Study Protocol and Statistical Analysis Plan

Cover Page

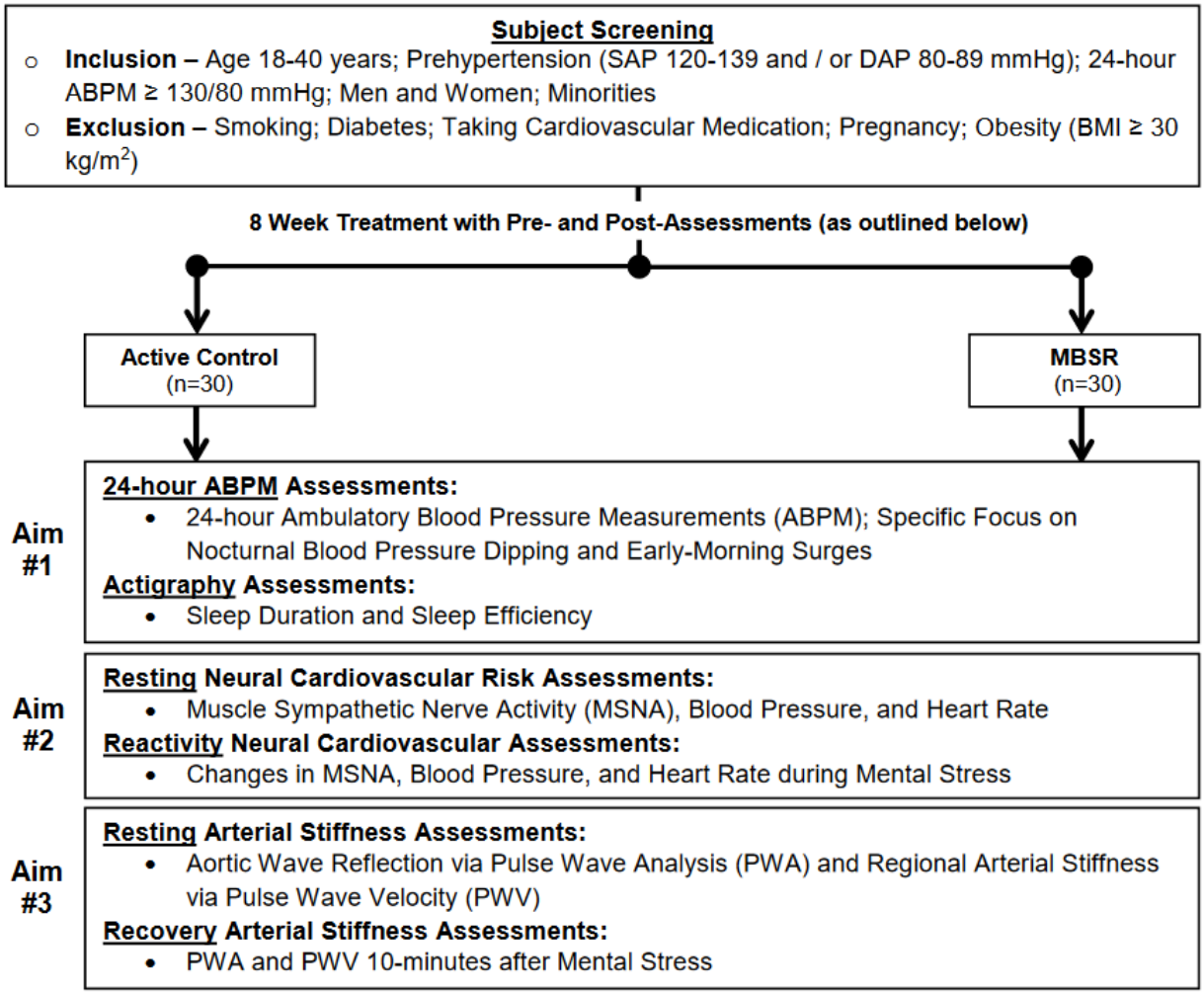
NCT03626363

Mindfulness and Neural Cardiovascular Control in Humans

February 23, 2021 (Purdue IRB Approval Date)

Study Protocol

The figure below provides a conceptual overview of this R15 project. Our study assessed traditional cardiovascular disease risk factors such as blood pressure, but also focused on non-traditional risk factors such as muscle sympathetic nerve activity (MSNA) and arterial stiffness. In addition, we included key psychological assessments such as anxiety, perceived stress, and mindfulness. Finally, our neural cardiovascular assessments were completed at rest and during acute mental stress. We attempted to recruit 60 participants with elevated blood pressure to undergo an 8-week MBSR or active control protocol as outlined below to meet the proposed specific aims. We randomized qualified participants into the MBSR or active control. All autonomic and arterial stiffness measurements were completed at a similar time of day for pre-treatment assessments within one week before participants started the active control (i.e. stress management education) or MBSR interventions, and post-data was collected within one week after participants completed their intervention again at a similar time of day. Pre- and post-intervention ambulatory blood pressure monitor (ABPM) measurements started at a similar time on a work or school day.



Statistical Analysis Plan

The statistical approach for the research aims are outlined below. The power analyses were based on previous MBSR and MSNA-related work. A priori power analysis indicated that a sample size of 40 participants (20 per group) was needed to provide sufficient statistical power (~0.89) to detect a ~4 bursts/min in mean difference for resting MSNA using a mixed-effect analysis of variance model with repeated measures and an alpha of 0.05. We aimed to enroll a total of 60 individuals to ensure a minimum final sample size of 40 (MBSR = 20; active control = 20) with an estimated power of ~89%. We expected that some participants may not complete the 8-week protocol and we may occasionally have unsuccessful MSNA recordings. Thus, we aimed to recruit 30 participants for each group as outlined in Figure 1 and expected a minimum 67% retention rate to yield a final sample of at least 20 per group.

Aim 1: The primary objectives of this aim were to determine if MBSR would reduce 24-hour ABPM, improve nocturnal blood pressure dipping, and attenuate the early-morning blood pressure surges in adults with elevated blood pressure. We utilized repeated measures analysis of variance (ANOVA) with 2 groups (MBSR and active control) and 2 times (pre and post). The a priori alpha was 0.05. The primary response variable is nighttime blood pressure dipping.

Aim 2: The primary objective of this aim were to determine if MBSR would lower MSNA in adults with elevated blood pressure. We utilized repeated measures ANOVA as in aim 1. Pearson correlations were utilized to probe for relationships between DAP and MSNA to evaluate spontaneous sympathetic baroreflex sensitivity. The a priori alpha was 0.05. The primary response variables were resting MSNA (quantified as bursts/min and bursts per 100 heart beats), MSNA / blood pressure reactivity, and spontaneous sympathetic baroreflex sensitivity (slopes).

Aim 3: The primary objective of this aim was to determine if MBSR would lower arterial stiffness in men and women who had elevated baseline blood pressure. We utilized repeated measures ANOVA as in aims 1 and 2. The a priori alpha was 0.05. The primary response variables were baseline arterial stiffness (i.e. AIx and cfPWV) and arterial stiffness recovery at post-10-minutes mental stress. Recovery analyses compared the change from the supine baseline to 10-minutes post mental stress for each variable (i.e. the delta) for before (pre), and after (post) the 8-week interventions.

Published Results

We have three peer-reviewed publications accepted or published so far related to this project:

Durocher JJ, Phelan HL, Toorongian CA, Vyas AP, and Morin BE. Effect of Single-Session Meditation on Aortic Pulsatility and Anxiety in Moderately Anxious Adults. *Advances in Mind-Body Medicine* spring; 37(2): 32-36, 2023.

Bigalke JA, Durocher JJ, Greenlund IM, Keller-Ross A, and Carter JR. Blood Pressure and Muscle Sympathetic Nerve Activity Are Associated with Trait Anxiety in Humans. *American Journal of Physiology: Heart and Circulatory Physiology,* 324(4): H494-H503, 2023.

Elmer SJ and Durocher JJ. Moving student research forward during the COVID-19 pandemic. *Advances in Physiology Education* 44(4): 741-743, 2020.

We have published four abstracts from this project in the FASEB Journal:

Vyas AP, Thivierge GS, Toorongian CA, Larson RA, and Durocher JJ. Mental Stress Pressor Response and Post-Stress Aortic Wave Reflection. *FASEB J* May 2022 36(S1). *Federation of American Societies for Experimental Biology*.

Vyas AP, Petushek EJ, Morin BE, and Durocher JJ. Effects of 8-week active mindfulness and stress management on decentering and anxiety during the COVID-19 pandemic. *FASEB J* May 2021 35(S1). *Federation of American Societies for Experimental Biology*.

Basala TR, Toorongian CA, and Durocher JJ. Decentering and Nocturnal Blood Pressure Dipping in Young Adults. *FASEB J* May 2021 35(S1). *Federation of American Societies for Experimental Biology*.

LewAllen SE, Vyas A, Thivierge GS, Morin BE, and Durocher JJ. Decentering, Aortic Wave Reflection, and Arterial Stiffness. *FASEB J* April 2020 34(S1). *Federation of American Societies for Experimental Biology*.

We have also published four abstracts from this project in Physiology:

Thivierge GS, Vyas AP, Morin BE, Larson RA, and Durocher JJ. The Effects of Mindfulness-Based Stress Reduction and Stress Management Education on Arterial Stiffness, Trait Anxiety, and Sympathetic Regulation. *Physiology* May 2023 38(S1): Late-breaking Neural Control of Autonomic Physiology.

Bishop RE, Thivierge GS, Larson RA, and Durocher JJ. Decentering and baroreflex sensitivity in adults with elevated blood pressure. *Physiology* May 2023 38(S1): Blood Pressure Regulation.

Toorongian CA, Bauman MJ, Thivierge GS, Stanic RS, and Durocher JJ. The disidentification component of decentering is a predictor of nighttime systolic and diastolic blood pressure dipping. *Physiology* May 2023 38(S1): Blood Pressure Regulation.

Bigalke JA, Durocher JJ, Greenlund IM, Keller-Ross M, and Carter JR. Trait Anxiety is Associated with Blood Pressure and Muscle Sympathetic Nerve Activity. *Physiology* May 2023 38(S1): Neural Control of Autonomic Physiology and Disease.

Key Outcomes or Other Achievements:

Key outcomes and primary achievements include one Michigan Tech MS student completing her thesis related to this project and another Michigan Tech PhD student completing her dissertation on this project. Two Purdue University Northwest MS students completed their theses related to this project in 2022 and 2023, respectively. The primary personnel and supported graduate students presented at the Experimental Biology Conference in April 2022 and at the Physiology Summit Conference in April 2023. Several more peer-reviewed manuscripts will be submitted from this project now that data collection is complete.

Date: 9-26-2024

IRB #: IRB-2020-1547
Title: Mindfulness and Neural Cardiovascular Control in Humans
Creation Date: 10-21-2020
End Date:
Status: Closed
Principal Investigator: John Durocher
Review Board: Institutional Review Board FY 2024
Sponsor: US Department of Health and Human Services - DHHS

Study History

Submission Type Initial	Review Type Full	Decision Approved
Submission Type Renewal	Review Type Full	Decision Approved
Submission Type Modification	Review Type Exempt	Decision Exempt
Submission Type Modification	Review Type Expedited	Decision Approved
Submission Type Modification	Review Type Expedited	Decision Approved
Submission Type Closure	Review Type Unassigned	Decision

Key Study Contacts

Member Colleen Toorongian	Role Co-Principal Investigator	Contact ctoorong@purdue.edu
Member Grant Thivierge	Role Co-Principal Investigator	Contact gthivier@purdue.edu
Member John Durocher	Role Principal Investigator	Contact jjduroch@purdue.edu
Member John Durocher	Role Primary Contact	Contact jjduroch@purdue.edu

Initial Submission

Study Personnel

*required

Study Personnel

In this section you will name all staff who will participate in the study.

*required

A Principal Investigator (PI) is responsible for all aspects of a research study.
STUDENTS ARE NOT AUTHORIZED TO BE PRINCIPAL INVESTIGATORS

Provide the name of the Principal Investigator of this study.
All faculty (tenured, tenure-track, research and clinical) are eligible to be Principal Investigators. Others requesting to submit proposals as the Principal Investigator for the first time must obtain special approval.

Once the name is selected, training courses from the CITI system should appear when you click "View". If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: John Durocher
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: jjduroch@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

*required

Please check your Purdue University PI classification.

- ✓ Faculty (tenured, tenure-track, research and clinical)
- Student

Purdue non-faculty staff member granted special PI status.

*required

Primary Contact

Provide the name of the Primary Contact of this study. The Primary Contact will be copied on all correspondence regarding the IRB review. Note that the Primary Contact and the Principal Investigator may be the same. The Primary Contact must be a current Purdue University faculty, staff, postdoc, or student and must have a role as Key Personnel on the study.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: John Durocher
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: jjduroch@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

If you wish to provide a campus phone number for the Primary Contact, you may list it here.

This field is optional. Most correspondences from the IRB will arrive via the Cayuse system.
219-989-2625

*required

Key Personnel

Below is a definition of Key Personnel. Please read the definition and decide who will need to be listed as Key Personnel on the study. The PI defines the roles of each staff member based on the definition below.

Key personnel: The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

*required

Does your study have additional Key Personnel besides the PI and Point of Contact?

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

✓ Yes

*required

Where are the Key Personnel from?

Check all that apply.

✓ I have key personnel from Purdue University.

I have key personnel from another external site (outside of Purdue).

No, the only personnel on the project are the PI and Point of Contact.

Key Personnel From Purdue University

- *The Principal Investigator and Primary Contact are considered Key Personnel. You do not need to list these names again.*

- *Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.*
- *If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.*

Name: Colleen Toorongian
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: ctoorong@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. For researchers outside of Purdue university, please use the next section and click "external investigators".

(First Name: Last Name: Purdue e-mail address)
Toorongian

*required

Provide a brief description of each person's position at Purdue (e.g. student, staff, faculty) and their role in the study.

Examples:
Prof. Principal (faculty) will oversee all aspects of the study design and conduct
John Researcher (graduate student) will recruit and consent participants and collect data
Purdue Pete (staff) will analyze collected study data.

