, Milestone +
- 



Write something...





See Pages Feed

Posts from Pages you've liked as your Page



Invite friends to like this Page

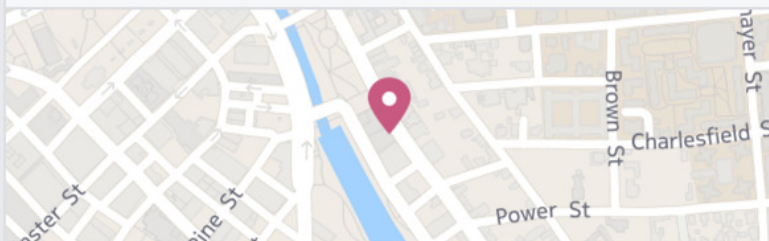
### More Reach. Less Money.



Reach 96,000 people near Mindfulness-Based Intervention for Blood Pressure Reduction. Get started for \$20.00.

Promote Local Business

### ABOUT



**Research study looking at the effects of mindfulness meditation on blood pressure at the Brown University School of Public Health under PI Dr. Eric Loucks**

**121 S Main ST  
Providence, RI**

Save

Add phone number

<http://mindfulnesscvlab.w...>

Promote Website



## Mindfulness-Based Intervention for Blood Pressure Reduction

Just now ·

We're enrolling participants now for our cycle beginning in June -- contact us if you're interested!

### MINDFULNESS-BASED INTERVENTION FOR BLOOD PRESSURE REDUCTION



#### Free to qualified participants

This is a 9-week program that includes free training in mindfulness meditation, mindful movements, education about hypertension, and support for reducing hypertension risk factors. The research study is testing whether this intervention lowers blood pressure. The course consists of nine weekly sessions that are 2.5 hours, as well as an all-day weekend retreat. People who have a current regular meditation practice (i.e. meditate more than once per week) are not eligible.

Research participation includes interviews, questionnaires and health measurements, such as blood pressure, height, and weight, completed both before and after the meditation program.

**Contact:** For more information, or to see if you qualify, call the Brown University Mindfulness & Cardiovascular Health Lab at: 401-400-4768 or email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu).


**Brown University  
School of Public Health**



Boost Post

---

## Long Description


The Mindfulness-Based Intervention for Blood Pressure Reduction (MBBP) is a research study currently being conducted in the Brown University School of Public Health in the Center for Population Health and Clinical Epidemiology.  [Edit](#)

Dr. Eric Loucks is the Principal Investigator of this study. As a cardiovascular physiologist and social epidemiologist, Dr. Loucks's research agenda focuses on elucidating biological mechanisms by which social and psychosocial factors may influence cardiovascular disease.

---



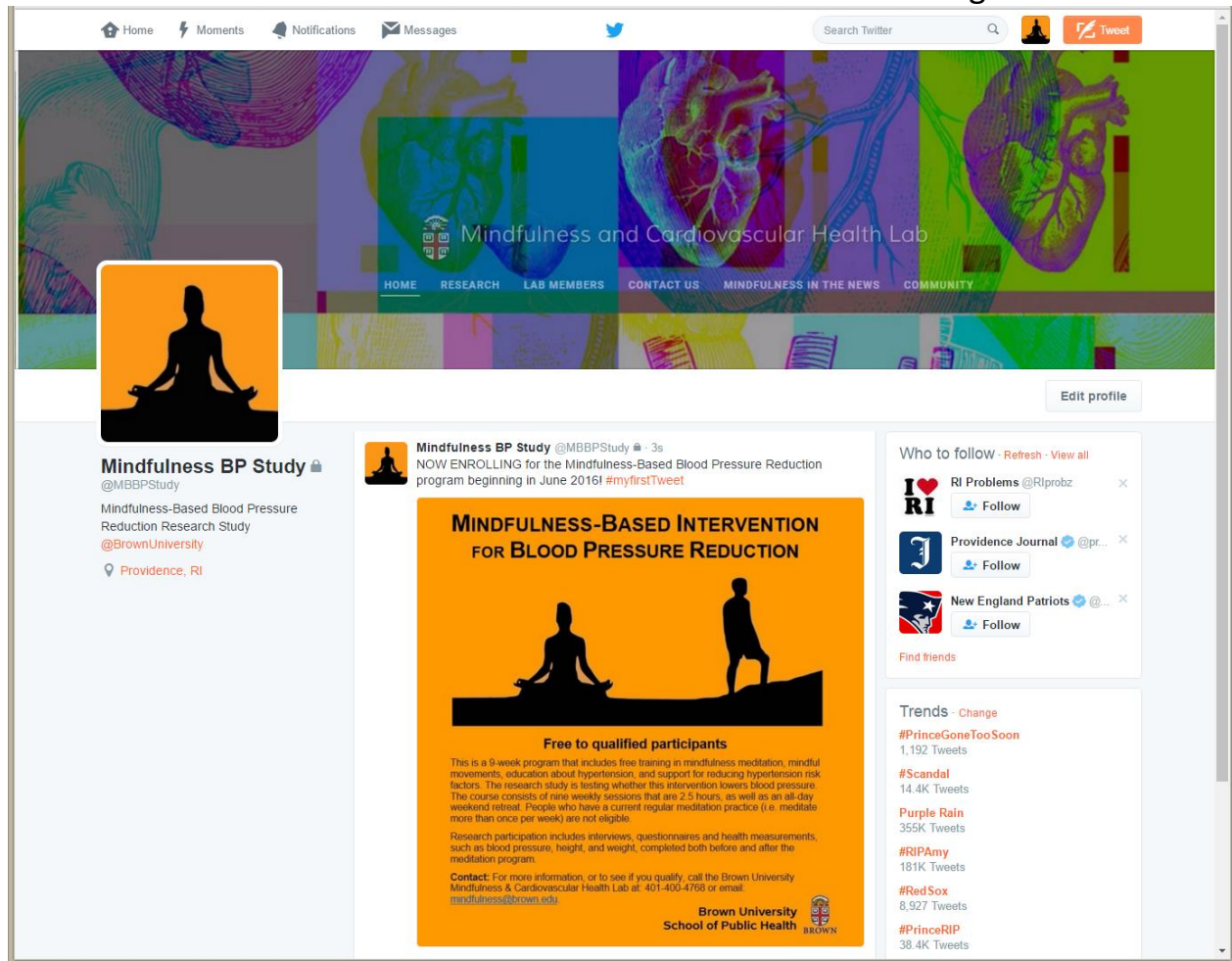
## PAGE INFO

Category	Companies & Organizations : Health/Medical/Pharmaceuticals
Name	Mindfulness-Based Intervention for Blood Pressure Reduction
Subcategories	Medical Research and Alternative & Holistic Health
Facebook Web Address	www.facebook.com/brown.mbbp
Address	121 S Main ST, Providence, Rhode Island 02912
Start Date	Enter your start date
Short Description	Studying the effects of mindfulness meditation on cardiovascular health at the Brown University School of Public Health under PI Dr. Eric Loucks
Impressum	Input Impressum for your Page
Long Description	We are in the Brown University School of Public Health, specifically in the Center for Population Health and Clinical Epidem... See More
Mission	To enable community members to partake in a Mindfulness-Based Intervention for blood pressure reduction  Edit
Founded	+ Enter founding date
Awards	+ Enter awards
Safety Information	+ Enter safety information
Products	+ Enter products
Phone	Add a phone number
Email	mindfulness@brown.edu
Website	http://mindfulnesscvlab.weebly.com
Official Page	Enter the official brand, celebrity or organization your Page is about
Facebook Page ID	1121982851167360

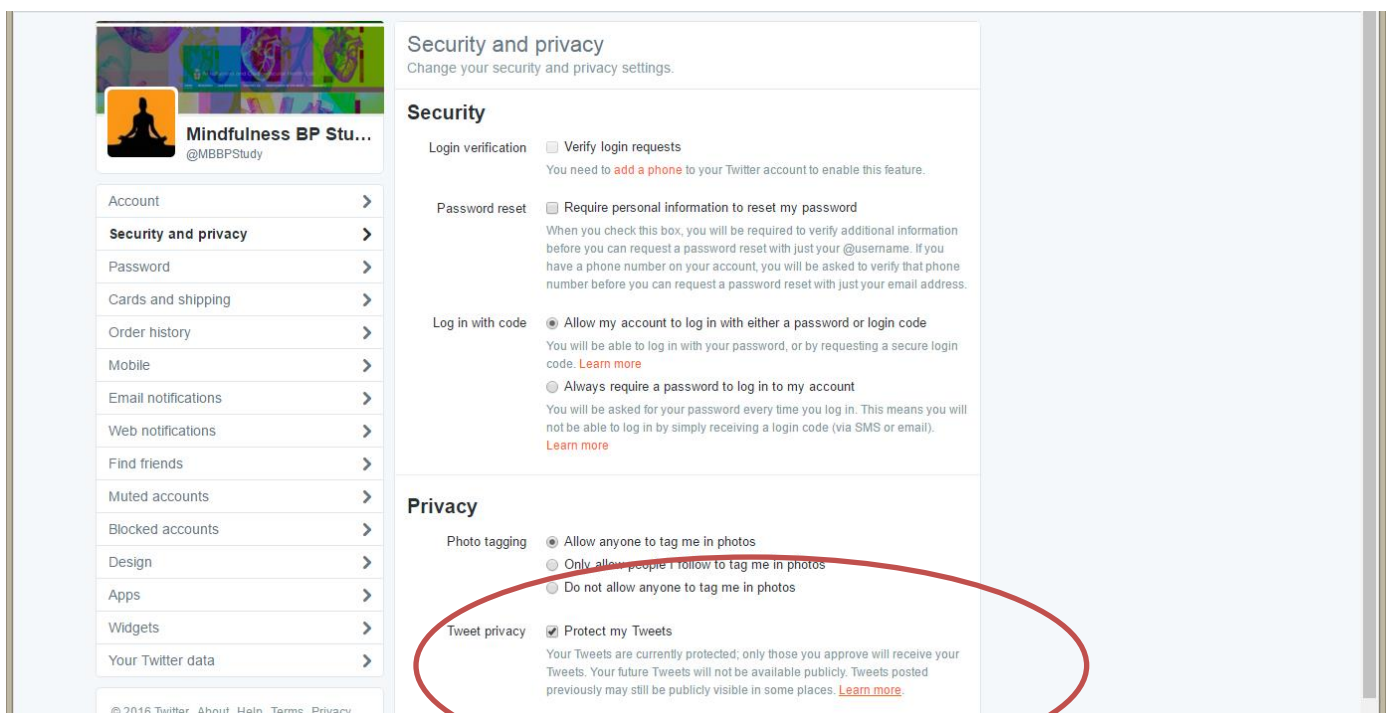
**Appendix 5:**  
**MB-BP Study Twitter**  
**Account Screenshots**

# Mindfulness-Based Blood Pressure Reduction Study – Twitter Account

Below is a screenshot from the MB-BP Twitter Page



Note: that the current privacy setting is set so that no one can see the MB-BP tweets. This setting will remain in effect until IRB approval has been received.



**Appendix 6:**  
**MB-BP Study Craigslist**  
**Advertisement Screenshots**

# Mindfulness-Based Blood Pressure Reduction Study – Craigslist Advertisement

Screenshots of the MB-BP Craigslist Advertisement is shown below.

← → ↻

craigslist, inc [US]

https://post.craigslist.org/k/yC4Wqq8L5hGrjy37LOFI3A/FSTfg?s=preview

☆ ☰

CL rhode island > jobs > et cetera > create posting

[ logged in as mindfulness@brown.edu ] [ log out ]

Description

Price

High Blood Pressure? Interested in Mindfulness meditation?

rhode island > et cetera

\$25.00 USD

Total amount charged: \$25.00 USD

Attention: Your posting will expire from the site in 30 days.

this is an unpublished draft.

publish

edit post edit location edit images

CL rhode island > jobs > et cetera


reply

Posted: less than a minute ago

print

High Blood Pressure? Interested in Mindfulness meditation? (Providence)

MINDFULNESS-BASED INTERVENTION  
FOR BLOOD PRESSURE REDUCTION




Free to qualified participants

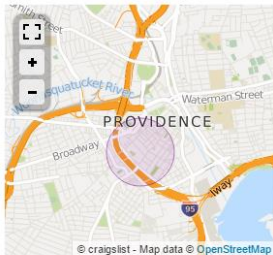
This is a 9-week program that includes free training in mindfulness meditation, mindful movements, education about hypertension, and support for reducing hypertension risk factors. The research study is testing whether this intervention lowers blood pressure. The course consists of nine weekly sessions that are 2.5 hours, as well as an all-day weekend retreat. People who have a current regular meditation practice (i.e. meditate more than once per week) are not eligible.

Research participation includes interviews, questionnaires and health measurements, such as blood pressure, height, and weight, completed both before and after the meditation program.

Contact: For more information, or to see if you qualify, call the Brown University Mindfulness & Cardiovascular Health Lab at 401-400-4768 or email [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

**Brown University**  
School of Public Health





© craigslist - Map data © OpenStreetMap

South Main Street

[\(google map\)](#)

compensation: **Contact us for details.**

employment type: **employee's choice**

non-profit organization

NOW ENROLLING: for the Brown University Mindfulness-Based Blood Pressure Reduction Study

This is a 9-week program that includes free training in mindfulness meditation, mindful movements, education about hypertension, and support for reducing hypertension risk factors. The study is testing whether this intervention lowers blood pressure. The course consists of nine weekly sessions that are 2.5 hours, as well as an all-day weekend retreat. People who have a current regular meditation practice (i.e. meditate more than once per week) are not eligible.

Research participation includes interviews, questionnaires and health measurements, such as blood pressure, height, and weight, completed both before and after the meditation program.

Contact: For more information, or to see if you qualify, contact the Brown University Mindfulness & Cardiovascular Health Lab at 401-400-4768 (call or text) or email at [mindfulness@brown.edu](mailto:mindfulness@brown.edu).

- Principals only: Recruiters, please don't contact this job poster.
- do NOT contact us with unsolicited services or offers

posted: 2016-04-26 9:15am

[email to friend](#)

♥ [best of](#)

edit post edit location edit images

publish

**Appendix 7:**  
**MB-BP Study webpage**  
**screenshots**

# Mindfulness-Based Blood Pressure Reduction Study Webpage – Brown University

Screenshots of the MB-BP study webpage are shown below.

## HOME PAGE:

The screenshot shows the homepage of the Mindfulness-Based Blood Pressure Reduction Study at Brown University. The browser address bar displays the URL: <https://www.brown.edu/research/projects/blood-pressure-reduction/home>. The page features a dark red header with the Brown University logo and navigation links: INFORMATION FOR, CURRENT STUDENTS, FACULTY, STAFF, FAMILIES, ALUMNI, and FRIENDS & NEIGHBORS. Below the header is a navigation bar with links: About Brown, Academics, Admission, Research, Campus Life, A to Z INDEX, and PEOPLE DIRECTORY. The main content area has a large banner image of a Brown University building with the text "Mindfulness Study for Blood Pressure Reduction". Below the banner, the title "Mindfulness-Based Intervention for Blood Pressure Reduction" is displayed. A sidebar on the left contains links: Home, About the Study, What is Mindfulness?, News, Contact Us, PRINT THIS PAGE, and SHARE THIS PAGE. The main content area includes a section titled "Now recruiting for MB-BP June Cycle!" with a yellow background and silhouettes of two people meditating. The text on this section reads: "MINDFULNESS-BASED INTERVENTION FOR BLOOD PRESSURE REDUCTION", "High blood pressure?", "Interested in mindfulness meditation?", and "For more info: call/text 401-400-4768 or email [mindfulness@brown.edu](mailto:mindfulness@brown.edu)". Below this is a "Study Flyer" section with a detailed description of the study. The footer contains contact information for Brown University, social media links, and a list of resources: A to Z Index, Career Opportunities, Make a Gift, and People Directory.

https://www.brown.edu/research/projects/blood-pressure-reduction/home

BROWN UNIVERSITY

Information for: CURRENT STUDENTS FACULTY STAFF FAMILIES ALUMNI FRIENDS & NEIGHBORS

About Brown Academics Admission Research Campus Life A to Z INDEX PEOPLE DIRECTORY

**Mindfulness Study for Blood Pressure Reduction**

**Mindfulness-Based Intervention for Blood Pressure Reduction**

Home

About the Study

What is Mindfulness?

News

Contact Us

PRINT THIS PAGE

SHARE THIS PAGE

Mindfulness-Based Intervention for Blood Pressure Reduction  
Brown University  
121 South Main Street  
Room 211  
Providence, RI 02912  
Phone (401)-400-4768  
[mindfulness@brown.edu](mailto:mindfulness@brown.edu)  
edit

**Now recruiting for MB-BP June Cycle!**

**MINDFULNESS-BASED INTERVENTION FOR BLOOD PRESSURE REDUCTION**

High blood pressure?

Interested in mindfulness meditation?

For more info: call/text 401-400-4768 or email [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Study Flyer

Thank you for your interest in the Mindfulness-Based Intervention for Blood Pressure Reduction (MBBP). The study intervention teaches participants mindfulness meditation, mindful movements, education about hypertension risk factors, and support for reducing hypertension risk factors. The study is testing whether this intervention lowers blood pressure and hypertension risk factors. The program consists of nine weekly sessions that are 2.5 hours, and an all-day retreat on a weekend day. People who have a current regular meditation practice (i.e. meditate more than once per week) are not eligible.

Research participation includes interviews, questionnaires, and measurements of blood pressure, height, weight, and waist circumference -- before and after the meditation program.

To find out more information about the study, please click [here](#) for a link to further information.

If you are interested in taking part in the program, please contact the Brown University Mindfulness & Cardiovascular Health Lab via phone call or text at (401)-400-4768 or by email at [mindfulness@brown.edu](mailto:mindfulness@brown.edu) to see if you qualify.

Admin Only

BROWN UNIVERSITY  
Providence, Rhode Island 02912, USA  
Phone: 401-863-1000  
Maps & Directions / Contact Us  
© 2016 Brown University  
Connect: [Social@Brown](mailto:Social@Brown)

RESOURCES  
A to Z Index  
Career Opportunities  
Make a Gift  
People Directory

UNIVERSITY CALENDAR

APR 22 Summer registration closed for Fall registration (online via Banner for continuing students)

APR 25 Registration for Semester I, 2016-17 (Note: No student will be permitted to register for his or her fifth semester unless an approved declaration of concentration has been filed.)

APR 29 Reading Period (optional and at the discretion of the instructor)

[VIEW ALL CALENDARS](#)



SUB-PAGES:

Fwd: Blood Pressure Red...

About this Study | Mindfu...

https://www.brown.edu/research/projects/blood-pressure-reduction/about

Information for:

CURRENT STUDENTS

FACULTY

STAFF

FAMILIES

ALUMNI

FRIENDS & NEIGHBORS

BROWN UNIVERSITY

Google Custom Search

About Brown

Academics

Admission

Research

Campus Life

A TO Z INDEX

PEOPLE DIRECTORY

MINDFULNESS STUDY FOR BLOOD PRESSURE REDUCTION | ABOUT THIS STUDY

<



## CONTACT US PAGE:


Find: Blood Pressure Redu... X

Contact Us | Mindfulness X

← → ↻ https://www.brown.edu/research/projects/blood-pressure-reduction/about/contact


☆ ☰

INFORMATION FOR: CURRENT STUDENTS FACULTY STAFF FAMILIES ALUMNI FRIENDS & NEIGHBORS

 BROWN UNIVERSITY

About Brown Academics Admission Research Campus Life A TO Z INDEX PEOPLE DIRECTORY

MINDFULNESS STUDY FOR BLOOD PRESSURE REDUCTION - CONTACT US



# Mindfulness Study for Blood Pressure Reduction

## Contact Us


Home

About the Study

What is Mindfulness?

News

Contact Us



PRINT THIS PAGE

SHARE THIS PAGE

Mindfulness-Based Intervention for Blood Pressure Reduction

Brown University

Room 211

121 South Main Street

Providence, RI 02912

Phone (401)-400-4768

Mindfulness@brown.edu

edit

If you are interested in the study, or have any questions or concerns, please feel free to contact us with the information below.

Mindfulness-Based Intervention for Blood Pressure Reduction

Brown University School of Public Health

121 South Main Street [\(map\)](#)

Providence, RI, 02912

Email: [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

Phone: 401-400-4768

Study Lead Investigator: Dr. Eric Loucks

Email: [eric\\_loucks@brown.edu](mailto:eric_loucks@brown.edu)

Admin Only

UNIVERSITY CALENDAR

APR 22

Summer registration closed for Fall registration (online via Banner for continuing students)

APR 25

Registration for Semester I, 2016-17 (Note: No student will be permitted to register for his or her fifth semester unless an approved declaration of concentration has been filed.)

APR 29

Reading Period (optional and at the discretion of the instructor)

[VIEW ALL CALENDARS](#)

BROWN UNIVERSITY

Providence, Rhode Island 02912, USA

Phone: 401-863-1000

[Maps & Directions](#) / [Contact Us](#)

© 2016 Brown University

RESOURCES

[A to Z Index](#)

[Career Opportunities](#)

[Make a Gift](#)

# Mindfulness-Based Blood Pressure Reduction Study Webpage

The MB-BP study webpage is found within the Mindfulness and Cardiovascular Health Lab Website. The Mindfulness CV and Health Lab main page is shown below. Note that there is MB-BP content within the General Update section. This section can be used to draw attention to study enrollment phases.

BUILD

PAGES

THEME

STORE

SETTINGS

UPGRADE

PUBLISH

Mindfulness and Cardiovascular Health Lab

HOME

RESEARCH

LAB MEMBERS


CONTACT US

MINDFULNESS IN THE NEWS

COMMUNITY

### GENERAL UPDATES

**MINDFULNESS-BASED INTERVENTION  
FOR BLOOD PRESSURE REDUCTION**



High blood pressure?

Interested in mindfulness meditation?


For more info: call/text 401-400-4768  
or email [mindfulness@brown.edu](mailto:mindfulness@brown.edu)

**NOW ENROLLING** for the  
*Mindfulness-Based Blood Pressure  
Reduction program beginning in  
June 2016!*

[MORE INFO](#)

“ Mindfulness is developed by purposefully paying attention in a sustained and non-judgmental way, to what is going on in your body, your mind, and in the world around you. It is about being awake and aware, living in the present—simply being yourself and knowing something about who that is.”

—Jon Kabat-Zinn, *Full Catastrophe Living*




Mind Full, or Mindful?

## What is mindfulness?

**Mindfulness** is often defined as the ability to attend in a nonjudgmental way to one's own physical and mental processes during ordinary, everyday tasks [1]. A consensus two-component mindfulness definition stated that "The first component involves the self-regulation of attention so that it is maintained on immediate experience, thereby allowing for increased recognition of mental events in the present moment. The second component involves adopting a particular orientation toward one's experiences in the present moment, an orientation that is characterized by curiosity, openness, and acceptance" [2]. Other traditional versions of mindfulness definitions include elements of "remembering" or "holding something in mind", which could be important if what is held in mind are values such as personal health.


1. Epstein RM. Mindful practice. *JAMA*. 1999;282(9):1039-4.  
2. Bishop SR, Lau M, Shapiro S, et al. Mindfulness: A proposed operational definition. *Clin Psychol Sci Pr*. 2004;11(2):230-41.

### Three-step way of thinking about mindfulness [3]




**Approach**

Readjusting our approach to our thoughts, feelings, and mindset.



**Practice**

Meditation is just one way to cultivate and practice mindfulness.




**Integration**

Integrating mindfulness off-the-mat and into daily life.

3. Puddicombe Andy. Get Some Headspace: How Mindfulness Can Change Your Life in Ten Minutes a Day. 2015.

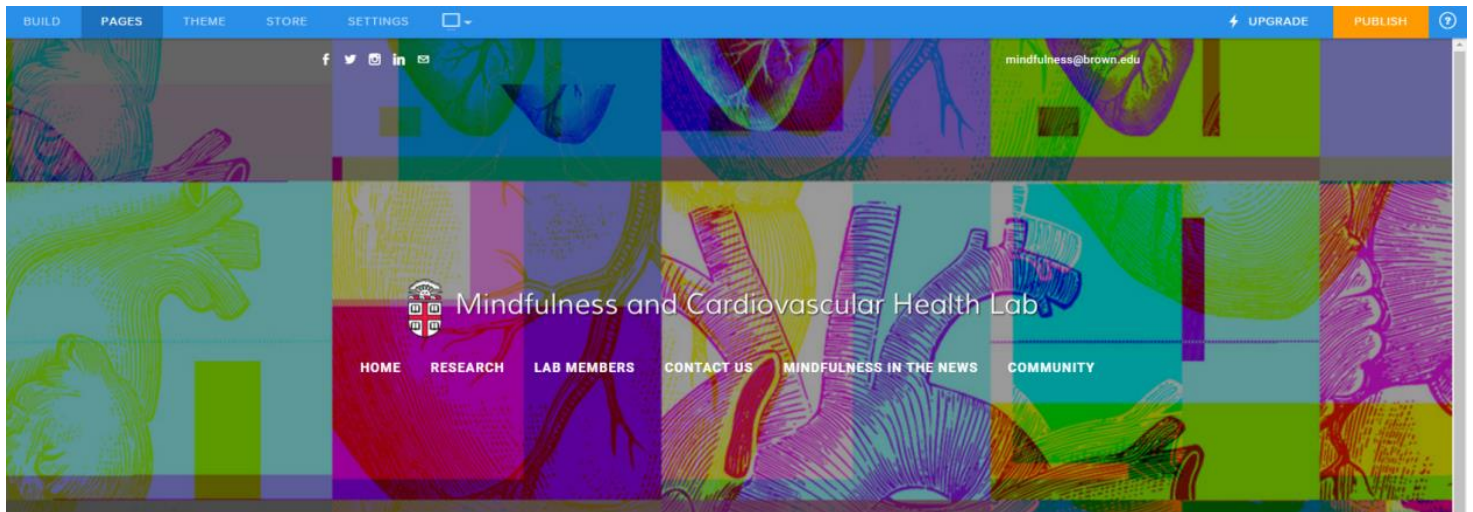
THE CENTER FOR  
**Population Health & Clinical  
Epidemiology**



**BROWN**  
School of Public Health

# Mindfulness-Based Blood Pressure Reduction Study Webpage

The MB-BP study webpage is shown below.



## Mindfulness-Based Intervention for Blood Pressure Reduction

ENROLLING NOW!



This is a 9-week program that includes free training in mindfulness meditation, mindful movements, education about hypertension, and support for reducing hypertension risk factors. The study is testing whether this intervention lowers blood pressure. The course consists of nine weekly sessions that are 2.5 hours, as well as an all-day weekend retreat. People who have a current regular meditation practice (i.e. meditate more than once per week) are not eligible.

Research participation includes interviews, questionnaires and health measurements, such as blood pressure, height, and weight, completed both before and after the meditation program.

What do participants learn?

The study intervention teaches participants mindfulness meditation, mindful movements, education about hypertension risk factors, and support for reducing hypertension risk factors.

What is the goal of the study?

The purpose of the study is to see whether the mindfulness-based intervention lowers blood pressure and reduces hypertension risk factors.

What does the study entail?

The program consists of 9 weekly sessions that are 2.5 hours, and an all-day weekend retreat. Research participation includes interviews, questionnaires, and health measurements such as blood pressure, height, and weight, completed both before and after the meditation program.

Who is eligible?

To see if you qualify for the study, please contact us to schedule a brief phone screener. Please note that individuals who have a current regular meditation practice (i.e. meditate more than once per week) are not eligible.

If you are interested in taking part in the program, please **contact us** to see if you qualify.

CONTACT US

MB-BP Webpage settings are shown below:

The screenshot displays the Weebly website editor interface. The top navigation bar includes links for BUILD, PAGES, THEME, STORE, and SETTINGS. The left sidebar contains a menu with options like General, SEO, Editors, Members, My Apps, Store, and Blog. The main content area is titled 'General' and contains the following sections:

- Site Address:** Displays the current address as [mindfulnesscvlab.weebly.com](http://mindfulnesscvlab.weebly.com) with a 'Change' button.
- Site Title:** Displays the title as 'Brown University Mindfulness and Cardiovascular Health Lab' with a 'Save' button. A checkbox for 'Show title on the top of your pages' is checked.
- SSL:** A toggle switch is set to 'Off' with an 'Upgrade' button.
- Favcon:** Displays a default favicon with an 'Upgrade' button.
- Site Password:** A text input field for a password with a 'Save' button. A note states: 'Your site password will automatically apply to all your pages. You can change this for individual pages in the "visibility" section of the "Pages" tab.'
- Navigation:** A checkbox for 'Group excess pages under "More..."' is checked.
- Facebook Sharing:** Status is 'Not Connected' with a 'Setup Facebook Share' button.
- Archive:** A section for creating a .zip archive of the site, with an 'Email Archive' button.
- SimpleChat:** A section for installing SimpleChat with an 'Install SimpleChat' button.
- Site Formatting:** A section for setting site language and date/time format, including dropdowns for Date format (MM/DD/YYYY), Time format (12 hour), Time zone (Eastern Time (US & Canada) (UTC-05:00)), and Site Language (English).
- Cookie Notification:** A section for notifying visitors that the site uses cookies, with a 'Location' dropdown set to 'off'.
- Un-publish:** A section showing the last published date as '2016-04-15' with an 'Un-publish Site' button.

## **Appendix 8:**

**Week 4: Goal Related to Diet, Alcohol Consumption, Physical  
Activity, or Stress Reaction/Response -  
with Track Changes (v.1.1)**

Participant ID# \_\_\_\_\_

**Week 4: Goal Related to Diet, Alcohol Consumption, Physical Activity,  
or Stress Reaction/Response**

W4\_GO\_1. What is your goal related to diet, alcohol consumption, physical activity, or stress reaction/response for the week?

W4\_GO\_2. On a scale of 1-10, where 10 is high, how MOTIVATED are you to achieve this goal?

W4\_GO\_3. On a scale of 1-10, how CONFIDENT are you that you will achieve the goal?

W4\_GO\_4. What could you do that would bring your motivation or confidence a little higher?

W4\_GO\_5. What might make it difficult to achieve the goal this week, and if that happens, what will you do?

W4\_GO\_6. What is a way to measure this goal that resonates with you?