John Durocher is the PI and tenured associate professor that will oversee all aspects of the study.
Colleen Toorongian is an MS student in Biological Sciences that will assist with data collection, analyses, and dissemination of results.
Brigitte Morin MS is a senior lecturer at Michigan Tech that has been involved with teaching the MBSR class since the start of this project. She recently agree to teach the 8-week course one more time in the summer of 2021 and will fly down to Chicago once each week to travel to our Hammond campus to lead the MBSR class.

Research Sites

*required

Where will the study take place?

✓ Purdue University

*required

Please check the following locations.

West Lafayette

✓ Regional Campus (PFW, PNW, IUPUI)

*required

Select the regional campus

✓ Hammond

Fort Wayne

Westville

Indianapolis

Polytechnic Institute Statewide Sites

Extension Sites

*required

Please provide a brief description of the Purdue University location(s).

Provide building names, course titles, event names as applicable.

Gyte Building - Room 6 (Clinical and Applied Human Physiology Laboratory)

External Site (non Purdue University)

Getting started with your submission

*required

Welcome to the submission system for the Purdue HRPP/IRB. Before you begin, you should be familiar with the framework of human research protections and how they relate to your proposed study. The materials to help you appear on our website.

Be certain that all personnel have completed online training prior to submitting the protocol.

Helpful Tip: Use the Create PDF button at the top of the page if you need to share a PDF version of this protocol for discussion with a reviewer outside of the Cayuse system.

The choices you make on the first two sections will help populate the required sections for your submission. Please look through the options and make the choice closest to your research. You can always seek assistance by scheduling an appointment with the HRPP Office or reviewing the materials at www.irb.purdue.edu.

Exempt study

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

Non-exempt study

✓ *Research that does not fit into an exempt category typically involves the collection of new data from a participant.*

Just-in-time

I have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but my application to the IRB is dependent on other factors such as:

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible at the time of the sponsor request, please do not select this option. The research team should affirm that their sponsor will accept documentation for a development protocol.

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

Quality Improvement

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

I need to know if my project is considered "Human Subjects Research"

I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).

When Purdue University will be engaged in human subject research with one or more institutions, investigators may submit a Request for Deferral asking that the review be deferred to one institution's Institutional Review Board (IRB).

Research Classification and Special Considerations

Would you determine that this research is predominately social or biomedical in nature

When you provide an answer to this question, a series of additional questions will display, and checking on each of these questions will generate a new form to the left that you will need to complete. These forms will ask the questions we used to ask, but in a clearer and more organized way, which will help the reviewer, as well as the investigator.

✓ **Biomedical**
My research has a biomedical focus.

Social / Behavioral
My research has a social or behavioral focus.

A combination of social science and biomedical, or I'm not sure.

*required

Please check any of the following that apply to the proposed research.

Each of these involves special considerations in the IRB review. If none of these items apply, click on "None of These" and continue forward in the application.

Potentially Vulnerable Populations
Examples: Children, Pregnant Women/Fetuses, Prisoners, those that lack capacity to consent), economically disadvantaged persons, minorities.

Use of an Experimental Drug
A substance manufactured via chemical process and intended for use in the diagnosis, cure, mitigation, than food) intended to affect the structure or any function of the body of man.

Note: Studies of this nature are considered Applicable Clinical Trials and may require an Investigational and Drug Administration and involvement of a physician investigator.
https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/investigational-new-d

Use of an Investigational Medical Device
An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or

or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, m in man or other animals, OR intended to affect the structure or any function of the body of man or other primary intended purposes through chemical action within or on the body of man or other animals and v metabolized for the achievement of its primary intended purposes.

Note: Studies of this nature are considered Applicable Clinical Trials and may require an Investigationa Drug Administration and involvement of a physician investigator.
https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/investigational-new-d

Clinical Trial
PLEASE READ THIS DEFINITION CLOSELY.

✓ *NIH defines a Clinical Trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."*

If this determination applies, please check this box.

Research with Food
Articles used for food or drink (or for components of such articles) and NOT intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

Radiation and/or Imaging
X-ray, CT, PET scans, nuclear medicine procedures, and MRI scans.
This protocol requires for research purposes 1) radiological assessments and procedures that involve radiation exposure (X-ray, CT, PET scans) 2) nuclear medicine procedures (imaging or therapeutic) or 3) MRI scans.

Nursing or Study Physician Resources
This protocol will have Nursing or Study Physician Resources

Blood Collection for Research Purposes
This protocol involves collection of blood samples other than discarded specimens. Examples are collections involving finger stick, venipuncture, or indwelling catheters.

Human Biological Specimen Repository
This protocol involves the establishment of a biological specimen repository.
Repositories are used for prospective collections of specimens that are processed, stored and

distributed to multiple investigators for use in research.

Gene Research Classification

The study will collect samples from individuals and look at a single gene, group of genes, or full genome for the purposes of research.

Stem Cells

This protocol includes an intervention with human subjects that involves either
a) the derivation of stem cells,
b) the implantation of stem cells.

International Research

This protocol includes research that is conducted at a non US location.

Data Controlled Under HIPAA and/or FERPA

Health Insurance Portability and Accountability Act (HIPAA) covers individually identifiable health information held or transmitted by a covered entity. This often involves healthcare providers and insurance companies.
AND/OR
Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records.

Biological Product

A substance manufactured via biological process and otherwise meets the above definition of a drug; includes a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

Dietary Supplement

A product taken by mouth that is intended to supplement the diet and that contains one or more dietary ingredients.

Community-engaged research

This is community-engaged research. For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.

Incidental Findings

Incidental findings are discoveries of individual-level findings that are unrelated to the goals of the study. (e.g. genetic data, MRI or test results).

Deception or incomplete disclosure

Deception occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.

Incomplete Disclosure occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

None of the above apply.

Protocol Description

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

Tell the IRB what specific trait(s), function(s) or behavior(s) you would like to study. Give a brief summary of your study in simple terms.

Describe why you are conducting the study. Identify the research question(s).

More than 50% of U.S. adults have elevated blood pressure or hypertension which increases the risk of cardiovascular disease (CVD). Early detection of elevated blood pressure or stage 1 hypertension offers a window of opportunity to prevent progression to overt hypertension and CVD through behavioral modification. Sympathetic activation and arterial stiffness are both deleterious factors that concomitantly contribute to elevated blood pressure. Mindfulness-Based Stress Reduction (MBSR) programs have been shown to reduce blood pressure in adults, but the mechanisms for the reduction remain speculative.

*required

Specific Aims/Objectives

Give the IRB an example of potential discoveries you hope to make or insight you hope to share. For example, outline a disease state, social characteristic or behavior that might benefit from the study results.

We will systematically examine 24-hour blood pressure regulation and two potential mechanisms for the anti- hypertensive effects of MBSR by directly assessing muscle sympathetic nerve activity (MSNA) and arterial stiffness. Aim 1 will determine if MBSR improves 24-hour blood pressure regulation, aim 2 will determine if MBSR reduces sympathetic neural activity, and aim 3 will determine if MBSR will decrease arterial stiffness in prehypertensive adults. This project will also provide advanced research opportunities to undergraduate and graduate students in health-related fields at Purdue University Northwest, consistent with the goals of the Academic Research Enhancement Award (R15) mission.

*required

Background and Significance

Include how previous research studies and their results support your study or how you will build upon existing information.

The proposed research is relevant to public health because over 50% of adults in the U.S. have elevated blood pressure or hypertension. The project is relevant to NIH's mission because it will provide rigorous investigation on Mindfulness-Based Stress Reduction as a proactive anti-hypertensive lifestyle intervention that may improve blood pressure regulation through sympathetic nerve control and arterial stiffness.

*required

Research Hypotheses

Please list any relevant study hypothesis/hypotheses. If this does not apply, type "Not Applicable".

Our central hypothesis is that MBSR will: 1) improve nocturnal blood pressure dipping and / or reduce early-morning surges, 2) reduce resting MSNA and attenuate the neural cardiovascular responses to acute stress, and 3) decrease arterial stiffness. We will utilize a parallel, randomized, control design (MBSR vs. active control) that includes gold-standard techniques for measuring blood pressure (24-hour ambulatory assessment), MSNA (microneurography), and arterial stiffness (applanation tonometry).

*required

How long will participants be asked to be in the study?

List the approximate duration in the fashion below.

- *Number of Visits =*
- *Minutes or Hours per visit =*
- *Single Day or Multiple Days?*
- *Total number of months until all data are collected =*

Potential participants visit the laboratory on three non-consecutive days for screening visits that take approximately 15 minutes each. We have included 3 pre-screening blood pressures to ensure that participants meet the primary requirement for elevated blood pressure. This procedure was proposed in

the original NIH proposal, has been used throughout this study so far, and has been used in previous projects we had funded through the NIH.

Qualified participants visit the lab two more times, once before and once after the 8-week intervention (within 10 days of the start and finish). Each of those visits take about 3 hours. The mindfulness-based stress reduction (MBSR) and stress management education (SME) classes (interventions) meet once per week for 2 to 2.5 hours. There is also one Saturday requirement at the end of the 6th week for about 7-8 hours. At home daily practice for participants in the two classes ranges from 30-45 minutes. The entire study with pre- and post-testing is approximately 10 weeks.

We specifically set up these courses for the research study. However, eight week mindfulness-based stress reduction courses are offered around the world by qualified instructors. We plan to have one of our previous instructors (Brigitte Morin) offer the course to the final cohort of participants in the summer of 2021. I will assist my graduate student Colleen Toorongian to offer the 8-week stress management education course. The SME course is traditionally used as an active control course for meditation studies, and to my knowledge it is not offered as an independent course like MBSR.

*required

Specific Study Procedures

Describe in detail what a research participant will be asked to do.

- Prior to the start of the 8-week program, a 24-hour blood pressure reading will be taken. The device is compact and easily attached to a belt. Participants will also be fitted with a wrist accelerometer (similar to a Fitbit) that will track sleep-wake cycle for five consecutive nights. Participants will also complete questionnaires for anxiety, five-facets of mindfulness, and the ability to decenter.

- Following the accelerometer recordings, nervous system functions will be tested with microneurography (small electrode needle that can measure electrical activity in nerves) in a baseline setting along with a mental stress test (doing mental math calculations). Nerve activity will be continuously measured during the baseline and mental stress test. In addition to the nerve recordings, heart rate will be recorded with 3-lead electrocardiography, and continuous blood pressure with a small cuff on the middle finger. We will also estimate arterial stiffness with a small probe that will be placed at the radial (wrist), carotid (neck), and femoral (groin) pulse sites. We can also estimate breathing rate with an elastic pneumobelt that goes around the rib cage (fits gently outside of the participant's clothing). Breathing rate is not considered a primary variable, but we may report breathing rate (breaths per minute) if we calculate results for heart rate variability.

- With the programs outlined, participants will then proceed with the 8-week program to which they were randomly assigned. It is requested that you do not change your normal exercise schedule or eating habits. Both the MBSR and active stress management control programs will require a once weekly group meeting and at home exercises. The home practice for MBSR participants includes things like breathing awareness, body scanning, and gentle Yoga. The home practice for SME

participants includes daily reading from the book "Why Zebras Don't Get Ulcers" and gentle resistance band training. We have free copies of the required book that are lent out to participants during the 8-week class.

- Once the 8-week program is completed, participants will once more complete the questionnaires, 24- hour blood pressure readings, accelerometry, microneurography, heart rate, blood pressure, and arterial stiffness readings.

- Related to our laboratory safety, our new Tuttnauer 1730M autoclave is 20+ feet away from where participant testing would take place, and will never be used while a participant is in the laboratory. We have used this same autoclave for more than 15 years, and it has a very secure door latch. We have always worn neoprene gloves when prepping the electrodes to be autoclaved and when removing the electrodes from the autoclave in the sterilized pouches. We will use 3.5" x 10" self seal sterilization pouches made by PlastCare USA, that have an indicator strip that changes from blue to brown during the autovclaving process. We will follow additional PPE protocols during the COVID pandemic such as wearing a facemask during the autoclaving procedure.

In long term studies, a visual representation of a timeline is helpful. You may upload a visual representation as a Word (.docx) or PDF file here.

MBSR Conceptual Overview.pdf

Attach any surveys, questionnaires, assessments

For purposes of recordkeeping, the HRPP/IRB will need to have a Word or PDF version of any Qualtrics or electronic survey questionnaires. Please include more than a link to the survey.
MBSR Study Questionnaires.pdf

UFI_Pneumotrace_Datasheet.pdf

Actiwatch Spectrum PRO Brochure.pdf

Flow charts, schemas

MBSR Conceptual Overview.pdf

References

Below are references that we cite in our complete IRB proposal:

- 1.**Baer RA, Carmody J, and Hunsinger M**. Weekly change in mindfulness and perceived stress in a mindfulness-based stress reduction program. *Journal of clinical psychology* 68: 755- 765, 2012.
- 2.**Baer RA, Smith GT, Lykins E, Button D, Krietemeyer J, Sauer S, Walsh E, Duggan D, and Williams JM**. Construct validity of the five facet mindfulness questionnaire in meditating and nonmeditating samples. *Assessment* 15: 329-342, 2008.
- 3.**Brguljan-Hitij J, Thijs L, Li Y, Hansen TW, Boggia J, Liu YP, Asayama K, Wei FF, Bjorklund-Bodegard K, Gu YM, Ohkubo T, Jeppesen J, Torp-Pedersen C, Dolan E, Kuznetsova T, Katarzyna SS, Tikhonoff V, Malyutina S, Casiglia E, Nikitin Y, Lind L, Sandoya E, Kawecka-Jaszcz K, Filipovsky J, Imai Y, Wang J, O'Brien E, Staessen JA, and International Database on Ambulatory Blood Pressure in Relation to Cardiovascular Outcome I**. Risk stratification by ambulatory blood pressure monitoring across JNC classes of conventional blood pressure. *Am J Hypertens* 27: 956-965, 2014.
- 4.**Callister R, Suwarno NO, and Seals DR**. Sympathetic activity is influenced by task difficulty and stress perception during mental challenge in humans. *The Journal of Physiology* 454: 373-387, 1992.
- 5.**Cardoso CR, and Salles GF**. Prognostic Importance of Ambulatory Blood Pressure Monitoring in Resistant Hypertension: Is It All that Matters? *Curr Hypertens Rep* 18: 85, 2016.
- 6.**Carmody J, and Baer RA**. Relationships between mindfulness practice and levels of mindfulness, medical and psychological symptoms and well-being in a mindfulness-based stress reduction program. *Journal of behavioral medicine* 31: 23-33, 2008.
- 7.**Carter JR, Durocher JJ, Larson RA, DellaValla JP, and Yang H**. Sympathetic neural responses to 24-hour sleep deprivation in humans: sex differences. *Am J Physiol Heart Circ Physiol* 302: H1991-1997, 2012.
- 8.**Carter JR, Stream SF, Durocher JJ, and Larson RA**. Influence of acute alcohol ingestion on sympathetic neural responses to orthostatic stress in humans. *Am J Physiol Endocrinol Metab* 300: E771-778, 2011.
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Participant Information

*required

Total Study Enrollment

Please enter the number of subjects that will be enrolled at all sites, that are required to complete data analysis. Include the rationale for this number (e.g. statistical analyses, population composition). If at a later time it becomes apparent you need to increase your sample size, you will need to submit a Revision Request.

In the first two years of the award (while at Michigan Tech), we have randomized 43 participants into either the 8-week mindfulness-based stress reduction (MBSR) class or the stress management education (SME) active control course. We unfortunately lost our ability to post-test 19 participants in the spring of 2020 due to COVID-19 concerns. Our total project enrollment goal for NIH was 60 participants, but due to lost data on many participants we would like to be able to enroll and test up to 30 more participants at Purdue University Northwest.

*required

Attrition Considerations

If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through Purdue University. Please describe the rationale.

Consider:

- *Whether the withdrawal of the subjects might result from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and*
- *Whether the withdrawal might occur from all components of the research study or just the primary interventional component.*

Based on our previous cohorts we have lost up to 20% of enrolled participants during the longitudinal study. We have set a target to complete 24 more participants through the longitudinal study, so enrolling 30 new participants should help us to meet that objective.

*required

Age(s) of Participants in Study Population

Please include an age range for subjects, if relevant. If the research has multiple subject groups, describe the requirements for each separately.

Newborn to less than 10 years old

10 years old and less than 18 years old

✓ 18 to 65 years old

Enter specific age range if the target population age is less than 65.

18 to 55 years old

65 years and older

Unknown- Data are deidentified of any age or date of birth

*required

Inclusion criteria - Please identify the population that you would like to study.

Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study.

Age between 18 and 55 years
Must have an average seated clinical blood pressure >120 mmHg systolic and / or >80 mmHg diastolic
Must have a body mass index < 30 kg / sq. m
Not be taking any cardiovascular medication

*required

Exclusion criteria - Please identify the characteristics that do not represent your intended study population.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition. Please provide information about why the group will need to be excluded.

For NIH funded protocols: If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

Anyone with signs, symptoms, or diagnosis of COVID-19
Pregnant women
Taking cardiovascular medication
History of autonomic dysfunction such as postural orthostatic tachycardia syndrome (POTS) or syncope (fainting)
Smokers or those that use vaporized nicotine
Diabetics
Those with a pacemaker
Those with a history of MRSA, neuropathy, or illicit substance abuse

Please consider the population being studied. Are there any other safeguards that you are putting in place to address participant protections?

We will follow strict guidelines in regard to COVID-19.

Recruitment

*required

Recruitment Processes

How will people find out about your study? It's common for studies to be advertised on flyers, social media, or ads. The IRB must know what language and materials are used to recruit participants.

*required

Does your study use a known group of participants or records to recruit up-front? Check any of the following sources of information which will be used to identify potential subjects

Yes, a known group or subject pool.

✓ No, only the general population

Both a known group AND also the general population.

*required

Do the researchers hold any authority over the targeted population?
Examples:

- Teacher/student
- Supervisor/Employee

Please keep in mind the researcher that conducts recruitment, collects, and analyzes identifiable data cannot have authority over the potential participant due to the potential for undue influence. If necessary, a third party (listed as key personnel) who does not have authority over the targeted population must conduct recruitment and strip all identifiers prior to researchers/authority figures have access to the data.

✓ Yes

*required

Please detail how the study will prevent against undue influence or coercion to participate.

There is a chance that a student from one of my courses might volunteer as a participant, but they would not be the primary targeted population. Participation in this study is voluntary and participants may withdraw at any time without any penalty. Please let me know if you would prefer to have my department chair or someone from the Purdue University Northwest Faculty Research Board to monitor and mitigate this potential risk.

No

*required

How will you recruit the intended participants from the general population for your study?

It's common for studies to be advertised on fliers, ads, or social media. The IRB must know how people will find out about the study.
Points to consider:

- *Is the setting, location and timing of recruitment appropriate for the research being conducted?*
- *Are recruitment methods well defined and appropriate for the population?*
- *Are all recruitment materials non-coercive, and easily understood?*

We will include a study flyer as part of our submission. In the past we have shared the flyers by posting them around campus, and have also posted them in local newspapers and on social media. We will respond to interested potential participants by email, but will not use list serves unless we gain approval from the manager of the list serve and then the Purdue University IRB. The PI has completed NIH Good Clinical Practice training recently so that the flyer will not be coercive (for example, in regard to monetary compensation).

*required

Privacy During Recruitment

Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).

Examples of issues:
Potential subjects may not want to be approached for research purposes by someone they do not know.
Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc. If your study is not anticipated to generate privacy concerns during recruitment, please state this below.

The study PI and all students that help on the project will have completed the appropriate CITI training courses. The PI has been a leader of human participant research for more than 15 years. We will not access medical records, and will store any electronic study data on a password protected computer with non-identifiable data. Any paper data will be stored in a locked file cabinet in the PI's lab on the Hammond campus (in Gyte 6).

*required

Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?

✓ Yes

*required

Please describe how frequently and in what manner individuals will be contacted. Indicate the endpoint for contact.

Participants may be contacted by phone or text message, but the preferred method of contact will be via email listserves. The endpoint for contact will be the PI (John Durocher).

No

*required

Check any of the following recruitment materials which will be used to contact potential subjects.

✓ Direct mail/email

*required

Upload the recruitment letter that will be used.

MBSR Recruitment Email -2.pdf

MBSR Flyer Updated.pdf

✓ Flyers/Brochures

*required

Upload the text or draft of this flyer or brochure.

MBSR Recruitment Email -2.pdf

MBSR Flyer Updated.pdf

Published Advertisements

Verbal Scripts

Website

Social Media

Other

None of the above

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research. Describe the likelihood and seriousness of each risk.

Participation in research is voluntary. Consider the risks that a participant might encounter if they participate in the study. Risks may be physical, psychological, social, legal, etc. Please note that all research exposes to subjects to some risk.

For example, if the only foreseeable risk is breach of confidentiality, please describe the potential consequences to the participant's reputation, lifestyle, employability, or legal status that might occur if it became known that they participated in the study.

Potential Risks or Discomforts:

Measurement of Blood Pressure: *Blood pressure will be measured similar to a similar doctor's office visit. There are no known risks with this procedure. If discomfort is experienced the cuff can be deflated.*

24-Hour Blood Pressure Recording (ABPM): *It is possible for 24-hour blood pressure recordings to interfere with normal activity and sleep habits. We will try to minimize disruption to normal habits by gaining snapshots of 24-hour blood pressures once before, and once after, the 8-week intervention. We will record on a work or school day according to previous recommendations. To enhance user comfort, our ABPM devices are very compact, lightweight, and can be easily attached to a belt. We will collect only two readings per hour at night to help reduce the chance of sleep interference.*

Questionnaires: *We do not anticipate risk or discomfort in regard to questionnaires, but if a participant feels uncomfortable with any question, or any questionnaire, they can leave it blank.*

Microneurography: *There is a potential risk of infection after insertion of the leg electrode. Sterile techniques will be used to help prevent infection. We have never had any participants report infection after the procedure. Also, about 7% of subjects experience some aching or "pins and needles" sensations for a few days after the procedure. There is no specific treatment for these sensations, which are believed to be the result of tissue inflammation. Study volunteers who have experienced these sensations report they*

have disappeared spontaneously and completely without treatment within a few days. Dr. Durocher has safely performed over 300 successful microneurography sessions since 2010. We will mention to qualified participants during the screening visits that they should wear a pair of shorts underneath their clothing, or bring a pair of shorts, for the autonomic testing days. We have a private room in the lab with a locking door where participants can change into shorts. We have blue medical exam shorts that will be provided to participants that do not bring a pair of shorts with them. Microneurography (a small electrode needle that can measure electrical activity in nerves) will be completed prior to a 10-minute baseline and the mental stress test (doing mental math calculations) protocol. Nerve activity will be continuously measured during the baseline and mental stress test. The microneurography electrode would remain inserted for approximately 1 hour, and does not typically cause any discomfort after the initial insertion. We use a tungsten microelectrode behind the right knee as the recording electrode and a small acupuncture electrode about 3 cm away as the ground.

ECG: *There is a risk of skin irritation from the electrodes used for ECG. This is unusual, but we can stop the experiment if this irritation occurs. To date, we have never had a problem with our electrodes.*

Finger Cuff*: Rarely, some people experience mild discomfort in the fingers from the blood pressure cuff. If this occurs, we will stop the finger cuff.*

Arterial Stiffness: *This is a non-invasive procedure that is comparable to someone checking your radial (wrist) or carotid (neck) pulse via finger. A buildup of fats on artery walls are known as plaques. The use of a tonometry device could cause hardened plaques to dislodge. If aortic pulse pressure is 50 mmHg or greater, as estimated from the radial (wrist) pulse site with the tonometer, then we will not proceed with carotid (neck) or femoral (groin) pulse recordings. Individuals with aortic pulse pressures greater than 50 mmHg may have an increased risk for arterial plaques, and potentially disrupting these plaques could increase the risk for a cerebrovascular event such as a stroke. We will inform participants if they have an aortic pulse pressure greater than or equal to 50 mmHg, and explain that elevated pulse pressure has been associated with an increased risk of arterial plaques in one previous study. We would suggest that the participant could visit their primary care physician if they have any concerns about the elevated value. We use this cutoff out of an abundance of caution to not press on the carotid artery for the arterial stiffness measurements, which is why we would exclude the participant from carotid to femoral pulse wave velocity measurements if they have an elevated aortic pulse pressure.*

These measurements will be led by John Durocher, PhD who has more than 15 years of experience with this type of research. Some of the non-invasive measurements such as blood pressure or ECG may also be led by graduate student Colleen Toorongian. Colleen has worked with Dr. Durocher for several years in his previous laboratory that had nearly identical equipment, and she holds a BS in Exercise Science.

Breach of confidentiality: *This is always a risk with data, but we will take precautions to minimize this risk as described in the confidentiality section.*
Under Indiana law, Purdue researchers must report any suspected child abuse or neglect to law enforcement or to the Department of Child Services hotline.
Under federal law, Purdue researchers must report all incidents of discrimination, harassment, and/or retaliation in the Purdue workplace and/or educational environment to the Title IX Coordinator or Equal Opportunity/Affirmative Action Officer. "Harassment" includes sexual harassment, sexual violence, rape, and any non-consensual sexual act. If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

*required

Describe how risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

Points to Consider

- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*
- *Are medical or psychological resources available that participants might require as a consequence of the research?*

The PI of the Clinical and Applied Human Physiology Laboratory at Purdue University Northwest has an extensive history of research with human participants for more than the past 15 years. The current project is supported by NIH, and study data has been collected for the last 2+ years at Michigan Technological University. The laboratory will continue to consider the following to minimize risks:
1. All laboratory staff will complete CITI training to promote responsible conduct of research in regard to safety and confidentiality.
2. Strict protocols will be followed for techniques such as the microneurography procedure, such as autoclaving one-time use tungsten microelectrodes in a sterile pouch, wearing protective gloves during the procedure, and using alcohol wipes to thoroughly clean the site before starting insertion of any recording or reference electrode.
3. Arterial stiffness measurements always start with the pulse wave analysis (PWA) technique at the radial pulse site to ensure that aortic pulse pressure is less than 50 mmHg before proceeding to a more delicate pulse site such as the carotid artery. For participants with an estimated aortic pulse pressure greater than 50 mmHg, we will not proceed to any pulse wave velocity (PWV) recordings.
4. The PI will continually monitor the participant throughout the autonomic testing sessions.

*required

Please provide the risk level that you believe applies to the study.

In addition to the population being studied, consider the this definition:

Minimal Risk: *Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.*

The researchers believe the study is no greater than minimal risk.

✓ The researchers believe the study is greater than minimal risk.

*required

Are there potential direct benefits to a participant or benefits to society from your research?

The IRB must consider the risk/benefit ratio of each study.
Please note that payment for participation is not considered a benefit. If there are no direct benefits, please state this fact.

✓ Yes, there are potential benefit(s) to be gained by the individual subject/participant.
*required

Please list the potential benefit(s) to the individual.

There are numerous potential benefits to participating in this study, but nothing is guaranteed. You may learn how to better manage the stress in your life and your cardiovascular risk could be lowered.

✓ Yes, there are potential benefits to be gained by society.
*required

Please list the potential benefit(s) to society.

The findings of this study may help to indicate how adults could lower their cardiovascular risk through mindfulness-based stress reduction or stress management education.

No, there are no benefits.

*required

How does the investigator evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

Please provide an assessment of the risk:benefit ratio associated with your study. The HRPP/IRB must assess that the risks and benefits are appropriate . This is a crucial consideration for your study.