Deleted: August 31, 2015



Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
Tues Date:	W4_GO_D2_1.	<u>W4_GO_D2_2a.</u> <b>Before:</b>	W4_GO_D2_3a. <b>Before:</b>	W4_GO_D2_4.	W4_GO_D2_5.
		<u>W4_GO_D2_2b.</u> <b>During:</b>	W4_GO_D2_3b. <b>During:</b>		
		<u>W4_GO_D2_2c.</u> <b>After:</b>	W4_GO_D2_3c. <b>After:</b>		
Wed Date:	W4_GO_D3_1.	<u>W4_GO_D3_2a.</u> <b>Before:</b>	<u>W4_GO_D3_3a.</u> <b>Before:</b>	<u>W4_GO_D3_4.</u>	<u>W4_GO_D3_5.</u>
		<u>W4_GO_D3_2b.</u> <b>During:</b>	<u>W4_GO_D3_3b.</u> <b>During:</b>		
		<u>W4_GO_D3_2c.</u> <b>After:</b>	<u>W4_GO_D3_3c.</u> <b>After:</b>		

**Comment [SF2]:** Corrected the cut and paste error on variables shown below

Deleted: 2a

Deleted: 3a

Deleted: 4

Deleted: Before:¶

¶

¶

¶

W4\_GO\_D2\_3b.¶

During:¶

¶

¶

W4\_GO\_D2\_3c.¶

After:¶

Deleted: 2

Deleted: 2

Deleted: W4\_GO\_D2\_1.¶

Deleted: W4\_GO\_D3\_3a.¶

Before:¶

¶

¶

¶

¶

¶

¶

W4\_GO\_D3\_3b.¶

During:¶

¶

¶

¶

¶

W4\_GO\_D3\_3c.¶

After:¶

Deleted: W4\_GO\_D3\_4.¶

Deleted: W4\_GO\_D3\_2a.¶

Before:¶

¶

¶

¶

¶

¶

¶

Deleted: August 31, 2015



Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
Thurs Date:	W4_GO_D4_1.	<u>W4_GO_D4_2a.</u> <b>Before:</b>  <u>W4_GO_D4_2b.</u> <b>During:</b>  <u>W4_GO_D4_2c.</u> <b>After:</b>	<u>W4_GO_D4_3a.</u> <b>Before:</b>  <u>W4_GO_D4_3b.</u> <b>During:</b>  <u>W4_GO_D4_3c.</u> <b>After:</b>	<u>W4_GO_D4_4.</u> ▼	<u>W4_GO_D4_5.</u> ▼
Fri Date:	W4_GO_D5_1.	<u>W4_GO_D5_2a.</u> <b>Before:</b>  <u>W4_GO_D5_2b.</u> <b>During:</b>  <u>W4_GO_D5_2c.</u> <b>After:</b>	<u>W4_GO_D5_3a.</u> <b>Before:</b>  <u>W4_GO_D5_3b.</u> <b>During:</b>  <u>W4_GO_D5_3c.</u> <b>After:</b>	<u>W4_GO_D5_4.</u> ▼	<u>W4_GO_D5_5.</u> ▼

Deleted: W4\_GO\_D4\_3a.¶  
Before:¶

¶  
¶  
¶  
W4\_GO\_D4\_3b.¶  
During:¶  
¶  
¶  
¶  
W4\_GO\_D4\_3c.¶  
After:¶  
¶  
¶

Deleted: W4\_GO\_D4\_4.¶

Deleted: W4\_GO\_D4\_2a.¶  
Before:¶

¶  
¶  
¶  
W4\_GO\_D4\_2b.¶  
During:¶  
¶

Deleted: W4\_GO\_D4\_1.¶  
¶  
¶

Deleted: W4\_GO\_D5\_3a.¶  
Before:¶

¶  
¶

Deleted: W4\_GO\_D5\_4.¶

Deleted: W4\_GO\_D5\_2a.¶  
Before:¶

¶  
¶

Deleted: W4\_GO\_D5\_1.¶

¶  
¶

Deleted: August 31, 2015

Day/Date	Event related to goal	How did your body feel, in detail, before, during and after this experience?	What moods, feelings, and thoughts were there before, during and after this event?	How did it contribute, or not, to achieving the goal?	What thoughts are in your mind now as you write about this event?
Sat Date:	W4_GO_D6_1.	<u>W4_GO_D6_2a.</u> <b>Before:</b>  <u>W4_GO_D6_2b.</u> <b>During:</b>  <u>W4_GO_D6_2c.</u> <b>After:</b>	<u>W4_GO_D6_3a.</u> <b>Before:</b>  <u>W4_GO_D6_3b.</u> <b>During:</b>  <u>W4_GO_D6_3c.</u> <b>After:</b>	<u>W4_GO_D6_4.</u>  	<u>W4_GO_D6_5.</u>  
Sun Date:	W4_GO_D7_1.	<u>W4_GO_D7_2a.</u> <b>Before:</b>  <u>W4_GO_D7_2b.</u> <b>During:</b>  <u>W4_GO_D7_2c.</u> <b>After:</b>	<u>W4_GO_D7_3a.</u> <b>Before:</b>  <u>W4_GO_D7_3b.</u> <b>During:</b>  <u>W4_GO_D7_3c.</u> <b>After:</b>	<u>W4_GO_D7_4.</u>  	<u>W4_GO_D7_5.</u>  

Deleted: W4\_GO\_D6\_3a.¶  
Before:¶

¶  
¶  
¶  
W4\_GO\_D6\_3b.¶  
During:¶  
¶  
¶  
W4\_GO\_D6\_3c.¶  
After:¶  
¶

Deleted: W4\_GO\_D6\_4.¶

Deleted: W4\_GO\_D6\_2a.¶  
Before:¶

¶  
¶  
¶  
W4\_GO\_D6\_2b.¶  
During:¶  
¶

Deleted: W4\_GO\_D6\_1.¶  
¶  
¶

Deleted: W4\_GO\_D7\_3a.¶  
Before:¶

¶  
¶

Deleted: W4\_GO\_D7\_4.¶

Deleted: W4\_GO\_D7\_2a.¶  
Before:¶

¶  
¶

Deleted: W4\_GO\_D7\_1.¶

¶  
¶

Deleted: August 31, 2015

# **Appendix 9: Revised Phone Screener with Track Changes**

*(v.1.5– April 14, 2016)*

# PHONE-DELIVERED SCREENING QUESTIONNAIRE

Deleted: MBHT

## PHONE SCREENING QUESTIONNAIRE - PART 1 of 2

The script is shown below in **bold italics**.

PID. Participant ID: \_\_\_\_\_

SQ01. Staff ID: \_\_\_\_\_

SQ02. Today's Date (MMDDYY): \_\_\_\_\_

SQ03. Current Time (24 hour time, e.g. 14:45): \_\_\_\_\_

Please now call the participant.

SQ04. Was the participant reached? YES NO

***Hello, my name is \_\_\_\_\_. I am calling from the Brown University School of Public Health because (name of participant) expressed interest in participating in our mindfulness blood pressure study. Is he/she available to talk at this time?***

***I would like to do a 10-15 minute phone interview with you to determine if you are a good match for this particular study.***

SQ05. ***Is now a good time to speak?***

*[If yes, proceed to SQ05 script below]*

If no... ***When would be a good time to talk?***

SQ06. Day to call back (DDMMYY) \_\_\_\_\_

SQ07. Time to call back \_\_\_\_\_ AM/PM

***OK, great. I'm going to give you a quick overview of the study first and can then move on to the screener to see if you may qualify. Feel free to interrupt me at any point if you have a question. Okay?***

***STUDY OVERVIEW: In this study, we are looking to see if mindfulness practices improve blood pressure, and if education about hypertension risk factors may also improve blood pressure. If eligible, we will provide you with training in meditation, mindful movements, and the roles of things like diet, physical activity and medication in reducing blood pressure.***

***You will be taught by a very experienced teacher who is an expert in these fields. The course is free and will take place over a 9-week period, where you come to a class once each week for 2.5 hours each time. There is also a one-day weekend retreat that will be 7.5 hours long. IGo over days / times of course and retreat ]***

***As part of the project, we will also ask you to participate in health assessments before and after the study. Health assessments include measures such as blood pressure,***

Deleted: How about I

Deleted: answer any questions you may have to see if it is a good fit for you. We will then go through a screening questionnaire to see if you qualify for the study. Does this sound OK?

Deleted: on a Saturday

Comment [SF1]: Retreat is 7.5hrs long and can be on a Saturday or a Sunday.

Deleted: 8

Deleted: MBHT

**height and weight, and questionnaires about your health and experiences. At the end of the study, you will be given \$100 USD to express our gratitude. Do you have any questions about the study? [Answer questions]**

SQ08. **Does this study sound like something you would be interested in doing? Yes No**

[If yes, proceed to next statement below. If no, politely thank the participant for considering being in this study, and end the call].

**Great. There are a few things that I would like to go over before we start the interview. First, some of the questions that I will ask now to figure out if you are eligible to be in this study will be of personal nature, including asking about your mental health and life's experiences.**

Deleted: make clear

Deleted: First of all, s

SQ09. **Are you in a private place to talk?**

[If yes, proceed to text below. If no, reschedule meeting using variables SQ06 and SQ07 above].

**Because this interview is of a personal nature, it is important that you understand that everything you say will be kept strictly confidential. No one outside of our project will ever be able to see your answers, and we will not keep your name in the same place as any of your answers. If you are not eligible after the phone screen, we will destroy your information. If you like, though, we can keep your information on file for future studies.**

**Ok, to begin, I am going to start by recording your name and contact information.**

SQ10. Participant's First Name: \_\_\_\_\_

SQ11. Participant's Last Name: \_\_\_\_\_

Participant's Address (in case we need to send any study materials to you):

SQ12a. Street address: \_\_\_\_\_

SQ12b. City: \_\_\_\_\_

SQ12c. State: \_\_\_\_\_

SQ12d. Zip Code: \_\_\_\_\_

SQ13a. Participant's Phone number #1 (in case we need to contact you by phone)

\_\_\_\_\_  
Type of Phone: work / home / cell / other

SQ13b. Participant's Phone number #2

\_\_\_\_\_  
Type of Phone: work / home / cell / other

**Comment [SF2]:** Type of phone was added so that communication with participants can be more informed.

SQ14. Participant's email address (or mailing address if no email): \_\_\_\_\_

SQ15. Notes from interviewer related to participants' contact information (if any):

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Deleted: MBHT

## PHONE SCREENING QUESTIONNAIRE - PART 2 of 2

PID. Participant ID #: \_\_\_\_\_

**SQ.recruit** How did you find out about the study? *Select one.*

From a friend / family member / coworker..... [ ]

From a former or current participant..... [ ]

From PCP or other health care provider ..... [ ]

Facebook ..... [ ]

Twitter..... [ ]

Craigslist ..... [ ]

Saw an orange flier / card (note location ) ..... [ ]

Other (please describe ) ..... [ ]

**Comment [SF3]:** For internal tracking to know how best to recruit

**Comment [SF4]:** Use of Facebook, Twitter, and Craigslist are subject to IRB approval

**INCLUSION CRITERIA:** All answers in 3<sup>rd</sup> column must be YES. If an answer is NO, immediately proceed to question SQ40.

		YES	NO	Comments
SQ26.	<b>What is your age?</b> [Is age at least 18 years?]			
SQ27.	<b>Can you read and write in English?</b>			

**EXCLUSION CRITERIA:** All answers in 3<sup>rd</sup> column must be NO with the exception of SQ32a and SQ33a. If an answer (other than SQ32a and SQ33a) is YES, then immediately proceed to question SQ40.

		YES	NO	Comments
<b>I will now start to ask some questions about your mental health.</b>				
SQ28.	<b>Has anyone ever told you that you have bipolar disorder or manic depression?</b>			
SQ29.	<b>Has anyone ever used the word "Borderline" to describe you?</b>			
SQ30a.	<b>Have you ever had a hallucination or seen things that other people can't see, or hear things other people can't hear?</b>			
SQ30b.	<b>Have you ever been diagnosed with schizophrenia or psychosis?</b>			
SQ31_1	<b>Have you ever taken any of the following medications that I am about to read to you?</b> <b>Lithium</b>			
SQ31_2	<b>Seroquel (quetiapine)</b>			
SQ31_3	<b>Abilify (aripiprazole)</b>			
SQ31_4	<b>Zyprexa (olanzapine)</b>			
SQ31_5	<b>Clozaril (clozapine)</b>			
SQ31_6	<b>Haldol/Haloperidol</b>			
SQ31_7	<b>Geodon (ziprasidone)</b>			
SQ31_8	<b>Risperdal (risperidone)</b>			

Deleted: MBHT

SQ32a	<b>Have you ever had a suicide attempt?</b>	YES NO	
SQ32b	<b>[If yes, ask...] Have you considered killing yourself during the past month?</b>	YES NO	
SQ32c	<b>[If yes, ask...] Are you currently suicidal?</b> <b>[If yes, keep participant on the phone, and follow suicide safety plan below]</b>	YES NO	
SQ32d	<b>[If no, ask...] Are you getting any help for that? If not, then provide list of resources from Safety Plan including Gateway, Anchor and The Providence Center] Not urgent, but inform Dr. Flynn about what was discussed.</b>	YES NO	
EXCLUSION CRITERIA: All answers in 3 <sup>rd</sup> column must be NO with the exception of SQ32a and SQ33a. If an answer (other than SQ32a and SQ33a) is YES, then immediately proceed to question SQ40.			
SQ33a	<b>Would you say you have a trauma history?</b> <b>[If yes...]</b>	YES NO	
SQ33b	<b>In the past month, have you had any problems with dissociation (memory loss)?</b>	YES NO	
SQ33c	<b>In the past month, have you had any flashbacks (i.e. sudden and disturbing vivid memory) about the trauma?</b>	YES NO	
SQ34a	<b>In the past month, have you had any problems with obsessions or compulsions, such as washing your hands or checking the oven over and over again?</b>	YES NO	
SQ34b	<b>[If yes...] Has anyone diagnosed you with obsessive compulsive disorder?</b>	YES NO	
SQ35	<b>In the past month, have you had a panic attack (i.e. sweating, heart palpitations, nausea, trouble breathing, fear of dying/choking/going crazy)?</b>	YES NO	
SQ36	<b>Have you had any problems with alcoholism or drug use in the past year?</b>	YES NO	
SQ37	<b>In the past year, have you had an eating disorder, such as starving, binge eating, or vomiting?</b>	YES NO	
SQ38a	<b>Do you currently have a mindfulness practice, such as meditation or yoga?</b>	YES NO	
SQ38b	<b><u>If Yes –</u> Please tell me more about your mindfulness practice, including how often you practice per week.</b>	Fill in response in comments section to	

Deleted: MBHT



SQ38c	<b>Do you currently practice meditation more than once per week? (yoga does not count as meditation in this context)</b>	the right YES NO	
SQ39	<b>This class will take place at Brown University in-person. Do you have any medical or mobility issues that would affect you being able to attend class?</b>	YES NO	
SQ40	Participant qualifies for next step of study (next step is 1 <sup>st</sup> blood pressure screening)	YES NO  If YES go to SQ41.  If NO, go to SQ42.	

SQ41a. **Thank you for taking the time to answer these questions. You qualify for the next stage of screening, which is to take your blood pressure at our office. If you're still interested, we'd like to schedule a time to have you come in to complete the in-person screener. It will only take 30 minutes or less and will involve taking your blood pressure 3-5 times, as well as measuring your height and weight. Is there a day or time that works best for you?** [Schedule the In-Person Screening visit now]

**Comment [SF5]:** These measures were moved to the In-Person screener from the In-Person Baseline.

SQ41b. **As I mentioned earlier, there is a mindfulness intervention that is part of this study. If you are eligible based on the In-Person screening, you will then be invited to take part in a 9 week Mindfulness Course. We will be scheduling the mindfulness intervention at a time that works best with most of the participants. What days and times of the week typically work best with your schedule? Please keep in mind that the sessions are 2.5 hours long, and take place once per week for 9 weeks.**

[Record participant's availability for Intervention and then proceed with the script]

**Thank you for your time and interest in this study. We look forward to meeting you in person on [DATE / TIME]. Do you have any questions before we end this call?**

**IF INELIGIBLE:**

SQ42a. **Thank you for taking the time to answer these questions. According to the survey, you do not qualify for the study at this time. There may be other studies you qualify for.**

SQ42b. **Would you like me to keep your information to pass on to these studies?** YES / NO

SQ42c. [If yes...] **OK, thank you. We will keep this information for future studies you may qualify for. Thank you for taking the time to talk with me today. Can I answer any questions before hanging up?**

Deleted: MBHT

SQ42d. [If no...] ***OK, our copy of this information will be destroyed. Thank you for taking the time to talk with me today. Can I answer any questions before hanging up?***

Deleted: MBHT

## SAFETY PLAN

Enter details below on paper during screening (These variables should be entered in the survey via questions SQ10-SQ13). Destroy this paper after screening is complete.

Participant's First Name: \_\_\_\_\_

Participant's Last Name: \_\_\_\_\_

Participant's Address:

Street address: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Zip Code: \_\_\_\_\_

Participant's Phone number #1: \_\_\_\_\_

Participant's Phone number #2: \_\_\_\_\_

During the phone-based screening, if participants respond yes to "Are you currently suicidal?", the interviewer should perform the following 2 steps:

1. **Immediately have 911 and Dr. Ellen Flynn called by a colleague who has been informed beforehand that this is a possibility.**

**Specifically, while keeping the participant on the phone, show the text below in the box to a colleague.**

***I have a study participant on the phone who is currently suicidal. Please call 911 immediately, and tell them:***

***"I am calling on behalf of [my name] who is performing a research study at Brown University. He has a participant on the phone who says they are currently suicidal." Please provide the participants' contact information to the 911 operator (i.e. name, address, phone #, email address) as requested. This information is shown above.***

***Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.***

2. While speaking calmly with the participant, let them know what you are doing. Specifically, let them know we are calling our study's psychiatrist Dr. Flynn and 911, and why you are doing that (i.e. because we are concerned about you). You can speak with participant to keep him/her on the phone, but the discussion should not be clinical in nature.

Deleted: MBHT

Examples of questions that could be asked in order to keep them on the phone:

- “Tell me what is going on.”
- “What’s happening right now?”
- Tell me more about why you are interesting in being part of this study.
- What are you hoping to get out of this study?

The following information can be provided to study participants if they state they have had considered killing themselves in the past month. If they are currently suicidal, the main priority is to keep them on the phone while 911 and Dr. Flynn are being contacted.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020

Deleted: MBHT

# **Appendix 10: Revised In-Person Screener with Track Changes**

*(v.1.5– April 14, 2016)*

IN-PERSON SCREENING  
ASSESSMENT FORM

Deleted: MBHT  
Deleted: December 21, 2015

PID. Participant ID # \_\_\_\_\_

BA01. Staff ID # \_\_\_\_\_

BA02. Today's date (MMDDYY): \_\_\_\_\_

**Comment [SF1]:** Variable numbering was off. Should be "BA##" not "BA02\_##". Changed for all.

Deleted: 2\_

**Blood Pressure:**

BA03a. Blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA03b. Blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA03c. Blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA03d. Blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA03e. Blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA03f. Blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA04. Were the 2<sup>nd</sup> and 3<sup>rd</sup> systolic blood pressure readings within 20 mmHg of each other?

☐ Yes

☐ No (**repeat measurements**)

BA05. Were the 2<sup>nd</sup> and 3<sup>rd</sup> diastolic blood pressure readings within 10 mmHg of each other?

☐ Yes

☐ No (**repeat measurements**)

BA06a. Repeated blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA06b. Repeated blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA06c. Repeated blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA06d. Repeated blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA06e. Repeated blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg

BA06f. Repeated blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

Blood Pressure Safety Protocol – The out-of-range blood pressure values are as follows: systolic blood pressure >200 mmHg or <90 mmHg; diastolic blood pressure >110 mmHg.

In absence of symptoms (chest pain, shortness of breath, dizziness, headache), for a SBP>200 or DBP>110 or both, we will strongly encourage participants to see their doctor right away or to go to urgent care. If there are symptoms, we will immediately call 911.

In absence of symptoms (chest pain, shortness of breath, dizziness, passing out), for a SBP<90, we will strongly encourage participants to see their doctor right away or to go to urgent care. If there are symptoms, we will immediately call 911.

**Comment [SF2]:** This is part of our Safety Monitoring Plan, which is also reported to the NCCIH

BA07. Blood pressure cuff size used: ☐ S ☐ Reg ☐ L ☐ XL

BA08. Arm that cuff was placed on: ☐ L ☐ R

Deleted: MBHT

Deleted: December 21, 2015

**ELIGIBILITY OUTCOME** - based on the average of the 2<sup>nd</sup> and 3<sup>rd</sup> BP (repeat) readings, note the participant's eligibility below and read the corresponding script:

**Comment [SF3]:** Scripts were added for ease of administration. The actual eligibility criteria has NOT been changed.

**Not Eligible:** mean systolic BP < 120mmHg AND mean diastolic BP < 80mmHg

**Unfortunately, at this time you are not eligible for the study. If participant is interested, we can keep his/her contact information on file for future studies. END ASSESSMENT.**

**Eligible:** mean systolic BP ≥ 120mmHg OR mean diastolic BP ≥ 80mmHg

**Congratulations, you are eligible for the study! At this time we would like to take your height and weight, ask a few follow up questions and go over the next steps of the study. Note that if the participant does not wish to continue, thank the participant for his/her time and then END THE ASSESSMENT. Otherwise, continue below.**

BA09. Height: \_\_\_\_\_ cm (one decimal place)

BA10. Weight: \_\_\_\_\_ lbs (one decimal place)

**Comment [SF4]:** Height and weight were moved here from the In-Person Baseline assessment. These variables are needed in order to set up the Fitbit equipment, which is given to participant at baseline.

BA11. What is your date of birth? \_\_\_\_ / \_\_\_\_ / \_\_\_\_ [mm/dd/yyyy]

BA12. How old are you?: \_\_\_\_\_ years

BA13. Is participant male or female? ☐ Male ☐ Female ☐ Unknown

BA14. Do you currently take any prescription medications to reduce blood pressure?

- ☐ Yes – go over eCAP protocol; equipment will be given to participant at baseline  
☐ No

**Comment [SF5]:** This information is needed to set up the Fitbit and eCAP equipment. This was moved here from the In-Person Baseline so that the equipment could be set up prior to the baseline assessment rather than during the assessment in order to save the participant time at baseline.

**Go over the next phase of the study, including discussing the Fitbits and eCAPs (if applicable). Before participant leaves, schedule the in-person baseline assessment (must be within 1-3 weeks of the scheduled intervention) or have the Project Coordinator follow up to schedule.**

**END ASSESSMENT**

Deleted: MBHT

Deleted: December 21, 2015



# **Appendix 11: Revised In-Person Baseline Assessment with Track Changes**

*(v.1.5– April 22, 2016)*

IN-PERSON BASELINE  
QUESTIONNAIRE AND ASSESSMENT FORMS

Deleted: MBHT  
Deleted: December 21, 2015

PID. Participant ID # \_\_\_\_\_  
BA01. Staff ID # \_\_\_\_\_  
BA02. Today's date (MMDDYY): \_\_\_\_\_

**Blood Pressure:**

BA03a. Blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03b. Blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03c. Blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03d. Blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03e. Blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03f. Blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

BA04. Were the 2<sup>nd</sup> and 3<sup>rd</sup> systolic blood pressure readings within 20 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA05. Were the 2<sup>nd</sup> and 3<sup>rd</sup> diastolic blood pressure readings within 10 mmHg of each other?

- ☐ Yes  
☐ No (**repeat measurements**)

BA06a. Repeated blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06b. Repeated blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06c. Repeated blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06d. Repeated blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06e. Repeated blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06f. Repeated blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

**Blood Pressure Safety Protocol – The out-of-range blood pressure values are as follows: systolic blood pressure >200 mmHg or <90 mmHg; diastolic blood pressure >110 mmHg.**

**In absence of symptoms (chest pain, shortness of breath, dizziness, headache), for a SBP>200 or DBP>110 or both, we will strongly encourage participants to see their doctor right away or to go to urgent care. If there are symptoms, we will immediately call 911.**

**In absence of symptoms (chest pain, shortness of breath, dizziness, passing out), for a SBP<90, we will strongly encourage participants to see their doctor right away or to go to urgent care. If there are symptoms, we will immediately call 911.**

BA07. Blood pressure cuff size used: ☐ S ☐ Reg ☐ L ☐ XL

BA08. Arm that cuff was placed on: ☐ L ☐ R

BA10. Weight: \_\_\_\_\_ . \_\_\_\_ **lb.** (one decimal place)

**Comment [SF1]:** This is part of our Safety Monitoring Plan, which is also reported to the NCCIH

**Comment [SF2]:** Height was moved to the In-Person Screener.

**Deleted:** BA09. Height: \_\_\_\_\_ . \_\_\_\_ cm (one decimal place)

**Comment [SF3]:** Weight is measured in pounds not kilograms on our study scale.

**Deleted:** kg

**Comment [SF4]:** Waist Circumference was dropped as a measure due to too much variability in measurement and to reduce participant burden.

**Deleted:** Waist Circumference:

**Deleted:** ¶  
BA11a. Measurement 1 \_\_\_\_\_ . \_\_\_\_ cm (one decimal place) ¶  
BA11b. Measurement 2 \_\_\_\_\_ . \_\_\_\_ cm (one decimal place) ¶

¶  
BA12. Is the difference between Measurement 1 and Measurement 2 greater than 1.0cm? ¶  
☐ Yes (**repeat measurements 3&4**) ¶  
☐ No ¶

¶  
BA13a. Measurement 3 \_\_\_\_\_ . \_\_\_\_ cm ¶  
BA13b. Measurement 4 \_\_\_\_\_ . \_\_\_\_ cm ¶

**Deleted:** MBHT

**Deleted:** December 21, 2015

## **Medications (ME)**

ME01. Do you take any prescription medications or over-the-counter drugs?

- ☐ No → ***skip to end of medications questions***  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

ME02a. What is the name of the first prescription medication or over-the-counter drug that you take?

☐ Label product name:

---

☐ Label generic name:

---

☐ Don't know

☐ Prefer not to answer

ME02b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME02c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME02d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME02f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME02g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME02h. What is the medication used for?

ME02i. **Interviewer comments:**

ME02j. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

**Comment [SF5]:** Total dosage per day (ME.2-10.e) was dropped to reduce participant burden since this variable can be calculated.

**Deleted:** ME02e. - Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

**Deleted:** =====Section Break (Continuous)=====

<#> \_\_\_\_\_ %¶  
<#> \_\_\_\_\_ mg¶  
<#> \_\_\_\_\_ mcg¶  
<#> \_\_\_\_\_ grams¶  
<#> \_\_\_\_\_ I.U.¶  
<#> \_\_\_\_\_ Other unit: \_\_\_\_\_¶  
<#> Don't know¶  
<#> Prefer not to answer¶

=====Section Break (Continuous)=====

¶

=====Section Break (Continuous)=====

**Deleted:** MBHT

**Deleted:** December 21, 2015

ME03a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME03b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME03d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

Deleted: ME03c. . How frequently do you take it?

<#>Section Break (Continuous)

<#> \_\_\_\_\_ times per day ¶

<#> \_\_\_\_\_ times per week ¶

<#> \_\_\_\_\_ times per month ¶

<#> Don't know ¶

<#> Prefer not to answer ¶

Section Break (Continuous)

¶

ME03e. Total dosage per day. (Record strength of how it is actually taken, not how it is prescribed.)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME3f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME03g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME03h. What is the medication used for?

\_\_\_\_\_

ME03i. **Interviewer comments:**

\_\_\_\_\_

ME03j. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

ME04a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

\_\_\_\_\_

☐ Label generic name:

\_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME04b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME04c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME04d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME04f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

**Deleted:** ME04e. Total dosage per day.  
(**Record strength of how it is actually taken, not how it is prescribed.**)

=====Section Break (Continuous)=====

<#> \_\_\_\_\_ %¶  
<#> \_\_\_\_\_ mg¶  
<#> \_\_\_\_\_ mcg¶  
<#> \_\_\_\_\_ grams¶  
<#> \_\_\_\_\_ I.U.¶  
<#> \_\_\_\_\_ Other unit: \_\_\_\_\_¶  
<#> Don't know¶  
<#> Prefer not to answer¶  
=====Section Break (Continuous)=====

¶

**Deleted:** MBHT

**Deleted:** December 21, 2015



ME04g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME04h. What is the medication used for?

ME04i. **Interviewer comments:**

ME04j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications section**

☐ Yes

☐ Don't know

☐ Prefer not to answer

ME05a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME05b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME05c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME05d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME05f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME05g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME05h. What is the medication used for?

ME05i. **Interviewer comments:**

ME05j. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of end of medications questions**  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

Deleted: ¶

Section Break (Continuous)

ME05e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

Section Break (Continuous)

<#> \_\_\_\_\_ %¶  
<#> \_\_\_\_\_ mg¶  
<#> \_\_\_\_\_ mcg¶  
<#> \_\_\_\_\_ grams¶  
<#> \_\_\_\_\_ I.U.¶  
<#> \_\_\_\_\_ Other unit:  
\_\_\_\_\_¶

<#> Don't know¶

<#> Prefer not to answer¶

Section Break (Continuous)

Deleted: MBHT

Deleted: December 21, 2015

ME06a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME06b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME06c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

☐ \_\_\_\_\_ times per month

☐ Don't know

☐ Prefer not to answer

ME06d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit:

\_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME06f. Do you take it regularly or only as needed?

☐ Regularly

☐ Only as needed

☐ Don't know

☐ Prefer not to answer

ME06g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME06h. What is the medication used for?

---

ME06i. **Interviewer comments:**

---

ME06i. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications questions**

☐ Yes

☐ Don't know

☐ Prefer not to answer

ME07a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

---

☐ Label generic name:

---

☐ Don't know

☐ Prefer not to answer

Deleted: ME06e. Total dosage per day.  
(Record strength of how it is actually taken, not how it is prescribed.)

.....Section Break (Continuous).....

<#> \_\_\_\_\_ %

<#> \_\_\_\_\_ mg

<#> \_\_\_\_\_ mcg

<#> \_\_\_\_\_ grams

<#> \_\_\_\_\_ I.U.

<#> \_\_\_\_\_ Other unit:

\_\_\_\_\_

<#> Don't know

<#> Prefer not to answer

.....Section Break (Continuous).....

ME07b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME07c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME07d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME07f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

**Deleted:** ME07e. Total dosage per day.  
(**Record strength of how it is actually taken, not how it is prescribed.**)

.....Section Break (Continuous).....

<#> \_\_\_\_\_ %¶  
<#> \_\_\_\_\_ mg¶  
<#> \_\_\_\_\_ mcg¶  
<#> \_\_\_\_\_ grams¶  
<#> \_\_\_\_\_ I.U.¶  
<#> \_\_\_\_\_ Other unit: \_\_\_\_\_¶  
<#> Don't know¶  
<#> Prefer not to answer¶

.....Section Break (Continuous).....

**Deleted:** MBHT

**Deleted:** December 21, 2015

ME07g For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME07h. What is the medication used for?

ME07i. **Interviewer comments:**

ME07j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications questions**

☐ Yes

☐ Don't know

☐ Prefer not to answer

ME08a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME08b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME08c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME08d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME08f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed

- ☐ Don't know  
☐ Prefer not to answer

ME08g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days  
☐ For \_\_\_\_\_ weeks  
☐ For \_\_\_\_\_ months

- ☐ For \_\_\_\_\_ years  
☐ Don't know  
☐ Prefer not to answer

ME08h. What is the medication used for?

ME08i. **Interviewer comments:**

ME08j. Do you take any other prescription medications or over-the-counter drugs?

- ☐ No → **skip to end of medications questions**  
☐ Yes

- ☐ Don't know  
☐ Prefer not to answer

Deleted: ¶

ME08e. Total dosage per day. (**Record strength of how it is actually taken, not how it is prescribed.**)

Section Break (Continuous)

<#> \_\_\_\_\_ %¶  
<#> \_\_\_\_\_ mg¶  
<#> \_\_\_\_\_ mcg¶  
<#> \_\_\_\_\_ grams¶  
<#> \_\_\_\_\_ I.U.¶  
<#> \_\_\_\_\_ Other unit: \_\_\_\_\_  
<#> \_\_\_\_\_ ¶  
<#> Don't know¶  
<#> Prefer not to answer¶

Section Break (Continuous)

Deleted: MBHT

Deleted: December 21, 2015

ME09a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

ME09b. What is the dosage form?

Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

Inhaled

☐ Inhaler or nebulizer

Injected

☐ Injection

Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

Other:

☐ Don't know

☐ Prefer not to answer

ME09c. How frequently do you take it?

☐ \_\_\_\_\_ times per day

☐ \_\_\_\_\_ times per week

☐ \_\_\_\_\_ times per month

☐ Don't know

☐ Prefer not to answer

ME09d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*)

☐ \_\_\_\_\_ %

☐ \_\_\_\_\_ mg

☐ \_\_\_\_\_ mcg

☐ \_\_\_\_\_ grams

☐ \_\_\_\_\_ I.U.

☐ \_\_\_\_\_ Other unit: \_\_\_\_\_

☐ Don't know

☐ Prefer not to answer



ME09f. Do you take it regularly or only as needed?

☐ Regularly

☐ Only as needed

☐ Don't know

☐ Prefer not to answer

ME09g. For how long have you been taking it?

☐ For \_\_\_\_\_ days

☐ For \_\_\_\_\_ weeks

☐ For \_\_\_\_\_ months

☐ For \_\_\_\_\_ years

☐ Don't know

☐ Prefer not to answer

ME09h. What is the medication used for?

ME09i. **Interviewer comments:**

ME09j. Do you take any other prescription medications or over-the-counter drugs?

☐ No → **skip to end of medications questions**

☐ Yes

☐ Don't know

☐ Prefer not to answer

ME10a. What is the name of the next prescription medication or over-the-counter drug that you take?

☐ Label product name:

☐ Label generic name:

☐ Don't know

☐ Prefer not to answer

Deleted: ME09e. Total dosage per day.  
(Record strength of how it is actually taken, not how it is prescribed.)

Section Break (Continuous)

<#> \_\_\_\_\_ %

<#> \_\_\_\_\_ mg

<#> \_\_\_\_\_ mcg

<#> \_\_\_\_\_ grams

<#> \_\_\_\_\_ I.U.

<#> \_\_\_\_\_ Other unit:

<#> \_\_\_\_\_

<#> Don't know

<#> Prefer not to answer

Section Break (Continuous)

ME10b. What is the dosage form?

Oral

- ☐ Pill, tablet, or capsule  
☐ Sublingual or orally-disintegrating tablet  
☐ Liquid solution or suspension (drink, syrup)  
☐ Powder

Topical

- ☐ Liquid, cream, gel, or ointment  
☐ Ear drops (otic)  
☐ Eye drops (ophthalmic)  
☐ Skin patch (transdermal)

Inhaled

- ☐ Inhaler or nebulizer

Injected

- ☐ Injection

Suppository

- ☐ Rectal (e.g., enema)  
☐ Vaginal (e.g., douche, pessary)

Other:

- ☐ Don't know  
☐ Prefer not to answer

ME10c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day  
☐ \_\_\_\_\_ times per week  
☐ \_\_\_\_\_ times per month

- ☐ Don't know  
☐ Prefer not to answer

ME10d. What is the strength? (**Record strength of how it is actually taken, not how it is prescribed.**)

- ☐ \_\_\_\_\_ %  
☐ \_\_\_\_\_ mg  
☐ \_\_\_\_\_ mcg  
☐ \_\_\_\_\_ grams  
☐ \_\_\_\_\_ I.U.

- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_  
☐ Don't know  
☐ Prefer not to answer

ME10f. Do you take it regularly or only as needed?

- ☐ Regularly  
☐ Only as needed  
☐ Don't know  
☐ Prefer not to answer

**Deleted:** ME10e. Total dosage per day.  
(**Record strength of how it is actually taken, not how it is prescribed.**)

.....Section Break (Continuous).....  
<#> \_\_\_\_\_ %¶  
<#> \_\_\_\_\_ mg¶  
<#> \_\_\_\_\_ mcg¶  
<#> \_\_\_\_\_ grams¶  
<#> \_\_\_\_\_ I.U.¶  
<#> \_\_\_\_\_ Other unit: \_\_\_\_\_¶  
<#> Don't know¶  
<#> Prefer not to answer¶  
.....Section Break (Continuous).....

**Deleted:** MBHT

**Deleted:** December 21, 2015

ME10g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks
- ☐ For \_\_\_\_\_ months
- ☐ For \_\_\_\_\_ years
- ☐ Don't know
- ☐ Prefer not to answer

ME10h. What is the medication used for?

---

ME10i. **Interviewer comments:**

---

## FOOD FREQUENCY QUESTIONNAIRE:

RA Script to be read to participants: At this time, we are going to have you complete a few forms on your own. The first is a Food Frequency Questionnaire that will ask you about the types of foods and drinks that you consume. It should take around 20 minutes to complete. Please let me know if you have any questions.

**Comment [SF6]:** To reduce participant burden we have dropped several of the variables collected on the Food Frequency Questionnaire. See attached document with mark up for FFQ variables that were dropped.

**Deleted:** MBHT

**Deleted:** December 21, 2015

ID: [ ] [ ] [ ] [ ] [ ] — [ ] [ ]

**1. Do you currently take multi-vitamins? (Please report **other individual** vitamins in question 2.)**

☐ No ☐ Yes **→ If YES, a) How many do you take per week?**  
☐ 2 or less ☐ 3-5 ☐ 6-9 ☐ 10 or more

**b) For how many years have you taken them?**

☐ 0-1      ☐ 2-4      ☐ 5-9      ☐ 10 or more

c) What specific brand do you usually use? 

Specify exact brand and type

2. **Not counting multi-vitamins, do you take any of the following preparations:**

a) **Vitamin A?**

☐ No    ☐ Yes, seasonal only    ☐ Yes, most months

**If YES,**

<b>How many years?</b>	<input type="radio"/> 0-1 yr.	<input type="radio"/> 2-4 years	<input type="radio"/> 5-9 years	<input type="radio"/> 10+ years	<input type="radio"/> Don't know
<b>What dose per day?</b>	<input type="radio"/> Less than 8,000 IU	<input type="radio"/> 8,000 to 12,000 IU	<input type="radio"/> 13,000 to 22,000 IU	<input type="radio"/> 23,000 IU or more	<input type="radio"/> Don't know

**b) Vitamin C?**

☐ No    ☐ Yes, seasonal only    ☐ Yes, most months

**→ If YES:**

How many years?	What dose per day?
<input type="radio"/> 0-1 yr.	<input type="radio"/> Less than 400 mg
<input type="radio"/> 2-4 years	<input type="radio"/> 400 to 700 mg
<input type="radio"/> 5-9 years	<input type="radio"/> 750 to 1250 mg
<input type="radio"/> 10+ years	<input type="radio"/> 1300 mg. or more
<input type="radio"/> Don't know	<input type="radio"/> Don't know

c) **Vitamin B<sub>6</sub>?**  
☐ No ☐ Yes → If YES, {  
 How many years? ☐ 0-1 yr. ☐ 2-4 years ☐ 5-9 years ☐ 10+ years ☐ Don't know  
 What dose per day? ☐ Less than 10 mg. ☐ 10 to 39 mg. ☐ 40 to 79 mg. ☐ 80 mg. or more ☐ Don't know

d) **Vitamin E?**  
☐ No ☐ Yes **→ If YES,**

<b>How many years?</b>	<input type="radio"/> 0-1 yr.	<input type="radio"/> 2-4 years	<input type="radio"/> 5-9 years	<input type="radio"/> 10+ years	<input type="radio"/> Don't know
<b>What dose per day?</b>	<input type="radio"/> Less than 100 IU	<input type="radio"/> 100 to 250 IU	<input type="radio"/> 300 to 500 IU	<input type="radio"/> 600 IU or more	<input type="radio"/> Don't know

e) **Selenium?** ☐ No ☐ Yes **→ If YES,**

How many years?	0-1 yr.	2-4 years	5-9 years	10+ years	Don't know
What dose per day?	<input type="radio"/> Less than 80 mcg.	<input type="radio"/> 80 to 130 mcg.	<input type="radio"/> 140 to 250 mcg.	<input type="radio"/> 260 mcg. or more	<input type="radio"/> Don't know

f) **Iron?** ☐ No ☐ Yes **→ If YES,**

How many years?	What dose per day?
<input type="radio"/> 0-1 yr.	<input type="radio"/> Less than 51 mg.
<input type="radio"/> 2-4 years	<input type="radio"/> 51 to 200 mg.
<input type="radio"/> 5-9 years	<input type="radio"/> 201 to 400 mg.
<input type="radio"/> 10+ years	<input type="radio"/> 401 mg. or more
<input type="radio"/> Don't know	<input type="radio"/> Don't know

g) Zinc? ☐ No ☐ Yes **If YES,**

<b>How many years?</b>	<input type="radio"/> 0-1 yr.	<input type="radio"/> 2-4 years	<input checked="" type="radio"/> 5-9 years	<input type="radio"/> 10+ years	<input type="radio"/> Don't know
<b>What dose per day?</b>	<input type="radio"/> Less than 25 mg.	<input type="radio"/> 25 to 74 mg.	<input type="radio"/> 75 to 100 mg.	<input type="radio"/> 101 mg. or more	<input type="radio"/> Don't know

**h) Calcium?** (Include Calcium in Dolomite and lums, etc.)

☐ No ☒ Yes **→ If YES,**

How many years?	What dose per day?
<input type="radio"/> 0-1 yr.	<input type="radio"/> Less than 400 mg.
<input type="radio"/> 2-4 years	<input type="radio"/> 400 to 900 mg.
<input type="radio"/> 5-9 years	<input type="radio"/> 901 to 1300 mg.
<input type="radio"/> 10+ years	<input type="radio"/> 1301 mg. or more
<input type="radio"/> Don't know	<input type="radio"/> Don't know

i) Are there other supplements that you take on a regular basis? Please mark if yes:

<input type="radio"/> Metamucil	<input type="radio"/> Cod liver oil	<input type="radio"/> Iodine	<input type="radio"/> Beta-carotene	<input type="radio"/> Other (please specify)
<input type="radio"/> Vitamin D	<input type="radio"/> Folic acid	<input type="radio"/> Copper	<input type="radio"/> Niacin	
<input type="radio"/> B-Complex Vitamins	<input type="radio"/> Omega-3 fatty acids	<input type="radio"/> Brewer's yeast	<input type="radio"/> Magnesium	

**3. For each food listed, fill in the circle indicating how often on average you have used the amount specified during the past year.**

<p><b>I</b> <b>in the circle indicating how often on</b> <b>d the amount specified during the</b></p>	<p><b>AVERAGE USE LAST YEAR</b></p>								
	<p><b>NEVER OR LESS THAN ONCE PER MONTH</b></p>	<p><b>1-3 PER MONTH</b></p>	<p><b>1 PER WEEK</b></p>	<p><b>2-4 PER WEEK</b></p>	<p><b>5-6 PER WEEK</b></p>	<p><b>1 PER DAY</b></p>	<p><b>2-3 PER DAY</b></p>	<p><b>4-5 PER DAY</b></p>	<p><b>6+ PER DAY</b></p>
<p><b>DAIRY FOODS</b></p>									
Skim or low fat milk (8 oz. glass)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Whole milk (8 oz. glass)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Yogurt (1 cup)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ice Cream (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cottage or ricotta cheese (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other cheese, e.g., American, cheddar, etc., plain or as part of a dish (1 slice or 1 oz. serving)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Margarine (pat), added to food or bread; exclude use in cooking	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Butter (pat), added to food or bread; exclude use in cooking	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**4. What form of margarine do you usually use?**

☐ None    ☐ Stick    ☐ Tub    ☐ Extra light  
☐ 'Lite' stick    ☐ 'Lite' tub    ☐ Squeeze

What specific brand and type (e.g., Parkay Corn Oil Spread)

3. (Continued) Please fill in your **average use, during the past year, of each specified food.**

Please try to average your seasonal use of foods over the entire year. For example, if a food such as peaches are eaten 4 times a week during the approximate 3 months that it is in season, then the **average use** would be once per week.

	NEVER OR LESS THAN ONCE PER MONTH	1-3 PER MONTH	1 PER WEEK	2-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2-3 PER DAY	4-5 PER DAY	6+ PER DAY
<b>FRUITS</b>									
Fresh apples or pears (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oranges (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Orange juice or grapefruit juice (small glass)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peaches, apricots or plums (1 fresh, or 1/2 cup canned)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bananas (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other fruits, fresh, frozen, or canned (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	NEVER OR LESS THAN ONCE PER MONTH	1-3 PER MONTH	1 PER WEEK	2-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2-3 PER DAY	4-5 PER DAY	6+ PER DAY
<b>VEGETABLES</b>									
Tomatoes (1) or Tomato juice (small glass)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
String beans (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Broccoli (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cabbage, cauliflower, or Brussels sprouts (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carrots, raw (1/2 carrot or 2-4 sticks)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carrots, cooked (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Corn (1 ear or 1/2 cup frozen or canned)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peas or lima beans (1/2 cup fresh, frozen, canned)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Yams or sweet potatoes (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Spinach or collard greens, cooked (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beans or lentils, baked or dried (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Yellow (winter) squash (1/2 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

	NEVER OR LESS THAN ONCE PER MONTH	1-3 PER MONTH	1 PER WEEK	2-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2-3 PER DAY	4-5 PER DAY	6+ PER DAY
<b>MEAT, SWEETS, BAKED GOODS, CEREAL, MISC.</b>									
Eggs (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chicken or turkey, with skin (4-6 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chicken or turkey, without skin (4-6 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Bacon (2 slices)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hot dogs (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Processed meats, e.g., sausage, salami, bologna, etc. (piece or slice)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Liver (3-4 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hamburger (1 patty)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beef, pork, or lamb as a sandwich or mixed dish, e.g., stew, casserole, lasagna, etc.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beef, pork, or lamb as a main dish, e.g. steak, roast, ham, etc. (4-6 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Fish (3-5 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chocolate (1 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Candy without chocolate (1 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pie, homemade (slice)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pie, ready made (slice)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cake (slice)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cookies (1)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cold breakfast cereal (1 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
White bread (slice), including pita bread	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dark bread (slice), including wheat pita bread	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
French fried potatoes (4 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Potatoes, baked, boiled (1) or mashed (1 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Rice or Pasta, e.g., spaghetti, noodles, etc. (1 cup)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Potato chips or corn chips (small bag or 1 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nuts (small packet or 1 oz.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Peanut butter (1 Tbs)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Oil and vinegar dressing, e.g., Italian, (1 Tbs)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (W)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> (D)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



4. (Continued) Please fill in your average use, during the past year, of each specified food.

### BEVERAGES

	NEVER OR LESS THAN ONCE PER MONTH	1-3 PER MONTH	1 PER WEEK	2-4 PER WEEK	5-6 PER WEEK	1 PER DAY	2-3 PER DAY	4-5 PER DAY	6+ PER DAY	P
Coffee, <u>not</u> decaffeinated (1 cup)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Tea (1 cup), not herbal tea	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Beer (1 glass, bottle, can)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Wine (4 oz. glass)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Liquor, e.g., whiskey, gin, etc. (1 drink or shot)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Low calorie carbonated beverage, e.g., Diet Coke	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Carbonated beverage with sugar, e.g., Coke, Pepsi	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Hawaiian Punch, lemonade, or other fruit drinks	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/> W	<input type="radio"/>	<input type="radio"/>	<input type="radio"/> D	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Consider the serving size as 1 glass, bottle or can for these fruit and carbonated beverages.

5. How many teaspoons of sugar do you add to your beverages or food each day?

tsp.  0 1 2 3 4 5 6 7 8 9 5

6. Which cold breakfast cereal do you usually eat?

☐ Don't eat cold breakfast cereal

Specify exact brand and type

0 1 2 3 4 5 6 7 8 9 6  
0 1 2 3 4 5 6 7 8 9 8

7. How much of the visible fat on your beef, pork or lamb do you remove before eating?

☐ Remove all visible fat ☐ Remove most ☐ Remove small part of fat ☐ Remove none ☐ Don't eat meat

8. What kind of fat do you usually use for frying and sautéing at home? (Exclude "Pam"-type spray)

☐ Real butter ☐ Margarine ☐ Vegetable oil ☐ Vegetable shortening ☐ Lard

9. What kind of fat do you usually use for baking at home?

☐ Real butter ☐ Margarine ☐ Vegetable oil ☐ Vegetable shortening ☐ Lard

10. How often do you eat food that is fried at home? (Exclude "Pam"-type spray)

☐ Less than once a week ☐ 1-3 times per week ☐ 4-6 times per week ☐ Daily

11. How often do you eat fried food away from home? (e.g., french fries, fried chicken, fried fish)

☐ Less than once a week ☐ 1-3 times per week ☐ 4-6 times per week ☐ Daily

12. What type of cooking oil do you usually use at home (e.g., Mazola Corn Oil)?

Specify brand and type

0 1 2 3 4 5 6 7 8 9 12  
0 1 2 3 4 5 6 7 8 9 a

13. Do you use a microwave oven?

☐ Yes ☐ No

If yes, for how many years?

Number of years using a microwave

0 1 2 3 4 5 6 7 8 9 13  
0 1 2 3 4 5 6 7 8 9 a

14. Do you currently follow a physician-prescribed special diet?

☐ Yes ☐ No

a) If yes, for how many years?

Number of years on diet

0 1 2 3 4 5 6 7 8 9 14  
0 1 2 3 4 5 6 7 8 9 a

b) If yes, what kind of diet do you follow? (Select more than one if necessary.)

☐ Weight reduction (low calorie) ☐ Low cholesterol ☐ Low sodium  
☐ Diabetic ☐ Low fat ☐ Low triglyceride ☐ Ulcer ☐ High potassium

☐ Other

Specify type of diet

0 1 2 3 4 5 6 7 8 9 b  
0 1 2 3 4 5 6 7 8 9

15. How has your use of the following foods and beverages changed over the PAST FIVE YEARS?

FOOD	USE HAS DECREASED	USE ABOUT THE SAME	USE HAS INCREASED	15
a) Whole milk	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b) Butter	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c) Margarine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d) Eggs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e) Fish	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f) Red meat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g) Fruits	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h) Vegetables	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i) Whole wheat bread	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j) Whole grains	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k) Sugar	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
l) Alcohol	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

### Questions for Participants to Answer on Their Own In-Person on Paper:

For each statement, please place a mark in the column that best describes how you have been feeling.

	Not at all or less than 1 day last week	1 or 2 days last week	3 to 4 days last week	5 to 7 days last week	Nearly every day for two weeks	I do not know	I prefer not to answer
DS_1. My appetite was poor.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_2. I could not shake off the blues.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_3. I had trouble keeping my mind on what I was doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_4. I felt depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_5. My sleep was restless.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_6. I felt sad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_7. I could not get going.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_8. Nothing made me happy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C_9. I felt like a bad person.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_10. I lost interest in my usual activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_11. I slept much more than usual.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_12. I felt like I was moving too slowly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_13. I felt fidgety.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_14. I wished I were dead.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_15. I wanted to hurt myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_16. I was tired all the time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_17. I did not like myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_18. I lost a lot of weight without trying to.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_19. I had a lot of trouble getting to sleep.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DS_20. I could not focus on the important things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015



Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by that symptom during the past month, including today, by marking the box in the corresponding space in the column next to each symptom.

	Not At All	Mildly – it didn't bother me much	Moderately – it wasn't pleasant at all times	Severely – it bothered me a lot	I do not know	I prefer not to answer
BE_1. Numbness or tingling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_2. Feeling hot	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_3. Wobbliness in legs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_4. Unable to relax	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_5. Fear of worst happening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_6. Dizzy or lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_7. Heart pounding/racing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_8. Unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_9. Terrified or afraid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_10. Nervous	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_11. Feeling of choking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_12. Hands trembling	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_13. Shaky/unsteady	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_14. Fear of losing control	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_15. Difficulty in breathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_16. Fear of dying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_17. Scared	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_18. Indigestion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_19. Faint/lightheaded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_20. Face flushed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BE_21. Hot/cold sweats	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

After questionnaires are complete, participants will be asked to perform the following two computer-based tests:

### **Sustained Attention to Response Task (15 minutes)**

The Sustained Attention to Response Task (SART) is a computerized test of sustained attention, response inhibition (executive function) and self-regulation. Subjects are instructed to press a key in response to rapidly displayed integers (1-9) and withhold response to a designated "no-go" integer. SART errors consist of summed commission errors (button press on no-go trial) and omission errors (button not pressed on "go" integers). SART performance is associated with prefrontal cortex functioning, has been found to increase with mindfulness training and is correlated with scores on mindfulness questionnaires (specifically, the Mindful Attention Awareness Scale).

**Comment [SF7]:** We switched the order of administration for the ANT and SART. The SART is a better measure of attention, so it is important that it is completed first, in case the first measure has an effect on the outcome of the second measure completed.

**Moved (insertion) [1]**

### **Attention Control: Attention Network Test (20 minutes)**

*Attention Network Test (ANT)* is a brief computerized battery measuring three independent behavioral components of attention: Conflict resolution (ability to overcome distracting stimuli), spatial Orienting (the benefit of valid spatial pre-cues), and Alerting (the benefit of temporal pre-cues). Efficiency of orienting is examined by changes in RT that accompany cues indicating where the target will occur. The efficiency of the executive conflict resolution network is examined by requiring the subject to respond by pressing two keys indicating the direction (left or right) of a central arrow surrounded by congruent, incongruent or neutral flankers. Moderate to high reliabilities are found for all networks.

#### **ANT data to be entered by RA prior to ANT:**

PPT Age: \_\_\_\_\_

PPT Sex: Male / Female

Category: Normal

Diagonal of "subject info" window: 10"

Press "distance between eyes and screen" button to calculate. Should be 23.2.

#### **ANT data to be entered by RA after ANT:**

PPT Age: \_\_\_\_\_

Alerting effect (ms): \_\_\_\_\_

Orienting effect (ms): \_\_\_\_\_

Conflict effect (ms): \_\_\_\_\_

Mean RT for correct trials (ms): \_\_\_\_\_

Mean accuracy (%): \_\_\_\_\_

#### **Moved up [1]: Sustained Attention to Response Task (15 minutes)¶**

¶  
The Sustained Attention to Response Task (SART) is a computerized test of sustained attention, response inhibition (executive function) and self-regulation. Subjects are instructed to press a key in response to rapidly displayed integers (1-9) and withhold response to a designated "no-go" integer. SART errors consist of summed commission errors (button press on no-go trial) and omission errors (button not pressed on "go" integers). SART performance is associated with prefrontal cortex functioning, has been found to increase with mindfulness training and is correlated with scores on mindfulness questionnaires (specifically, the Mindful Attention Awareness Scale). ¶

**Deleted: MBHT**

**Deleted: December 21, 2015**

## SAFETY PLAN

After the participant has completed the Beck Anxiety Inventory questionnaire and the Centers for Epidemiologic Studies Depressive Symptomatology questionnaire, ask the participant to wait for a few minutes while you check that all forms and assessments are completed. While the participant is waiting in a different room, check the scores according to the criteria below. If any scores trigger the safety plan, move forward with steps below as written.

### Beck Anxiety Inventory (BA)

If participant scores  $\geq 26$  on the Beck Anxiety Inventory, while having the participant wait, immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and your phone # will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, please leave a phone message for her with your contact information and provide her with the Beck Anxiety Inventory results on the message. If Dr. Flynn is not immediately reachable, or following participant release after consulting with Dr. Flynn, immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).

### Depressive Symptomatology (DS)

The CESD-R will be administered during the in-person assessment visits, and scores will be reviewed immediately upon completion of the in-person assessments.

1. Sadness (dysphoria): Question numbers 2, 4, 6
2. Loss of Interest (anhedonia): Question numbers 8, 10
3. Appetite: Question numbers 1, 18
4. Sleep: Question numbers 5, 11, 19
5. Thinking / concentration: Question numbers 3, 20
6. Guilt (worthlessness): Question numbers 9, 17
7. Tired (fatigue): Question numbers 7, 16
8. Movement (agitation): Question numbers 12, 13
9. Suicidal ideation: Question numbers 14, 15

Participants are considered to meet criteria for major depressive episode if they have anhedonia or dysphoria nearly every day for the past two weeks, plus symptoms in an additional 4 DSM symptom groups noted as occurring nearly every day for the past two weeks. If participants meet criteria for major depressive episode, while having the participant wait, immediately notify the collaborating psychiatrist, Dr. Ellen Flynn (cell phone # 401-258-9829), to determine need for a psychiatric consultation. She has provided her cell phone #, and your phone # will be entered into her phone recognition software to indicate it is a call from the MBHT study. It is likely she will answer the phone. If Dr. Flynn cannot be reached, please leave a phone message for her with your contact information and provide her with the Depressive Symptomatology results on the message. If Dr. Flynn is not immediately reachable, or following participant release after consulting with Dr. Flynn, immediately contact the PI, Dr. Eric Loucks (cell phone #401-369-0443).

Deleted: MBHT

Deleted: December 21, 2015

If participants respond having any suicidal ideation (DS questions 14 or 15), perform the following 2 steps:

1. Immediately call 911 and Dr. Ellen Flynn.

**Specifically, while the participant is in the waiting room, call 911 immediately, and tell them:**

***“My name is \_\_\_\_\_. I am working on a research study at Brown University. I have a study participant in the waiting room who has shared that he/she is currently suicidal.” Please provide the participants’ name to the 911 operator, as requested.***

***Finally, after calling 911, please call Dr. Ellen Flynn, who is the psychiatrist supporting this study. Her cell phone # is 401-258-9829. Please provide her with the same information as was done during the 911 call.***

2. While speaking calmly with the participant, let them know that you have called 911 and Dr. Flynn, and why (i.e. because we are concerned about you). You can speak with participant to keep him/her in the waiting room if 911 has sent assistance, but the discussion should not be clinical in nature.

Examples of questions that could be asked in order to keep them in the waiting room:

- “Tell me what is going on.”
- “What’s happening right now?”
- Tell me more about why you are interested in being part of this study.
- What are you hoping to get out of this study?

The following information can be provided to study participants.

National Suicide Prevention Lifeline: 1-800-273-8255

Other options are to:

- Call your doctor’s office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Local Non-Urgent Free or Inexpensive Mental Health Services:

Gateway Healthcare: 401-729-8701

Anchor Counseling Center: 401-475-9979

The Providence Center: 401-276-4020

Deleted: MBHT

Deleted: December 21, 2015

# **Appendix 12: Revised Home Baseline Assessment with Track Changes**

*(v.1.5– April 22, 2016)*

# HOME BASELINE ASSESSMENT

QUESTIONNAIRES ANSWERED BY PARTICIPANTS  
AT BASELINE (VIA ONLINE OR PAPER FORM)

Deleted: MBHT

Deleted: December 21, 2015

## Questionnaire Table of Contents

<u>Introductory Questions.....</u>	<u>3</u>
<u>Background Questions.....</u>	<u>5</u>
<u>Physical Activity.....</u>	<u>8</u>
<u>Eating Practices.....</u>	<u>10</u>
<u>Alcohol Consumption.....</u>	<u>13</u>
<u>Smoking.....</u>	<u>14</u>
<u>About You.....</u>	<u>15</u>
<u>Parent's Education.....</u>	<u>37</u>
<u>Your Childhood Experiences.....</u>	<u>39</u>
<u>Chronic Illness.....</u>	<u>42</u>
<u>Blood Pressure Medication Use.....</u>	<u>43</u>
<u>More About You.....</u>	<u>44</u>
<u>Family History of Hypertension.....</u>	<u>48</u>
<u>Your Sleep.....</u>	<u>49</u>
<u>END SCRIPT.....</u>	<u>49</u>

**Deleted:** Introductory Questions .3¶  
Background Questions .5¶  
Physical Activity .8¶  
Eating Practices .10¶  
Alcohol Consumption .13¶  
Smoking .14¶  
About You .15¶  
Parent's Education .37¶  
Your Childhood Experiences .39¶  
Blood Pressure Medication Use .42¶  
More About You .43¶  
Family History of Hypertension .47¶  
Your Sleep .48¶  
END SCRIPT .48¶

**Deleted:** MBHT

**Deleted:** December 21, 2015

### **Introduction**

We appreciate you taking the time to participate in this research study. These questionnaires will ask a series of questions on various aspects of your health, health behaviours, family, and other life circumstances. It should take approximately one hour. Please keep in mind that you can refuse to answer any questions that you are not comfortable with.

### **Introductory Questions**

IQ1\_01. Please enter the 4-digit ID number you were given. \_\_\_\_ \_\_\_\_ \_\_\_\_ \_\_\_\_.

IQ1\_02. What is your main reason for participating in this study?

IQ1\_03. What do you care about most?

IQ1\_04. What gives you the most pleasure in your life?

IQ1\_05. What are your greatest worries?

Deleted: MBHT

Deleted: December 21, 2015



Please list three personal goals you have for taking this mindfulness program:

PG1\_01. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

PG1\_02. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

PG1\_03. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Deleted: MBHT

Deleted: December 21, 2015

## **Background Questions**

BQ1\_01. How many years old are you?

BQ1\_02. Are you Latino or Hispanic?

- ☐ No → **skip to B3**
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

B1\_02a. Which of the following represents your family's country of origin? (**check all that apply**)

- |  |   |
|--|---|
| <input type="checkbox"/> Cuba          | <input type="checkbox"/> Dominican Republic     |
| <input type="checkbox"/> Mexico        | <input type="checkbox"/> Other Central American |
| <input type="checkbox"/> Puerto Rico   | <input type="checkbox"/> Other: _____           |
| <input type="checkbox"/> Spain         | <input type="checkbox"/> I do not know          |
| <input type="checkbox"/> South America | <input type="checkbox"/> I prefer not to answer |
| <input type="checkbox"/> Columbia      |   |

BQ1\_03. If you were asked to put yourself into only one of these groups, in which one would you place yourself? (**select one only**):

- |   |   |
|---|---|
| <input type="checkbox"/> Asian                  | <input type="checkbox"/> Native American        |
| <input type="checkbox"/> Pacific Islander       | <input type="checkbox"/> Other : _____          |
| <input type="checkbox"/> African American/Black | <input type="checkbox"/> I do not know          |
| <input type="checkbox"/> Caucasian/White        | <input type="checkbox"/> I prefer not to answer |

BQ1\_04. Which of the following best describes your current work situation? (**select one only**)

- |   |  |
|---|--|
| <input type="checkbox"/> Working full-time                          | <input type="checkbox"/> Keeping house or raising children full-time |
| <input type="checkbox"/> Working part-time                          | <input type="checkbox"/> Military                                    |
| <input type="checkbox"/> Retired                                    | <input type="checkbox"/> Full-time student                           |
| <input type="checkbox"/> Unemployed: Looking for work               | <input type="checkbox"/> Other: _____                                |
| <input type="checkbox"/> Unemployed: Not currently looking for work | <input type="checkbox"/> I do not know                               |
| <input type="checkbox"/> Unemployed due to disability               | <input type="checkbox"/> I prefer not to answer                      |

Deleted: MBHT

Deleted: December 21, 2015

BQ1\_05. What is the highest grade or level of regular school you have completed?

- ☐ Elementary School
- ☐ Junior High
- ☐ High School
- ☐ College
- ☐ Graduate School
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_06. What is the highest degree you earned? (*select one only*)

- ☐ Elementary school
- ☐ Some high school, but no GED
- ☐ GED
- ☐ High school
- ☐ Associate degree (Junior College)
- ☐ Bachelor's degree
- ☐ Master's degree
- ☐ Doctorate (PhD, EdD, etc)
- ☐ Professional (MD, JD, DDS, DVM, etc.)
- ☐ Other: \_\_\_\_\_
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_07. Did you ever attend any other school like a technical, vocational, or trade school?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_08. In total, about how many full-time years of education have you had, including 1<sup>st</sup> grade and all years of school after 1<sup>st</sup> grade?

\_\_\_\_\_ years

Deleted: MBHT

Deleted: December 21, 2015

BQ1\_09a. Do you currently live alone?

- ☐ No
- ☐ Yes → *skip to next section*
- ☐ I do not know
- ☐ I prefer not to answer

BQ1\_09b. How many people currently live in your household, including yourself?

\_\_\_\_\_

BQ1\_09c. Of these people, how many are under 18?

\_\_\_\_\_

BQ1\_09d. Of the adults in your household (including yourself), how many bring income into the household?

\_\_\_\_\_

**Deleted:** MBHT

**Deleted:** December 21, 2015

## **Physical Activity**

Physical activities are activities where you move and increase your heart rate above its resting rate, whether you do them for pleasure, work, or transportation. The following questions ask about the amount and intensity of physical activity you usually do. The intensity of the activity is related to *the amount of energy* you use doing these activities.

### **Examples of physical activity intensity levels:**

#### **Light activities**

Your heart beats slightly faster than normal  
You can talk and sing



Light exercise



Light stretching



Light vacuuming  
or yard work

#### **Moderate activities**

Your heart beats faster than normal  
You can talk but not sing



Brisk walking



Aerobics class



Strength training



Swim gently

#### **Vigorous activities**

Your heart rate increases a lot  
You can't talk, or your talking is broken  
up by large breaths



Aerobics classes



Jogging, Running,  
or Power Walking



Singles tennis,  
Racquetball, Pickle ball

Deleted: MBHT

Deleted: December 21, 2015

### How physically active are you?

	YES	NO	I do not know	I prefer not to answer
PA1_01. I rarely or never do any physical activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_02. I do some light and/or moderate physical activities, but not every week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_03. I do some light physical activity every week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_04. I do moderate physical activity every week but less than 5 days per week or less than 30 minutes on those days.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_05. I do vigorous physical activities every week, but less than 3 days per week or less than 20 minutes on those days.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_06. I do 30 minutes or more per day of moderate physical activities 5 or more days per week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_07. I do 20 minutes or more per day of vigorous physical activities 3 or more days per week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_08. I do activities to increase muscle strength, such as lifting weights or calisthenics, once a week or more.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA1_09. I do activities to improve flexibility, such as stretching or yoga, once a week or more.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

## **Eating Practices**

	Definitely True	Mostly True	Mostly False	Definitely False	I Do Not Know	I Prefer Not to Answer
EE1_01. I deliberately take small helpings to control my weight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_02. I start to eat when I feel anxious.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_03. Sometimes when I start eating, I just can't seem to stop.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_04. When I feel sad, I often eat too much.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_05. I don't eat some foods because they make me fat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_06. Being with someone who is eating, often makes me want to also eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_07. When I feel tense or "wound up", I often feel I need to eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_08. I often get so hungry that my stomach feels like a bottomless pit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_09. I'm always so hungry that it's hard for me to stop eating before finishing all of the food on my plate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_10. When I feel lonely, I console myself by eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_11. I consciously hold back on how much I eat at meals to keep from gaining weight.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_12. When I smell a sizzling steak or see a juicy piece of meat, I find it very difficult to keep from eating even if I've just finished a meal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_13. I'm always hungry enough to eat at any time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_14. If I feel nervous, I try to calm down by eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_15. When I see something that looks very delicious, I often get so hungry that I have to eat right away.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EE1_16. When I feel depressed, I want to eat.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

	Almost Never	Seldom	Usually	Almost Always	I Do Not Know	I Prefer Not to Answer
EE1_17. How often do you avoid 'stocking up' on tempting foods?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Unlikely	A little likely	Somewhat likely	Very likely	I Do Not Know	I Prefer Not to Answer
EE1_18. How likely are you to make an effort to eat less than you want?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Never	Rarely	Sometimes	At least once a week	I Do Not Know	I Prefer Not to Answer
EE1_19. Do you go on eating binges even though you're not hungry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Only at mealtimes	Sometimes between meals	Often between meals	Almost always	I Do Not Know	I Prefer Not to Answer
EE1_20. How often do you feel hungry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	1	2	3	4	5	6	7	8	I Do Not Know	I Prefer Not to Answer
EE1_21. On a scale from 1 to 8, where 1 means no restraint in eating and 8 means total restraint, what number would you give yourself? Mark the number that best applies to you:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015



**Table Salt Use:**

**TS1\_01** Please report your average total use, during the past year, of “salt added at the table”.  
Would you say...

- Never ..... ☐
- Less than once per month ..... ☐
- 1-3 shakes per month ..... ☐
- 1 shake per week ..... ☐
- 2-4 shakes per week ..... ☐
- 5-6 shakes per week ..... ☐
- 1 shake per day ..... ☐
- 2-3 shakes per day ..... ☐
- 4-5 shakes per day ..... ☐
- 6+ shakes per day ..... ☐

**Deleted:** MBHT

**Deleted:** December 21, 2015

## **Alcohol Consumption**

A drink of alcohol is defined as 1 can or bottle of beer, 1 glass of wine, 1 can or bottle of wine cooler, 1 cocktail, or 1 shot of liquor.