I consider this study to be more than minimal risk due to the invasive microneurography procedure. The PI has completed over 300 successful sessions independently and has also served as a participant for muscle sympathetic nerve activity (MSNA) recordings at least a dozen times. We have not had any serious adverse events in the hundreds of sessions that we have conducted, but there is some discomfort during the procedure during the first few seconds when the electrode makes contact with the peroneal (common fibular nerve) and there is a chance for some pins and needles sensations for a few days after the procedure. We will also make clear recommendations to each participant to not undertake any heavy exercise with the legs for at least 48 hours after the procedure to reduce the chance of pins and needles or feelings of discomfort. The risk for this procedure is very small with and experienced microneurographer and sterile techniques. Microneurography is the only method to directly assess post-ganglionic sympathetic activity in humans, and MSNA provides crucial insight into autonomic regulation of blood pressure. To explain briefly, higher MSNA induces vasoconstriction which increases blood pressure, while lowering MSNA induces vasodilation to lower blood pressure. Thus, the benefits of the measurement is very high, and provides significant mechanistic insight to the causes underlying hypertension, cardiovascular, and cerebrovascular disease.

Privacy and Confidentiality

*required

Privacy During Data Collection

Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant?s ability to privately provide information used for your study.

Privacy refers to a person's desire to control access of others to themselves.Participants must be able to control their right to participate in research (such as the timing and location of data collection. Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study. Subjects may not want to be seen in areas that may stigmatize them or at times when they are working or competing other tasks).

The pre- and post-testing sessions for this study will be held in private in the Gyte 6 laboratory. There will only be a single participant in the lab at a time at a designated desk for questionnaire data collection, and at a designated seat and / or on the laboratory tilt table for other cardiovascular assessments. The small window on the lab door is covered so that no one can see into the room during data collection.

We will treat your identity with professional standards of confidentiality. The information obtained in this study may be published, but your identity will not be revealed. Subject information and corresponding six digit alphanumeric codes will be stored in a secured file cabinet in Dr. Durocher’s laboratory (Gyte 6). This study is funded by the National Institutes of Health. The project's research records may be reviewed by the National Institutes of Health, Food and Drug Administration (if FDA regulated), US DHHS Office for Human Research Protections, and by departments at Purdue University responsible for regulatory and research oversight. Summary (but not individual) results will be registered and published at ClinicalTrials.gov in accordance with requirements from the National Institutes of Health.

*required

Confidentiality

Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.

- *For identifiable data in electronic format, describe the system that will be used.*
- *For identifiable data in hard copy or tangible format, describe methods on how to secure the data*

Hard copy data will be stored in a locked file cabinet in the PI's laboratory. Only the PI will have a key for the cabinet, but approved student researchers will be able to access the data during normal approved working hours.
Electronic data will be stored on a password protected computer on a specialized laboratory R drive that was created by the PNW Information Services Department only for Dr. Durocher and graduate student Colleen Toorongian, and electronic data will not include any participant's name.

*required

Provide a plan to protect the identifiers from improper use and disclosure.

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.

*required

Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers.

Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes. For protocols that may be subject to future continuing and secondary data analysis, the IRB needs to have the justification for not destroying identifiers permanently.

We will keep the hard copy data for a minimum of 3 years beyond the completion of this NIH project. No identified data will be stored electronically or used for a future study or analysis. If hard copy data were to be destroyed it would be via a confidential shredding process.

*required

Will a Certificate of Confidentiality be obtained from NIH for this research?

What is a Certificate of Confidentiality?

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are automatically granted for NIH-funded research (as of 2017). The IRB may request that the investigator seek a CoC if disclosure of identifiable sensitive information.

Consider this option if your study may place participants at risk due to the potential to identify situations such as disease state or criminal activity.

Please note that if a CoC applies, the consent form must have appropriate language (found in our template).

✓ Yes, the study is funded by an NIH grant or subaward and therefore automatically has CoC protections.

Yes, our team will seek a CoC from NIH if approval is granted for this IRB application. I will amend the study if this CoC is granted by attaching the document here.

No, this study will not require a CoC.

Data and Safety Monitoring

*required

Which individual or group will be responsible for monitoring the data and safety for this study?

- ✓ Principal Investigator/Research Team
- Independent Study Monitor(s)
- Internal Committee
- Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Independent of PI and Sponsor
- Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Not Independent of PI and Sponsor
- Other

*required

Describe the provisions for monitoring the data to ensure the safety of subjects.

The individual responsible for data safety and monitoring will be the principal investigator (PI), Dr. John J. Durocher. The greater than minimal risk activities include microneurography. Risks and safeguards for the procedure have been previously discussed (see microneurography attachment). If abnormal signs are detected during testing (ex. abnormal cardiac rhythm) or participants experience post-procedure adverse effects such as infection or prolonged paresthesia (i.e. beyond 48 hours) they will be referred to their primary care physician. In the event of a medical emergency, or detection of a hypertensive crisis (resting blood pressure 180 / 120 mmHg or higher and associated symptoms such as chest pain or shortness of breath), Dr. Durocher or research staff would immediately dial 911. Abnormal or adverse events will be documented by Dr. Durocher and reported as outlined below.

Throughout this study, Dr. Durocher will monitor the participants for adverse events. Events determined by the PI to be unanticipated problems involving risks to subjects or others (UPIRTSOs) will be reported by the PI to the IRB (via written memo) within 5 days per policy (SOP 409) for serious adverse events and within 14 days for other unanticipated problems (according to SOP 409). Additionally, in accordance with the National Institutes of Health (NIH) policy, the UPIRTSOs will be reported to the program official within 30 calendar days. All studies will be suspended in the laboratory until the issue has been resolved between the PI, IRB, and NIH. Adverse events that are determined by the PI to not be UPIRTSOs will be reported per IRB policy at the time of continuing review (i.e., annual review). All subjects and study staff

members will be informed by Dr. Durocher (via written memo) about any UPIRTSOs. If any protocol changes are needed, the PI will submit a modification request to the IRB. Protocol changes will not be implemented prior to IRB approval.

We will keep an electronic and printed copy of the Purdue University Unanticipated Problems and Adverse Event Reporting SOP 409 within the laboratory.

*required

Provide a description of the individuals who will be responsible for data safety monitoring

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Include the following details:
(1) association with the research and/or study sponsor;
(2) nature of their expertise and;
(3) whether they are independent of the commercial sponsor

If those monitoring the study are not independent of the sponsor, please describe how any potential conflicts of interest or biases will be avoided.

1) John Durocher the PI will be responsible for data safety monitoring.
2) Dr. Durocher has a PhD in Biological Sciences - Exercise Physiology, is a certified Exercise Physiologist through the American College of Sports Medicine, and certified Strength and Conditioning Specialist through the National Strength and Conditioning Association. Dr. Durocher was extensively trained in microneurography by two leading experts (William Cooke, PhD at Michigan Tech and Jason Carter, PhD at Montana State University) and has been leading the technique independently for more than a decade.
3) The PI is independent of the government sponsor.

Upload CVs

John Durocher's PNW Curriculum Vitae (2021).pdf

*required

What data will be reviewed?

Provide a description of the parameters that will be evaluated to ensure safety.

- ✓ Adverse events/Unanticipated problems
- ✓ Aggregate data
- ✓ Enrollment numbers
- ✓ Individual subject data/case report forms
- Protocol violations/deviations
- ✓ Subject withdrawals/terminations
- Other

*required

How often will data and safety monitoring be performed?

Please specify if this is a specific number of times, at defined time points, after a certain number of subjects have been recruited or as needed (i.e. every 6 months, every SAE, every 5 subjects, etc.)

As needed if there is an SAE.

*required

Describe the responsibilities that have been given to the data and safety monitoring function.

This should include a discussion of whether the data and safety monitoring plan includes a charter, whether stopping rules will be developed, and if any interim analysis will be performed (if so, on what basis). If this information is in protocol, please specify where relevant information is located.

Dr. Durocher will complete an annual report detailing the study progress, subject status, adverse events, and any protocol deviations. He has completed the first two annual reports that have already been submitted to the NIH.

*required

If this protocol is for a multi-center trial what mechanisms are in place to either receive or distribute results of the data and safety monitoring function in a prompt manner.

Describe each site's role in contributing to the data and safety monitoring.

This study will be conducted on the Hammond campus of Purdue University Northwest, and not at any other locations.

If a DSM Board charter exists, please upload it.

A charter includes identification and description of individuals responsible for monitoring the trial (their roles, qualifications, and the frequency of the monitoring activities. The proposed membership and assurances should be described within the document to ensure that there are no conflicts of interest with the study team or proposed institutions.

John Durocher's PNW Curriculum Vitae (2021).pdf

Compensation for Research Participation

Describe any compensation that subjects will receive when they participate in your study. Consider what happens to the compensation amount if the participant withdraws or is disqualified from the study. If course credit will be offered, please provide the amount and the percentage of the total grade.

---

*required

Will subjects be compensated for their participation in the study?

Will the study provide (money/gift cards/inducements/discounts/entry into a drawing/course credit) in exchange for a person's participation in the study? Please note that Purdue University policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

✓ Yes

*required

Describe the payment arrangement, including amount and timing of disbursement.

If the compensation includes a lottery or raffle-style drawing, please provide the approximate odds of winning (number of prizes, anticipated number of participants).

If course credit will be offered, please provide the amount and the percentage of the total grade. Extra credit should be no more than 3% of the course grade in order to avoid undue influence.

Participants will receive the following: 1) $50 for each microneurography (autonomic) session completed; and 2) $200 for the completion of the 8-week MBSR or SME course (prorated as $25 per week completed if there is any need to withdraw before the completion of the 8-week course). The maximum payment that you can receive from this study is $300. According to the rules of the Internal Revenue Service (IRS), payments that are made as a result of participation in a study may be considered taxable income. Participants will be asked to

provide their full name, address, and social security number for our Human Subject Invoice Log so that our Business Office at Purdue University Northwest can process and send a payment to the participant.

We did not have any budgeted funds through NIH for the screening visits, and have already screened 139 potential participants while at Michigan Tech that did not receive payment for screening. Thus, it would not be feasible or ethical to add payments for screening at this point.

*required

Justify the proposed payment arrangement described above, specifically why payment does not provide undue influence for subject participation

---

Explain how the amount is reasonable for the study.

The proposed $50 payment for each microneurography session is consistent with what is paid at other institutions. This amount is thought to compensate the participant for their time. The proposed $25 per week for the MBSR or SME classes is designed to compensate participants for their time investment to the intervention. The compensation provides some compensation for the investment of time in the study, and potentially something towards transportation to and from the laboratory or class site, but not enough to be coercive to simply participate in the study for financial gain.

*required

Will partial payment be provided if the subject withdraws or is disqualified prior to completion of the study?

For example, are there starting and stopping points where the participation will be pro-rated?

✓ Yes

*required

Explain the plan for providing partial payment.

Participants will receive a prorated $25 for each week completed for the MBSR or SME courses if there is any need to withdraw before the completion of the 8-week course.

No

No

Informed Consent Process Section title

Informed consent is more than a form; it's a process and a responsibility.

Please answer all questions regarding the ways that participants will provide informed consent to participate in your study.

---

*required

Identify which subjects will consent to participate in the research.

- ✓ All subjects (or their legally authorized representative) will consent to participate in the research.
- Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.
- No subjects (or their legally authorized representative) will consent to participate in the research.

*required

For subjects who will consent to participate, choose whether the consent process will be documented by a **signature** from subjects.

Please note that you may request a waiver of the signature requirement if this study is minimal risk OR if the only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality.

- ✓ All consented subjects will provide a written signature as documentation of consent
- Some subjects will provide a signature as documentation of consent, and some subjects will not.
- No subjects will provide a signature as documentation of consent.

*required

Indicate in what language(s) the consent conversation will be conducted.

✓ English

Language(s) other than English

*required

Will subjects participate in any study activity prior to signing a consent document?

For example, some studies require subjects to fast, to refrain from drinking or smoking, pass a phone screening process or keep a journal/log prior to enrollment in the study.

✓ Yes

*required

List the activities in which subjects will participate prior to signing the consent document. Each activity must present no more than minimal risk of harm to subjects AND involve no activities for which written consent is normally required outside of the research. Please note that subjects should provide verbal consent to these activities.

Participants will be asked to refrain from eating for 3 hours, and from exercise, caffeine, and alcohol for 12 hours prior to seated blood pressure screenings.

No

Waiver of Informed Consent or Signed Consent

If any or all subjects will not provide written, signed informed consent for all parts of the study. Please complete the following information to request either a waiver of consent or a waiver of *signed* consent.

---

*required

Does the research pose greater than minimal risk to subjects (greater than everyday activities)?

This study is considered more than minimal risk due to the microneurography procedure, so we will not ask for any waiver of informed consent.

*required

Will the waiver adversely affect subjects? rights and welfare? Please justify.

---

not applicable.

Why would the research be impracticable without the waiver?

---

*required

How will pertinent information be reported to subjects, if appropriate, at a later date?

Through peer-reviewed publications for the overall study outcomes.

*required

Will any other materials (videos, brochure, drug/device information, etc) be used to present information to potential subjects?

Yes

✓ No

*required

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

The informed consent would be provided as an option at the end of the 3rd blood pressure screening visit for qualified participants.

*required

Consent form Elements

The following components are required for informed consent forms. If any of these elements are missing, you must provide justification for the reasoning.
Please confirm that all elements of informed consent are present. Use the Purdue IRB template found on the Purdue HRPP/IRB website

BASIC REQUIRED ELEMENTS OF INFORMED CONSENT
Please confirm that all elements of informed consent are present.

- Key Information at the beginning of the consent form
- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others that may reasonably be expected
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained
- A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

---

*required

Please confirm that all basic elements of consent appear in your draft consent form.

✓ The research team has drafted a consent form and affirmed that it contains all of these basic considerations of informed consent.

Our research team is omitting a basic section from the consent form.

Our research team requested a complete waiver of informed consent and will not be attaching a consent form to this submission.

SPECIAL REQUIRED ELEMENTS OF INFORMED CONSENT

Please check if these items apply and are addressed in the draft consent form.

If any of these elements apply, but are missing, you must provide justification for the reason(s) to omit this information.

- *A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.*
- *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*
- *Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.*
- *Any additional costs to the subject that may result from participation in the research.*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

- *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
- *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- *Disclosure of any conflicts of interest.*
- *Registration of the trial on Clinicaltrials.gov*
- *NIH Certificate of Confidentiality coverage.*
- *Future uses of identifiable or deidentified data.*

---

*required

Please confirm that all items that apply to your study have been addressed in the consent form.