AC1\_01. During the past 30 days, how many days per week or per month did you have at least 1 drink of any alcoholic beverage? [if none, ***skip to next section***]

\_\_\_\_\_

AC1\_02. On the days when you drank, about how many drinks did you drink on average?

\_\_\_\_\_

AC1\_03. **Men:** Considering all types of alcoholic beverages, how many times during the past 30 days did you have 5 or more drinks on an occasion?

**Women:** Considering all types of alcoholic beverages, how many times during the past 30 days did you have 4 or more drinks on an occasion?

\_\_\_\_\_

Deleted: MBHT

Deleted: December 21, 2015

## **Smoking**

SM1\_01. Have you smoked at least 100 cigarettes in your entire life?

- ☐ Yes
- ☐ No
- ☐ I Do Not Know
- ☐ Prefer not to answer

SM1\_02. Did you ever become a daily smoker (that is, smoke every day or nearly every day for two months or longer)?

- ☐ Yes
- ☐ No → *skip to next section*
- ☐ I Do Not Know
- ☐ Prefer not to answer

SM1\_03. How old were you when you last smoked daily?

Age \_\_\_\_\_ (in years)

- ☐ I Do Not Know
- ☐ Prefer not to answer
- ☐ Still smoking daily

SM1\_04. Do you smoke cigarettes now?

- ☐ Yes
- ☐ No → *skip to next section*
- ☐ I Do Not Know
- ☐ Prefer not to answer

SM1\_04a. How many cigarettes per day do you smoke? (One pack equals 20 cigarettes)

Number of cigarettes \_\_\_\_\_

- ☐ I Do Not Know
- ☐ Prefer not to answer

Deleted: MBHT

Deleted: December 21, 2015

## **About You**

Please bring to mind a type of very tasty food that may contribute to hypertension through high salt intake or through eating too many calories (e.g., sweet sugary dessert, salty snack foods, etc.).

Think about the LAST WEEK you MOST WANTED this type of food. For each item, select a number (0 to 10) to indicate your rating.

At that time...	Not at All 0	1	2	3	4	5	6	7	8	9	Extremely 10
1. ...how much did you want it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ...how much did you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. ...how strong was the urge to have it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time, how vividly did you...											
4. ...picture it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. ...imagine its taste?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. ...imagine its smell?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. ...imagine what it would feel like in your mouth or throat?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. ...imagine how your body would feel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time...											
9. ...how hard were you trying not to think about it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. ...how intrusive were the thoughts?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. ...how hard was it to think about anything else?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

Please bring to mind any times in the LAST WEEK when you had a desire to do sedentary activities (e.g., read a book, watch a movie, be on the computer, etc.) instead of physical activities (e.g., walking, gardening, exercise).

Think about the LAST WEEK you MOST WANTED to do a sedentary activity. For each item, select a number (0 to 10) to indicate your rating.

At that time...	Not at All 0	1	2	3	4	5	6	7	8	9	Extremely 10
1. ...how much did you want it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ...how much did you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. ...how strong was the urge to have it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time, how vividly did you...											
4. ...picture it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. ...imagine how your body would feel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time...											
6. ...how hard were you trying not to think about it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. ...how intrusive were the thoughts?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. ...how hard was it to think about anything else?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please bring to mind any times in the LAST WEEK when you had a desire to drink alcohol, such as wine, beer or spirits.

Think about the LAST WEEK you MOST WANTED alcohol. For each item, select a number (0 to 10) to indicate your rating.

At that time...	Not at All 0	1	2	3	4	5	6	7	8	9	Extremely 10
1. ...how much did you want it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. ...how much did you need it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. ...how strong was the urge to have it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time, how vividly did you...											
4. ...picture it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. ...imagine its taste?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. ...imagine its smell?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. ...imagine what it would feel like in your mouth or throat?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. ...imagine how your body would feel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
At that time...											
9. ...how hard were you trying not to think about it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. ...how intrusive were the thoughts?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. ...how hard was it to think about anything else?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

Using the scale provided, please indicate how much each of the following statements reflects how you typically are.

	Not at all	A little	Somewhat	Fair Amount	Very much	I do not know	I prefer not to answer
SC1_01. I am good at resisting temptation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_02. I have a hard time breaking bad habits.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_03. I am lazy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_04. I say inappropriate things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_05. I do certain things that are bad for me, if they are fun.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_06. I refuse things that are bad for me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_07. I wish I had more self-discipline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_08. People would say that I have iron self-discipline.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_09. Pleasure and fun sometimes keep me from getting work done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_10. I have trouble concentrating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_11. I am able to work effectively toward long-term goals.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_12. Sometimes I can't stop myself from doing something, even if I know it is wrong.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SC1_13. I often act without thinking through all the alternatives.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

	Almost never	Not very often	Sometimes	Frequently	Almost always	I Do Not Know	Prefer not to answer
CO1_O1. When I fail at something important to me, I become consumed by feelings of inadequacy.							
CO1_O2. I try to be understanding and patient towards those aspects of my personality I don't like.							
CO1_O3. When something painful happens I try to take a balanced view of the situation.							
CO1_O4. When I'm feeling down, I tend to feel like most other people are probably happier than I am.							
CO1_O5. I try to see my failings as part of the human condition.							
CO1_O6. When I'm going through a very hard time, I give myself the caring and tenderness I need.							
CO1_O7. When something upsets me I try to keep my emotions in balance.							
CO1_O8. When I fail at something that's important to me, I tend to feel alone in my failure							
CO1_O9. When I'm feeling down I tend to obsess and fixate on everything that's wrong.							

Deleted: MBHT

Deleted: December 21, 2015

	Almost never	<u>Not very often</u>	<u>Sometimes</u>	<u>Frequently</u>	Almost always	<u>I Do Not Know</u>	<u>Prefer not to answer</u>
CO1_10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.							
CO1_11. I'm disapproving and judgmental about my own flaws and inadequacies.							
CO1_12. I'm intolerant and impatient towards those aspects of my personality I don't like.							

**Deleted:** MBHT

**Deleted:** December 21, 2015



The questions in this scale ask you about your feelings and thoughts during the last month. In each case, you will be asked to indicate by circling how often you felt or thought a certain way.

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
PS1_01. In the last month, how often have you been upset because of something that happened unexpectedly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_02. In the last month, how often have you felt that you were unable to control the important things in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_03. In the last month, how often have you felt nervous and "stressed"?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_04. In the last month, how often have you felt confident about your ability to handle your personal problems?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_05. In the last month, how often have you felt that things were going your way?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_06. In the last month, how often have you found that you could not cope with all the things that you had to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_07. In the last month, how often have you been able to control irritations in your life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_08. In the last month, how often have you felt that you were on top of things?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_09. In the last month, how often have you been angered because of things that were outside of your control?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PS1_10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

Please indicate how often the following statements apply to you by checking the box that best describes your experience.

	Almost Never (0-10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_01. I am clear about my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_02. I pay attention to how I feel.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_03. I experience my emotions as overwhelming and out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_04. I have no idea how I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_05. I have difficulty making sense out of my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_06. I am attentive to my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_07. I know exactly how I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_08. I care about what I am feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_09. I am confused about how I feel.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_10. When I'm upset, I acknowledge my emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_11. When I'm upset, I become angry with myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_12. When I'm upset, I become embarrassed for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

	Almost Never (0-10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_13. When I'm upset, I have difficulty getting work done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_14. When I'm upset, I become out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_15. When I'm upset, I believe that I will remain that way for a long time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_16. When I'm upset, I believe that I will end up feeling very depressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_17. When I'm upset, I believe that my feelings are valid and important.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_18. When I'm upset, I have difficulty focusing on other things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_19. When I'm upset, I feel out of control.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_20. When I'm upset, I can still get things done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_21. When I'm upset, I feel ashamed at myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_22. When I'm upset, I know that I can find a way to eventually feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

	Almost Never (0- 10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_23. When I'm upset, I feel like I am weak.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_24. When I'm upset, I feel like I can remain in control of my behaviours.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_25. When I'm upset, I feel guilty for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_26. When I'm upset, I have difficulty concentrating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_27. When I'm upset, I have difficulty controlling my behaviours.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_28. When I'm upset, I believe there is nothing I can do to make myself feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_29. When I'm upset, I become irritated at myself for feeling that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_30. When I'm upset, I start to feel very bad about myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_31. When I'm upset, I believe that wallowing in it is all I can do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_32. When I'm upset, I lose control over my behaviour.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

	Almost Never (0- 10%)	Sometimes (11-35%)	About Half The Time (36-65%)	Most of the Time (66-90%)	Almost Always (91-100%)	I Do Not Know	I Prefer Not to Answer
ER1_33. When I'm upset, I have difficulty thinking about anything else.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_34. When I'm upset I take time to figure out what I'm really feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_35. When I'm upset, it takes me a long time to feel better.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ER1_36. When I'm upset, my emotions feel overwhelming.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Deleted:** MBHT

**Deleted:** December 21, 2015

This scale is made up of a list of statements each of which may or may not be true about you. For each statement, select “definitely true” if you are sure it is true about you and “probably true” if you think it is true but are not absolutely certain. Similarly, you should select “definitely false” if you are sure the statement is false and “probably false” if you think it is false but are not absolutely certain.

	Definitely False	Probably False	Probably True	Definitely True	I do not know	I prefer not to answer
<b>IS1_01</b> If I wanted to go on a trip for a day (for example, to the country or mountains), I would have a hard time finding someone to go with me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_02</b> I feel that there is no one I can share my most private worries and fears with.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_03</b> If I were sick, I could easily find someone to help me with my daily chores.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_04</b> There is someone I can turn to for advice about handling problems with my family.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_05</b> If I decide one afternoon that I would like to go to a movie that evening, I could easily find someone to go with me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_06</b> When I need suggestions on how to deal with a personal problem, I know someone I can turn to.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_07</b> I don't often get invited to do things with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_08</b> If I had to go out of town for a few weeks, it would be difficult to find someone who would look after my house or apartment (the plants, pets, garden, etc.).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_09</b> If I wanted to have lunch with someone, I could easily find someone to join me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

	Definitely False	Probably False	Probably True	Definitely True	I do not know	I prefer not to answer
<b>IS1_10</b> If I was stranded 10 miles from home, there is someone I could call who could come and get me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_11</b> If a family crisis arose, it would be difficult to find someone who could give me good advice about how to handle it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>IS1_12</b> If I needed some help in moving to a new house or apartment, I would have a hard time finding someone to help me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Deleted:** MBHT

**Deleted:** December 21, 2015

Please indicate how often each of the statements below is descriptive of you.

Statement	Never	Rarely	Sometimes	Often	I Do Not Know	Prefer not to answer
LS1_01. I feel in tune with the people around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	S
LS1_02. I lack companionship	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_03. There is no one I can turn to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_04. I do not feel alone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_05. I feel part of a group of friends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_06. I have a lot in common with the people around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_07. I am no longer close to anyone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_08. My interests and ideas are not shared by those around me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_09. I am an outgoing person	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_10. There are people I feel close to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_11. I feel left out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_12. My social relationships are superficial	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_13. No one really knows me well	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_14. I feel isolated from others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_15. I can find companionship when I want it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_16. There are people who really understand me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_17. I am unhappy being so withdrawn	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_18. People are around me but not with me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_19. There are people I can talk to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LS1_20. There are people I can turn to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015



Below you will find a list of statements. Please indicate how often each statement applies to you generally in daily life.

	0- Never	1	2	3	4	5 - Always
IA1_01. When I am tense I notice where the tension is located in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_02. I notice when I am uncomfortable in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_03. I notice where in my body I am comfortable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_04. I notice changes in my breathing, such as whether it slows down or speeds up.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_05. I do not notice (I ignore) physical tension or discomfort until they become more severe.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_06. I distract myself from sensations of discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_07. When I feel pain or discomfort, I try to power through it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_08. When I feel physical pain, I become upset.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_09. I start to worry that something is wrong if I feel any discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_10. I can notice an unpleasant body sensation without worrying about it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_11. I can pay attention to my breath without being distracted by things happening around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_12. I can maintain awareness of my inner bodily sensations even when there is a lot going on around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_13. When I am in conversation with someone, I can pay attention to my posture.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_14. I can return awareness to my body if I am distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_15. I can refocus my attention from thinking to sensing my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_16. I can maintain awareness of my whole body even when a part of me is in pain or discomfort.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_17. I am able to consciously focus on my body as a whole.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_18. I notice how my body changes when I am angry.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_19. When something is wrong in my life I can feel it in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_20. I notice that my body feels different after a peaceful experience.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_21. I notice that my breathing becomes free and easy when I feel comfortable.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_22. I notice how my body changes when I feel happy / joyful.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

	0- Never	1	2	3	4	5 - Always
IA1_23. When I feel overwhelmed I can find a calm place inside.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_24. When I bring awareness to my body I feel a sense of calm.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_25. I can use my breath to reduce tension.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_26. When I am caught up in thoughts, I can calm my mind by focusing on my body/breathing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_27. I listen for information from my body about my emotional state.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_28. When I am upset, I take time to explore how my body feels.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_29. I listen to my body to inform me about what to do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_30. I am at home in my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_31. I feel my body is a safe place.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IA1_32. I trust my body sensations.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

We are interested in your recent experiences. Below is a list of things that people sometimes experience. Next to each item are five choices: “never”, “rarely”, “sometimes”, “often”, and “all the time”. Please choose one of these to indicate how much you currently have experiences similar to those described.

Please do not spend too long on each item—it is your first response that we are interested in. Please be sure to answer every item.

	Never	Rarely	Sometimes	Often	All the time
RD1_01. I think about what will happen in the future.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_02. I remind myself that thoughts aren't facts.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_03. I am better able to accept myself as I am.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_04. I notice all sorts of little things and details in the world around me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_05. I am kinder to myself when things go wrong.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_06. I can slow my thinking at times of stress.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_07. I wonder what kind of person I really am.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_08. I am not so easily carried away by my thoughts and feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_09. I notice that I don't take difficulties so personally.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_10. I can separate myself from my thoughts and feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_11. I analyze why things turn out the way they do.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_12. I can take time to respond to difficulties.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_13. I think over and over again about what others have said to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_14. I can treat myself kindly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_15. I can observe unpleasant feelings without being drawn into them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_16. I have the sense that I am fully aware of what is going on around me and inside me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_17. I can actually see that I am not my thoughts.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_18. I am consciously aware of a sense of my body as a whole.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_19. I think about the ways in which I am different from other people.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RD1_20. I view things from a wider perspective.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

**How do you cope with events?** Everyone gets confronted with negative or unpleasant events now and then and everyone responds to them in his or her own way. By the following questions you are asked to indicate what you generally think, when you experience negative or unpleasant events.

	(Almost) Never	Some- times	Regularly	Often	(Almost) Always
CR1_01. I think that I have to accept that this has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_02. I often think about how I feel about what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_03. I think I can learn something from the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_04. I feel that I am the one who is responsible for what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_05. I think that I have to accept the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_06. I am preoccupied with what I think and feel about what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_07. I think of pleasant things that have nothing to do with it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_08. I think that I can become a stronger person as a result of what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_09. I keep thinking about how terrible it is what I have experienced.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_10. I feel that others are responsible for what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_11. I think of something nice instead of what has happened.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_12. I think about how to change the situation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_13. I think that it hasn't been too bad compared to other things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_14. I think that basically the cause must lie within myself.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_15. I think about a plan of what I can do best.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_16. I tell myself that there are worse things in life.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_17. I continually think how horrible the situation has been.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CR1_18. I feel that basically the cause lies with others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

Instructions: Below is a collection of statements about your everyday experience. Using the scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what really reflects your experience rather than what you think your experience should be. Please treat each item separately from every other item.

**Please indicate the degree to which you agree with each of the following items using the scale below. Simply check your response to each item**

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never	I do not know	I prefer not to answer
MA1_01. I could be experiencing some emotion and not be conscious of it until some time later.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_02. I break or spill things because of carelessness, not paying attention, or thinking of something else.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_03. I find it difficult to stay focused on what's happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_04. I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_05. I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_06. I forget a person's name almost as soon as I've been told it for the first time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never	I do not know	I prefer not to answer
MA1_07. It seems I am “running on automatic” without much awareness of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_08. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_09. I get so focused on the goal I want to achieve that I lose touch with what I am doing right now to get there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_10. I do jobs or tasks automatically, without being aware of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_11. I find myself listening to someone with one ear, doing something else at the same time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_12. I drive places on “automatic pilot” and then wonder why I went there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_13. I find myself preoccupied with the future or the past.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_14. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_15. I snack without being aware that I’m eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes *your own opinion* of what is *generally true for you*.

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_01. When I'm walking, I deliberately notice the sensations of my body moving.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_02. I'm good at finding words to describe my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_03. I criticize myself for having irrational or inappropriate emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_04. I perceive my feelings and emotions without having to react to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_05. When I do things, my mind wanders off and I'm easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_06. When I take a shower or bath, I stay alert to the sensations of water on my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_07. I can easily put my beliefs, opinions, and expectations into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_08. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_09. I watch my feelings without getting lost in them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_10. I tell myself I shouldn't be feeling the way I'm feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_12. It's hard for me to find the words to describe what I'm thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_13. I am easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_15. I pay attention to sensations, such as the wind in my hair or sun on my face.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_16. I have trouble thinking of the right words to express how I feel about things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_17. I make judgments about whether my thoughts are good or bad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_18. I find it difficult to stay focused on what's happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_21. In difficult situations, I can pause without immediately reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_23. It seems I am "running on automatic" without much aware-ness of what I'm doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_24. When I have distressing thoughts or images, I feel calm soon after.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_25. I tell myself that I shouldn't be thinking the way I'm thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_26. I notice the smells and aromas of things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_27. Even when I'm feeling terribly upset, I can find a way to put it into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_28. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015



	Never	Almost Never	Sometimes	Fairly Often	Often	I do not know	I prefer not to answer
FF1_29. When I have distressing thoughts or images, I am able just to notice them without reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_32. My natural tendency is to put my experiences into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_33. When I have distressing thoughts or images, I just notice them and let them go.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_34. I do jobs or tasks automatically without being aware of what I'm doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_35. When I have distressing thoughts or images, I judge myself as good or bad depending what the thought or image is about.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_36. I pay attention to how my emotions affect my thoughts and behavior.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_37. I can usually describe how I feel at the moment in consider- able detail.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_38. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_39. I disapprove of myself when I have irrational ideas.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

### **Parent's Education**

CS1\_01. Please check the box beside the highest grade or degree that your BIOLOGICAL MOTHER completed.

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

CS1\_02. Please check the box beside the highest grade or degree that your BIOLOGICAL FATHER completed.

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

Now please think of the two most important adults in your home between the time you were born and age 18 years. Please check the category below that best described their level of education during this time period.

CS1\_03. First adult's highest level of education:

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

CS1\_04. Second adult's highest level of education

Never went to school	<input type="checkbox"/>
Grades 1 to 3	<input type="checkbox"/>
Grades 4 to 8	<input type="checkbox"/>
Grades 9 to 11	<input type="checkbox"/>
Grade 12	<input type="checkbox"/>
GED	<input type="checkbox"/>
One or more years of Vocational or Professional School after High School	<input type="checkbox"/>
One or more years of College	<input type="checkbox"/>
One or more years of Graduate or Professional School after College	<input type="checkbox"/>
I Do Not Know	<input type="checkbox"/>
I prefer not to answer	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

## **Your Childhood Experiences**

The following questions ask about some difficult experiences that you might have had as a child. These questions may be emotionally difficult to answer. Just as a reminder, you do not need answer any questions that you would prefer not to. Your answers to these questions, as with all questions, will remain confidential.

CE1\_01. Before you were 18 years old, did a parent or other adult in the household often or very often...

Swear at you, insult you, put you down, or humiliate you?

or

Act in a way that made you afraid that you might be physically hurt?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_02. Before you were 18 years old, did a parent or other adult in the household often or very often...

Push, grab, slap, or throw something at you?

or

Ever hit you so hard that you had marks or were injured?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_03. Before you were 18 years old, did an adult or person at least 5 years older than you ever...

Touch or fondle you or have you touch their body in a sexual way?

or

Attempt or actually have oral, anal, or vaginal intercourse with you?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

Deleted: MBHT

Deleted: December 21, 2015

CE1\_04.Before you were 18 years old, did you often or very often feel that ...

No one in your family loved you or thought you were important or special?

or

Your family didn't look out for each other, feel close to each other, or support each other?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_05.Before you were 18 years old, did you often or very often feel that ...

You didn't have enough to eat, had to wear dirty clothes, and had no one to protect you?

or

Your parents were too drunk or high to take care of you or take you to the doctor if you needed it?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_06.Before you were 18 years old, was a biological parent ever lost to you through divorce, abandonment, or other reason?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_07.Before you were 18 years old, was your mother or stepmother:

Often or very often pushed, grabbed, slapped, or had something thrown at her?

or

Sometimes, often, or very often kicked, bitten, hit with a fist, or hit with something hard?

or

Ever repeatedly hit over at least a few minutes or threatened with a gun or knife?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

Deleted: MBHT

Deleted: December 21, 2015

CE1\_08. Before you were 18 years old, did you live with anyone who was a problem drinker or alcoholic, or who used street drugs?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_09. Before you were 18 years old, was a household member depressed or mentally ill, or did a household member attempt suicide?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

CE1\_10. Before you were 18 years old, did a household member go to prison?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

**Deleted:** MBHT

**Deleted:** December 21, 2015

## Chronic Illness

CD1\_01. Do you have a chronic illness, health problem or disease?

- ☐ Yes  
☐ No (if responding "no", please skip to the next section).

CD1\_02. Please select the illness from the list below that has the greatest effect on your life or feels like the *most important* for you to be able to manage. You may have more than one, but the purpose of this question is to identify what you might view as your PRIMARY chronic illness/problem/disease.

- |   |  |
|---|--|
| <input type="checkbox"/> Diabetes           | <input type="checkbox"/> Depression                      |
| <input type="checkbox"/> Heart Disease      | <input type="checkbox"/> Anxiety                         |
| <input type="checkbox"/> Hypertension       | <input type="checkbox"/> Insomnia                        |
| <input type="checkbox"/> Obesity            | <input type="checkbox"/> Substance use                   |
| <input type="checkbox"/> Metabolic Syndrome | <input type="checkbox"/> Tobacco use                     |
| <input type="checkbox"/> Arthritis          | <input type="checkbox"/> Alcohol overuse                 |
| <input type="checkbox"/> Chronic Pain       | <input type="checkbox"/> Prescription medication overuse |
| <input type="checkbox"/> Asthma             | <input type="checkbox"/> Illicit drug use                |
| <input type="checkbox"/> COPD               | <input type="checkbox"/> Other _____                     |

We would like to know how confident you are in doing certain activities related to the chronic illness or disease you selected above. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time. Please keep the chronic illness or disease in mind as you answer the following questions.

How confident are you that....	Not at All Confident 1	2	3	4	5	6	7	8	9	Totally Confident 10
CD1_03a ...you can keep the fatigue caused by your disease from interfering with the things you want to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CD1_03b ...you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CD1_03c ...you can keep the emotional distress caused by your disease from interfering with the things you want to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CD1_03d ...you can keep any other symptoms or health problems you have from interfering with the things you want to do?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CD1_03e ...you can do the different tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CD1_03f ...you can do things other than just taking medication to reduce how much your illness affects your everyday life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Comment [SF1]:** This is a new scale. It was added so that our study findings can be analyzed and compared to the other concurrent studies.

**Formatted:** Font: 11 pt

**Deleted:** MBHT

**Deleted:** December 21, 2015

### **Blood Pressure Medication Use**

BM1\_01. Do you currently take medication for your blood pressure?

- ☐ Yes
- ☐ No (if responding “no”, please skip to the next page).

	Yes	No
BM1_02. Do you sometimes forget to take your blood pressure pills?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_03. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_04. Have you ever cut back or stopped taking your blood pressure medicine without telling your doctor because you felt worse when you took it?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_05. When you travel or leave home, do you sometimes forget to bring along your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_06. Did you take all your blood pressure medicine yesterday?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_07. When you feel like your symptoms are under control, do you sometimes stop taking your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_08. Taking blood pressure medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	<input type="checkbox"/>	<input type="checkbox"/>

BM1\_09. How often do you have difficulty remembering to take all your blood pressure medicine?

- ☐ Never/rarely
- ☐ Once in a while
- ☐ Sometimes
- ☐ Usually
- ☐ All the time

Deleted: MBHT

Deleted: December 21, 2015



## More About You

Below are some modifiable factors that likely influence blood pressure. These may not all apply to you, as you may already have excellent levels of these factors.

### Physical activity:

The United States Office of Disease Prevention and Health Promotion 2008 Physical Activity Guidelines for Americans states that “Most health benefits occur with at least 150 minutes (2 hours and 30 minutes) a week of moderate intensity physical activity, such as brisk walking. Additional benefits occur with more physical activity. Both aerobic (endurance) and muscle-strengthening (resistance) physical activity are beneficial.”

RC1\_01. How motivated are you to make changes to your physical activity, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

Little intention of changing			Mixed feelings towards taking action				Motivated to take action		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_02. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your physical activity?

Not confident			Moderately confident				Confident		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Diet:

The Dietary Approaches to Stop Hypertension (DASH) diet eating plan is a diet rich in fruits, vegetables, low fat or nonfat dairy. It also includes mostly whole grains; lean meats, fish and poultry; nuts and beans. It is high fiber and low to moderate in fat. It is a plan that follows US guidelines for sodium content, along with vitamins and minerals. It can be considered to be an Americanized version of the Mediterranean diet.

RC1\_03. How motivated are you to make changes to your diet to be consistent with the DASH diet, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

Little intention of changing			Mixed feelings towards taking action				Motivated to take action		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_04. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your diet to be more consistent with the DASH diet?

Not confident			Moderately confident				Confident		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

### Salt Intake:

The 2010 [Dietary Guidelines for Americans](#) recommend that everyone age 2 years and up should consume less than 2,300 milligrams (mg) of sodium each day. Some groups of people should further limit sodium intake to 1,500 mg per day, including:

- Adults age 51 years or older.
- All African Americans.
- Anyone who has high blood pressure, diabetes, or chronic kidney disease.

RC1\_05. How motivated are you to make changes to your salt intake, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

Little intention of changing			Mixed feelings towards taking action				Motivated to take action		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_06. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your salt intake?

Not confident			Moderately confident				Confident		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Overweight/Obesity:

Extensive scientific evidence shows that being overweight or obese increases risk of having high blood pressure.

RC1\_07. How motivated are you to make changes to your body weight, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

Little intention of changing			Mixed feelings towards taking action				Motivated to take action		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_08. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in your body weight?

Not confident			Moderately confident				Confident		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

### Stress, and Stress Response:

Several studies showed that stress, and being slower at emotionally recovering from stressful events, increase risk of hypertension.

RC1\_09. How motivated are you to make changes to the amount of stress in your life, or your response to that stress, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

Little intention of changing			Mixed feelings towards taking action				Motivated to take action		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_10. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in the amount of stress in your life, or your response to that stress?

Not confident			Moderately confident				Confident		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Alcohol Consumption:

Heavy and regular use of alcohol can increase blood pressure substantially. The American Heart Association recommends limiting alcohol consumption to no more than two drinks per day for men and one drink per day for women.

RC1\_11. How motivated are you to make changes to the amount of alcohol you consume, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

Little intention of changing			Mixed feelings towards taking action				Motivated to take action		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_12. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes in the amount of alcohol you consume?

Not confident			Moderately confident				Confident		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

### Blood Pressure (Antihypertensive) Medication Use:

Blood pressure medication has been shown in many studies to be very effective at lowering blood pressure.

RC1\_13. How motivated are you to make changes to your blood pressure medication use, using a scale of one to ten, where one = definitely not ready to change, and 10 = definitely ready to change?

Little intention of changing			Mixed feelings towards taking action				Motivated to take action		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RC1\_14. On a scale of 1-10, with 10 being 100% confident, how confident are you that you can make changes your blood pressure medication use?

Not confident			Moderately confident				Confident		
1	2	3	4	5	6	7	8	9	10
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Deleted: MBHT

Deleted: December 21, 2015

### **Family History of Hypertension**

FH1\_01. Did your biological mother ever have hypertension?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

FH1\_02. Did your biological father ever have hypertension?

- ☐ No
- ☐ Yes
- ☐ I do not know
- ☐ I prefer not to answer

FH1\_03. How many full brothers and sisters do you have (***Please include any brothers or sisters who may have died, but do not include half or step brothers and sisters.***)

- ☐ I do not have any brothers or sisters → ***Skip to the page***  
\_\_\_\_\_ brothers, \_\_\_\_\_ sisters
- ☐ I do not know
- ☐ I prefer not to answer

FH1\_04. Of these brothers and sisters, how many have ever had hypertension?

- \_\_\_\_\_ (***if none, write 0***)
- ☐ I do not know
  - ☐ I prefer not to answer

Deleted: MBHT

Deleted: December 21, 2015

## **Your Sleep**

The following question relates to your usual sleep habits during the past month only. Your answer should indicate the most accurate reply for the majority of days and nights in the past month.

SL1\_04. **During the past month**, how many hours of actual sleep did you get on average at night? (This may be different than the number of hours you spent in bed.)

AVERAGE HOURS OF SL1\_EEP PER NIGHT \_\_\_\_\_

- ☐ I do not know
- ☐ I prefer not to answer

## **END SCRIPT**

Thank you for completing this survey!

Please note that these responses will not be seen immediately. Resources are shown below if you feel that you would like to talk with someone immediately for assistance.

National Suicide Prevention Lifeline: 1-800-273-8255

National Sexual Assault Hotline: 1-800-656-4673

Other options are to:

- Call your doctor's office
- Call 911 for emergency services
- Go to the nearest hospital emergency room.

Deleted: MBHT

Deleted: December 21, 2015

**Appendix 13:**  
**Measurement of Formal and Informal Mindfulness**  
**Practice Post-intervention - *NEW***

# **MB-BP Study: Measurement of Mindfulness Practice post-Intervention** (To be administered at each Follow-up assessment)

MP1\_01 **10wk follow up:** Since the date of the last mindfulness class, have you practiced mindfulness, either formally or informally, in any way?

**6mo / 1yr follow ups:** Think about the last six months. During that time, have you practiced mindfulness, either formally or informally, in any way?

No ..... 0 **(Skip to MP1\_04)**  
Yes ..... 1

On average, how minutes PER WEEK do you engage in the following types of mindfulness activities?	Average # Minutes per week	Less than weekly	Don't Know	Prefer not to answer
MP1_02a Body Scan .....	_____	666	777	888
MP1_02b Yoga .....	_____	666	777	888
MP1_02c Awareness of breath meditation .....	_____	666	777	888
MP1_02d Sitting Meditation .....	_____	666	777	888
MP1_02e Walking Meditation .....	_____	666	777	888
MP1_02f Loving-kindness Meditation .....	_____	666	777	888
MP1_02g Mountain Meditation .....	_____	666	777	888
MP1_02h Visual Meditation .....	_____	666	777	888
MP1_02i Eating Meditation .....	_____	666	777	888
MP1_02j Meditation moving through regions, such as breath, physical sensations, sound, thoughts, and open awareness .....	_____	666	777	888
MP1_02k Goal-related activity (e.g., physical activity, diet change, etc.). <i>Please describe</i> .....	_____	666	777	888
MP1_02l Other mindful activities: Other 1 <i>describe</i> : ..... Other 2 <i>describe</i> : ..... Other 3 <i>describe</i> : .....	_____	666	777	888



MP1\_03.a-l **If > 0 min per day, skip. All others, ask:** Which of the following statements, BEST describes your current attitude towards [*insert mindfulness activity from table above*]?

- I do not plan on practicing this activity .....1
- I see value in this activity but do not practice it regularly .....2
- Something else: *Describe* .....3
- Don't Know* .....7
- Prefer not to answer*.....8

MP1\_04 **If NO Mindfulness Practice, Ask:** Which of the following statements, BEST describes your current attitude towards mindfulness?

- I do not plan on practicing mindfulness .....1
- I see value in mindfulness but do not practice it regularly .....2
- Other (*please describe* ..... ).....3
- Don't Know* .....7
- Prefer not to answer*.....8

MP1\_05 Which of the following, if any, have you participated in [since completing the course / the last six months]?

*None, I have not practiced mindfulness* ..... 00

*Check ALL that apply*

- MB-BP Study Booster Sessions..... [ ]
- MB-BP All day retreats ..... [ ]
- Meditation group *not* related the MB-BP Study ..... [ ]
- Mindful yoga group *not* related the MB-BP Study .... [ ]
- Other 1 *describe:* ..... [ ]
- Other 2 *describe:* ..... [ ]
- Other 3 *describe:* ..... [ ]
- Don't Know*..... 77
- Prefer not to answer*..... 88

MP1\_06 We are interested in the ways in which mindfulness practice may or may not impact your life. Please describe below your relationship to mindfulness since completing your course.