You must review the study-specific parameters that were discussed within your application in previous sections. Please refer to the sections on the left for any items that may apply.

✓ The research team has drafted a consent form and affirmed that it contains all special considerations of informed consent applicable to our study.

Our research team is omitting an applicable section from the consent form.

Our research team requested a complete waiver of informed consent and will not be attaching a consent form to this submission.

*required

Please attach all versions of your consent form here.

Consent forms should follow the structure of the template on the IRB website.
MBSR Pre-Screening Consent.pdf

MBSR Pre-Screening Consent.docx

MBSR Consent-9.docx

MBSR Consent-9.pdf

Funding Source(s)

*required

CURRENT Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI's responsibility to update funding sources as a modification to the protocol and associated forms (such as the consent form) when funding changes.

Please list any sources of funding that are **confirmed** by contract, agreement, or other support of a sponsor.
You will list any pending sources in the next question.

If the research is funded by a subcontract, please add both the subcontract source and the prime sponsor.

✓ Externally sponsored (federal, state, corporate, foundations, industry, donor)

Please search for the sponsor(s) here. Be certain to include any funding that originates or includes US federal sources.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

US Department of Health and Human Services - DHHS

If you do not see the name of the funding source using the "Find Sponsors" button above, please enter the full sponsor name in the text box below.

Please use the full name of the sponsor and include any subcontracted efforts.

National Institutes of Health - National Heart, Lung, and Blood Institute

Internal Purdue University Funds (Includes departmental funds, start-up funds.)
(Note, this does not include Purdue Research Foundation or Purdue Research Park companies-please list as external sponsor above).

None - There are no confirmed funding sources at this time.

ANTICIPATED Funding Source(s) - Required

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

Please list any sources of funding where sponsorship is **anticipated** or pending a final decision.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

There are no pending funding sources at this time.

Conflict of Interest and/or Outside Activities Disclosure

Conflicts of Interest or outside activities must be disclosed and managed prior to IRB approval. For more information about these policies, please consult the resources listed in the question marks in each section.

The IRB may request confirmation of proper disclosures.

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*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ I attest that I understand the outside activities policy and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Receiving more than $5,000 in compensation from, or having ownership interests in, outside entities, constitute Significant Financial Interests that need to be disclosed. Definitions of SFI, Investigator and Institutional Responsibilities, can be found at https://www.purdue.edu/policies/ethics/iiib2.html#definitions.

Yes

✓ No

*required

Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?

Yes

✓ No

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

Other attachments

*required

Do you have any other supporting documents to attach?

You may attach COVID-19 Research Space Standard Operating Procedures here if this is a new protocol submitted during the COVID-19 pandemic.

Investigators are invited to submit reference lists, study instruments, supporting information, training data, device pictures, or other relevant items for their study that were not addressed in the application.

✓ Yes

Attach any other documents. Please use a file name that describes the document.

You may attach multiple files to this entry.

PLEASE DO NOT UPLOAD PARTICIPANT DATA OR IDENTIFIABLE RESEARCH DATA.

citiCompletionReport1728324-Durocher Certificate.pdf

citiCompletionReport1728324RCR-Durocher Certificate.pdf

Previously Approved IRB Proposal from Michigan Tech - includes appendix on microneurography.docx

citiCompletionReport6623673-Toorongian.pdf

signed Durocher Data Transfer Memo.pdf

COVID-19 Prevention and SOPs for PNW Clinical and Applied Human Physiology Laboratory - Gyte 6.pdf

Data Transfer and Use Request - Durocher.pdf

No

Renewal Submission

Renewal of Protocol - For Studies Enrolling Participants, or Analyzing Data

Please choose the option that describes the renewal need for your study

If you've been contacted by the IRB Office to submit this renewal, please see the instructions in the request.

✓ **Continuing Review for Full-Board**
I need to submit a **continuing review** for IRB renewal of an expiration.

Administrative Check-in Only
I am requesting a new approval letter to update my study records because data collection and/or data analyses of the original research purpose continues without change.

Study Closure
I need to request closure of this study.

STUDY STATUS

*required

What is the current status of the study?
If you plan to close the study, please proceed back to the main protocol screen and click "Closure" to complete the correct form.

✓ Open to Enrollment
Enrollment of new participants or review of records/specimens continues.

*required

Do you have a copy of the current consent form(s) for your study?

✓ Yes, I am attaching an editable version of the current consent form(s) for this study.

*required

MBSR Consent-9.docx

MBSR Pre-Screening Consent.docx

No, my research was granted a partial or complete waiver of informed consent.

Closed to Enrollment
No new participants are being enrolled but they are still receiving research-related intervention, interaction, or follow-up.
Follow-up includes:

- *Research interactions that involve no more than minimal risk to subjects, or*
- *Collection of follow-up data from procedures or intervention that would be done as part of routine clinical care. Research interventions which would not be performed for clinical purposes are considered research-related interventions and are not considered follow-up.*

Data Analysis Only

- *Participants have completed research-related intervention or interaction and follow-up has been completed, AND*
- *Remaining research activities are limited to only data analysis (for the original study aim) that may require access to identifiable records and/or specimens identified directly or via code with existing code key.*

*required

Has the approval for this study already expired?

Yes

✓ No

*required

Is there anything that needs to change in the protocol since your last submission?

✓ Yes

*** Please submit this Renewal then submit a Modification. All modifications must be approved by the HRPP/IRB prior to implementation.**

No

FUNDING SOURCE

---

*required

Has the funding source changed since the last IRB review?

The current funding source on file is listed in the study record. Click on "Study" above and look at the main information.

Yes, funding has changed since the last review.

✓ No, the funding source remains the same (or unfunded).

RECRUITMENT AND ENROLLMENT

---

*required

Please indicate the number of participants enrolled in the study.

**** Note that for federally-funded studies, the sponsor will request a breakdown of*

participants by sex/gender, ethnicity, and racial category. You would, therefore, be wise to have that information ready for reports to funders.

If this section is not applicable, please type "N/A" in the boxes below.

Since the last review, how many people have been enrolled in your study?

Please list the number here, or the reason that the number is not available.

5 have been screened for the study, with 4 qualifying for enrollment.

Since the beginning of the study, how many people have been enrolled in your study?

Please list the number here, or the reason that the number is not available.

5 have been screened for the study, with 4 qualifying for enrollment.

*required

Has the study recruited participants at a faster or slower rate than expected?

Recruitment has been **faster** than anticipated.

✓ Recruitment has been **slower** than anticipated.

Recruitment is occurring at the anticipated rate.

The study does not recruit participants because only existing data are utilized.

The study was not open for participant recruitment since the last IRB review.

*required

Are there study risk/benefit considerations that could be affecting the rate of participation?

Please provide a brief assessment of the reasons that might be contributing to the enrollment rate.

We believe slow enrollment rates may be due in part to COVID-19, with lower numbers of students, faculty, staff and community members present on and around campus. We believe we are also the first research lab on the Hammond campus to conduct human subject research, and we are working to increase awareness of our presence.

STUDY EVENTS

*required

Since the last IRB approval, did any unanticipated problems involving risks to subjects or others, adverse events, protocol deviations, subject complaints or noncompliance occur that required prompted reporting to the IRB?

- Yes
- ✓ No

*required

Since the last IRB approval, did any protocol-related adverse events, protocol deviations or subject complaints occur that did not require prompt reporting to the IRB?

- Yes
- ✓ No

RECENT FINDINGS RELEVANT TO THE STUDY AND RISK/BENEFIT

*required

Summarize the recent literature that has been published or presented by the investigator or others relevant to this study since the last IRB approval. Include in the summary if there has been a demonstrated significant impact on the well-being of subjects.

Data from this research was presented at the Experimental Biology 2021 conference. Our preliminary data suggests that individuals with a greater ability to decenter may have a lower cardiovascular disease risk (i.e., greater SAP and DAP dipping during sleep). It has been previously demonstrated in larger sample sizes that less nocturnal blood pressure dipping may be associated with significant risk of developing cardiovascular disease. Our results suggests a potential relationship between the ability to decenter and nocturnal blood pressure dipping patterns.

Meditation has been shown to improve the ability to decenter, thus participants in our study should have a beneficial response and lower cardiovascular risk.

*required

Has the risk/benefit ratio of this study been altered since the inception of the study?

Yes, the investigators believe that the risks and/or benefits have changed.

✓ No, the investigators believe that the risks and benefits remain the same as the originally approved protocol.

CONFLICT OF INTEREST

Conflicts of Interest and/or outside activities must be disclosed and managed prior to IRB approval or renewal.

---

*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ *I attest that I understand the outside activities and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Yes

✓ No

*required

Are there any other attachments that you need to include for the renewal of your protocol?

Do not duplicate the attachments from other sections.

Yes

✓ No

Modification Submission

Modification/Amendment to a Protocol

Changes to a study must be approved by the HRPP/IRB.

Examples include (but are not limited to) changes in:

- Recruitment methods
- Screening materials
- Intended study population
- Inclusion/Exclusion criteria

For a list of minor changes that do not require IRB review, please see Purdue HRPP Standard Operating Procedure 305. (Link appears in the "?" button above.) Also, see www.irb.purdue.edu for additional changes not requiring modification during the COVID-19 pandemic.

---

*required

What type of change(s) would you like to make?

IMPORTANT:
All revisions to the protocol must be made to the relevant sections of your study in the sidebar. Please note, that more than one section may require change. For non-exempt protocols, please review your current consent form and edit language as needed.

Remember to review any advertisements, scripts, information sheets and consent forms. Attach them to the relevant sections of your protocol. Please title any attachments with dates or version control numbering in the file name to assist with review.

✓ Personnel

*required

Are you changing the Principal Investigator?

Yes

✓ No

Study Procedures

Change to the recruitment and/or data collection status.
(For example, click here if you are finished with data collection and would like to notify the IRB that the study will only analyze the collected data.)

Something else (e.g. participant compensation amounts)

(For resuming on-campus in-person research)- COVID-19 Research Space Standard Operating Procedure approval.

(For resuming off-campus in-person research)- COVID-19 off-campus research certification of practices outlined in the EVPRP Guidance for Off-Campus Research Activities

*required

Study Personnel

In this section you will name all staff who will participate in the study.

*required

A Principal Investigator (PI) is responsible for all aspects of a research study.
STUDENTS ARE NOT AUTHORIZED TO BE PRINCIPAL INVESTIGATORS

Provide the name of the Principal Investigator of this study.
All faculty (tenured, tenure-track, research and clinical) are eligible to be Principal Investigators. Others requesting to submit proposals as the Principal Investigator for the first time must obtain special approval.

Once the name is selected, training courses from the CITI system should appear when you click "View". If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.
Name: John Durocher
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: jjduroch@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

*required

Please check your Purdue University PI classification.

- ✓ Faculty (tenured, tenure-track, research and clinical)
- Student
- Purdue non-faculty staff member granted special PI status.

*required

Primary Contact

Provide the name of the Primary Contact of this study. The Primary Contact will be copied on all correspondence regarding the IRB review. Note that the Primary Contact and the Principal Investigator may be the same. The Primary Contact must be a current Purdue University faculty, staff, postdoc, or student and must have a role as Key Personnel on the study.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: John Durocher
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: jjduroch@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

If you wish to provide a campus phone number for the Primary Contact, you may list it here.

This field is optional. Most correspondences from the IRB will arrive via the Cayuse system.
219-989-2625

*required

Key Personnel

Below is a definition of Key Personnel. Please read the definition and decide who will need to be listed as Key Personnel on the study. The PI defines the roles of each staff member based on the definition below.

Key personnel: The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

*required

Does your study have additional Key Personnel besides the PI and Point of Contact?

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

✓ Yes

*required

Where are the Key Personnel from?

Check all that apply.

✓ I have key personnel from Purdue University.

I have key personnel from another external site (outside of Purdue).

No, the only personnel on the project are the PI and Point of Contact.

Key Personnel From Purdue University

- *The Principal Investigator and Primary Contact are considered Key Personnel. You do not need to list these names again.*
- *Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.*
- *If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.*

Name: Colleen Toorongian
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: ctoorong@purdue.edu

Name: Grant Thivierge
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: gthivier@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. For researchers outside of Purdue university, please use the next section and click "external investigators".

(First Name: Last Name: Purdue e-mail address)

*required

Provide a brief description of each person's position at Purdue (e.g. student, staff, faculty) and their role in the study.

Examples:
Prof. Principal (faculty) will oversee all aspects of the study design and conduct
John Researcher (graduate student) will recruit and consent participants and collect data
Purdue Pete (staff) will analyze collected study data.

John Durocher is the PI and tenured associate professor that will oversee all aspects of the study.
Grant Thivierge is a Research Study Coordinator and will assist with data collection, analyses, and dissemination of results.
Colleen Toorongian is an MS student in Biological Sciences that will assist with data collection, analyses, and dissemination of results.
Brigitte Morin MS is a senior lecturer at Michigan Tech that has been involved with teaching the MBSR class since the start of this project. She recently agree to teach the 8-week course one more time in the summer of 2021 and will fly down to Chicago once each week to travel to our Hammond campus to lead the MBSR class.

Research Sites

*required

Where will the study take place?

✓ Purdue University

*required

Please check the following locations.

West Lafayette

✓ Regional Campus (PFW, PNW, IUPUI)

*required

Select the regional campus

✓ Hammond

Fort Wayne

Westville

Indianapolis

Polytechnic Institute Statewide Sites

Extension Sites

*required

Please provide a brief description of the Purdue University location(s).

Provide building names, course titles, event names as applicable.

Gyte Building - Room 6 (Clinical and Applied Human Physiology Laboratory)

External Site (non Purdue University)

Getting started with your submission

*required

Welcome to the submission system for the Purdue HRPP/IRB. Before you begin, you should be familiar with the framework of human research protections and how they relate to your proposed study. The materials to help you appear on our website.

Be certain that all personnel have completed online training prior to submitting the protocol.

Helpful Tip: Use the Create PDF button at the top of the page if you need to share a PDF version of this protocol for discussion with a reviewer outside of the Cayuse system.