- Don't Know* .....7
- Prefer not to answer*.....8

**Brown University**  
Research Protections Office  
Institutional Review Board  
**Modification Request**

**Date of Request:** 8/9/16 **Investigator's Name and Title:** Eric Loucks, PhD, Assistant Professor

**Study Title:** Mindfulness-based Hypertension Therapy Pilot Study (#1412001171)

**Original Type of Review:** ☐ Exempt ☐ Expedited ☒ Full Board

**1) Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project. (Attach summary to this form)**

See attached summary

**2) Provide a detailed description of the changes being requested (Use additional pages, if necessary):**

See attached summary

**3.) State the reason (justification) for the requested modification. (Use additional pages, if necessary):**

See attached summary

**4.) What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

See attached summary

**5.) Does the requested modification require new documents or changes to the approved consent form or other documents?**

☐ Consent/assent documents (attach revised version with changes highlighted)

☒ New/revised instruments (attach - if revised, highlight changes)

☐ New/revised advertising materials (attach - if revised, highlight changes)

**Do you have a conflict of interest on this project according to Brown's policy?** ☐ YES ☒ NO

**If YES, has this conflict been previously disclosed to the IRB?** ☐ YES ☐ NO

PI signature: \_\_\_\_\_



Date: 8/7/16

**1. Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project.**

The World Health Organization reported that suboptimal blood pressure (BP) is responsible for more than half of cardiovascular disease mortality world-wide. Furthermore, greater than half of those with hypertension have uncontrolled BP. A 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.” Evidence-based mindfulness interventions, including Mindfulness-Based Stress Reduction, may have some effects on blood pressure, where a recent meta-analysis and systematic review of 4 randomized controlled trials demonstrated significant effects, but evidence of heterogeneity in effect sizes. The methodologically highest quality studies had the smallest effect sizes (range 0-5 mmHg). Mindfulness-Based Stress Reduction (MBSR) has been customized to a number of disease processes, such as Mindfulness-Based Cognitive Therapy for patients with recurrent depression, and Mindfulness-Based Relapse Prevention for patients with substance use addictions. Effect sizes have been increased by customizing mindfulness interventions to diseases of interest. The same may be true for hypertension, however mindfulness interventions customized for prehypertensive/hypertensive patients have never been investigated. Until methodologically rigorous studies to evaluate customized interventions for hypertension are performed, we will not know if the observed preliminary effects of general mindfulness interventions on blood pressure reduction could be much more effective with a tailored approach. Consequently, we propose to conduct a stage I behavioral therapy intervention study to evaluate whether MBSR customized to prehypertensive and hypertensive patients has the potential to provide clinically relevant reductions in BP. Consequently the specific aims are:

**Stage 1a: Therapy Development/Manual Writing**

1. To outline and evaluate key novel elements of mindfulness-based hypertension therapy (MBHT), customized from the evidence-based MBSR. *We hypothesize that the most important novel element will be generation of mindfulness skills specifically applied to hypertension risk factors such as diet, physical activity, obesity, alcohol consumption and antihypertensive medication adherence.* This aim will be achieved using (1) focus groups of participants undergoing the MBHT behavioral intervention, (2) discussion with experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) prior to, and following pilot testing of MBHT in participants, and (3) clinical judgment of the investigators performing the intervention.
2. To determine effectiveness of MBHT on primary outcomes (systolic blood pressure, retention rates, recruitment rates, and adverse effects) and secondary outcomes (hypertension risk factors such as diet, physical activity, obesity, and antihypertensive medication adherence) in hypertension subgroups, specifically participants with (1) prehypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. Initial decisions about the targeted sample based on hypertension status will be made.
3. To develop an MBHT therapist manual and training program, including procedures for training, supervising, and evaluating therapists. Furthermore, acceptable therapist characteristics will be developed. The manual and training program will include themes such as specification of unique and common elements of MBHT vs. other interventions, description of interventions excluded from MBHT, and specification of key treatment parameters such as frequency and duration of treatment, session length, topics addressed, sequence of sessions, as well as therapist adherence and competency

measures. The MBHT training will consist of a therapist manual, a formal didactic training seminar, and at least one closely supervised training session.

*Stage 1b: Pilot Trial*

4. To determine whether a mindfulness-based hypertension therapy (MBHT) intervention, customized from the evidence-based MBSR, has promise to be an effective behavioral therapy for participants with hypertension and/or prehypertension. We will perform a randomized controlled pilot trial for MBHT vs. enhanced usual care control. *We hypothesize that MBHT will have adequate recruitment rates ( $\geq 10\%$  of prehypertensive/hypertensive participants invited from physicians' offices), fairly low drop out rates ( $< 15\%$ ), and medium effect sizes (e.g. 5-10 mmHg systolic BP) for reduction in blood pressure.*

These findings will provide publishable pilot data that will inform future randomized clinical trials that evaluate effects of MBHT on long-term changes in blood pressure vs. usual care and active control groups. *If proven effective, MBHT could be offered as a complementary program in the prehypertensive/hypertensive patient population that contributes to over half of the cardiovascular disease mortality world-wide.*

## **2. Provide a detailed description of the changes being requested (Use additional pages, if necessary):**

We are requesting the following changes...

- **Addition of two new questions to the Home Baseline Assessment** – We would like to add two new questions about hypertension (BP1\_1 and BP1\_2) to the home baseline assessment (see attached pdf with track changes). Please note that these questions would be administered during the Home Baseline assessment only. However, for participants who have already completed the baseline questionnaire, we would capture this information during their next follow up assessment.
- **Permission to provide financial compensation to participants who withdrew from the study intervention but are still willing to complete follow up assessments** – since the start of our study, we have had two participants who have decided to withdraw from the study after the start of the intervention. We would be interested in re-contacting these and future individuals who withdraw to invite them to participate in the follow up assessments and would like to be able to provide them with \$50 per follow up as an expression of gratitude for their time and effort.

## **3. State the reason (justification) for the requested amendment:**

Please see justifications in Section 2 above.

#### **4. What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

We do not anticipate any major changes to the risk/benefit ratio. Both of the new baseline questions are yes/no and take well under a minute to complete. Following up with participants who withdrew from the intervention about the possibility of completing the follow ups does not cause any significant additional risks. Study staff will be trained to remind participants that their participation is voluntary. Some individuals may have withdrawn from the study because of reasons related to their ability to complete the 9 week course, but may actually still be interested in participating in the research questionnaires. This would allow them that opportunity.

#### **5. Does the requested amendment require new documents or changes to the approved consent form or other documents?**

Yes. Changes to the Home Baseline Assessment (two new questions). See attached document with track changes – only p.43 was affected and is being attached.

#### **References**

<sup>1</sup> Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care. 1986;24 (1):67-74.

# HOME BASELINE ASSESSMENT

QUESTIONNAIRES ANSWERED BY PARTICIPANTS  
AT BASELINE (VIA ONLINE OR PAPER FORM)

## **Blood Pressure and Blood Pressure Medication Use**

### **The following questions are about blood pressure.**

BP1\_1. Does your blood pressure tend to be HIGHER when you have it measured in a clinical setting, such as a doctor's office? This is sometimes called "white coat hypertension."

- ☐ No  
☐ Yes → **SKIP TO BM1\_01**  
☐ I do not know  
☐ I prefer not to answer

BP1\_2. Does your blood pressure tend to be LOWER when you have it measured in a clinical setting, such as a doctor's office? This is sometimes called "masked hypertension."

- ☐ No  
☐ Yes  
☐ I do not know  
☐ I prefer not to answer

BM1\_01. Do you currently take medication for your blood pressure?

- ☐ Yes  
☐ No (if responding "no", please skip to the next page).

	Yes	No
BM1_02. Do you sometimes forget to take your blood pressure pills?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_03. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_04. Have you ever cut back or stopped taking your blood pressure medicine without telling your doctor because you felt worse when you took it?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_05. When you travel or leave home, do you sometimes forget to bring along your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_06. Did you take all your blood pressure medicine yesterday?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_07. When you feel like your symptoms are under control, do you sometimes stop taking your blood pressure medicine?	<input type="checkbox"/>	<input type="checkbox"/>
BM1_08. Taking blood pressure medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	<input type="checkbox"/>	<input type="checkbox"/>

BM1\_09. How often do you have difficulty remembering to take all your blood pressure medicine?

- ☐ Never/rarely  
☐ Once in a while  
☐ Sometimes  
☐ Usually  
☐ All the time

**Brown University**  
Research Protections Office  
Institutional Review Board  
**Modification Request**

**Date of Request:** 11/6/17 **Investigator's Name and Title:** Eric Loucks, PhD, Assistant Professor

**Study Title:** Mindfulness-based Blood Pressure Reduction (MB-BP) Study (#1412001171)

**Original Type of Review:** ☐ Exempt ☐ Expedited ☒ Full Board

- 1) **Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project.** (Attach summary to this form)

See attached summary

- 2) **Provide a detailed description of the changes being requested** (Use additional pages, if necessary):

See attached summary

- 3.) **State the reason (justification) for the requested modification.** (Use additional pages, if necessary):

See attached summary

- 4.) **What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

See attached summary

- 5.) **Does the requested modification require new documents or changes to the approved consent form or other documents?**

☒ Consent/assent documents (attach revised version with changes highlighted)

☒ New/revised instruments (attach - if revised, highlight changes)

☐ New/revised advertising materials (attach - if revised, highlight changes)

**Do you have a conflict of interest on this project according to Brown's policy?** ☐ YES ☒ NO

**If YES, has this conflict been previously disclosed to the IRB?** ☐ YES ☐ NO

PI signature: \_\_\_\_\_



Date: \_\_\_\_\_

11/6/17



**1. Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to evaluate the requested change(s) within the context of the overall project.**

Original lay summary providing broad overview of the project:

The World Health Organization reported that suboptimal blood pressure (BP) is responsible for more than half of cardiovascular disease mortality world-wide. Furthermore, greater than half of those with hypertension have uncontrolled BP. A 2009 Institute of Medicine report recommended prioritizing research to “Compare the effectiveness of mindfulness-based interventions (e.g. yoga, meditation, deep breathing training) and usual care in treating... cardiovascular risk factors.” Evidence-based mindfulness interventions, including Mindfulness-Based Stress Reduction, may have some effects on blood pressure, where a recent meta-analysis and systematic review of 4 randomized controlled trials demonstrated significant effects, but evidence of heterogeneity in effect sizes. The methodologically highest quality studies had the smallest effect sizes (range 0-5 mmHg). Mindfulness-Based Stress Reduction (MBSR) has been customized to a number of disease processes, such as Mindfulness-Based Cognitive Therapy for patients with recurrent depression, and Mindfulness-Based Relapse Prevention for patients with substance use addictions. Effect sizes have been increased by customizing mindfulness interventions to diseases of interest. The same may be true for hypertension, however mindfulness interventions customized for prehypertensive/hypertensive patients have never been investigated. Until methodologically rigorous studies to evaluate customized interventions for hypertension are performed, we will not know if the observed preliminary effects of general mindfulness interventions on blood pressure reduction could be much more effective with a tailored approach. Consequently, we propose to conduct a stage I behavioral therapy intervention study to evaluate whether MBSR customized to prehypertensive and hypertensive patients has the potential to provide clinically relevant reductions in BP. Consequently the specific aims are:

*Stage 1a: Therapy Development/Manual Writing*

1. To outline and evaluate key novel elements of mindfulness-based hypertension therapy (MBHT), customized from the evidence-based MBSR. *We hypothesize that the most important novel element will be generation of mindfulness skills specifically applied to hypertension risk factors such as diet, physical activity, obesity, alcohol consumption and antihypertensive medication adherence.* This aim will be achieved using (1) focus groups of participants undergoing the MBHT behavioral intervention, (2) discussion with experts (including cardiologists, epidemiologists, mindfulness experts, mindfulness intervention instructors) prior to, and following pilot testing of MBHT in participants, and (3) clinical judgment of the investigators performing the intervention.
2. To determine effectiveness of MBHT on primary outcomes (systolic blood pressure, retention rates, recruitment rates, and adverse effects) and secondary outcomes (hypertension risk factors such as diet, physical activity, obesity, and antihypertensive medication adherence) in hypertension subgroups, specifically participants with (1) prehypertension, (2) controlled hypertension, and (3) uncontrolled hypertension. Initial decisions about the targeted sample based on hypertension status will be made.
3. To develop an MBHT therapist manual and training program, including procedures for training, supervising, and evaluating therapists. Furthermore, acceptable therapist characteristics will be developed. The manual and training program will include themes such as specification of unique and common elements of MBHT vs. other interventions, description of interventions excluded from MBHT, and specification of key treatment

parameters such as frequency and duration of treatment, session length, topics addressed, sequence of sessions, as well as therapist adherence and competency measures. The MBHT training will consist of a therapist manual, a formal didactic training seminar, and at least one closely supervised training session.

*Stage 1b: Pilot Trial*

4. To determine whether a mindfulness-based hypertension therapy (MBHT) intervention, customized from the evidence-based MBSR, has promise to be an effective behavioral therapy for participants with hypertension and/or prehypertension. We will perform a randomized controlled pilot trial for MBHT vs. enhanced usual care control. *We hypothesize that MBHT will have adequate recruitment rates ( $\geq 10\%$  of prehypertensive/hypertensive participants invited from physicians' offices), fairly low drop out rates ( $< 15\%$ ), and medium effect sizes (e.g. 5-10 mmHg systolic BP) for reduction in blood pressure.*

These findings will provide publishable pilot data that will inform future randomized clinical trials that evaluate effects of MBHT on long-term changes in blood pressure vs. usual care and active control groups. *If proven effective, MBHT could be offered as a complementary program in the prehypertensive/hypertensive patient population that contributes to over half of the cardiovascular disease mortality world-wide.*

**Project update as of November 2017:**

The Mindfulness-Based Blood Pressure Reduction (MB-BP) Study, formerly known as Mindfulness-Based Hypertension Therapy (MBHT), is currently in Year 2 of a five year NIH UH2 grant.

Data collection for Stage 1a of the project has ended and analysis is on-going. In total we ran three separate Mindfulness-Based Blood Pressure reduction (MB-BP) intervention courses, with a total sample size of 43 eligible participants who both enrolled and completed the 9-week intervention. We had eight eligible participants enroll in the study who later decided to not complete the course.

In June 2017 we began enrollment for the next phase (referenced as Stage 1b above, but now called 'Stage 2a') of the study, which is to conduct a Randomized Controlled Trial (RCT) with *enhanced usual care*. This phase will continue for the next 12-18 months, at which point we will transition to the third and final phase, an RCT with an *active control* (i.e., Mindfulness-Based Stress Reduction - MBSR) as well as ambulatory blood pressure monitoring.

## 2. Provide a detailed description of the changes being requested (Use additional pages, if necessary):

This amendment covers the following four requests:

- (1) Qualitative Phone Interviews - First, we are requesting permission to modify the already approved focus group discussion questions into a one-on-one qualitative phone interview (see enclosed "Semi-structured qualitative phone interview"). Our intent is to then randomly select and re-contact Stage 1 participants, who did not participate in the focus group discussions, and invite them to take part in the one-on-one qualitative phone interviews instead. We would attempt to complete ten interviews. Participants who complete the phone interviews would be mailed \$25 gift cards for their time and effort. **Related enclosures: Appendices 1-3**
- (2) 2-year Follow Ups – Second, we would like to re-contact participants who completed the course and invite them to come back into the office for a quick two year in-person assessment. This optional assessment is estimated to take 20-30 minutes to complete and would be a small sub-set of what is already approved by the IRB (i.e., blood pressure, weight, hypertension medication questions, and mindfulness practice questions). Participants would be given \$50 USD for this additional component. For participants who have already been consented, we would have them sign the attached addendum to the consent form. For newly enrolled participants we would ask them to sign the attached revised consent form. It is already part of the approved study protocol and screening process to ask participants if we can keep their information on file to contact them about possible future studies or opportunities to participate in research. We would only re-contact participants who gave us permission to do so. **Related enclosures: Appendices 3-4**
- (3) Participant Compensation – Third, we are requesting permission to alter the order in which participants are compensated. As it is currently written, participants are given \$25, \$25, and \$50 USD at their 10 week, 6 month and 12 month follow ups respectively. We are seeking to reverse that order and instead provide participants \$50, \$25, and \$25 USD at their three follow ups. The total amount provided as compensation for participation would remain the same (\$100 USD). Participants already enrolled into the study would be compensated in the manner already outlined and approved. However, we are proposing that newly enrolled participants would be compensated under the new guidelines outlined in this amendment (if approved). See p.1 of the revised consent form for this change. **Related enclosure(s): Appendix 3**
- (4) Recruitment assistance for UMass fMRI sub-study – the MB-BP Study is one of several concurrent studies being funded under the NCCIH Science of Behavior Change UH2 project "Mindfulness Influences on Self-Regulation: Mental and Physical Health Implications." Our collaborators at the UMass medical school have recently received IRB approval from the UMass Medical School IRB to conduct a related clinical trial that involves fMRI imaging of MB-BP participants to evaluate several mechanistic self-regulation targets of the Mindfulness-based blood pressure therapy (MB-BP), their neural substrates, and their potential impact on autonomic system measures. Their proposed project (titled, Mindful Self-Regulation for blood pressure MRI study) involves recruiting, screening, enrolling, and scanning a sub-set of MB-BP participants (i.e., goal is to enroll and image 60 eligible MB-BP participants over the 12-18 months). Eligible participants who agree to take part in the fMRI study at UMass Medical School

will be invited to travel up to the UMass facility twice – once at baseline and once at the 10 week follow up period – to undergo two MRI sessions (~1.5 hours each). Participants will be compensated \$150 USD for each neuroimaging session. Note: see attached UMass Medical School IRB submission for the full version of their study protocol, informed consent form, phone screener, and IRB approval letter.

In this amendment we are requesting permission to approach newly enrolled MB-BP participants about the UMass Medical School fMRI study and to see if they would be interested in being contacted by the UMass medical school research staff to complete a brief 15-minute phone screener to determine their eligibility for the related neuroimaging study. To do this, Brown University research staff would use the attached “UMass Medical School fMRI Study Recruitment Talking Points” document. This document outlines the main features of the neuroimaging study and what participant involvement would entail. However, it is important to note that both the screening and the informed consent procedures will be conducted by UMass Medical School research staff and not by Brown University. Our role will be to introduce the fMRI study to our MB-BP participants and document their consent for UMass Medical School staff to contact them by phone for screening. We will only provide UMass Medical School research staff with the contact information of MB-BP participants who agree to be contacted regarding the neuroimaging study. Contact information of MB-BP participants who do not wish to be contacted by UMass will not be passed along. ***Related enclosures: Appendices 5-6***

### **3. State the reason (justification) for the requested amendment:**

- (1) The data collected in the proposed qualitative phone interviews will complement the qualitative data previously collected in the focus group discussions. It will also hopefully help to address any potential selection bias due to the more engaged and enthusiastic participants opting to take part in the focus group discussions.
- (2) Analysis of the one year follow up data has been very promising, showing sustained reductions in blood pressure and other important outcomes. There are very few research studies that explore sustained effects at 12 months or even 24 months. Recontacting participants to have them complete a 2 year follow up would offer novel research findings to the field of mindfulness and cardiovascular health.
- (3) We are proposing a change in the compensation protocol for two reasons. First, we believe that providing participants the larger sum for the first follow up rather than the last follow up will help with retention rates overall. We have often struggled to get participants to come in for the first follow up, particularly with members of the control group, who did not get the intervention. However, we have not had as much difficulty getting participants to complete their final follow up. We find that once individuals have already invested time to complete the first two follow ups, they are often intrinsically motivated to complete the final follow up and therefore don't require as much external motivation to participate. The second justification for altering the payment structure is that the 12 month data are not as important to the overall study and analyses as the 10 week data are.

- (4) The UMass Medical School Mindful Self-Regulation for blood pressure MRI study is a related concurrent study on the same UH2 grant that is funding MB-BP. Since it involves recruiting a sub-set of MB-BP participants it makes the most sense for the research staff at Brown University to be the individuals to recruit.

**4. What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

We do not anticipate any shifts in the risk / benefit ratio of the study. Participation in all aspects of the study is optional and will be explicitly stated at the time of recruitment and informed consent. This includes when approaching participants about potential involvement in the one on one qualitative phone interviews, 2 year follow ups, and possible participation in the fMRI study.

**5. Does the requested amendment require new documents or changes to the approved consent form or other documents?**

See enclosed attachments related to this amendment:

Appendix 1 - Protocol for semi-structured qualitative phone interview scripts and talking points.

Appendix 2 – Addendum to consent form to be signed by already enrolled participants

Appendix 3 – Revised Informed Consent (v.2.2) – with track changes

Appendix 4 – Two year in-person follow up assessment

Appendix 5 – UMass Medical School fMRI Study Recruitment Talking Points for research staff at Brown University to utilize

Appendix 6 – UMass Medical School IRB submission for fMRI sub-study

# **Appendix 1 - Semi-structured qualitative phone interviews**

*Created from the already approved focus group discussion  
protocol and modified to be relevant for a one-on-one  
qualitative phone interview.*

## MB-BP qualitative phone interview protocol

### Semi-Structured Script and Talking Points

"Hello, my name is \_\_\_\_\_ and I am calling from Brown University regarding the Mindfulness Based Blood Pressure Reduction Study that you took part in just over a year ago. As we begin to evaluate the intervention we would like to get a better understanding of what worked and didn't work by conducting personalized one-on-one phone interviews with yourself and other graduates of the program.

The interview would be done by phone, would take 20 minutes to a half an hour to complete, and could be scheduled at a time that is convenient for you. You would also receive a \$25 gift card for your time. Would you be willing to offer feedback on your experiences with the mindfulness program?"

#### TALKING POINTS –

- **Confidentiality:** As a reminder, everything you say will remain confidential. No one outside of our project will be able to see your answers and your name and other identifying information will not be used in any reports or publications.
- **Why and How?** "We are hoping to get your feedback about the mindfulness course and use it to make the program more effective. Please feel free to share your point of view and know that we welcome both positive and negative feedback. There are no right or wrong answers just your perspective about the program."

#### Important points:

- We are trying to improve the intervention
- Discussing your opinions on the different activities
- Please share your point of view
- No wrong answers
- We equally welcome positive and negative feedback
- **Suggestions:** "We would like to record this call with your permission so that it can be transcribed later by members of our team. If you would prefer not to be recorded, please let me know. Also, please understand that any report we write regarding your feedback and what we hear from you today will not be identified with you in any way and remains anonymous."
  - Suggestions to help us have a good discussion
    - Speak up
    - Audio recording if that is ok
    - Any report that we write about what we hear today will not be associated with your identity
- **What to expect:** "So before we begin I just want to let you know that we will be asking you a series of open ended questions. My role is listen and ask questions to better understand your experiences. So I might ask you for clarification or more detail about a comment but your thoughts are the important part of this discussion. However, in the interest of getting to all the questions I may need to move us along please know that this is only due to time considerations."
  - My role is to listen ask questions that help to understand your experience
  - In the interest of time, I may move to the next question to get your thoughts regarding the whole program

Any questions before we begin?

Discuss Class Overview: Each sessions central activity

"First I am going to read through a list of the major class activities you participated in. While I read through the activities I would like you to think about which was the most memorable for you and why."

"So, hearing the course activities, which is most memorable for you? Why?"

"Next I have a series of 4 questions for you about your experiences in the program."

1. What was most helpful about this course, and why?

2. After going through this mindfulness intervention, what is your understanding of how it works to improve your blood pressure?

3. We want to make this intervention better. You have been through it once. How do you think we can make it better?

4. Every instructor can improve. How can this instructor improve?

Read the survey: record responses.

- Each weekly session was 2.5 hours long. Do you think the session should be 2 hours, 2.5 or 3 and why?
- The retreat day was scheduled to be 7.5 hours long. How long do you think the day should be (5,6,7, or 8) and why?
- Please provide us with an additional feedback we may not have asked about at this time.

## **Appendix 2 -**

### **Addendum to Informed Consent**

*To be signed by participants who have already enrolled in the study and who opt to complete the optional two year follow up assessment*



**Brown University**

**Consent to Participate in a Research Study**

**Addendum to provide additional information to subject after original consent and to seek permission to complete a two year follow up assessment**

---

**IRB Study #** 1412001171

**Consent Form Version Date:** 12/6/2017

**Title of Study:** Mindfulness-Based Blood Pressure Reduction (MB-BP) Study

**Principal Investigator:** Eric B. Loucks, PhD

**Study Contact telephone number:** 401-400-4768

**Study Contact email:** mindfulness@brown.edu

---

The following information should be read as an addition to the original Consent form that you read and signed at the beginning of the study. Unless specifically stated otherwise in the following paragraphs, all information contained in that original Consent Form is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate, or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your health care provider.

**New or additional information**

You are being asked to participate in an optional two year follow up assessment that will take place in-person at the Brown University Mindfulness & Cardiovascular Health Lab located at 121 South Main Street, Providence, RI 02912. The two year follow up assessment is estimated to take around 20 to 30 minutes to complete and will consist of a subset of measures that you previously completed as a participant in the MB-BP Study. Specifically, we will be taking your blood pressure and weight as well as asking you a series of questions about hypertension medications and mindfulness practices.

**Subject's Agreement:**

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to continue to participate in this research study.

---

Signature of Research Subject

---

Date

---

Printed Name of Research Subject

---

Signature of Research Team Member Obtaining Consent

---

Date

---

Printed Name of Research Team Member Obtaining Consent

**Appendix 3 -**  
**Revised Informed Consent**  
**(v.2.2 – with track changes)**

*For newly enrolled participants to complete  
at time of screening. The revisions in this document cover  
the request to follow up at two years as well as the change  
in payment structure.*

# **The Mindfulness-Based Blood Pressure Reduction (MB-BP) Study**

## **Agreement to Participate in a Research Study**

### ***Investigation of the Effects of Mindfulness on Blood Pressure and Well-Being***

You are being asked to take part in a Brown University research study about the effects of mindfulness and hypertension education on blood pressure and risk factors for hypertension. This form will explain the purpose of the study, how the study will be carried out and what you will be expected to do. It will also explain the possible risks and possible benefits of being in the study. If any part of the following description is not clear to you, you are encouraged to contact the researcher to answer any questions before you decide whether to take part in the study. If you decide to participate, please fill out and sign the last page of this form.

#### **1a. Nature and Purpose of the Study**

The purpose of the study is to investigate the impact of mindfulness practices and health education on blood pressure. You have been selected for this study because you expressed interest in the project and because you met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program. Eligibility for the study is still being assessed. Therefore, it is possible you may not be eligible for the study even after signing this consent form. Your participation in this study is voluntary and can be withdrawn at any point in the project.

In order to assess the effects of the customized mindfulness intervention, you will be asked to complete some questionnaires and laboratory assessments before and after the intervention. Specifically, assessments will be completed at: baseline, 10 weeks, 6 months and 1 year. To express our gratitude for participation, you will be given ~~\$25~~<sup>\$50</sup>, \$25, and ~~\$50~~<sup>\$25</sup> (up to \$100 USD total) at the 10 week, 6 month and 12 month follow ups respectively. As part of the study you will also be given a wireless blood pressure monitor (estimated value of \$90) to use throughout the study. [There is an optional 2 year follow up that you may be invited to complete, for which you will be given an additional \\$50 USD.](#)

This is a Randomized Control Trial. Participants enrolled into the study will be randomly assigned to one of two groups: (1) the intervention group or (2) the wait-list control group. The wait-list control group will be given the opportunity to participate in the intervention after the six month follow up assessments are completed. Both the intervention and the control group will be asked to participate in the research assessments.

#### **1b. Explanation of Procedures**

If you agree to participate, you will be asked to consent to the following:

- 1) Participation in an interview in which you will be asked questions about past and present mental health, including depression and suicide (previously completed with your verbal consent).

- 2) Completion of an in-person screening assessment, during which your blood pressure, height, weight and other basic demographic and health data will be collected and assessed in order to determine eligibility for the study.
- 3) Completion of questionnaires administered in-person and online that ask about a wide range of topics, including your diet, physical activity, smoking, medication use, personality, emotions, attention and past experiences, including stressful or traumatic experiences. These questions will probe sensitive psychological areas, including physical, emotion and sexual abuse. These questionnaires may take up to 3 hours to complete. By completing the interviews and questionnaires, you are giving the researchers permission to use the information you have provided. You have the right not to answer any of the questions.
- 4) Directly assessed blood pressure, heart rate, height, weight, physical activity, and antihypertensive (blood pressure) medication use at baseline and after the mindfulness course. Physical activity will be assessed for a week at a time using small actigraphy monitors (i.e., Fitbits) that attach to your wrist. If you take antihypertensive medication, we will provide you with an electronic bottle cap that will automatically record when the pill bottle is opened during the study. This will help us measure how often the medication is used. We will also provide you with a wireless blood pressure monitor and will ask that you take your blood pressure at home systematically during each of the research assessment periods (i.e., baseline, 10 week, 6 month and 12 month).
- 5) You will be asked to perform some cognitive tasks. Some of these tasks may involve computer-based tests of attention or decision-making. Together these tests may take as long as 20 minutes.
- 6) During the in-person assessments you will also be given a battery of stress tests that are designed to induce a stress response so that we can monitor your cardiovascular response and recovery.
- 7) Attendance at an information session that is to be held within two weeks of the start of the intervention.
- 8) If randomized into the intervention group, you will participate in the mindfulness program, which consists of 9 weekly sessions of 2.5 hours each and will include one 7.5 hour weekend retreat. Daily at home practice assignments may take as long as one hour and consist of practicing mindfulness exercises with the aid of a guided meditations and completing worksheets related to stress, thoughts, and common reactions to various types of events. If you are randomized into the wait-list control group, you will be invited to take part in the mindfulness class after the completion of the 6 month follow up assessments.
- 9) Class sessions may be audio taped so we can analyze the quality of the treatment you receive. The recordings will be transcribed so that we may analyze the text. The recordings will be identified by study number, will only be heard by study staff and will be destroyed after transcription.

- 10) You may be asked to complete a few short questionnaires each week during the 9 week condition.
- 11) After 10 weeks from the start of the intervention, you will be asked to complete questionnaires and return to the laboratory to repeat the same procedures for a second day of testing. If in the intervention arm, you will also be invited to participate in a focus group to share any advice you may have on how to improve the intervention.
- 12) Six months and one year after the beginning of the study, you will be asked to return to the laboratory to repeat the same testing procedures.
- ~~12)~~13) In addition to the six month and one year follow up, you will also be re-contacted to participate in an optional, very brief two year follow up assessment. The two year follow up assessment is estimated to take around 20 to 30 minutes to complete and will consist of a subset of measures that you would have previously completed as a participant in the MB-BP Study. Specifically, we will be taking your blood pressure and weight as well as asking you a series of questions about hypertension medications and mindfulness practices. For this additional follow up you will be given \$50 USD.

**Table Summarizing Activities and Time Commitment for this Study.**

Activity	Estimated Time Commitment
In-person screening assessment	0.5 hours
Baseline	
In-person assessment	2.0 hours
Online questionnaire	1.0 hours
At home health monitoring (e.g., fitbit, BP, etc.)	1.0 hours
Information session	1.0 hour
Intervention*	
Mindfulness course	Nine 2.5 hour sessions
Home practice assigned during course	7.5 hour all day retreat
	Up to 1hr daily home practice assignments
	<i>Total course time: 30.0 hours</i>
	<i>Max. practice time: 48 hours</i>
Focus group participation post intervention ( <i>intervention group only</i> )	1.5 hours
Follow Ups – 10 week, 6 month, 12 month	Total follow up time:
In-person assessments	6.0 hours
Online questionnaires	3.0 hours
At home health monitoring (e.g., fitbit, BP, etc.)	3.0 hours
<a href="#">Follow Up – 2 year (in person only)</a>	<a href="#">30 minutes</a>
<b>TOTAL ESTIMATED TIME COMMITMENT</b>	<del>17.5</del> <u>18.0</u> hours – CONTROL 97. <del>0</del> <u>5</u> hours - INTERVENTION

### Feedback:

At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing % change (increase or decrease) on scales of attention, stress, mood, health behaviours, weight, and blood pressure across the study.

### Uncontrolled Hypertension:

If during the in-person assessments it appears that you have uncontrolled hypertension (your average systolic blood pressure reading is 140 mmHg or greater and/or your average diastolic blood pressure is 90 mmHg or greater) AND you indicate to us that you are not currently being treated for hypertension, then we will be requesting your permission to contact your health care provider to notify him/her of the blood pressure results. If you do not have a health care provider and/or do not have health insurance, our staff will provide you with resources to help you search for one; although we cannot guarantee that we will be able to find you one nor that it will be free. It is your choice on whether or not you would like us to follow up with your health care provider. Your participation in the study is not contingent on this communication; however, it is our recommendation that all individuals with uncontrolled hypertension be under the care of a health care professional.