The choices you make on the first two sections will help populate the required sections for your submission. Please look through the options and make the choice closest to your research. You can always seek assistance by scheduling an appointment with the HRPP Office or reviewing the materials at www.irb.purdue.edu.

Exempt study

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

Non-exempt study

✓ *Research that does not fit into an exempt category typically involves the collection of new data from a participant.*

Just-in-time

I have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but my application to the IRB is dependent on other factors such as:

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible at the time of the sponsor request, please do not select this option. The research team should affirm that their sponsor will accept documentation for a development protocol.

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

Quality Improvement

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

I need to know if my project is considered "Human Subjects Research"

I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).

When Purdue University will be engaged in human subject research with one or more institutions, investigators may submit a Request for Deferral asking that the review be deferred to one institution's Institutional Review Board (IRB).

Research Classification and Special Considerations

Would you determine that this research is predominately social or biomedical in nature

When you provide an answer to this question, a series of additional questions will display, and checking on each of these questions will generate a new form to the left that you will need to complete. These forms will ask the questions we used to ask, but in a clearer and more organized way, which will help the reviewer, as well as the investigator.

✓ **Biomedical**
My research has a biomedical focus.

Social / Behavioral
My research has a social or behavioral focus.

A combination of social science and biomedical, or I'm not sure.

*required

Please check any of the following that apply to the proposed research.

Each of these involves special considerations in the IRB review. If none of these items apply, click on "None of These" and continue forward in the application.

Potentially Vulnerable Populations
Examples: Children, Pregnant Women/Fetuses, Prisoners, those that lack capacity to consent), economically disadvantaged persons, minorities.

Use of an Experimental Drug
A substance manufactured via chemical process and intended for use in the diagnosis, cure, mitigation, than food) intended to affect the structure or any function of the body of man.

Note: Studies of this nature are considered Applicable Clinical Trials and may require an Investigational and Drug Administration and involvement of a physician investigator.
https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/investigational-new-d

Use of an Investigational Medical Device
An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or

or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, m in man or other animals, OR intended to affect the structure or any function of the body of man or other primary intended purposes through chemical action within or on the body of man or other animals and v metabolized for the achievement of its primary intended purposes.

Note: Studies of this nature are considered Applicable Clinical Trials and may require an Investigationa Drug Administration and involvement of a physician investigator.
https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/investigational-new-d

Clinical Trial
PLEASE READ THIS DEFINITION CLOSELY.

✓ *NIH defines a Clinical Trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."*

If this determination applies, please check this box.

Research with Food
Articles used for food or drink (or for components of such articles) and NOT intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

Radiation and/or Imaging
X-ray, CT, PET scans, nuclear medicine procedures, and MRI scans.
This protocol requires for research purposes 1) radiological assessments and procedures that involve radiation exposure (X-ray, CT, PET scans) 2) nuclear medicine procedures (imaging or therapeutic) or 3) MRI scans.

Nursing or Study Physician Resources
This protocol will have Nursing or Study Physician Resources

Blood Collection for Research Purposes
This protocol involves collection of blood samples other than discarded specimens. Examples are collections involving finger stick, venipuncture, or indwelling catheters.

Human Biological Specimen Repository
This protocol involves the establishment of a biological specimen repository.
Repositories are used for prospective collections of specimens that are processed, stored and

distributed to multiple investigators for use in research.

Gene Research Classification

The study will collect samples from individuals and look at a single gene, group of genes, or full genome for the purposes of research.

Stem Cells

This protocol includes an intervention with human subjects that involves either
a) the derivation of stem cells,
b) the implantation of stem cells.

International Research

This protocol includes research that is conducted at a non US location.

Data Controlled Under HIPAA and/or FERPA

Health Insurance Portability and Accountability Act (HIPAA) covers individually identifiable health information held or transmitted by a covered entity. This often involves healthcare providers and insurance companies.
AND/OR
Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records.

Biological Product

A substance manufactured via biological process and otherwise meets the above definition of a drug; includes a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

Dietary Supplement

A product taken by mouth that is intended to supplement the diet and that contains one or more dietary ingredients.

Community-engaged research

This is community-engaged research. For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.

Incidental Findings

Incidental findings are discoveries of individual-level findings that are unrelated to the goals of the study. (e.g. genetic data, MRI or test results).

Deception or incomplete disclosure

Deception occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.

Incomplete Disclosure occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

None of the above apply.

Protocol Description

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

Tell the IRB what specific trait(s), function(s) or behavior(s) you would like to study. Give a brief summary of your study in simple terms.

Describe why you are conducting the study. Identify the research question(s).

More than 50% of U.S. adults have elevated blood pressure or hypertension which increases the risk of cardiovascular disease (CVD). Early detection of elevated blood pressure or stage 1 hypertension offers a window of opportunity to prevent progression to overt hypertension and CVD through behavioral modification. Sympathetic activation and arterial stiffness are both deleterious factors that concomitantly contribute to elevated blood pressure. Mindfulness-Based Stress Reduction (MBSR) programs have been shown to reduce blood pressure in adults, but the mechanisms for the reduction remain speculative.

*required

Specific Aims/Objectives

Give the IRB an example of potential discoveries you hope to make or insight you hope to share. For example, outline a disease state, social characteristic or behavior that might benefit from the study results.

We will systematically examine 24-hour blood pressure regulation and two potential mechanisms for the anti- hypertensive effects of MBSR by directly assessing muscle sympathetic nerve activity (MSNA) and arterial stiffness. Aim 1 will determine if MBSR improves 24-hour blood pressure regulation, aim 2 will determine if MBSR reduces sympathetic neural activity, and aim 3 will determine if MBSR will decrease arterial stiffness in prehypertensive adults. This project will also provide advanced research opportunities to undergraduate and graduate students in health-related fields at Purdue University Northwest, consistent with the goals of the Academic Research Enhancement Award (R15) mission.

*required

Background and Significance

Include how previous research studies and their results support your study or how you will build upon existing information.

The proposed research is relevant to public health because over 50% of adults in the U.S. have elevated blood pressure or hypertension. The project is relevant to NIH's mission because it will provide rigorous investigation on Mindfulness-Based Stress Reduction as a proactive anti-hypertensive lifestyle intervention that may improve blood pressure regulation through sympathetic nerve control and arterial stiffness.

*required

Research Hypotheses

Please list any relevant study hypothesis/hypotheses. If this does not apply, type "Not Applicable".

Our central hypothesis is that MBSR will: 1) improve nocturnal blood pressure dipping and / or reduce early-morning surges, 2) reduce resting MSNA and attenuate the neural cardiovascular responses to acute stress, and 3) decrease arterial stiffness. We will utilize a parallel, randomized, control design (MBSR vs. active control) that includes gold-standard techniques for measuring blood pressure (24-hour ambulatory assessment), MSNA (microneurography), and arterial stiffness (applanation tonometry).

*required

How long will participants be asked to be in the study?

List the approximate duration in the fashion below.

- *Number of Visits =*
- *Minutes or Hours per visit =*
- *Single Day or Multiple Days?*
- *Total number of months until all data are collected =*

Potential participants visit the laboratory on three non-consecutive days for screening visits that take approximately 15 minutes each. We have included 3 pre-screening blood pressures to ensure that participants meet the primary requirement for elevated blood pressure. This procedure was proposed in

the original NIH proposal, has been used throughout this study so far, and has been used in previous projects we had funded through the NIH.

Qualified participants visit the lab two more times, once before and once after the 8-week intervention (within 10 days of the start and finish). Each of those visits take about 3 hours. The mindfulness-based stress reduction (MBSR) and stress management education (SME) classes (interventions) meet once per week for 2 to 2.5 hours. There is also one Saturday requirement at the end of the 6th week for about 7-8 hours. At home daily practice for participants in the two classes ranges from 30-45 minutes. The entire study with pre- and post-testing is approximately 10 weeks.

We specifically set up these courses for the research study. However, eight week mindfulness-based stress reduction courses are offered around the world by qualified instructors. We plan to have one of our previous instructors (Brigitte Morin) offer the course to the final cohort of participants in the summer of 2021. I will assist my graduate student Colleen Toorongian to offer the 8-week stress management education course. The SME course is traditionally used as an active control course for meditation studies, and to my knowledge it is not offered as an independent course like MBSR.

*required

Specific Study Procedures

Describe in detail what a research participant will be asked to do.

- Prior to the start of the 8-week program, a 24-hour blood pressure reading will be taken. The device is compact and easily attached to a belt. Participants will also be fitted with a wrist accelerometer (similar to a Fitbit) that will track sleep-wake cycle for five consecutive nights. Participants will also complete questionnaires for anxiety, five-facets of mindfulness, and the ability to decenter.

- Following the accelerometer recordings, nervous system functions will be tested with microneurography (small electrode needle that can measure electrical activity in nerves) in a baseline setting along with a mental stress test (doing mental math calculations). Nerve activity will be continuously measured during the baseline and mental stress test. In addition to the nerve recordings, heart rate will be recorded with 3-lead electrocardiography, and continuous blood pressure with a small cuff on the middle finger. We will also estimate arterial stiffness with a small probe that will be placed at the radial (wrist), carotid (neck), and femoral (groin) pulse sites. We can also estimate breathing rate with an elastic pneumobelt that goes around the rib cage (fits gently outside of the participant's clothing). Breathing rate is not considered a primary variable, but we may report breathing rate (breaths per minute) if we calculate results for heart rate variability.

- With the programs outlined, participants will then proceed with the 8-week program to which they were randomly assigned. It is requested that you do not change your normal exercise schedule or eating habits. Both the MBSR and active stress management control programs will require a once weekly group meeting and at home exercises. The home practice for MBSR participants includes things like breathing awareness, body scanning, and gentle Yoga. The home practice for SME

participants includes daily reading from the book "Why Zebras Don't Get Ulcers" and gentle resistance band training. We have free copies of the required book that are lent out to participants during the 8-week class.

- Once the 8-week program is completed, participants will once more complete the questionnaires, 24- hour blood pressure readings, accelerometry, microneurography, heart rate, blood pressure, and arterial stiffness readings.

- Related to our laboratory safety, our new Tuttnauer 1730M autoclave is 20+ feet away from where participant testing would take place, and will never be used while a participant is in the laboratory. We have used this same autoclave for more than 15 years, and it has a very secure door latch. We have always worn neoprene gloves when prepping the electrodes to be autoclaved and when removing the electrodes from the autoclave in the sterilized pouches. We will use 3.5" x 10" self seal sterilization pouches made by PlastCare USA, that have an indicator strip that changes from blue to brown during the autovclaving process. We will follow additional PPE protocols during the COVID pandemic such as wearing a facemask during the autoclaving procedure.

In long term studies, a visual representation of a timeline is helpful. You may upload a visual representation as a Word (.docx) or PDF file here.

MBSR Conceptual Overview.pdf

Attach any surveys, questionnaires, assessments

For purposes of recordkeeping, the HRPP/IRB will need to have a Word or PDF version of any Qualtrics or electronic survey questionnaires. Please include more than a link to the survey.

MBSR Study Questionnaires.pdf

UFI_Pneumotrace_Datasheet.pdf

Actiwatch Spectrum PRO Brochure.pdf

Flow charts, schemas

MBSR Conceptual Overview.pdf

References

Below are references that we cite in our complete IRB proposal:

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- 7.**Carter JR, Durocher JJ, Larson RA, DellaValla JP, and Yang H**. Sympathetic neural responses to 24-hour sleep deprivation in humans: sex differences. *Am J Physiol Heart Circ Physiol* 302: H1991-1997, 2012.
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Participant Information

*required

Total Study Enrollment

Please enter the number of subjects that will be enrolled at all sites, that are required to complete data analysis. Include the rationale for this number (e.g. statistical analyses, population composition). If at a later time it becomes apparent you need to increase your sample size, you will need to submit a Revision Request.

In the first two years of the award (while at Michigan Tech), we have randomized 43 participants into either the 8-week mindfulness-based stress reduction (MBSR) class or the stress management education (SME) active control course. We unfortunately lost our ability to post-test 19 participants in the spring of 2020 due to COVID-19 concerns. Our total project enrollment goal for NIH was 60 participants, but due to lost data on many participants we would like to be able to enroll and test up to 30 more participants at Purdue University Northwest.

*required

Attrition Considerations

If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through Purdue University. Please describe the rationale.

Consider:

- *Whether the withdrawal of the subjects might result from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and*
- *Whether the withdrawal might occur from all components of the research study or just the primary interventional component.*

Based on our previous cohorts we have lost up to 20% of enrolled participants during the longitudinal study. We have set a target to complete 24 more participants through the longitudinal study, so enrolling 30 new participants should help us to meet that objective.

*required

Age(s) of Participants in Study Population

Please include an age range for subjects, if relevant. If the research has multiple subject groups, describe the requirements for each separately.

Newborn to less than 10 years old

10 years old and less than 18 years old

✓ 18 to 65 years old

Enter specific age range if the target population age is less than 65.

18 to 55 years old

65 years and older

Unknown- Data are deidentified of any age or date of birth

*required

Inclusion criteria - Please identify the population that you would like to study.

Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study.

Age between 18 and 55 years
Must have an average seated clinical blood pressure >120 mmHg systolic and / or >80 mmHg diastolic
Must have a body mass index < 30 kg / sq. m
Not be taking any cardiovascular medication

*required

Exclusion criteria - Please identify the characteristics that do not represent your intended study population.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition. Please provide information about why the group will need to be excluded.

For NIH funded protocols: If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

Anyone with signs, symptoms, or diagnosis of COVID-19
Pregnant women
Taking cardiovascular medication
History of autonomic dysfunction such as postural orthostatic tachycardia syndrome (POTS) or syncope (fainting)
Smokers or those that use vaporized nicotine
Diabetics
Those with a pacemaker
Those with a history of MRSA, neuropathy, or illicit substance abuse

Please consider the population being studied. Are there any other safeguards that you are putting in place to address participant protections?

We will follow strict guidelines in regard to COVID-19.

Recruitment

*required

Recruitment Processes

How will people find out about your study? It's common for studies to be advertised on flyers, social media, or ads. The IRB must know what language and materials are used to recruit participants.