## 2. Discomforts and Risks

The risks to you in this study are small. The questionnaires used in the study are routine, standardized forms for epidemiologic research. Certain questions may be upsetting as they may probe sensitive psychological areas and inquire about upsetting or traumatic events, including physical, sexual or emotional abuse and/or current psychiatric symptoms. The cognitive tests and stress battery may also invoke a stress response that may be uncomfortable. All aspects of the study are voluntary; you have the right to skip anything during the study that makes you uncomfortable.

Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience an initial increase in undesirable feelings with increased attention to them.

It is possible that injuries could be sustained during the study either from the gentle mindful movements (i.e., yoga), or from physical activities that participants engage in as a way to reduce blood pressure. To help limit this, you will receive a handout showing the yoga poses that will be offered during the course that you can show your health care provider so that they can advise on which poses to do, and which to avoid. Modifications of poses will be available as needed. None of the poses (or the yoga as a whole) are mandatory to be done. You will also be encouraged to explore physical activities that promote strength and conditioning as a way to reduce blood pressure. You will be encouraged to not go beyond any physical limits of your body, and will be encouraged to ask your healthcare provider about advised physical activities and mindful movements if you have any physical limitations.

While physical and mental injury is always a possibility the potential for harm is limited. Note that a research injury is any physical or mental injury or illness caused by your participation in

the study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and potential added medical expenses, it is important to follow all study directions carefully. If you are covered by insurance and suffer a research injury, it is possible that some or all of the costs of treating your condition could appropriately be billed to your insurance company. If such costs are not covered your health insurance company, it is possible you would have to pay for these costs out of pocket. Brown University's policies do not cover payment for such things as lost wages, medical care expenses, or pain and suffering.

Precautions should be taken to avoid injuries. If you do become injured during the study, you should call your doctor immediately. You should also alert the study staff that you have been injured. Heart attack and sudden death related to heart problems have been known to occur in people while they are exercising. This is very rare, however. Estimates of sudden cardiac death range from 0 to 2 per 100,000 hours. However, the researchers cannot guarantee that no complications will happen to you.

### 3. Benefits

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) receiving information about your psychological and physical functioning. As part of the study, you will receive a wireless blood pressure monitor that will be yours to keep. This monitor may provide additional opportunity to monitor your blood pressure at home, which may benefit your health by providing additional biofeedback.

### 4. Alternative Therapies

A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

### 5. Confidentiality

Your responses for this study will be kept confidential. All data that we collect will be linked to a study ID# instead of your name. All questionnaires in this study will be filled out through an online survey or a paper version of the survey if you prefer. All of these questionnaires will be linked solely to your study ID#, so that your identity is protected and your answers are confidential. Although these measures have been taken to protect your personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet.

While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then a collaborator (Dr. Ellen Flynn) who is a licensed psychiatrist, may contact you to discuss your responses and possible referral to a treatment provider. Questionnaire items that may warrant follow-up include endorsements of statements about



hurting yourself, any high scores in depression, anxiety, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires researchers to report abuse or neglect of people age 60 and older to the Division of Elderly Affairs.

The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a unique code number and initials. All study records and specimens will be stored in a secure storage area.

*Keeping study records:* The Principal Investigator for this study will keep your research records indefinitely for research purposes.

*Certificate of Confidentiality:* This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Center for Complementary and Integrative Health, which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of situations of child abuse and neglect, or harm to self or others.

## 6. Refusal/Withdrawal

Participation is voluntary, and you may decide to opt out or refuse any part of participation, including not answering certain questions. If you decide now to participate, you can change your mind later and quit the study. The decision to not participate or to withdraw from the study will not adversely affect current or future interactions with Brown University. The decision to not participate or to withdraw from the study will also not adversely affect your relationship with your physician.

If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

## 7. Contact Information

If you have questions about study procedures at any time you may contact the researchers: Dr. Eric B. Loucks, email: [eric.loucks@brown.edu](mailto:eric.loucks@brown.edu), telephone (401) 863-6283. If you would like more information about the rules for research studies, or the rights of people who take part in those studies, you may contact the Brown University Human Research Protection Program, telephone number 1-866-309-2095 or 401-863-3050.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**CONSENT FORM:**  
**Please sign and return.**

Please read the following agreement and sign to consent to participating.

**I HAVE READ THE ABOVE DESCRIPTION OF THIS STUDY. ALL OF MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED, AND, I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY.**

\_\_\_\_\_  
PRINT NAME

\_\_\_\_\_  
Signature of participant

\_\_\_\_\_  
Date

**STUDY PARTICIPANT CONTACT INFORMATION**

Name (print): \_\_\_\_\_

Permanent Address: \_\_\_\_\_

Email(s): \_\_\_\_\_

Telephone: \_\_\_\_\_ (cell) \_\_\_\_\_ (other)

**Appendix 4 -  
Two year in-person follow up  
assessment**

*Estimated to take 20-30 minutes to complete and consists  
of a subset of already approved measures*

# MB-BP STUDY: 2 YEAR IN PERSON FOLLOW UP ASSESSMENT

PID. Participant ID # \_\_\_\_\_  
BA01. Staff ID # \_\_\_\_\_  
BA02. Today's date (MMDDYY): \_\_\_\_\_

Blood Pressure:

BA03a. Blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03b. Blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03c. Blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03d. Blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA03e. Blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA03f. Blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

***If the difference of the 2<sup>nd</sup> and 3<sup>rd</sup> systolic BP reading is 20 mmHg or greater OR the difference of the 2<sup>nd</sup> and 3<sup>rd</sup> diastolic reading is 10 mmHg or greater, then repeat the BP readings. Otherwise, skip to BA07.***

BA06a. Repeated blood pressure 1<sup>st</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06b. Repeated blood pressure 1<sup>st</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06c. Repeated blood pressure 2<sup>nd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06d. Repeated blood pressure 2<sup>nd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg  
BA06e. Repeated blood pressure 3<sup>rd</sup> reading, systolic blood pressure: \_\_\_\_\_ mmHg  
BA06f. Repeated blood pressure 3<sup>rd</sup> reading, diastolic blood pressure: \_\_\_\_\_ mmHg

Blood Pressure Safety Protocol – The out-of-range blood pressure values are as follows: systolic blood pressure >200 mmHg or <90 mmHg; diastolic blood pressure >110 mmHg.

In absence of symptoms (chest pain, shortness of breath, dizziness, headache), for a SBP>200 or DBP>110 or both, we will strongly encourage participants to see their doctor right away or to go to urgent care. If there are symptoms, we will immediately call 911.

In absence of symptoms (chest pain, shortness of breath, dizziness, passing out), for a SBP<90, we will strongly encourage participants to see their doctor right away or to go to urgent care. If there are symptoms, we will immediately call 911.

Follow Safety Protocol for Uncontrolled Hypertension (140/90 mmHg or greater)

BA07. Blood pressure cuff size used: ☐ S ☐ Reg ☐ L ☐ XL  
BA08. Arm that cuff was placed on: ☐ L ☐ R

BP monitor BP monitor used:

- ☐ Unit #1 - HEM-705CP (1)  
☐ Unit #2 - HEM-705CP (2)  
☐ Other (specify: (3) \_\_\_\_\_

**We are now going to take your weight.** Have ppt remove his/her shoes and empty his/her pockets. Remove bulky clothing as well.

BA10. Weight: \_\_\_\_\_ . \_\_\_\_ lb (one decimal place)

## **Medications (ME)**

**The next questions are about medications used to treat hypertension or high blood pressure.**

ME01. Not including vitamins and supplements, do you currently take any prescription medications or over-the-counter drugs for high blood pressure?

☐ No

☐ Don't know

☐ Yes

☐ Prefer not to answer

ME01a IF NO, Have you ever taken medication for high blood pressure?

☐ No → *skip to end of medications questions*

☐ Yes → *skip to end of medications questions*

**If you brought your medications with you, please take them out now as we will use them to complete the next section.**

ME01b INTERVIEWER CHECKPOINT - Please select one:

☐ Rx info not known or available – *skip to end of ME questions; will need to follow up*

☐ Ppt brought medications -- *continue*

☐ Ppt did not bring medications but knows info – *continue, may need follow up*

ME01c In total how many different medications and/or over the counter drugs do you currently take for high blood pressure? Again, do not count vitamins or supplements. \_\_\_\_\_ # of BP meds

**Next we're going to ask you questions about each of the medications you currently take for high blood pressure.**

ME02-10a. What is the name of the first prescription medication or over-the-counter drug that you take?

\_\_\_\_\_  
☐ Don't know

☐ Prefer not to answer

ME02-10b. What is the dosage form?

### Oral

☐ Pill, tablet, or capsule

☐ Sublingual or orally-disintegrating tablet

☐ Liquid solution or suspension (drink, syrup)

☐ Powder

### Topical

☐ Liquid, cream, gel, or ointment

☐ Ear drops (otic)

☐ Eye drops (ophthalmic)

☐ Skin patch (transdermal)

### Inhaled

☐ Inhaler or nebulizer

### Injected

☐ Injection

### Suppository

☐ Rectal (e.g., enema)

☐ Vaginal (e.g., douche, pessary)

### Other:

☐ Other \_\_\_\_\_

☐ Don't know

☐ Prefer not to answer

ME02-10c. How frequently do you take it?

- ☐ \_\_\_\_\_ times per day
- ☐ \_\_\_\_\_ times per week
- ☐ \_\_\_\_\_ times per month
- ☐ Don't know
- ☐ Prefer not to answer

ME02-10d. What is the strength? (*Record strength of how it is actually taken, not how it is prescribed.*) \_\_\_\_\_ %

- ☐ \_\_\_\_\_ mg
- ☐ \_\_\_\_\_ mcg
- ☐ \_\_\_\_\_ grams
- ☐ \_\_\_\_\_ I.U.
- ☐ \_\_\_\_\_ Other unit: \_\_\_\_\_
- ☐ Don't know
- ☐ Prefer not to answer

ME02-10f. Do you take it regularly or only as needed?

- ☐ Regularly
- ☐ Only as needed
- ☐ Don't know
- ☐ Prefer not to answer

ME02-10g. For how long have you been taking it?

- ☐ For \_\_\_\_\_ days
- ☐ For \_\_\_\_\_ weeks
- ☐ For \_\_\_\_\_ months
- ☐ For \_\_\_\_\_ years
- ☐ Don't know
- ☐ Prefer not to answer

ME02-10h. What is the medication used for?

- ☐ High blood pressure
- ☐ Prescribed for something other than high blood pressure but also acts as a hypertensive medication (*describe:* \_\_\_\_\_)

ME02-10i. **Interviewer comments:**

---

*Repeat for all blood pressure medications the participant is currently taking.*

**Self-report scales for participant to complete:**

**PROMIS Global Health Scale v.1.2** – *standardized scale (found on proceeding pages)*

**SLEEP** – *1 question only taken from the Pittsburgh Sleep Quality Index*

**Mindful Attention Awareness Scale (MAAS)** - *standardized scale (found on proceeding pages)*

**Five Facet Mindfulness Questionnaire (FFMQ)** - *standardized scale (found on proceeding pages)*

**SART and Mindfulness Practice questions** *found on proceeding pages*



## Global Health

Please respond to each question or statement by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is: .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global02	In general, would you say your quality of life is: .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global03	In general, how would you rate your physical health? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global04	In general, how would you rate your mental health, including your mood and your ability to think? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global06	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.).....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global07	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair? .....	Completely	Mostly	Moderately	A little	Not at all
Global08		<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1

22 August 2016

© 2010-2016 PROMIS Health Organization and PROMIS Cooperative Group

Page 1 of 2

In the past 7 days...		Never	Rarely	Sometimes	Often	Always						
Global10r	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1						
		None	Mild	Moderate	Severe	Very severe						
Global08r	How would you rate your fatigue on average? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1						
Global07r	How would you rate your pain on average? .....	<input type="checkbox"/> 0 No pain	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10 Worst pain imaginable

**SLEEP** - The following question relates to your usual sleep habits during the past month only. Your answer should indicate the most accurate reply for the majority of days and nights in the past month.

SL1\_04. **During the past month**, how many hours of actual sleep did you get on average at night? (This may be different than the number of hours you spent in bed.)

AVERAGE HOURS OF SL1\_EEP PER NIGHT \_\_\_\_\_

- ☐ I do not know
- ☐ I prefer not to answer

**MAAS Instructions:** Below is a collection of statements about your everyday experience. Using the scale below, please indicate how frequently or infrequently you currently have each experience. Please answer according to what really reflects your experience rather than what you think your experience should be. Please treat each item separately from every other item.

*Please indicate the degree to which you agree with each of the following items using the scale below. Simply check your response to each item*

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost never
MA1_01. I could be experiencing some emotion and not be conscious of it until some time later.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_02. I break or spill things because of carelessness, not paying attention, or thinking of something else.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_03. I find it difficult to stay focused on what's happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_04. I tend to walk quickly to get where I'm going without paying attention to what I experience along the way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_05. I tend not to notice feelings of physical tension or discomfort until they really grab my attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_06. I forget a person's name almost as soon as I've been told it for the first time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Almost always	Very frequently	Somewhat frequently	Somewhat infrequently	Very infrequently	Almost Never
MA1_07. It seems I am “running on automatic” without much awareness of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_08. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_09. I get so focused on the goal I want to achieve that I lose touch with what I am doing right now to get there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_10. I do jobs or tasks automatically, without being aware of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_11. I find myself listening to someone with one ear, doing something else at the same time.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_12. I drive places on “automatic pilot” and then wonder why I went there.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_13. I find myself preoccupied with the future or the past.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_14. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MA1_15. I snack without being aware that I’m eating.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**FFMQ** - Please rate each of the following statements using the scale provided. Write the number in the blank that best describes *your own opinion* of what is *generally true* for you.

	1 – Never or very rarely true	2 – Rarely true	3 – Sometimes true	4- Often true	5 – Very often or always true
FF1_01. When I'm walking, I deliberately notice the sensations of my body moving.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_02. I'm good at finding words to describe my feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_03. I criticize myself for having irrational or inappropriate emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_04. I perceive my feelings and emotions without having to react to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_05. When I do things, my mind wanders off and I'm easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_06. When I take a shower or bath, I stay alert to the sensations of water on my body.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_07. I can easily put my beliefs, opinions, and expectations into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_08. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_09. I watch my feelings without getting lost in them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_10. I tell myself I shouldn't be feeling the way I'm feeling.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_12. It's hard for me to find the words to describe what I'm thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_13. I am easily distracted.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_15. I pay attention to sensations, such as the wind in my hair or sun on my face.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	1 – Never or very rarely true	2 – Rarely true	3 – Sometimes true	4- Often true	5 – Very often or always true
FF1_16. I have trouble thinking of the right words to express how I feel about things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_17. I make judgments about whether my thoughts are good or bad.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_18. I find it difficult to stay focused on what’s happening in the present.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_19. When I have distressing thoughts or images, I “step back” and am aware of the thought or image without getting taken over by it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_21. In difficult situations, I can pause without immediately reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_22. When I have a sensation in my body, it’s difficult for me to describe it because I can’t find the right words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_23. It seems I am “running on automatic” without much aware- ness of what I’m doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_24. When I have distressing thoughts or images, I feel calm soon after.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_25. I tell myself that I shouldn’t be thinking the way I’m thinking.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_26. I notice the smells and aromas of things.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_27. Even when I’m feeling terribly upset, I can find a way to put it into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_28. I rush through activities without being really attentive to them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	1 – Never or very rarely true	2 – Rarely true	3 – Sometimes true	4- Often true	5 – Very often or always true
FF1_29. When I have distressing thoughts or images, I am able just to notice them without reacting.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_32. My natural tendency is to put my experiences into words.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_33. When I have distressing thoughts or images, I just notice them and let them go.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_34. I do jobs or tasks automatically without being aware of what I'm doing.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_35. When I have distressing thoughts or images, I judge myself as good or bad depending what the thought or image is about.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_36. I pay attention to how my emotions affect my thoughts and behavior.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_37. I can usually describe how I feel at the moment in consider- able detail.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_38. I find myself doing things without paying attention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FF1_39. I disapprove of myself when I have irrational ideas.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

## Sustained Attention to Response Task

*The Sustained Attention to Response Task (SART) is a computerized test of sustained attention, response inhibition (executive function) and self-regulation. Subjects are instructed to press a key in response to rapidly displayed integers (1-9) and withhold response to a designated "no-go" integer. SART errors consist of summed commission errors (button press on no-go trial) and omission errors (button not pressed on "go" integers). SART performance is associated with prefrontal cortex functioning, has been found to increase with mindfulness training and is correlated with scores on mindfulness questionnaires (specifically, the Mindful Attention Awareness Scale).*

MP1\_01 Think about the last 12 months. During that time, have you practiced mindfulness, either formally or informally, in any way?

No ..... 0 **(Skip to MP1\_03)**  
 Yes ..... 1

On average, how minutes PER WEEK do you engage in the following types of mindfulness activities?	Average # Minutes per week	Less than weekly	Don't Know	Prefer not to answer
MP1_02a Body Scan .....	_____	666	777	888
MP1_02b Yoga .....	_____	666	777	888
MP1_02c Awareness of breath meditation .....	_____	666	777	888
MP1_02d Sitting Meditation .....	_____	666	777	888
MP1_02e Walking Meditation .....	_____	666	777	888
MP1_02f Loving-kindness Meditation .....	_____	666	777	888
MP1_02g Mountain Meditation .....	_____	666	777	888
MP1_02h Visual Meditation .....	_____	666	777	888
MP1_02i Eating Meditation .....	_____	666	777	888
MP1_02j Meditation moving through regions, such as breath, physical sensations, sound, thoughts, and open awareness .....	_____	666	777	888
MP1_02k Goal-related activity (e.g., physical activity, diet change, etc.). Please describe .....	_____	666	777	888



MP1_02I Other mindful activities:				
Other 1 <i>describe</i> : _____		666	777	888
Other 2 <i>describe</i> : _____	_____			
Other 3 <i>describe</i> : _____				

MP1\_03 Which of the following statements, BEST describes your current attitude towards mindfulness?

- I do not plan on practicing mindfulness .....1  
 I see value in mindfulness but do not practice it regularly.....2  
 I practice mindfulness regularly .....3  
 Other (*please describe* \_\_\_\_\_).....4  
 Don't Know .....7  
 Prefer not to answer.....8

MP1\_04 Which of the following, if any, have you participated in [since completing the course / the last six months]?

*None, I have not practiced mindfulness* ..... 00

*Check ALL that apply*

- MB-BP Study Regular 1-1.5 hour Booster Sessions ..... [ ]  
 MB-BP Study All Day Retreats.....[ ]  
 Meditation group *not* related the MB-BP Study .....[ ]  
 Mindful yoga group *not* related the MB-BP Study .....[ ]  
 Other 1 *describe*: \_\_\_\_\_ .....[ ]  
 Other 2 *describe*: \_\_\_\_\_ .....[ ]  
 Other 3 *describe*: \_\_\_\_\_ .....[ ]  
 Don't Know..... 77  
 Prefer not to answer..... 88

MP1\_05 We are interested in the ways in which mindfulness practice may or may not impact your life. Please describe below your relationship to mindfulness since completing your course.

- Don't Know .....7  
 Prefer not to answer.....8

**Appendix 5 -**  
**UMass Medical School fMRI Study**  
**Recruitment Talking Points**

*This form will be utilized by research staff at Brown University to approach MB-BP participants about possible involvement in a related sub-study*

## Recruitment Talking Points for UMass Medical School fMRI sub-study

*As a participant in the Mindfulness-based Blood Pressure Reduction (MB-BP) you may be eligible to take part in a related clinical trial that involves receiving two separate brain scans or functional magnetic resonance imaging (fMRI) of your brain. Participation in this additional study is entirely optional and will not affect your ability to participate in the MB-BP study in any way. Would you be interested in hearing more about the study?*

If Yes - Go over study details below with participant.

- This sub-study is being conducted by investigators at the UMass Medical School and is funded by the same NIH grant that is funding the MB-BP Study.
- Eligible participants who enroll in the fMRI study will be compensated \$150 USD for each neuroimaging session (\$300 USD total) completed.
- Neuroimaging will take place at the UMass Medical School at the Center for Comparative Neuroimaging (CCNI).
- Travel to and from UMass Medical School from Providence, Rhode Island is around 100 minutes (82 miles) round trip. Part of the compensation is intended to cover the cost of travel. There is free parking available for participants. If a participant does not have his/her own mode of transportation, study staff can arrange for transportation (e.g., Uber).
- Each participant will have two visits to UMass Med School Campus - before and after the MB-BP intervention (Visit 1 and 2, respectively). Each visit will include an MRI scan and is expected to last approximately 2 hours.
- Eligibility for the fMRI study will be determined by the research staff at UMass Medical school by completing a brief (15 minute) phone interview. However, some of the exclusion criteria include but are not limited to: contraindication(s) to entering the MR scanner such as the presence of metal in or on the body that cannot be removed or claustrophobia; pregnancy or trying to get pregnant; and a body weight of over 300 lbs.
- Informed consent will take place at UMass Medical School in person and all study procedures will be carried out by UMass research staff.
- The goal of this research is to determine the mental and neural mechanisms implicated in the modulation of blood pressure (associated with cardiovascular risk) by the adoption of a mindfulness-based blood pressure therapy.
- They are looking to enroll and scan up to 60 individuals from the MB-BP study.

*Would you be interested in being contacted by the research staff at the UMass Medical School regarding this study? Note that by saying yes you'd only be agreeing to allow us to pass along your contact information so that someone at CCNI could call you for the 15-minute phone screener. We are not asking you to sign up at this time.*

**Appendix 6 -  
UMass Medical School IRB Submission  
for fMRI sub-study**

*This includes the study protocol, informed consent form,  
phone screener, questionnaire, and IRB Approval*

Appendix 6A -  
Study Protocol for UMass Medical  
School fMRI sub-study

## INVESTIGATOR STUDY PLAN - REQUIRED

### 1. TITLE

# **Mindfulness Influences on Self-Regulation:** **Mental and Physical Health Implications for blood pressure** **(Mindful Self-Regulation for blood pressure MRI study)**

### 2. EXTERNAL IRB REVIEW HISTORY\*

NA

### 3. PRIOR APPROVALS:

Participants recruited will be from those eligible participants already enrolled in a project for mindfulness intervention for blood pressure ongoing at Brown University (Dr. Eric Loucks), entitled Mindfulness-Based Blood Pressure Reduction (MB-BP) Study (formerly known as Mindfulness-Based Hypertension Therapy (MBHT)).

There are no conflicts of interest, medical devices, biohazardous agents, or radiation.

### 4. OBJECTIVES\*

The goal of this research is to determine the mental and neural mechanisms implicated in the modulation of blood pressure (associated with cardiovascular risk) by the adoption of a mindfulness-based blood pressure therapy. All Participants, pre-selected based on Brown University MB-BP study enrollment, will have met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program. We aim to assess the neural correlates of mindfulness training on self-regulation, specifically inhibitory control, self-compassion, interoceptive attention, and emotion regulation, in these chronic disease patients.

We hypothesize that the blood pressure changes induced by the tailored mindfulness-based intervention will be associated with the differential engagement of brain regions implicated in emotional self-regulation. Specifically, we hypothesize that alterations both in resting state brain function and evoked upon prompts such as interoceptive attention, self-compassion, and inhibitory control will notably be linked to physiological measures of the autonomic system. We hypothesize that the altered cardiovascular risk measures can be understood through using advanced neuroimaging techniques such as functional connectivity and diffusion tensor imaging.

### 5. BACKGROUND\*

Self-regulation, or the ability to intentionally manage cognitive and emotional resources to accomplish goals, is crucial to addressing a wide range of health problems influenced by common behaviors, such as excessive eating, lack of physical activity, addiction, and poor adherence to medical regimens. Mindfulness interventions have initial evidence to influence self-regulation, however it is still poorly understood what specific elements of mindfulness interventions are most effective at influencing self-regulation, and if those changes in self-regulation translate into clinically

## INVESTIGATOR STUDY PLAN - REQUIRED

meaningful health behavior changes, such as improved medical regimen adherence. This study proposes to test the ability of customized mindfulness interventions to alter self-regulation in an ongoing study.

Mindfulness training is an evidence-based approach to patient-centered caring<sup>1</sup> and whole-person self-management.<sup>2</sup> Mindfulness is “the awareness that emerges through purposely, and non-judgmentally, paying attention to the unfolding of experience moment-by-moment”.<sup>3</sup>

Developed at the University of Massachusetts Medical School by Jon Kabat-Zinn, Saki Santorelli, and colleagues, Mindfulness-based Stress Reduction (MBSR) is an 8-week program that serves as the basis for multiple different condition-specific mindfulness-based interventions (MBI) provided in medical settings.<sup>4</sup> In 2013, National Institutes of Health invested 44.3 million U.S. dollars into direct funding for MBI research (NIH Reporter 2014), and publications related to mindfulness-related research have exponentially increased over the past 30 years, with more than 500 publications in 2013 alone.<sup>5</sup>

Multiple clinical trials have demonstrated that MBIs improved self-management in major areas of community health and chronic illness management.<sup>6,7</sup> One recent meta-analysis demonstrated that MBIs are broadly effective for anxiety, depression, and pain.<sup>8</sup> MBIs are associated with tobacco smoking reduction,<sup>9,10</sup> reduction in alcohol consumption,<sup>11,12</sup> reduction in prescription opioid misuse among patients with chronic pain<sup>13</sup> and reduced HIV-risk behaviors.<sup>14</sup> MBIs demonstrate increased asthma-related quality of life with reductions in stress and anxiety.<sup>15</sup> MBIs produce a reduction in systolic and diastolic blood pressure in patients with pre-hypertension,<sup>16</sup> and particularly large reductions in hypertension have been seen within studies of African-American patients.<sup>17,18</sup> Among patients with non-insulin dependent diabetes, one small MBI study demonstrated improved glycemic control,<sup>19</sup> while large studies with active controls have demonstrated effective integration of diabetes self-management skills,<sup>20</sup> decreased stress and improved quality of life.<sup>21</sup> MBIs can reduce the stress associated with chronic illness,<sup>6,7</sup> and they are particularly effective in reducing depressive relapse in Major Depressive Disorder.<sup>22</sup>

Despite all the evidence supporting MBIs, several gaps in the current research and models may be acting as barriers to rapid dissemination and integration of mindfulness into the healthcare delivery system. First, while a multitude of patient studies showing reductions in stress, pain, anxiety, and depression exist, little is known about any impact on the ability to self-manage and cope with chronic illness—although there is initial evidence for positive outcomes on these measures. Second, this study offers an opportunity to identify and test mechanistic self-regulation targets (physiologic, psychological, neuropsychological, etc.) that are influenced by mindfulness, in the context of a chronic medical condition.

The project has been funded as a core clinical trial for the NCCIH Science of Behavior Change UH2 project “Mindfulness Influences on Self-Regulation: Mental and Physical Health Implications.” We will conduct an experimental MRI study to evaluate several mechanistic self-regulation targets of the Mindfulness-based blood pressure therapy (MB-BP), their neural substrates, and their potential impact on autonomic system measures.

The 8-week, 9-session MB-BP curriculum (approved for ongoing study at Brown University) is based on systematic and intensive training in mindfulness meditation and mindful hatha yoga.

## INVESTIGATOR STUDY PLAN - REQUIRED

The curriculum, which is based on the manualized and standardized MBSR curriculum, is designed to teach program participants how to integrate and apply mindfulness in their everyday lives to the range of challenges arising from medical and psychological conditions and life stresses. Furthermore, this program has been further customized to participants that have prehypertension or hypertension.

Embedded within the context of behavioral medicine, the MB-BP curriculum focuses on the experiential cultivation of both “formal” and “informal” mindfulness practices as a foundation for the cultivation of positive health behaviors and psychological and emotional resilience that can be effectively utilized across the adult life span. The approach supports the learning, strengthening and integration of a range of mindfulness-based self-regulatory skills through the development and refinement of inherent internal resources. A primary aim is to cultivate ways of learning and being that can be utilized far beyond the completion of the program.

MB-BP builds a foundation of mindfulness skills (e.g. meditation, self-awareness, etc.) through the MBSR curriculum. MB-BP then directs attention towards hypertension risk factors. Early in the MB-BP, the importance of hypertension for health and mortality is described, along with hypertension risk factors. Participants will have their blood pressure and hypertension risk factors assessed at baseline, and be provided with this information during the first in-person MB-BP session. This phase aims to engage participants’ interest in hypertension risk factors, and increase motivation for behavior change. MB-BP encourages participants to explore personal readiness for change in the different hypertension risk factors, and explore utilizing mindfulness practices to engage with those risk factors that they choose to. Each week, focus is provided on different hypertension risk factors. However, common themes exist across all hypertension risk factors including (1) awareness of thoughts, emotions and physical sensations particularly surrounding hypertension risk factors such as overconsumption of palatable foods, sedentary activities, alcohol consumption, medication adherence; (2) craving, particularly for hypertension risk factors such as overconsumption of palatable foods, sedentary activities, and alcohol consumption; (3) the impact of bringing mindfulness to every moment, particularly in relation to hypertension risk factors. For example, when consuming highly palatable food, bringing awareness to the emotions, thoughts and physical sensations prior to eating it, during eating it, along with the many minutes, if not hours, afterwards. Participants are trained to bring non-judgmental attention to the often short-term pleasure of overconsumption of foods, sedentary activities, heavy alcohol consumption, or not taking medications, and bring non-judgmental attention to the longer term suffering associations with these activities. Through this process, participants are encouraged to reflect on if behavioral choices provide more benefit or harm to their well-being, and to choose the behaviors that bring benefit. (4) Self-care: as awareness of thoughts, emotions and physical sensations increases, and self-regulation will likely increase as a result of the meditation practices, the curriculum will emphasize to participants that it is common for people to start caring for themselves more. It is a way of better knowing ourselves, and through knowing ourselves in each moment, we often want to care for ourselves in each moment. This may mean taking medication that will help our health, or being more physical active, eating more healthily, or consuming more moderate amounts of alcohol. The intervention can be modified to change the dose of any of these 4 components, for example via (1) Increased use of specific meditations focused on health behaviors such as diet and physical activity. (2) Increased use of meditations focused on craving. Participants will be trained to notice craving



## INVESTIGATOR STUDY PLAN - REQUIRED

arising, and fading away in relation to hypertension risk factors such as palatable high caloric foods, sedentary activities, and alcohol consumption. (3) Increased use of mindfulness practices related to long term experiences of health behaviors such as alcohol consumption, diet, physical activity and medication use on thoughts, emotions, physical sensations and well-being. (4) Self-care: Increased use of modules that show how mindfulness practice increased self-awareness and in doing so can increase people's desire to care for themselves. The potential use of loving kindness meditation will be considered.

## REFERENCES

1. Krasner, M.S., R.M. Epstein, H. Beckman, A.L. Suchman, B. Chapman, C.J. Mooney, and T.E. Quill, *Association of an educational program in mindful communication with burnout, empathy, and attitudes among primary care physicians*. *Jama*, 2009. **302**(12): p. 1284-1293.
2. Benzo, R.P., *Mindfulness and motivational interviewing: two candidate methods for promoting self-management*. *Chronic respiratory disease*, 2013. **10**(3): p. 175-182.
3. Kabat-Zinn, J., *Wherever you go, there you are: Mindfulness meditation in everyday life*. 1994, Hyperion: New York. p. 277.
4. Cullen, M., *Mindfulness-based interventions: An emerging phenomenon*. *Mindfulness*, 2011. **2**(3): p. 186-193.
5. Black, D., *Research publications on mindfulness*. 2014.
6. Merkes, M., *Mindfulness-based stress reduction for people with chronic diseases*. *Australian Journal of Primary Health*, 2010. **16**(3): p. 200-210.
7. Niazi, A.K. and S.K. Niazi, *Mindfulness-based stress reduction: a non-pharmacological approach for chronic illnesses*. *North American journal of medical sciences*, 2011. **3**(1): p. 20.
8. Goyal, M., S. Singh, E.M. Sibinga, N.F. Gould, A. Rowland-Seymour, R. Sharma, Z. Berger, D. Sleicher, D.D. Maron, and H.M. Shihab, *Meditation programs for psychological stress and well-being: a systematic review and meta-analysis*. *JAMA internal medicine*, 2014. **174**(3): p. 357-368.
9. Brewer, J.A., S. Mallik, T.A. Babuscio, C. Nich, H.E. Johnson, C.M. Deleone, C.A. Minnix-Cotton, S.A. Byrne, H. Kober, and A.J. Weinstein, *Mindfulness training for smoking cessation: results from a randomized controlled trial*. *Drug and alcohol dependence*, 2011. **119**(1): p. 72-80.
10. Bowen, S., K. Witkiewitz, S.L. Clifasefi, J. Grow, N. Chawla, S.H. Hsu, H.A. Carroll, E. Harrop, S.E. Collins, and M.K. Lustyk, *Relative efficacy of mindfulness-based relapse prevention, standard relapse prevention, and treatment as usual for substance use disorders: a randomized clinical trial*. *JAMA psychiatry*, 2014. **71**(5): p. 547-556.
11. Garland, E.L., N.R. Schwarz, A. Kelly, A. Whitt, and M.O. Howard, *Mindfulness-oriented recovery enhancement for alcohol dependence: Therapeutic mechanisms and intervention acceptability*. *Journal of social work practice in the addictions*, 2012. **12**(3): p. 242-263.
12. Ostafin, B.D., K.T. Kassman, and I. Wessel, *Breaking the cycle of desire: Mindfulness and executive control weaken the relation between an implicit measure of alcohol*

## INVESTIGATOR STUDY PLAN - REQUIRED

- valence and preoccupation with alcohol-related thoughts*. Psychology of addictive behaviors, 2013. **27**(4): p. 1153.
13. Garland, E.L., E.G. Manusov, B. Froeliger, A. Kelly, J.M. Williams, and M.O. Howard, *Mindfulness-oriented recovery enhancement for chronic pain and prescription opioid misuse: results from an early-stage randomized controlled trial*. Journal of Consulting and Clinical Psychology, 2014. **82**(3): p. 448.
  14. Margolin, A., Z. Schuman-Olivier, M. Beitel, R.M. Arnold, C.E. Fulwiler, and S.K. Avants, *A preliminary study of spiritual self-schema (3-S+) therapy for reducing impulsivity in HIV-positive drug users*. Journal of clinical psychology, 2007. **63**(10): p. 979-999.
  15. Pbert, L., J.M. Madison, S. Druker, N. Olendzki, R. Magner, G. Reed, J. Allison, and J. Carmody, *Effect of mindfulness training on asthma quality of life and lung function: a randomised controlled trial*. Thorax, 2012: p. thoraxjnl-2011-200253.
  16. Hughes, J.W., D.M. Fresco, R. Myerscough, M. van Dulmen, L.E. Carlson, and R. Josephson, *Randomized controlled trial of mindfulness-based stress reduction for prehypertension*. Psychosomatic medicine, 2013. **75**(8).
  17. Schneider, R.H., F. Staggers, C.N. Alexander, W. Sheppard, M. Rainforth, K. Kondwani, S. Smith, and C.G. King, *A randomized controlled trial of stress reduction for hypertension in older African Americans*. Hypertension, 1995. **26**(5): p. 820-827.
  18. Palta, P., G. Page, R. Piferi, J. Gill, M. Hayat, A. Connolly, and S. Szanton, *Evaluation of a mindfulness-based intervention program to decrease blood pressure in low-income African-American older adults*. Journal of Urban Health, 2012. **89**(2): p. 308-316.
  19. Rosenzweig, S., D.K. Reibel, J.M. Greeson, and J.S. Edman, *Mindfulness-based stress reduction is associated with improved glycemic control in type 2 diabetes mellitus: a pilot study*. Alternative Therapies in Health and Medicine, 2007. **13**(5): p. 36.
  20. Miller, C.K., J.L. Kristeller, A. Headings, and H. Nagaraja, *Comparison of a mindful eating intervention to a diabetes self-management intervention among adults with type 2 diabetes: a randomized controlled trial*. Health Education & Behavior, 2014. **41**(2): p. 145-154.
  21. van Son, J., I. Nykliček, V.J. Pop, M.C. Blonk, R.J. Erdtsieck, P.F. Spooren, A.W. Toorians, and F. Pouwer, *The effects of a mindfulness-based intervention on emotional distress, quality of life, and HbA1c in outpatients with diabetes (DiaMind)*. Diabetes care, 2013. **36**(4): p. 823-830.
  22. Piet, J. and E. Hougaard, *The effect of mindfulness-based cognitive therapy for prevention of relapse in recurrent major depressive disorder: a systematic review and meta-analysis*. Clinical psychology review, 2011. **31**(6): p. 1032-1040.

## 6. INCLUSION AND EXCLUSION CRITERIA\*

Participants will have been enrolled in Brown University study with the following criteria

## INVESTIGATOR STUDY PLAN - REQUIRED

### Inclusion Criteria:

- men or women
- between the ages of 18 and 65
- participants that have prehypertension or hypertension.

### Exclusion Criteria:

- Current regular mindfulness practice (>1 week) or lifetime mindfulness meditation practice
- Diagnosis of an active medical illness
- Diagnosis of an active major psychiatric disorder
- Current medication use consistent with an active medical illness or psychiatric disorder
- A priori unable to commit time required for the study
- Inability to consent

### Exclusion Criteria for the present MRI application

- Contraindication(s) to entering the MR scanner such as the presence of metal in or on the body that cannot be removed or claustrophobia
- Pregnancy
- Weight > 300 lbs

### **7. STUDY-WIDE NUMBER OF SUBJECTS\***

60 participants in total, from those already recruited for ongoing, non-MRI study through Brown University study, all meeting study entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program; half enrolled in MB-BP at Brown University, whereas the other half will be waitlist controls.

### **8. STUDY-WIDE RECRUITMENT METHODS\***

All participants will have been previously recruited for a study at Brown University. Eligible and interested participants will be further recruited for this MRI add-on.

### **9. STUDY TIMELINES\***

Each participant will have two visits to UMass Med School Campus - before and after the MB-BP intervention (Visit 1 and 2, respectively). Each visit will include an MRI scan and is expected to last approximately 2 hours.

The endpoint of the study is after the second study visit (Visit 2) has been completed. However, the PI and study personnel may make study termination decisions in coordination with participants. A participant's involvement in this study will also end if the subject withdraws their consent, is unable to adhere to the study protocol (e.g., finds

## INVESTIGATOR STUDY PLAN - REQUIRED

the MRI procedure excessively uncomfortable), or is determined to be ineligible during the study by the investigators.

We anticipate that it will take approximately 3 years to enroll all 60 study participants, and that it will take 1 year to complete the primary analyses.

### 10. STUDY ENDPOINTS\*

The primary outcome will be differential over-time change in MRI **resting-state functional connectivity** (rsFC) patterns for the intervention versus comparison group (e.g. default-mode, salience, and central executive, networks comprising regions such as anterior cingulate cortex, medial orbital cortex, insula, amygdala, and hippocampus). **A significant group x time interaction will represent differential over-time change in the outcome (rsFC) for the intervention versus comparison group. The model for Hypothesis 1 will be parameterized with indicator variables for study group, time, and a group-time interaction (for example using FSL general linear model (GLM), which can estimate multivariable models, where the response  $Y$  at each voxel is modeled as a linear combination of one or more predictors; applying “Randomise” permutation function). As such we will also apply such a technique of regression modeling to predict change in hypertensive functional status, specifically blood pressure [standard-of-care clinic-assessed systolic and diastolic BP for monitoring hypertension treatment: baseline clinic BP obtained at two in-person screening visits  $\geq 1$  week apart, followed by in-person assessments at all follow-up periods (8w, 3m, 6m), all as part of Brown University project], while considering important clinical and demographic covariates.**

**The secondary outcomes will be in-scanner self-regulation task functional connectivity outcomes (1. emotional Go/NoGo inhibitory control task; 2. self-compassion task, which contrasts self-reassurance conditions with a self-criticism condition; 3. interoceptive attention task, which contrasts an interoceptive attention condition with an exteroceptive attention condition). We will test for differential brain connectivity relation to each self-regulation manipulation between the intervention versus comparison group. Finally, associations between any differential intervention effect on self-regulation-task associated brain connectivity change will be further modeled for predictive ability of blood pressure change.**

### 11. PROCEDURES INVOLVED\*

Participation will entail a total time commitment of about 4.5 hours over the course of the study.

#### **Telephone Screen:~15 minutes**

Potential participants, already enrolled in Brown University study, will be prescreened by telephone. Respondents are informed that everything they say will be kept strictly confidential and they may stop or ask questions at any time.

## **INVESTIGATOR STUDY PLAN - REQUIRED**

Respondents will already have satisfied age and medical or psychiatric illness inclusion and exclusion criteria for participation enrollment in Brown University study.

For this MRI study, women will be asked if they are currently pregnant or planning to become pregnant. If the subject meets all inclusion criteria and no exclusion criteria (see #6 Inclusion and Exclusion Criteria, above), they will be asked for their contact information (phone number and email address) and about scheduling considerations for providing consent, and determine study visits. This information will be stored in a locked cabinet.

Participants who do not meet eligibility criteria will be asked to verbally provide consent to be re-contacted for future studies. If consent is obtained, this will be recorded on the phone screen which will be stored in a locked cabinet, accessible only by study staff.

### **Informed and Written Consent:~15 minutes**

Consent will be obtained at Umass Medical School. The subject consent form will be reviewed in detail with the participant by trained study personnel. If needed, the participant will be given the consent form to take home for further consideration and discussion prior to signing. Sufficient time will be provided so that the subject can understand the study, ask questions, and express concerns.

Once the subject has read and understood the consent form and determined that they wish to participate in study, the IRB-approved written informed consent form will be signed and dated by the subject and the study personnel obtaining consent. The participant will be given a copy of the signed informed consent form; originals shall be kept on file by the investigator in a locked cabinet.

The study visit will proceed with the neuroimaging session to examine brain function and structure using diffusion tensor imaging (DTI), resting state and task-based functional magnetic resonance imaging (fMRI), as well as arterial spin labeling.

### **Neuroimaging sessions: ~1.5 hours each**

Subjects will undergo two MRI sessions – one at each of 2 study visits. These will include anatomic scans, arterial spin labeling, Diffusion Tensor Imaging (DTI), as well as resting state and task-based fMRI. Imaging will be conducted on a 3 Tesla magnetic resonance imaging scanner (Phillips 3 Tesla Ingenia CX dStream), which has been approved for research and clinical studies in children and adults by the FDA. Magnetic resonance (MR) technology does not use ionizing radiation like an X-ray. Instead, it uses strong magnetic fields and radio waves to collect the images and data. There are no known hazards or risks associated with these techniques. To ensure subjects can safely undergo MRI scanning, all participants will be screened by the Research Coordinator prior to scanning for the presence of any MRI incompatible medical implant, external device or metal (including jewelry, body piercings, tattoos with metallic pigments).

## INVESTIGATOR STUDY PLAN - REQUIRED

Acquisitions will include T1 and T2 images (in agreement with NINDS Common Data Elements, and suitable for incorporation in FITBIR), T1-weighted, ME-MPRAGE sequence; T2-weighted double echo fast spin echo sequence, (2) a multi-flip angle 3D spoiled gradient echo (FLASH type) compatible with the BIRN protocol; Resting state and functional MRI: a multiband echo-planar imaging sequence with T2\*-weighted BOLD contrast; a fieldmap for distortion correction; Diffusion Tensor Imaging sequence that uses a standard single shot, spin echo, echo planar acquisition with diffusion weighting gradient pulses comprised of multiple diffusion-encoding directions with additional weighted images; Arterial spin labeling ASL: pseudo-continuous ASL (PCASL) pulse sequence complemented by a single PCASL image with long repetition time (TR; proton density) for scaling perfusion-weighted maps to absolute units of cerebral blood flow (CBF; ml/100g/min). During the imaging session, autonomic system measures will also be obtained using respiratory belt, finger plethysmograph for heart rate (HRV), and finger sensors for skin conductance.

A quick questionnaire about mental and physical state during the scanning session (Amsterdam Resting-State Questionnaire (ARSEQ 2.0)) will be administered immediately after each MRI scanning session (< 5 minutes).

Post-processing of MRI data will be performed with standard software (Freesurfer, FSL, and DTIStudio) to quantify the regional gray and white matter structural properties, as well as functional, and arterial properties in the brain.

### 12. DATA AND SPECIMEN BANKING\*

Neuroimaging data and accompanying physiological, behavioral, and questionnaire, as well as participant data including telephone screening informed consent forms will be kept. All personally identifiable information will be "de-identified", and coded with the subject's identification number. Thus, all study data will be stored without personal identifiers.

All electronic information will be stored on a password-protected server accessible by study personnel only or on personal employee computers, located in locked offices at UMass Medical School. All written information will be locked in a file cabinet, located in a locked office. The office referred to is in the Center for Comparative NeuroImaging (CCNI). The CCNI is a secure building with swipe card entry access. Subjects will be assigned a code for all documentation and data analysis sheets. The key linking the names and codes will be stored on this password-protected server. Documents that contain identifying information will be stored separately from any primary research data. Imaging data will be transferred from the MRI system by means of a portable drive. Once the transfer is completed, the portable drive will be formatted to clean it of the acquired data. The data will only be stored in a password-protected computer accessible to study investigator and study staff. We also push the neuroimaging data to a server within the UMass system. This server is accessible only by the authorized personnel and it is backed-up regularly to password-protected drives. Aside from UMMS IRB representatives, only approved study personnel will have access to raw research data.

## INVESTIGATOR STUDY PLAN - REQUIRED

The master list of subjects' addresses and phone numbers will be destroyed at the end of the study. Data will be kept at least for a minimum of 5 years following publication of results, in accordance with American Psychological Association guidelines for data retention, and likely indefinitely. While there is no plan to destroy the raw data, if we later decide to destroy the raw data, paper raw data will be shredded and electronic raw data will be erased from hard drives and any electronic backup media. For the sake of transparency in our research practices, according to recommended practices the de-identified neuroimaging, physiological, task, questionnaire, and other participant data relevant for analysis may be made available to the public via a web repository (e.g. Open Science Framework). In that case, any de-identified data that have been posted publicly will remain publicly accessible in perpetuity.

### 13. Data Analysis and Management\*

We will follow current recommended methods for MRI data analysis. The fMRI data will be analyzed using the standard software package FSL, together with RETROICOR for retrospective correction of physiological motion artifacts using our peripheral measures of cardiac and respiratory activity as independent assessments of physiological noise in the blood oxygen level-dependent (BOLD) signal. Following standard preprocessing steps (de-warping, slice timing correction, motion correction, removal of physiological noise signals), the statistical analysis of brain activation data will be performed.

In addition to time point and group assignment, the statistical models will include among regressors of interest blood pressure, gender, age, in-scanner task outcomes, and the following regressors of no interest: head motion parameters and cardiac and respiratory components of physiological noise. Hypotheses will be expressed as: Is there any significant difference between the 2 time points in functional connectivity during resting state and task-specific induction (a, NoGo trials versus Go trials; b) self-reassurance versus self-criticism; and c) Interoception-versus-Exteroception. The null hypothesis will be that any brain network functional connectivity changes between the 2 time points is not significantly different between the intervention and the comparison groups. Significance testing will be done using permutation methods.

We estimate that after outlier or neuroimaging artifact exclusion and any withdrawals from the study, there will be about 50 total participants. Data analysis will be performed using standard statistical software. Based on our current observations, we may obtain high effect sizes, i.e. 1 or 1.5. We will recruit up to 60 participants so that we can exclude outliers.

### 14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS\*

A trained neuroradiologist associated with the MRI imaging center at University of Massachusetts Medical School will read the diagnostic MRI scans. In the event that there is a suspicious reading on the MRI, the principal investigator will be informed of this and arrange for the neuroradiologist to share with the subject the findings and facilitate in helping them determine what follow-up care is needed and appropriate.

## **INVESTIGATOR STUDY PLAN - REQUIRED**

### **15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT\***

A subject's participation in this neuroimaging study will normally end at the completion of the visit. However, subjects may withdraw at any time and for any reason. If the subject decides to withdraw, no special procedures need to be followed. The subject can simply leave the study at any time. Also, the trained study personnel may make study termination decisions if the subject is not able to adhere to the study protocol.

### **16. RISKS TO SUBJECTS\***

This study will be conducted in a 3T MR scanner which has been approved for research and clinical studies in children and adults by the FDA. Magnetic resonance (MR) technology does not use ionizing radiation like an X-ray. Instead, it uses strong magnetic fields and radio waves to collect the images and data. There are no known hazards or risks associated with these techniques.

As it is the case for any MR scanner, significant risks can arise if ferromagnetic materials (this includes many types of common metal objects) are brought into the high magnetic field environment of the scanner and immediate vicinity, as they can become hazardous projectiles.

During the scan, some people do report claustrophobia (fear of being in enclosed small spaces), dizziness, mild nausea, headaches, a metallic taste in their mouth, double vision, or sensation of flashing lights. In rare cases during certain types of scans, a very slight, uncomfortable tingling of the back due to the rapid switching of the magnetic field has been reported. Although the intensity is not harmful to their hearing, the sounds that subjects hear inside the scanner may be annoying.

During the scan, the comfort of the participant will be checked through the intercom system. The MRI technician can talk through the intercom system and the participant can hear through the head phones he/she will be wearing during the experiment. Similarly, the participants can talk during the experiment (in between the acquisitions) and the MRI technician can hear through the intercom system. In the unlikely event of any discomfort to the participant, the scan session will immediately be stopped and the participant will be taken out of the magnet.

Identification of a real or false positive abnormality, i.e. lesion or a tumor, during the MRI examination is possible. In the existence of such a condition, further investigation and/or treatment may be necessary. Although possible abnormalities are not related to the study, there may be emotional and physical risks associated with getting the follow-up medical evaluations. The initial diagnosis revealed by our scan may be false positive or it may be a true positive finding that may lead only to earlier identification of a condition. However, this condition may not have a survival possibility and the subject would need to live longer with the knowledge of this condition.



## INVESTIGATOR STUDY PLAN - REQUIRED

### Breach of Confidentiality:

As with all studies, there is a chance that data could be linked back to a subject's true identity, breaching confidentiality, and so there is a risk of psychological and social stigma that could adversely impact the subject. However, there will be many safeguards in place to prevent this occurrence.

### **17. POTENTIAL DIRECT BENEFITS TO SUBJECTS\***

Not Applicable

### **18. VULNERABLE POPULATIONS\***

Not Applicable

### **19. MULTI-SITE RESEARCH\***

This study is a collaboration between UMass Medical School (UMMS), Brown University, and MGH. All imaging acquisition will be done at UMMS. All imaging analyses will be done at UMMS, in collaboration with MGH for analysis of autonomic system data [respiratory belt, finger plethysmograph for heart rate (HRV), and finger sensors for skin conductance]. All recruitment, MB-BP intervention and other measures are done at Brown University.

### **20. COMMUNITY-BASED PARTICIPATORY RESEARCH\***

Not Applicable

### **21. SHARING OF RESEARCH RESULTS WITH SUBJECTS\***

Results will not be routinely shared with subjects. However, if an MRI reading is indicative of pathology, such as hemorrhagic stroke, ischemic stroke, multiple sclerosis, tumors, and aneurysms, these results will be shared with subjects. In addition, during the clinical interview the study clinicians may determine that the study subject has psychiatric symptoms that are in need of treatment, or that the subject might be harmful to themselves or someone else. In this case, these results will be shared with the subject, and we will help the subject find appropriate care.

### **22. SETTING**

All participants will be recruited from an ongoing MB-BP study at Brown University, for the neuroimaging visits at UMMS.

### **Facilities:**

Center for Comparative NeuroImaging (CCNI):

- **Telephone Screens and Data Analysis will be performed at the CCNI.**

## INVESTIGATOR STUDY PLAN - REQUIRED

- **Informed Consent will be done at the CCNI in a private office.**

The CCNI is a research laboratory of ~3,000sq-ft building on the main campus. This center contains a conference room, faculty offices (~140 square feet each), secretary cubicle, shared student room, a wet lab, and a small room for mechanical and electronic work.

CCNI offices and laboratories are networked with switched 10/100 Mb/sec TCP/IP communication lines. CCNI currently has five SGI, two Sun stations, and ten PC's. Some of these SGI and PC are in a "common" area where collaborators will have access to them for data analysis and software

In addition to the shared computers in the CCNI, we have computers within the offices located in BNRI. There are two identical Mac Pro5.1 with 2 2.4 GHz Quad-Core Intel Xeon processors. Each of has 6GB of memory and total of 8 cores. There are also two iMac9.1 with 3.06 GHz Intel Core 2 Duo processors. One of these is equipped with 4GB of memory while the other one has 6GB of memory and both of them have 2 cores. All of our Macintosh computers have dual boot capacity so that we can run Windows7 and use Windows System compatible software if needed. In addition, we have a Dell OptiPlex 755 Desktop, which has the Linux operating system installed on it.

Matlab2016 (Natick, MA) is available to perform various analyses. LCModel version 6.2.2 is installed on the Dell OptiPlex Desktop to perform proton spectroscopy analysis and to determine the measured metabolite levels. SPSS (to perform statistical analysis), Microsoft Office Applications as well as Adobe Application (to write our reports and papers and to prepare illustrations), EndNoteX8 (to manage references) are available for our researchers. We also have free image analysis software such as FreeSurfer (Martinos Center for Biomedical Imaging, Charles Town, MA), FSL (FMRIB, Oxford, UK) and SPM (Wellcome Trust Centre for NeuroImaging, London, UK) to perform the anatomical neuroimaging analysis.

### Advanced MRI Center (AMRIC):

- **Neuroimaging data will be acquired at AMRIC.**

The AMRIC facilitates a new Philips Ingenia CX dStream 3.0T system with a higher order shim function which enables us to obtain improved image quality in field-sensitive applications and techniques such as single-voxel spectroscopy, chemical shift imaging, single-shot EPI and balanced FFE.

This Ingenia 3.0T system has a higher order shim function which offers advanced shimming capabilities to obtain improved image quality in field-sensitive applications and techniques such as single-voxel spectroscopy, chemical shift imaging, single-shot EPI and balanced FFE.

## INVESTIGATOR STUDY PLAN - REQUIRED

This Ingenia 3.0T system features high performance whole body, non-resonant, self-shielded gradient technology with new amplifiers that deliver high peak and slew rates for the demanding requirements of the latest and emerging clinical imaging techniques. The Quasar Dual gradient system provides industry leading performance specifications for peak strength and slew rate with a dual mode capability that optimizes advanced applications requiring very high peak mode capabilities. The maximum gradient amplitudes and slew rates corresponding to the dual mode are 80 mT/m, 100 mT/m/ms and 40 mT/m, 200 mT/m/ms respectively.

This Ingenia 3.0T system has a multiple RF sources, which adapts the RF signals to suit each individual patient. This results in faster scans, enhanced image uniformity/consistency, over a broader range of applications.

This Ingenia 3.0T system features MultiBand SENSE which allows to use state-of-the-art acceleration factors in the brain by simultaneously exciting multiple slices. Due to a shorter minimum TR for fMRI, larger anatomical coverage or higher temporal resolution can be used. In the DWI/DTI sequences larger anatomical coverage or higher number of diffusion directions can be acquired. With MultiBand SENSE, fMRI and DTI exams can be performed with high speed and high resolution, simultaneously.

This Ingenia 3.0T system is equipped with a Multi-nuclear spectroscopy (MNS) system, which provide the ability to perform  $^{13}\text{C}$ ,  $^{31}\text{P}$ ,  $^7\text{Li}$ ,  $^{23}\text{Na}$ ,  $^{19}\text{F}$  and other nuclei spectroscopy and imaging. The multiple RF amplifiers in this system includes two 18 kW solid-state  $^1\text{H}$  channel narrowband amplifier and one 4 kW broadband (10-130 MHz) Multi-nuclear amplifier.

This Ingenia 3.0T system has a bore diameter of 60 cm and provides a full-size 50 cm field-of-view.

### *fMRI Stimulus Delivery System*

A fully integrated fMRI stimulus delivery system from MRA (Model: fMRI-0502-STD1; MRA; Washington, PA, USA; <http://www.mra1.com/>) and Presentation (Neurobehavioral Systems, Inc; Albany, CA, USA; <http://www.neurobs.com/>) is available for both clinical and research. The MRA complete system includes the fMRI stimulus delivery console, Windows computer system, patient response hand switches, video projection into the MRI bore, and MRI compatible patient headphones.

Presentation is the world's most popular experimental control software for neuroscience, is a stimulus delivery and experimental control program. It runs on PC, and delivers auditory, visual and multimodal stimuli with sub-millisecond temporal precision. Presentation is powerful enough to handle almost any behavioral, psychological or physiological experiment using fMRI, ERP, MEG, psychophysics, eye movements, single neuron recording, reaction time measures, other performance measures, and more.

### *MRI Compatible Goggle Set*

## INVESTIGATOR STUDY PLAN - REQUIRED

MediGoggle Adult Research Set (Cambridge Research Systems Ltd, England; <http://www.crsLtd.com/>) has interchangeable prescriptive goggles suitable for use in MRI and fMRI environments. It is fully MRI compatible with no metallic components and an easy 'click' lens system -6 to +6 dioptre lens sets in 0.5 dioptre increments.

### *In Vivo Physiological monitoring system*

Medrad Veris 8600 MR Vital Signs Monitor (Model: 8600; S/N: 023426; Medrad, Inc; Warrendale, PA, USA; <http://www.medrad.com/>) is available to monitor patients while they are undergoing an MR exam. It interprets and displays physiologic data as waveforms and numeric information which include ECG, NIBP, SpO<sub>2</sub>, CO<sub>2</sub>, respiration, temperature, O<sub>2</sub>, anesthetic gases, and IBP.

The Advanced MRI Center also includes a nurses' station, two patient holding rooms, and two patient changing rooms with lockers.

### *- Recruitment sites:*

The Subjects will be recruited through the Brown University study.

## 23. RESOURCES AVAILABLE

All staff are required initially and every 3 years to successfully complete a UMass - designated CITI program. All participating personnel will thoroughly review the study protocol and will review their roles and responsibilities with experienced study personnel and the Principal Investigator. Personnel are notified of protocol changes, and questions/discussion points are addressed at weekly lab meetings.

Below are the Roles, Responsibilities, and Training for the research staff involved in this study:

Role	Responsibilities	Training
<u>Principal Investigator</u>	Overseeing and managing all activities related to this protocol, including recruitment, data collection, analysis and interpretations. This also includes manuscript preparation and presenting data at conferences. The PI will oversee all IRB	Holds a graduate-level degree (PhD, MD, RN, PsyD, or equivalent) and has had 5 or more years of experience in the field of

## INVESTIGATOR STUDY PLAN - REQUIRED

	communications.	imaging in psychiatry.
<u>Data Analyst</u>	Collection, analysis and interpretation of data, including neuroimaging data and combining the neuroimaging data with clinical data. Participates in manuscript preparation and data presentation at conferences.	Formally trained in neuroimaging data collection, analysis.
<u>Study Coordinator:</u>	Assists with maintenance of regulatory documents, IRB communications, assists with subject recruitment. Administer telephone screen, consent subjects, coordinate visit dates/times with subjects, arrange subject compensation, measure height/weight, administer mood and psychological assessments, as well as other scales/questionnaires, administer neuropsychological/neurocognitive assessments, manage subject documentation. Participates in manuscript preparation.	Thoroughly review protocol, consenting process, and relevant study procedures with Principal Investigator and/or co-Investigators.

### 24. LOCAL RECRUITMENT METHODS

Dr. Eric Loucks at Brown University and his team have worked on several mindfulness projects. For the current MB-BP project, they have successfully recruited over 40 participants in a previous enrollment cycle for the MB-BP study, and they anticipate recruiting as many in each of the upcoming cycles, from which will be identified potential participants in the present MRI study. Recruitment will occur by Dr. Louck's team informing participants that we are actively looking for subjects who fit our research criteria, of the opportunity to participate in clinical research, and if the candidates are interested, ask them if they accept our study staff to approach them. Interested candidates will undergo a phone screen to determine their eligibility. If they appear eligible, they will be invited to participate in the study.

*Describe the amount, method, and timing of any payments to subjects.*

Participants will be compensated \$100 per imaging visit, plus \$50 in travel expenses (participants will receive free parking). Thus, a total of \$300 per participant for baseline and follow-up visit.

### 25. LOCAL NUMBER OF SUBJECTS

## **INVESTIGATOR STUDY PLAN - REQUIRED**

60 participants enrolled in total. As the participants will be recruited from an ongoing study of persons already screened, typical screen failures will be reduced to those individuals failing to satisfy the MRI requirements, which a fraction of usual screen failures. Nevertheless, we anticipate that more than 100 participants may need screening from the Brown University project.

### **26. CONFIDENTIALITY**

All data/documents will be stored in locked cabinets and/or on password protected computers, accessible only by study staff. Data/documents will be stored by subject ID number to avoid linkage of data to identity. Subject number and corresponding identifying information will be kept in separate locked file cabinets, accessible only by study staff. All data/documents will be stored indefinitely.

Approved study personnel are responsible for receipt or transmission of data/documents and specimens locally. Imaging data will be transferred from the AMRIC MRI system by means of a portable drive. All portable drives used to transfer data are encrypted in accordance with UMMS data security policies. Once the transfer is completed, the portable drive will be formatted to clean it of the acquired data. Data will be stored on a password-protected computer indefinitely, accessible only by study staff. Data will also be pushed to servers within the UMASS systems, this server is accessible only by the authorized personnel and it is backed up regularly to password-protected drives.

For the sake of transparency in our research practices, according to recommended practices the de-identified neuroimaging, physiological, task, questionnaire, and participant data will be made available to the public via a web repository (e.g. Open Science Framework). Only researchers who apply and get permission to use the information for a specific research project will be able to access the information. Qualified researchers who can access the national databases can be from government, academic, or commercial institutions.

### **27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS**

Subjects interact with and provide information to approved study staff only. Subjects are informed that study information will be kept strictly confidential, and that study staff will do everything that they can to prevent others from learning about the subject's participation. As frequently as possible, study procedures take place in rooms with closable doors, with a minimum number of participating staff.

For all study procedures, subjects are informed that study related information will be kept strictly confidential, and that study staff will do everything that they can to prevent others from learning about the subject's participation. Subjects are informed that their participation is entirely voluntary, and that they may stop and ask questions, or choose to not take part in/quit the study at any time.

## **INVESTIGATOR STUDY PLAN - REQUIRED**

All information acquired through research procedures is stored in locked cabinets and/or on password protected computers.

### **28. COMPENSATION FOR RESEARCH-RELATED INJURY**

No funds have been set aside for research-related injury compensation. In the unlikely event of injury, subjects or their insurance are responsible for coverage.

### **29. ECONOMIC BURDEN TO SUBJECTS**

Not Applicable

### **30. CONSENT PROCESS**

Participants are expected to be competent to give consent for themselves; no vulnerable populations are to take part in this study.

The consenting process will take place in the CCNI or AMRIC facilities. Consent will be obtained in person by Dr. King or a research coordinator, or a trained member of personnel. In order to obtain consent, the study protocol, purpose, risks, and benefits will be explained to the subject. Subjects will be asked to indicate their understanding of the key elements of the protocol including the purpose, risks, and benefits in order to determine that the participant understands the elements required for informed consent. We will only obtain consent if these direct questions have been answered appropriately.

The subject will have the option of thinking about participation for as long as they would like. This includes the option to take the informed consent form home and re-schedule the consent visit for a later date, if that would be helpful to the subject. The subject will also be informed that they can contact Dr. King or the research coordinator at any time if they have a question about the consent form and/or study procedure.

We will be following SOP: Informed Consent Process for Research (HRP-802).

### **31. PROCESS TO DOCUMENT CONSENT IN WRITING**

We will be following SOP: Written Documentation of Consent (HRP-803)

### **32. DRUGS OR DEVICES**

We are not testing any devices for safety or effectiveness

Appendix 6B -  
Phone Screener for UMass  
Medical School fMRI sub-study  
- to be administered by UMass  
research staff



## Mindful Self-Regulation for blood pressure MRI study – PHONE SCREEN

Date: \_\_\_\_\_ Time: \_\_\_\_\_ Interviewer: \_\_\_\_\_

Screening # \_\_\_\_\_ (month.date.year.hour.minute)

My name is \_\_\_\_\_. I am calling from the Center for Comparative NeuroImaging at the UMass Medical School, because you expressed interest in participating in our brain imaging study through your participation in the Brown University Mindfulness-Based Blood Pressure Reduction Study, formerly known as Mindfulness-Based Hypertension Therapy. Is that correct?

[If yes, proceed, if no, note in Potential Subject Log].

In order to determine if you are a good match for this particular study, I will be asking you some questions about your health and history which will take from 10 to 15 minutes. Is now a good time to speak? [If yes, proceed, if no, ask for other times and note in Potential Subject Log].

There are a few things that I'd like to make clear before we start the interview. First of all, some of the questions will be very personal and sensitive. Are you in a private place to talk? Because this interview is of a personal nature, it is important that you understand that everything you say will be kept strictly confidential. No one outside of our project will ever be able to see your answers, and we will not keep your name in the same place as any of your answers. Your answers to our brief questions about marijuana and other "recreational" drug use will also be kept strictly confidential and will not be reported.

I am asking these questions because you are participating in the Mindfulness for Blood Pressure Intervention Study at Brown University, we would like you to participate in a study where we will image your brain 2 times, before and after the intervention. Everything you say in this interview will be kept strictly confidential, and you may stop or ask questions at any time. If you don't understand what I am asking, please stop me and ask me to explain. If you are eligible for the study we will ask for your name once we finish with this interview, otherwise we will not ask for your name. If you like, though, we can keep your information on file for future studies.

These phone screens are kept in a ring binder in a secure location. They will not be destroyed. Are you comfortable with starting the interview now?