*required

Does your study use a known group of participants or records to recruit up-front? Check any of the following sources of information which will be used to identify potential subjects

Yes, a known group or subject pool.

✓ No, only the general population

Both a known group AND also the general population.

*required

Do the researchers hold any authority over the targeted population?
Examples:

- Teacher/student
- Supervisor/Employee

Please keep in mind the researcher that conducts recruitment, collects, and analyzes identifiable data cannot have authority over the potential participant due to the potential for undue influence. If necessary, a third party (listed as key personnel) who does not have authority over the targeted population must conduct recruitment and strip all identifiers prior to researchers/authority figures have access to the data.

✓ Yes

*required

Please detail how the study will prevent against undue influence or coercion to participate.

There is a chance that a student from one of my courses might volunteer as a participant, but they would not be the primary targeted population. Participation in this study is voluntary and participants may withdraw at any time without any penalty. Please let me know if you would prefer to have my department chair or someone from the Purdue University Northwest Faculty Research Board to monitor and mitigate this potential risk.

No

*required

How will you recruit the intended participants from the general population for your study?

It's common for studies to be advertised on fliers, ads, or social media. The IRB must know how people will find out about the study.
Points to consider:

- *Is the setting, location and timing of recruitment appropriate for the research being conducted?*
- *Are recruitment methods well defined and appropriate for the population?*
- *Are all recruitment materials non-coercive, and easily understood?*

We will include a study flyer as part of our submission. In the past we have shared the flyers by posting them around campus, and have also posted them in local newspapers and on social media. We will respond to interested potential participants by email, but will not use list serves unless we gain approval from the manager of the list serve and then the Purdue University IRB. The PI has completed NIH Good Clinical Practice training recently so that the flyer will not be coercive (for example, in regard to monetary compensation).

*required

Privacy During Recruitment

Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).

Examples of issues:
Potential subjects may not want to be approached for research purposes by someone they do not know.
Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc. If your study is not anticipated to generate privacy concerns during recruitment, please state this below.

The study PI and all students that help on the project will have completed the appropriate CITI training courses. The PI has been a leader of human participant research for more than 15 years. We will not access medical records, and will store any electronic study data on a password protected computer with non-identifiable data. Any paper data will be stored in a locked file cabinet in the PI's lab on the Hammond campus (in Gyte 6).

*required

Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?

✓ Yes

*required

Please describe how frequently and in what manner individuals will be contacted. Indicate the endpoint for contact.

Participants may be contacted by phone or text message, but the preferred method of contact will be via email listserves. The endpoint for contact will be the PI (John Durocher).

No

*required

Check any of the following recruitment materials which will be used to contact potential subjects.

✓ Direct mail/email

*required

Upload the recruitment letter that will be used.

MBSR Recruitment Email -2.pdf

MBSR Flyer Updated.pdf

✓ Flyers/Brochures

*required

Upload the text or draft of this flyer or brochure.

MBSR Recruitment Email -2.pdf

MBSR Flyer Updated.pdf

Published Advertisements

Verbal Scripts

Website

Social Media

Other

None of the above

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research. Describe the likelihood and seriousness of each risk.

Participation in research is voluntary. Consider the risks that a participant might encounter if they participate in the study. Risks may be physical, psychological, social, legal, etc. Please note that all research exposes to subjects to some risk.

For example, if the only foreseeable risk is breach of confidentiality, please describe the potential consequences to the participant's reputation, lifestyle, employability, or legal status that might occur if it became known that they participated in the study.

Potential Risks or Discomforts:

Measurement of Blood Pressure: *Blood pressure will be measured similar to a similar doctor's office visit. There are no known risks with this procedure. If discomfort is experienced the cuff can be deflated.*

24-Hour Blood Pressure Recording (ABPM): *It is possible for 24-hour blood pressure recordings to interfere with normal activity and sleep habits. We will try to minimize disruption to normal habits by gaining snapshots of 24-hour blood pressures once before, and once after, the 8-week intervention. We will record on a work or school day according to previous recommendations. To enhance user comfort, our ABPM devices are very compact, lightweight, and can be easily attached to a belt. We will collect only two readings per hour at night to help reduce the chance of sleep interference.*

Questionnaires: *We do not anticipate risk or discomfort in regard to questionnaires, but if a participant feels uncomfortable with any question, or any questionnaire, they can leave it blank.*

Microneurography: *There is a potential risk of infection after insertion of the leg electrode. Sterile techniques will be used to help prevent infection. We have never had any participants report infection after the procedure. Also, about 7% of subjects experience some aching or "pins and needles" sensations for a few days after the procedure. There is no specific treatment for these sensations, which are believed to be the result of tissue inflammation. Study volunteers who have experienced these sensations report they*

have disappeared spontaneously and completely without treatment within a few days. Dr. Durocher has safely performed over 300 successful microneurography sessions since 2010. We will mention to qualified participants during the screening visits that they should wear a pair of shorts underneath their clothing, or bring a pair of shorts, for the autonomic testing days. We have a private room in the lab with a locking door where participants can change into shorts. We have blue medical exam shorts that will be provided to participants that do not bring a pair of shorts with them. Microneurography (a small electrode needle that can measure electrical activity in nerves) will be completed prior to a 10-minute baseline and the mental stress test (doing mental math calculations) protocol. Nerve activity will be continuously measured during the baseline and mental stress test. The microneurography electrode would remain inserted for approximately 1 hour, and does not typically cause any discomfort after the initial insertion. We use a tungsten microelectrode behind the right knee as the recording electrode and a small acupuncture electrode about 3 cm away as the ground.

ECG: *There is a risk of skin irritation from the electrodes used for ECG. This is unusual, but we can stop the experiment if this irritation occurs. To date, we have never had a problem with our electrodes.*

Finger Cuff*: Rarely, some people experience mild discomfort in the fingers from the blood pressure cuff. If this occurs, we will stop the finger cuff.*

Arterial Stiffness: *This is a non-invasive procedure that is comparable to someone checking your radial (wrist) or carotid (neck) pulse via finger. A buildup of fats on artery walls are known as plaques. The use of a tonometry device could cause hardened plaques to dislodge. If aortic pulse pressure is 50 mmHg or greater, as estimated from the radial (wrist) pulse site with the tonometer, then we will not proceed with carotid (neck) or femoral (groin) pulse recordings. Individuals with aortic pulse pressures greater than 50 mmHg may have an increased risk for arterial plaques, and potentially disrupting these plaques could increase the risk for a cerebrovascular event such as a stroke. We will inform participants if they have an aortic pulse pressure greater than or equal to 50 mmHg, and explain that elevated pulse pressure has been associated with an increased risk of arterial plaques in one previous study. We would suggest that the participant could visit their primary care physician if they have any concerns about the elevated value. We use this cutoff out of an abundance of caution to not press on the carotid artery for the arterial stiffness measurements, which is why we would exclude the participant from carotid to femoral pulse wave velocity measurements if they have an elevated aortic pulse pressure.*

These measurements will be led by John Durocher, PhD who has more than 15 years of experience with this type of research. Some of the non-invasive measurements such as blood pressure or ECG may also be led by graduate student Colleen Toorongian. Colleen has worked with Dr. Durocher for several years in his previous laboratory that had nearly identical equipment, and she holds a BS in Exercise Science.

Breach of confidentiality: *This is always a risk with data, but we will take precautions to minimize this risk as described in the confidentiality section.*
Under Indiana law, Purdue researchers must report any suspected child abuse or neglect to law enforcement or to the Department of Child Services hotline.
Under federal law, Purdue researchers must report all incidents of discrimination, harassment, and/or retaliation in the Purdue workplace and/or educational environment to the Title IX Coordinator or Equal Opportunity/Affirmative Action Officer. "Harassment" includes sexual harassment, sexual violence, rape, and any non-consensual sexual act. If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

*required

Describe how risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

Points to Consider

- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*
- *Are medical or psychological resources available that participants might require as a consequence of the research?*

The PI of the Clinical and Applied Human Physiology Laboratory at Purdue University Northwest has an extensive history of research with human participants for more than the past 15 years. The current project is supported by NIH, and study data has been collected for the last 2+ years at Michigan Technological University. The laboratory will continue to consider the following to minimize risks:
1. All laboratory staff will complete CITI training to promote responsible conduct of research in regard to safety and confidentiality.
2. Strict protocols will be followed for techniques such as the microneurography procedure, such as autoclaving one-time use tungsten microelectrodes in a sterile pouch, wearing protective gloves during the procedure, and using alcohol wipes to thoroughly clean the site before starting insertion of any recording or reference electrode.
3. Arterial stiffness measurements always start with the pulse wave analysis (PWA) technique at the radial pulse site to ensure that aortic pulse pressure is less than 50 mmHg before proceeding to a more delicate pulse site such as the carotid artery. For participants with an estimated aortic pulse pressure greater than 50 mmHg, we will not proceed to any pulse wave velocity (PWV) recordings.
4. The PI will continually monitor the participant throughout the autonomic testing sessions.

*required

Please provide the risk level that you believe applies to the study.

In addition to the population being studied, consider the this definition:

Minimal Risk: *Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.*

The researchers believe the study is no greater than minimal risk.

✓ The researchers believe the study is greater than minimal risk.

*required

Are there potential direct benefits to a participant or benefits to society from your research?

The IRB must consider the risk/benefit ratio of each study.
Please note that payment for participation is not considered a benefit. If there are no direct benefits, please state this fact.

✓ Yes, there are potential benefit(s) to be gained by the individual subject/participant.
*required

Please list the potential benefit(s) to the individual.

There are numerous potential benefits to participating in this study, but nothing is guaranteed. You may learn how to better manage the stress in your life and your cardiovascular risk could be lowered.

✓ Yes, there are potential benefits to be gained by society.
*required

Please list the potential benefit(s) to society.

The findings of this study may help to indicate how adults could lower their cardiovascular risk through mindfulness-based stress reduction or stress management education.

No, there are no benefits.

*required

How does the investigator evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

Please provide an assessment of the risk:benefit ratio associated with your study. The HRPP/IRB must assess that the risks and benefits are appropriate . This is a crucial consideration for your study.

I consider this study to be more than minimal risk due to the invasive microneurography procedure. The PI has completed over 300 successful sessions independently and has also served as a participant for muscle sympathetic nerve activity (MSNA) recordings at least a dozen times. We have not had any serious adverse events in the hundreds of sessions that we have conducted, but there is some discomfort during the procedure during the first few seconds when the electrode makes contact with the peroneal (common fibular nerve) and there is a chance for some pins and needles sensations for a few days after the procedure. We will also make clear recommendations to each participant to not undertake any heavy exercise with the legs for at least 48 hours after the procedure to reduce the chance of pins and needles or feelings of discomfort. The risk for this procedure is very small with and experienced microneurographer and sterile techniques. Microneurography is the only method to directly assess post-ganglionic sympathetic activity in humans, and MSNA provides crucial insight into autonomic regulation of blood pressure. To explain briefly, higher MSNA induces vasoconstriction which increases blood pressure, while lowering MSNA induces vasodilation to lower blood pressure. Thus, the benefits of the measurement is very high, and provides significant mechanistic insight to the causes underlying hypertension, cardiovascular, and cerebrovascular disease.

Privacy and Confidentiality

*required

Privacy During Data Collection

Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant?s ability to privately provide information used for your study.

Privacy refers to a person's desire to control access of others to themselves.Participants must be able to control their right to participate in research (such as the timing and location of data collection. Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study. Subjects may not want to be seen in areas that may stigmatize them or at times when they are working or competing other tasks).

The pre- and post-testing sessions for this study will be held in private in the Gyte 6 laboratory. There will only be a single participant in the lab at a time at a designated desk for questionnaire data collection, and at a designated seat and / or on the laboratory tilt table for other cardiovascular assessments. The small window on the lab door is covered so that no one can see into the room during data collection.

We will treat your identity with professional standards of confidentiality. The information obtained in this study may be published, but your identity will not be revealed. Subject information and corresponding six digit alphanumeric codes will be stored in a secured file cabinet in Dr. Durocher’s laboratory (Gyte 6). This study is funded by the National Institutes of Health. The project's research records may be reviewed by the National Institutes of Health, Food and Drug Administration (if FDA regulated), US DHHS Office for Human Research Protections, and by departments at Purdue University responsible for regulatory and research oversight. Summary (but not individual) results will be registered and published at ClinicalTrials.gov in accordance with requirements from the National Institutes of Health.

*required

Confidentiality

Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.

- *For identifiable data in electronic format, describe the system that will be used.*
- *For identifiable data in hard copy or tangible format, describe methods on how to secure the data*

Hard copy data will be stored in a locked file cabinet in the PI's laboratory. Only the PI will have a key for the cabinet, but approved student researchers will be able to access the data during normal approved working hours.
Electronic data will be stored on a password protected computer on a specialized laboratory R drive that was created by the PNW Information Services Department only for Dr. Durocher and graduate student Colleen Toorongian, and electronic data will not include any participant's name.

*required

Provide a plan to protect the identifiers from improper use and disclosure.

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.

*required

Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers.

Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes. For protocols that may be subject to future continuing and secondary data analysis, the IRB needs to have the justification for not destroying identifiers permanently.

We will keep the hard copy data for a minimum of 3 years beyond the completion of this NIH project. No identified data will be stored electronically or used for a future study or analysis. If hard copy data were to be destroyed it would be via a confidential shredding process.

*required

Will a Certificate of Confidentiality be obtained from NIH for this research?

What is a Certificate of Confidentiality?

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are automatically granted for NIH-funded research (as of 2017). The IRB may request that the investigator seek a CoC if disclosure of identifiable sensitive information.

Consider this option if your study may place participants at risk due to the potential to identify situations such as disease state or criminal activity.

Please note that if a CoC applies, the consent form must have appropriate language (found in our template).

✓ Yes, the study is funded by an NIH grant or subaward and therefore automatically has CoC protections.

Yes, our team will seek a CoC from NIH if approval is granted for this IRB application. I will amend the study if this CoC is granted by attaching the document here.

No, this study will not require a CoC.

Data and Safety Monitoring

*required

Which individual or group will be responsible for monitoring the data and safety for this study?