INCLUSION CRITERIA: Need YES to all Yes/No questions		
1. How old are you? _____ D.O.B. _____ Between 18 and 65?	Yes ____	No ____
2. Are you participating in Brown University Mindfulness for Blood Pressure Intervention Study?	Yes ____	No ____

Additional information		
3. Are you male or female or identify as male or female?	Male ____	Female: ____
4. Are you right or left handed?	Right: ____	Left: ____
5. Current occupation?		
6. Are you currently diagnosed with Attention Deficit Hyperactivity Disorder?	Yes ____	No ____
• When were you diagnosed? _____		
• If diagnosis was age 7+: How young can you recall symptoms and		

## Mindful Self-Regulation for blood pressure MRI study – PHONE SCREEN

what kind of issues did you experience?		
7. Are you currently taking medication(s) for ADHD? • Drug: _____ Dose? _____ Freq: _____ • Since when: _____	Yes ____	No ____
8. Have you taken medications for ADHD before? • Drug(s): _____ • Dose(s): _____ Freq(s): _____ • When/How long: _____	Yes ____	No ____
9. Do you currently smoke tobacco cigarettes? • If yes, about how many cigarettes a day/week? _____ • How long have you smoked? _____	Yes: ____	No: ____
10. Do you currently smoke marijuana? • If yes, how many times per day/week do you smoke? _____ • How long have you smoked marijuana? _____	Yes: ____	No: ____
11. Do you currently use any other recreational drugs? • If yes, what? How often? For how long?	Yes: ____	No: ____

Medical History		
12. Have you ever had a neurological problem? (such as a seizure disorder, epilepsy, migraines or multiple sclerosis) • Describe _____ - • Any medications/treatments?(name, dose, frequency, how long?)	Yes: ____	No: ____
13. Have you ever had a head trauma or lost consciousness? Describe (eg. when, severity, diagnosed and by whom, how long the loss of consciousness):	Yes: ____	No: ____
14. Are you currently on any medications? Drug: _____ Dose: _____ Reason: _____  Drug: _____ Dose: _____ Reason: _____	Yes: ____	No: ____
15. Have you ever brain surgery or had a stroke? (Condition associated with structural brain alteration on MRI)	Yes: ____	No: ____
16. Do you experience claustrophobia?	Yes: ____	No: ____
17. Have you ever had an operation or other surgical procedure? • If yes, which types? When?	Yes: ____	No: ____
18. [If applicable] Are you pregnant?	Yes: ____	No: ____

## Mindful Self-Regulation for blood pressure MRI study – PHONE SCREEN

<b>Psychiatric History</b>		
19. Do you have a serious psychiatric, cognitive or medical disorder which could interfere with completion of the study?	Yes: ____	No: ____
<ul style="list-style-type: none"> <li>• Do you have a current or past diagnosis with any of these psychological disorders?</li> <li>• Schizophrenia or schizoaffective disorder</li> <li>• Autism or other Pervasive Developmental Disorder</li> <li>• Obsessive-Compulsive Disorder</li> <li>• Claustrophobia</li> <li>• Alcohol or substance abuse or dependence (past six months). (&gt;14/week or &gt;4 drinks at any one time for a male, or &gt;7 drinks/week or &gt;3 drinks at any one time for a female) or substance abuse) ?</li> </ul> <p><i>(above are exclusionary conditions)</i></p> <ul style="list-style-type: none"> <li>• Anxiety/Depression</li> <li>• Other _____  <div style="margin-left: 40px;">▪ Details:</div> </li> <li>• Are you currently taking medications for any psychological problems?  Drug: _____ Dose: _____ Freq: _____   Duration: _____</li> </ul>	  _____ _____ _____ _____ _____   _____   _____  _____  _____   _____  _____	  _____ _____ _____ _____ _____   _____   _____  _____  _____   _____  _____
20. Have you ever been hospitalized for psychosis or suicidal thoughts? When? _____ How long? _____	Yes ____	No ____

## Mindful Self-Regulation for blood pressure MRI study – PHONE SCREEN

MRI and Safety		
21. Do you have any metal in/on your body that cannot be removed? E.g. <input type="checkbox"/> surgical implants <input type="checkbox"/> pins <input type="checkbox"/> pacemakers <input type="checkbox"/> prosthetic heart valve <input type="checkbox"/> aneurism clips or other vascular stent, filters, or other devices <input type="checkbox"/> surgical clips <input type="checkbox"/> staples <input type="checkbox"/> neuro-stimulator devices <input type="checkbox"/> implanted infusion pumps <input type="checkbox"/> cochlear (ear) implants <input type="checkbox"/> Ocular (eye) implants or metal fragments in eyes <input type="checkbox"/> other prostheses <input type="checkbox"/> other: _____ Describe: _____	Yes: ____	No: ____
22. Do you have braces or any other metal which may be potentially magnetic? • This includes braces, false teeth, retainer, special hair dye, etc.	Yes: ____	No: ____
23. Do you have any tattoos? • If yes, is there any chance that it/they contain metallic pigments?	Yes: ____	No: ____
24. Have you ever been exposed to shrapnel or metal filings (e.g. employed as a machinist, metal worker, welder, or other?)	Yes: ____	No: ____
25. Is there any chance that you have ever been hit with any stray metal (BB's, metal shavings, etc)	Yes: ____	No: ____
26. Any condition known to be incompatible with MRI scan	Yes: ____	No: ____
27. Have you ever had an MRI or other scan? • If yes, were there any difficulties?	Yes: ____	No: ____
28. Are you over 300 lbs? (weight _____)	Yes: ____	No: ____

☐ At conclusion of the pre-screen, enter name and screening # in screen log

<p><b>If the candidate is NOT eligible for the current study:</b>          “I’m sorry, but you are not eligible for our study. if we have another study in the future that you might be eligible for, would you like to be contacted for that?”</p>	<p>Yes ____</p>	<p>No ____</p>
---	-----------------	----------------

**If the candidate appears to be eligible for the current study, and is interested:**

Phone #'s: _____	Ok to leave a message? Yes____ No____
Email address: _____	
Preferred method of contact? Phone/email (circle one)	
Scheduling considerations:	

☐ separate pages 1-4 from page 5, add the subject's study ID number to the top of pages 1-4 and store in locked file separate from page 5 and the screen log.

Investigator Signature: \_\_\_\_\_ d d / m m y y y y

<b>Pre-Screen</b>		
<b>Mindful Self-Regulation for blood pressure MRI study</b>		
<b>Name:</b>		
<b>Email:</b>		<b>Screening Date:</b>
<b>Phone</b>	<b>Phone</b>	<div><div><div></div><div>d</div><div></div></div><div></div><div>/</div><div><div></div><div>m</div><div></div></div><div></div><div>/</div><div><div></div><div>y</div><div></div></div><div></div><div><div></div><div>y</div><div></div></div><div></div><div><div></div><div>y</div><div></div></div><div></div><div><div></div><div>y</div><div></div></div></div>

Appendix 6C -  
Informed Consent form  
for UMass Medical School  
fMRI sub-study to be  
administered by UMass  
research staff

---

UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL  
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH  
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

***Title of research study:***

**Mindfulness Influences on Self-Regulation:**  
**Mental and Physical Health Implications for blood pressure**  
**(Mindfulness MB-BP Self-Regulation MRI)**

***Investigator:*** Jean King, Ph.D.

***Sponsor:*** The National Institutes of Health

***Why are you being invited to take part in a research study?***

You are being asked to participate because you are between 18 and 65 years of age and participating in the Mindfulness-Based Blood Pressure intervention study, have thus met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program, and do not have any other active medical or psychiatric illness, and are able to have MRI scanning done.

***What should you know about a research study?***

Your participation is entirely voluntary.

You may decide not to take part or decide to quit the study at any time, without any changes in the quality of the health care you receive.

You will be told about any new information or changes in the study that might affect your willingness to participate.

You are free to ask all the questions you want before deciding if you want to be in this study.

***Why are we doing this research?***

The purpose of the study is to begin to find out if a mindfulness-based blood pressure intervention affects brain function and whether any alterations are associated with mechanisms of self-regulation that accompany participation in such a program. We hope that such relationships exist, so that we can better understand the effect of mindfulness on self-regulation mental and behavioral changes that could impact blood pressure regulation. This knowledge may help researchers hone in on effective mechanisms, and healthcare providers to improve the care of people with prehypertension, hypertension, or other related cardiovascular risk factors.

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

---

### ***How long will the research last?***

We expect that you will be in this research study for 2 Visits, which should take approximately 4.5 hours in total to complete.

### ***How many people will be studied?***

We expect about 60 people to be in this portion of the research study at UMass Medical School.

### ***1- What happens if I say yes, I want to be in this research?***

If you want to participate in this research, you will be asked to come in for a total of two visits – before and after the Mindfulness-Based Blood Pressure intervention (Visits 1 and 2). Each visit includes an MRI scan, and should take about 2 hours total to complete.

Formatted: Indent: Left: 0", Hanging: 0.25", No bullets or numbering

#### **Magnetic Resonance Imaging (MRI) ~1.5 hours:**

This study includes two magnetic resonance imaging (MRI) scans. An MRI is a technique for taking images of the brain. It uses a magnetic field and radio waves - no ionizing radiation is used. We will take you to the MRI imaging suite at the University of Massachusetts Medical School's main campus and ask you a series of safety questions before we bring you into the MRI room. Some of these questions might be repetitive but is important that we make sure it is safe for you to have an MRI scan.

Because the scanner contains an extremely strong magnet you will be asked to remove all metal objects on you. This includes things like: watches, rings, necklaces, bracelets, earrings and other body piercings, belts, loose change, wallet (with credit cards), items of clothing containing magnetic materials (for example, under wire bras, certain types of zippers), and shoes. We will ask you change into a hospital gown and pants ("scrubs") before you go into the scanning room. Your clothing and personal items will be locked up in a safe place until the session is completed.

You will spend 90 minutes in an MRI scanner, which looks like a large cylinder with a tube running down the center. You will be asked to lie down on your back on a foam-padded table and to put your head into a special holder. The table slides inside the "hole" of the scanner. Soft foam rubber sponges may be placed on both sides of your head for comfort and to keep your head still. A headset with microphone allows you to hear and talk to the technician operating the scanner at all times.

During the scanning procedure, you will hear a number of different sounds. These sounds, which can be loud, are part of the normal operation of the scanner. These noises vary with the particular scan being performed, and include sounds like a hammer hitting a piece of wood, repetitive buzzing noises, and long series of loud beeps. Some scans are silent. These sounds, or combinations of them, will then be repeated several times, depending upon the specific scan sequence being used. The sounds you hear during the scanning session will not harm your hearing, but you will be given a pair of earplugs to wear for your comfort. Even with these earplugs in you will always be able hear the technician because they do not block all sound. You are free to talk during the preparation time and during the breaks, but you should not talk during the actual scanning process. During these sessions, you should try to remain as still as possible.

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt



The entire time that you will be in the scanner will be no longer than 90 minutes. When the session is over the technician will move you out of the scanner and assist you from the table. At this time, you will be asked a series of questions from a questionnaire that asks your experiences while in the MRI scanner (Amsterdam Resting-State Questionnaire).– This survey will take approximately 5 minutes to complete.

The MRI scanner takes moment-to-moment images of your brain's blood-flow and tissue. These images are digitally stored. Thousands of patients across the country safely undergo such procedures in radiology departments every day. The MRI procedure itself is not experimental; rather, it is well known to be safe.

### ***What are the risks of being in this study?***

Magnetic resonance (MR) technology does not use ionizing radiation like an X-ray. Instead, it uses strong magnetic fields and radio-frequency waves to collect the images and data. There are no known serious health hazards or risks associated with these techniques for most people. However, significant risks may exist for people with:

- Cardiac pacemakers
- Aneurysm clips (in your brain) and other vascular stents (tubes in your veins), filters, clips or other devices that have been surgically put in you for any reason
- Prosthetic heart valves (a mechanical device that helps your heart pump blood)
- Other prostheses (a piece of equipment that replaces a missing part of the body)
- Neuro-stimulator devices (a piece of equipment that activates nerves)
- Implanted infusion pumps (a device that stays in your body and helps give you medicine)
- Cochlear (ear) implants (a device used to help you hear)
- Ocular (eye) implants (a device put in your eye to help you see)
- Known metal fragments or pieces in eyes
- Contact with shrapnel (pieces of metal from something that has exploded)
- Contact with metal filings (people who are sheet metal workers, welders, or others could have this contact)
- Any surgeries where something metal was put in you
- Certain tattoos (please tell the study doctor if you have a tattoo so that we can make sure it is safe)
- Certain intrauterine contraception devices (IUD's)

You will be asked whether you have such devices and if so, you will not be able to participate in this study. Significant risks also can arise if certain types of metal objects are brought into the scanning area, as they can become hazardous projectiles. These types of items are not permitted in the scanning area. The exams are painless, and except for the pulsating sounds, you will not be aware that MR scanning is taking place.

This study will be conducted in an MR scanner which has been approved by the FDA for clinical and research studies. Although there are no known significant health risks from these scans, there could be adverse effects that are delayed or very mild, such that they have not yet been recognized. Most people experience no ill effects from the large magnetic field, but some people

do report claustrophobia (fear of being in small spaces), dizziness, mild nausea, headaches, a metallic taste in their mouth, double vision or sensation of flashing lights. These symptoms, if present, disappear shortly after leaving the MR machine. If you experience discomfort from being in the scanner, you should notify the examiner immediately and you will be removed from the scanner. You should also note you will be asked to remain as still as possible during the scanning session. Remaining motionless can result in physical discomfort.

You may feel cramped inside the scanner. The technologist will be able to hear you at all times and you are free to end the procedure at any time.

In rare cases, a very slight, uncomfortable tingling of the back due to the rapid switching of the magnetic field has been reported during certain types of scans. In case you have such a sensation, you are asked to report this immediately, so the scan can be changed to avoid this. Although these precautions will avoid all known risks associated with MR, this procedure may involve risks to you that are currently unforeseeable.

A qualified neuroradiologist will interpret your brain scan, as you are having images taken of your brain tissue and brain blood flow. We will retain your contact information in the event that it is medically important to tell you of any aspect of your brain scan. Any medically important findings on the MRI will be identified and reported to you. This process could also produce some discomfort, and would only be done if believed in your medical best interests. Please note that you will not be billed for the procedure, and that we will also help you get any follow-up care you might need.

Another risk of being in this study is a loss of your personal information. This is very unlikely to happen, and we will do everything to make sure that your information is protected.

### ***What are my responsibilities if I take part in this research?***

If you take part in the research, it is important for your safety that you:

- Follow the directions of the study doctor and research staff.
- Tell your health care providers that you are in a research study.
- Tell your study doctor and staff about all medications you are taking (prescription and over the counter) and all of your health issues.
- Call the study doctor or staff at 774-455-4272 if you have any questions.

### ***Will being in this study help me in any way?***

There may be no benefit to being in this study. However, knowledge gained from this study may help others with your condition in the future.

### ***Will being in this study cost me any money?***

Participating in this study will NOT require a payment, co-pay, or insurance charge. There will be no cost to you from being in this research study other than the cost of your transportation to UMass Medical School.

## What happens to information about me?

Efforts will be made to limit access to your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. The UMMS Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) and other representatives of UMMS may need to review records of individual subjects. As a result, they may see your name, but they are bound by rules of confidentiality not to reveal your identity to others. Your identity will remain confidential in any study results that are made public.

We will communicate the ~~results~~ results of this study to others by publishing the results in scholarly books or journals, presenting them at professional conferences, or using them for teaching purposes. In addition, for transparency in our research practices and according to current recommendations, we will make available the de-identified data -(including your and other participants' imaging, physiological, questionnaire, behavioral), we collect from you and other participants accessible to through a public bank ~~the public~~ vis via or a web repository such as through the Open Science Framework. This means that only researchers who apply and get permission to use the information for a specific research project will be able to access the information. Qualified researchers who can access the national databases can be from government, academic or commercial institutions. This will enable interested parties, like other researchers, to reproduce our results and use the acquired data in other analyses. All of your information will be kept in strict confidence; you will never be personally identified in any communication or publicly-accessible data sets.<sup>2</sup>

## What happens if I am injured because I took part in this research?

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

The University of Massachusetts Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

## Will I be given any money or other compensation for being in this study?

For ~~both your first~~ visit ~~s involving MRI's~~ you will receive \$~~1050~~ ~~each~~ for completing both the MRI and the questionnaires, and \$50 in travel expenses (free parking), even if you choose to discontinue your participation due to any discomfort you might experience during the scanning session. If your first visit is successful, you will be asked to return for a second visit, with the same compensation scheme, for a possible total of \$300.

## What happens if I do not want to be in this research?

Formatted: Font: Times New Roman, 12 pt

Formatted: Font: Times New Roman, 12 pt

Formatted: Font: Times New Roman, 12 pt

Formatted: Font: Times New Roman, 12 pt

Formatted: Font: Times New Roman, 12 pt

Formatted: Font: Times New Roman, 12 pt

Formatted: Font: Times New Roman, 12 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

If you decide not to take part in the research, it will not affect your usual care and it will not be held against you.

### ***What happens if I say yes, but I change my mind later?***

You are free to leave the study at any time. There are no penalties and you do not lose any benefits to which you are otherwise entitled. Data that has already been used will remain part of the study database and may not be removed in order to maintain the integrity of the research. However, any identifiable information will be destroyed so that no one can tell the data belonged to you. If you decide to stop your participation, we may ask if you are willing to have us contact you for safety follow-up purposes or to provide further data collection from routine medical care.

There are no risks to dropping out of the study.

### ***Can I be removed from the research without my OK?***

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include inability to comply with study procedures.

### ***Who can I talk to?***

If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to ~~the~~ [Dr. Jean King, PhD's](#) research team at 774-455-4272 or Dr. Eric Loucks' research team at 401-400-4768 ~~401-XXX-XXXX~~.

This research has been reviewed and approved by an Institutional Review Board. You may talk to them at (508) 856-4261 or [irb@umassmed.edu](mailto:irb@umassmed.edu) for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Formatted: Font: (Default) Times New Roman, (none)

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

---

**Signature Block for Capable Adult**

Your signature documents your permission to take part in this research.

---

Signature of subject

---

Date

---

Printed name of subject

---

Signature of person obtaining consent

---

Date

---

Printed name of person obtaining consent

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Formatted: Font: 10 pt

Appendix 6D -  
Questionnaire for UMass  
Medical School fMRI sub-study

## Amsterdam Resting-State Questionnaire 2.0

Below is a collection of statements about your experience in the scanner. Using the responses below, please indicate how you felt. Please answer according to what really reflects your experience rather than what you think your experience should be.

Version 1.A

	<b>Completely disagree</b>	<b>Somewhat disagree</b>	<b>Neither agree or disagree</b>	<b>Somewhat agree</b>	<b>Completely agree</b>
I imagined talking to myself.					
I pictured events.					
I felt relaxed.					
I thought about people I like.					
I thought about my heartbeat.					
I felt pain.					
I had difficulty staying awake.					
I thought about myself.					
I had difficulty holding on to my thoughts.					
I felt comfortable.					
I thought about the future.					
I thought in images.					
I thought in words.					
I felt tired.					
I was conscious of my body.					
I thought about my health.					
I thought about solving problems.					
I had busy thoughts.					
I felt ill.					
I thought about others.					
I felt sleepy.					
I felt happy.					
I thought about my feelings.					
I pictured places.					
I thought about things I need to do.					
I placed myself in other people's shoes.					
I had rapidly switching thoughts.					
I thought about my breathing.					
I had silent conversations.					
I thought about my behavior.					
I had my eyes closed					
I was able to rate the statements					

## Amsterdam Resting-State Questionnaire 2.0

Version 1.B

	Completely disagree	Somewhat disagree	Neither agree or disagree	Somewhat agree	Completely agree
I thought about my heartbeat.					
I thought about solving problems.					
I felt sleepy.					
I had difficulty holding on to my thoughts.					
I thought about people I like.					
I had rapidly switching thoughts.					
I pictured places.					
I thought about my behavior.					
I had difficulty staying awake.					
I was conscious of my body.					
I had silent conversations.					
I thought about others.					
I had busy thoughts.					
I thought about the future.					
I felt comfortable.					
I thought about things I need to do.					
I felt tired.					
I thought about my health.					
I thought about my feelings.					
I placed myself in other people's shoes.					
I felt pain.					
I thought in words.					
I thought in images.					
I pictured events.					
I felt relaxed.					
I thought about my breathing.					
I thought about myself.					
I imagined talking to myself.					
I felt happy.					
I felt ill.					
I had my eyes closed					
I was able to rate the statements					



Appendix 6E -  
UMass Medical School fMRI  
sub-study IRB Approval Letter

12/12/2017

Jean King, PhD  
University of Massachusetts  
Psychiatry

Dear Dr. King:

The IRB reviewed the following:

Type of Submission:	Study
Review Type:	Non-Committee
Project Title:	Mindfulness Influences on Self-Regulation: Mental and Physical Health Implications for blood pressure (Mindfulness MB-BP Self-Regulation MRI)
Investigator:	Jean King, PhD
IRB ID:	H00014090
Funding Agency:	NATIONAL INSTITUTES OF HEALTH
Grant Title:	MINDFULNESS INFLUENCES ON SELF- REGULATION: MENTAL AND PHYSICAL HEALTH IMPLICATIONS
Grant ID:	3UH2AT009145-03S1
IND or IDE:	None
IRB Review Date:	12/3/2017
Documents Reviewed:	umms-hrp-504---ISP MB-BP MRI-2017.12.12.docx Amsterdam Resting-State Questionnaire 2017.11.06.docx Phone Screen MB-BP MRI H00014090 2017.12.05.doc Consent_MB-BP MRI 2017.12.05.doc

The IRB approved the research from 12/12/2017 to 12/11/2018 inclusive. Before 10/27/2018 or within 30 days of closing the study, whichever is earlier, you are required to submit a completed Continuing Review Progress Report and necessary attachments to request continuing approval or study closure.

If continuing review approval is not granted before the expiration date of 12/11/2018, approval of this research expires on that date.

Stamped consent documents are included with this approval. Use these to document consent.

In conducting this research, you are required to follow the requirements listed in the INVESTIGATOR MANUAL.

Sincerely,

Crystal Davis, MPH  
IRB Protocol Specialist

cc: Payne, Laurelee



# BROWN

Research Protections Office  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Research Protections Office  
**Date:** March 12, 2015  
**RE:** Protocol Entitled: Mindfulness-Based Hypertension Therapy Pilot Study (#1412001171).

The above referenced protocol received a full board review and approval by the Brown University IRB on January 15, 2015. IRB approval is valid for 1 year from January 15, 2015 through January 15, 2016.

Should the research continue, the next progress report must be submitted two months prior to the expiration date for review and approval.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is March 31, 2015.

All pertinent federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Research Protections Office (RPO) at

<http://www.brown.edu/research/institutional-review-board-irb>. This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Research Protections Office  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Research Protections Office  
**Date:** July 01, 2015  
**RE:** Protocol Entitled: Mindfulness-Based Hypertension Therapy Pilot Study (#1412001171).  
Amendment #1

The above amendment to the protocol, received an expedited review and approval by the IRB on July 01, 2015.

This amendment dated 6/17/15, (originally submitted 4/8/15) includes changing the survey software to Qualtrix, updating the phone screening questionnaire, clarifying the study safety plan, modifying the consent form, adding questionnaires to the baseline survey, and modifying recruitment procedures.

This amendment approval date does not change the continuing review date for the overall project. Should the research continue, the next progress report must be submitted for review and approval two months prior to the expiration date.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is July 31, 2015.

All pertinent federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Research Protections Office (RPO) at <http://www.brown.edu/research/institutional-review-board-irb>. This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Research Protections Office  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Research Protections Office  
**Date:** August 07, 2015  
**RE:** Protocol Entitled: Mindfulness-Based Hypertension Therapy Pilot Study (#1412001171).  
Amendment #2

The above amendment to the protocol, received an expedited review and approval by the IRB on August 06, 2015.

This amendment dated 7/15/15 (revised and re-submitted on 8/5/15) included: The addition of a new participant population (NEFS sub-set) and new recruitment procedures for that population, revisions to the In-person Screening Assessments 1 and 2, revisions to wording of the phone screening questionnaire, addition of a place for staff to note contact information on the safety plan document, adding a version footer to the consent document.

This amendment approval date does not change the continuing review date for the overall project. Should the research continue, the next progress report must be submitted for review and approval two months prior to the expiration date.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*



The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is August 31, 2015.

All pertinent federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Research Protections Office (RPO) at <http://www.brown.edu/research/institutional-review-board-irb>. This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Research Protections Office  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Research Protections Office  
**Date:** September 03, 2015  
**RE:** Protocol Entitled: Mindfulness-Based Hypertension Therapy Pilot Study (#1412001171).  
Amendment #3

The above amendment to the protocol, received an expedited review and approval by the IRB on September 03, 2015.

This amendment dated 9/1/15 included the addition of a funding source (grant #1 UH2 AT009145-01, grant title: Mindfulness Influences on Self-Regulation: Mental and Physical Health Implications), a change in scope of work and related study activities secondary data analyses involving concurrent studies, additional measures and study procedures, and revised informed consent document.

This amendment approval date does not change the continuing review date for the overall project. Should the research continue, the next progress report must be submitted for review and approval two months prior to the expiration date.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is September 30, 2015.

All pertinent federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Research Protections Office (RPO) at <http://www.brown.edu/research/institutional-review-board-irb>. This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Research Protections Office  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Research Protections Office  
**Date:** January 08, 2016  
**RE:** Protocol Entitled: Mindfulness-Based Hypertension Therapy Pilot Study (#1412001171).  
Amendment #4

The above amendment to the protocol, received an expedited review and approval by the IRB on January 07, 2016.

This amendment (dated: 11/11/2015) requests approval to (a) add compensation, (b) add a NIH safety monitoring plan, (c) update the names and content of the phone screen and assessments, (d) add a 1-year follow-up visit, and (e) update the consent document to incorporate these changes.

This amendment approval date does not change the continuing review date for the overall project. Should the research continue, the next progress report must be submitted for review and approval two months prior to the expiration date.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is February 01, 2016.

All pertinent federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Research Protections Office (RPO) at <http://www.brown.edu/research/institutional-review-board-irb>. This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Research Protections Office  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Research Protections Office  
**Date:** February 26, 2016  
**RE:** Protocol Entitled: Mindfulness-Based Hypertension Therapy Pilot Study (#1412001171).  
Amendment #5

The above amendment to the protocol, received an expedited review and approval by the IRB on February 26, 2016.

This amendment (dated: 2/26/16) requests approval to allow participants, who are not able to come to the study site in person, the option to participate by online video conferencing.

This amendment approval date does not change the continuing review date for the overall project. Should the research continue, the next progress report must be submitted for review and approval two months prior to the expiration date.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is February 29, 2016.

All pertinent federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Research Protections Office (RPO) at <http://www.brown.edu/research/institutional-review-board-irb>. This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Office of Research Integrity  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Human Research Protection Program  
**Date:** May 09, 2016  
**RE:** Protocol Entitled: The Mindfulness-Based Blood Pressure Reduction Study (MB-BP) (#1412001171).  
Amendment #6

The above amendment to the protocol, received an expedited review and approval by the IRB on May 09, 2016.

This amendment (dated: 4/11/2016) requests approval to (a) change the study title; (b) revise the NCCIH Safety Monitoring Protocol; (c) separate the Baseline and Follow-up Assessments into two visits; (d) change the data collection mode to Qualtrics for Daily Practice Forms and Class questionnaires; (e) revise study recruitment material and use online advertising; (f) revise the in-class worksheets and assessments; and (g) revise the MB-BP Questionnaire, In-Person Assessment, Home Assessment, and Measurement of Mindfulness Practices.

This amendment approval date does not change the continuing review date for the overall project. Should the research continue, the next progress report must be submitted for review and approval two months prior to the expiration date.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.



\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is May 31, 2016.

All pertinent Federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Human Research Protection Program at <http://www.brown.edu/research/institutional-review-board-irb>. This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Office of Research Integrity  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Human Research Protection Program  
**Date:** September 13, 2016  
**RE:** Protocol Entitled: The Mindfulness-Based Blood Pressure Reduction Study (MB-BP) (#1412001171).  
Amendment #7

The above amendment to the protocol, received an expedited review and approval by the IRB on September 13, 2016.

Approval of the amendment (memo dated August 9, 2016) includes the addition of 2 new questions to the Home Baseline Assessment.

This amendment approval date does not change the continuing review date for the overall project. Should the research continue, the next progress report must be submitted for review and approval two months prior to the expiration date.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is September 30, 2016.

All pertinent Federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Human Research Protection Program at <http://www.brown.edu/research/institutional-review-board-irb>. This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Office of Research Integrity  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Human Research Protection Program  
**Date:** January 25, 2018  
**RE:** Protocol Entitled: The Mindfulness-Based Blood Pressure Reduction Study (MB-BP) (#1412001171).  
Amendment #10

The above amendment to the protocol, received an expedited review and approval by the IRB on January 25, 2018.

This amendment (dated: 11/6/2017) requests approval to (a) modify the approved focus group discussion questions into a one-on-one qualitative phone interview, (b) re-contact Stage 1 participants for a 2-year in-person assessment, (c) rearrange compensation amounts, (d) add recruitment for and data sharing from the UMass Medical School fMRI study, (e) add the "UMass Medical School fMRI Study Recruitment Talking Points," (f) add a consent addendum for enrolled participants to complete the phone interview, and (g) revise the approved consent to reflect the appropriate changes.

This amendment approval date does not change the continuing review date for the overall project. Should the research continue, the next progress report must be submitted for review and approval two months prior to the expiration date.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is January 31, 2018.

All pertinent Federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Human Research Protection Program at [HRPP](#). This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Research Protections Office  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Research Protections Office  
**Date:** December 17, 2015  
**RE:** Protocol Entitled: Mindfulness-Based Hypertension Therapy Pilot Study (#1412001171).  
Continuing Review #1

The above referenced progress report received a full board review and approval by the Brown University IRB on December 17, 2015. Continuation of this study is approved through January 15, 2017.

The Board determined that future progress reports of this full board protocol may be reviewed under expedited category #9.

Should the research continue, the next progress report must be submitted two months prior to the expiration date for review and approval.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is January 04, 2016.

All pertinent federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Research Protections Office (RPO) at <http://www.brown.edu/research/institutional-review-board-irb>. This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Office of Research Integrity  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Human Research Protection Program  
**Date:** December 16, 2016  
**RE:** Protocol Entitled: The Mindfulness-Based Blood Pressure Reduction Study (MB-BP) (#1412001171).  
Continuing Review #2

The above referenced progress report received an expedited review and approval under Expedited Category 9 by the Brown University IRB on December 15, 2016. Continuation of this study is approved through January 15, 2018.

Should the research continue, the next progress report must be submitted two months prior to the expiration date for review and approval.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is January 03, 2017.

All pertinent Federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Human Research Protection Program at



[HRPP](#). This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Office of Research Integrity  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Human Research Protection Program  
**Date:** January 02, 2018  
**RE:** Protocol Entitled: The Mindfulness-Based Blood Pressure Reduction Study (MB-BP) (#1412001171).  
Continuing Review #3

The above referenced progress report received an expedited review and approval under Expedited Category 9 by the Brown University IRB on January 02, 2018. Continuation of this study is approved through January 15, 2019.

Should the research continue, the next progress report must be submitted two months prior to the expiration date for review and approval.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is January 31, 2018.

All pertinent Federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Human Research Protection Program at

[HRPP](#). This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.



# BROWN

Office of Research Integrity  
Box 1986  
Providence, RI 02912  
Tel: (401) 863-3050  
Fax: (401) 863-7292

## Memorandum

**To:** Eric Loucks, Box G-S121-2  
**From:** Human Research Protection Program  
**Date:** January 09, 2019  
**RE:** Protocol Entitled: The Mindfulness-Based Blood Pressure Reduction Study (MB-BP) (#1412001171).  
Continuing Review #4

The above referenced progress report received an expedited review and approval under Expedited Category 9 by the Brown University IRB on January 09, 2019. Continuation of this study is approved through January 15, 2020.

Should the research continue, the next progress report must be submitted two months prior to the expiration date for review and approval.

Any amendments or changes to the research protocol including changes to the consent documents and questionnaires/surveys must be submitted to the IRB for review and approval prior to implementation. Also, any change in the status of participants to any of the vulnerable populations (as identified in 45 CFR 46) including, pregnant women, prisoners, or those with diminished capacity, requires IRB review and approval prior to their continuing in the study.

The IRB anticipates that investigators will employ recruitment procedures that allow for the equitable recruitment of women and minorities into research studies.

Note: All research staff must successfully complete the Brown University Education Program in the Protection of Human Research Participants (CITI at <http://www.citiprogram.org>) prior to beginning work on the project.

\*\*\* For Your Information \*\*\*

The next deadline for submission of new protocols, amendments to protocols, and annual progress reports requiring full board review is January 31, 2019.

All pertinent Federal and University policies and guidelines related to the involvement of participants in research can be obtained through the Human Research Protection Program at

[HRPP](#). This includes the *Belmont Report*, 45 CFR 46, and the Brown University Federal Wide Assurance #00004460.

cc: Webb, Julie