- ✓ Principal Investigator/Research Team
- Independent Study Monitor(s)
- Internal Committee
- Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Independent of PI and Sponsor
- Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Not Independent of PI and Sponsor
- Other

*required

Describe the provisions for monitoring the data to ensure the safety of subjects.

The individual responsible for data safety and monitoring will be the principal investigator (PI), Dr. John J. Durocher. The greater than minimal risk activities include microneurography. Risks and safeguards for the procedure have been previously discussed (see microneurography attachment). If abnormal signs are detected during testing (ex. abnormal cardiac rhythm) or participants experience post-procedure adverse effects such as infection or prolonged paresthesia (i.e. beyond 48 hours) they will be referred to their primary care physician. In the event of a medical emergency, or detection of a hypertensive crisis (resting blood pressure 180 / 120 mmHg or higher and associated symptoms such as chest pain or shortness of breath), Dr. Durocher or research staff would immediately dial 911. Abnormal or adverse events will be documented by Dr. Durocher and reported as outlined below.

Throughout this study, Dr. Durocher will monitor the participants for adverse events. Events determined by the PI to be unanticipated problems involving risks to subjects or others (UPIRTSOs) will be reported by the PI to the IRB (via written memo) within 5 days per policy (SOP 409) for serious adverse events and within 14 days for other unanticipated problems (according to SOP 409). Additionally, in accordance with the National Institutes of Health (NIH) policy, the UPIRTSOs will be reported to the program official within 30 calendar days. All studies will be suspended in the laboratory until the issue has been resolved between the PI, IRB, and NIH. Adverse events that are determined by the PI to not be UPIRTSOs will be reported per IRB policy at the time of continuing review (i.e., annual review). All subjects and study staff

members will be informed by Dr. Durocher (via written memo) about any UPIRTSOs. If any protocol changes are needed, the PI will submit a modification request to the IRB. Protocol changes will not be implemented prior to IRB approval.

We will keep an electronic and printed copy of the Purdue University Unanticipated Problems and Adverse Event Reporting SOP 409 within the laboratory.

*required

Provide a description of the individuals who will be responsible for data safety monitoring

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Include the following details:
(1) association with the research and/or study sponsor;
(2) nature of their expertise and;
(3) whether they are independent of the commercial sponsor

If those monitoring the study are not independent of the sponsor, please describe how any potential conflicts of interest or biases will be avoided.

1) John Durocher the PI will be responsible for data safety monitoring.
2) Dr. Durocher has a PhD in Biological Sciences - Exercise Physiology, is a certified Exercise Physiologist through the American College of Sports Medicine, and certified Strength and Conditioning Specialist through the National Strength and Conditioning Association. Dr. Durocher was extensively trained in microneurography by two leading experts (William Cooke, PhD at Michigan Tech and Jason Carter, PhD at Montana State University) and has been leading the technique independently for more than a decade.
3) The PI is independent of the government sponsor.

Upload CVs

John Durocher's PNW Curriculum Vitae (2021).pdf

*required

What data will be reviewed?

Provide a description of the parameters that will be evaluated to ensure safety.

- ✓ Adverse events/Unanticipated problems
- ✓ Aggregate data
- ✓ Enrollment numbers
- ✓ Individual subject data/case report forms
- Protocol violations/deviations
- ✓ Subject withdrawals/terminations
- Other

*required

How often will data and safety monitoring be performed?

Please specify if this is a specific number of times, at defined time points, after a certain number of subjects have been recruited or as needed (i.e. every 6 months, every SAE, every 5 subjects, etc.)

As needed if there is an SAE.

*required

Describe the responsibilities that have been given to the data and safety monitoring function.

This should include a discussion of whether the data and safety monitoring plan includes a charter, whether stopping rules will be developed, and if any interim analysis will be performed (if so, on what basis). If this information is in protocol, please specify where relevant information is located.

Dr. Durocher will complete an annual report detailing the study progress, subject status, adverse events, and any protocol deviations. He has completed the first two annual reports that have already been submitted to the NIH.

*required

If this protocol is for a multi-center trial what mechanisms are in place to either receive or distribute results of the data and safety monitoring function in a prompt manner.

Describe each site's role in contributing to the data and safety monitoring.

This study will be conducted on the Hammond campus of Purdue University Northwest, and not at any other locations.

If a DSM Board charter exists, please upload it.

A charter includes identification and description of individuals responsible for monitoring the trial (their roles, qualifications, and the frequency of the monitoring activities. The proposed membership and assurances should be described within the document to ensure that there are no conflicts of interest with the study team or proposed institutions.

John Durocher's PNW Curriculum Vitae (2021).pdf

Compensation for Research Participation

Describe any compensation that subjects will receive when they participate in your study. Consider what happens to the compensation amount if the participant withdraws or is disqualified from the study. If course credit will be offered, please provide the amount and the percentage of the total grade.

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*required

Will subjects be compensated for their participation in the study?

Will the study provide (money/gift cards/inducements/discounts/entry into a drawing/course credit) in exchange for a person's participation in the study? Please note that Purdue University policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

✓ Yes

*required

Describe the payment arrangement, including amount and timing of disbursement.

If the compensation includes a lottery or raffle-style drawing, please provide the approximate odds of winning (number of prizes, anticipated number of participants).

If course credit will be offered, please provide the amount and the percentage of the total grade. Extra credit should be no more than 3% of the course grade in order to avoid undue influence.

Participants will receive the following: 1) $50 for each microneurography (autonomic) session completed; and 2) $200 for the completion of the 8-week MBSR or SME course (prorated as $25 per week completed if there is any need to withdraw before the completion of the 8-week course). The maximum payment that you can receive from this study is $300. According to the rules of the Internal Revenue Service (IRS), payments that are made as a result of participation in a study may be considered taxable income. Participants will be asked to

provide their full name, address, and social security number for our Human Subject Invoice Log so that our Business Office at Purdue University Northwest can process and send a payment to the participant.

We did not have any budgeted funds through NIH for the screening visits, and have already screened 139 potential participants while at Michigan Tech that did not receive payment for screening. Thus, it would not be feasible or ethical to add payments for screening at this point.

*required

Justify the proposed payment arrangement described above, specifically why payment does not provide undue influence for subject participation

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Explain how the amount is reasonable for the study.

The proposed $50 payment for each microneurography session is consistent with what is paid at other institutions. This amount is thought to compensate the participant for their time. The proposed $25 per week for the MBSR or SME classes is designed to compensate participants for their time investment to the intervention. The compensation provides some compensation for the investment of time in the study, and potentially something towards transportation to and from the laboratory or class site, but not enough to be coercive to simply participate in the study for financial gain.

*required

Will partial payment be provided if the subject withdraws or is disqualified prior to completion of the study?

For example, are there starting and stopping points where the participation will be pro-rated?

✓ Yes

*required

Explain the plan for providing partial payment.

Participants will receive a prorated $25 for each week completed for the MBSR or SME courses if there is any need to withdraw before the completion of the 8-week course.

No

No

Informed Consent Process Section title

Informed consent is more than a form; it's a process and a responsibility.

Please answer all questions regarding the ways that participants will provide informed consent to participate in your study.

---

*required

Identify which subjects will consent to participate in the research.

- ✓ All subjects (or their legally authorized representative) will consent to participate in the research.
- Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.
- No subjects (or their legally authorized representative) will consent to participate in the research.

*required

For subjects who will consent to participate, choose whether the consent process will be documented by a **signature** from subjects.

Please note that you may request a waiver of the signature requirement if this study is minimal risk OR if the only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality.

- ✓ All consented subjects will provide a written signature as documentation of consent
- Some subjects will provide a signature as documentation of consent, and some subjects will not.
- No subjects will provide a signature as documentation of consent.

*required

Indicate in what language(s) the consent conversation will be conducted.

✓ English

Language(s) other than English

*required

Will subjects participate in any study activity prior to signing a consent document?

For example, some studies require subjects to fast, to refrain from drinking or smoking, pass a phone screening process or keep a journal/log prior to enrollment in the study.

✓ Yes

*required

List the activities in which subjects will participate prior to signing the consent document. Each activity must present no more than minimal risk of harm to subjects AND involve no activities for which written consent is normally required outside of the research. Please note that subjects should provide verbal consent to these activities.

Participants will be asked to refrain from eating for 3 hours, and from exercise, caffeine, and alcohol for 12 hours prior to seated blood pressure screenings.

No

Waiver of Informed Consent or Signed Consent

If any or all subjects will not provide written, signed informed consent for all parts of the study. Please complete the following information to request either a waiver of consent or a waiver of *signed* consent.

---

*required

Does the research pose greater than minimal risk to subjects (greater than everyday activities)?

This study is considered more than minimal risk due to the microneurography procedure, so we will not ask for any waiver of informed consent.

*required

Will the waiver adversely affect subjects? rights and welfare? Please justify.

---

not applicable.

Why would the research be impracticable without the waiver?

---

*required

How will pertinent information be reported to subjects, if appropriate, at a later date?

Through peer-reviewed publications for the overall study outcomes.

*required

Will any other materials (videos, brochure, drug/device information, etc) be used to present information to potential subjects?

Yes

✓ No

*required

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

The informed consent would be provided as an option at the end of the 3rd blood pressure screening visit for qualified participants.

*required

Consent form Elements

The following components are required for informed consent forms. If any of these elements are missing, you must provide justification for the reasoning.
Please confirm that all elements of informed consent are present. Use the Purdue IRB template found on the Purdue HRPP/IRB website

BASIC REQUIRED ELEMENTS OF INFORMED CONSENT
Please confirm that all elements of informed consent are present.

- Key Information at the beginning of the consent form
- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others that may reasonably be expected
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained
- A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

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*required

Please confirm that all basic elements of consent appear in your draft consent form.

✓ The research team has drafted a consent form and affirmed that it contains all of these basic considerations of informed consent.

Our research team is omitting a basic section from the consent form.

Our research team requested a complete waiver of informed consent and will not be attaching a consent form to this submission.

SPECIAL REQUIRED ELEMENTS OF INFORMED CONSENT

Please check if these items apply and are addressed in the draft consent form.

If any of these elements apply, but are missing, you must provide justification for the reason(s) to omit this information.

- *A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.*
- *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*
- *Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.*
- *Any additional costs to the subject that may result from participation in the research.*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

- *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
- *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- *Disclosure of any conflicts of interest.*
- *Registration of the trial on Clinicaltrials.gov*
- *NIH Certificate of Confidentiality coverage.*
- *Future uses of identifiable or deidentified data.*

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*required

Please confirm that all items that apply to your study have been addressed in the consent form.

You must review the study-specific parameters that were discussed within your application in previous sections. Please refer to the sections on the left for any items that may apply.

✓ The research team has drafted a consent form and affirmed that it contains all special considerations of informed consent applicable to our study.

Our research team is omitting an applicable section from the consent form.

Our research team requested a complete waiver of informed consent and will not be attaching a consent form to this submission.

*required

Please attach all versions of your consent form here.

Consent forms should follow the structure of the template on the IRB website.
MBSR Pre-Screening Consent.pdf

MBSR Pre-Screening Consent.docx

MBSR Consent-9.docx

MBSR Consent-9.pdf

Funding Source(s)

*required

CURRENT Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI's responsibility to update funding sources as a modification to the protocol and associated forms (such as the consent form) when funding changes.

Please list any sources of funding that are **confirmed** by contract, agreement, or other support of a sponsor.
You will list any pending sources in the next question.

If the research is funded by a subcontract, please add both the subcontract source and the prime sponsor.

✓ Externally sponsored (federal, state, corporate, foundations, industry, donor)

Please search for the sponsor(s) here. Be certain to include any funding that originates or includes US federal sources.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

US Department of Health and Human Services - DHHS

If you do not see the name of the funding source using the "Find Sponsors" button above, please enter the full sponsor name in the text box below.

Please use the full name of the sponsor and include any subcontracted efforts.

National Institutes of Health - National Heart, Lung, and Blood Institute

Internal Purdue University Funds (Includes departmental funds, start-up funds.)
(Note, this does not include Purdue Research Foundation or Purdue Research Park companies-please list as external sponsor above).

None - There are no confirmed funding sources at this time.

ANTICIPATED Funding Source(s) - Required

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

Please list any sources of funding where sponsorship is **anticipated** or pending a final decision.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

There are no pending funding sources at this time.

Conflict of Interest and/or Outside Activities Disclosure

Conflicts of Interest or outside activities must be disclosed and managed prior to IRB approval. For more information about these policies, please consult the resources listed in the question marks in each section.

The IRB may request confirmation of proper disclosures.

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*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ I attest that I understand the outside activities policy and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Receiving more than $5,000 in compensation from, or having ownership interests in, outside entities, constitute Significant Financial Interests that need to be disclosed. Definitions of SFI, Investigator and Institutional Responsibilities, can be found at https://www.purdue.edu/policies/ethics/iiib2.html#definitions.

Yes

✓ No

*required

Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?

Yes

✓ No

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

Other attachments

*required

Do you have any other supporting documents to attach?

You may attach COVID-19 Research Space Standard Operating Procedures here if this is a new protocol submitted during the COVID-19 pandemic.

Investigators are invited to submit reference lists, study instruments, supporting information, training data, device pictures, or other relevant items for their study that were not addressed in the application.

✓ Yes

Attach any other documents. Please use a file name that describes the document.

You may attach multiple files to this entry.

PLEASE DO NOT UPLOAD PARTICIPANT DATA OR IDENTIFIABLE RESEARCH DATA.

citiCompletionReport1728324-Durocher Certificate.pdf

citiCompletionReport1728324RCR-Durocher Certificate.pdf

Previously Approved IRB Proposal from Michigan Tech - includes appendix on microneurography.docx

citiCompletionReport6623673-Toorongian.pdf

signed Durocher Data Transfer Memo.pdf

COVID-19 Prevention and SOPs for PNW Clinical and Applied Human Physiology Laboratory - Gyte 6.pdf

Data Transfer and Use Request - Durocher.pdf

No

Modification Submission

Modification/Amendment to a Protocol

Changes to a study must be approved by the HRPP/IRB.

Examples include (but are not limited to) changes in:

- Recruitment methods
- Screening materials
- Intended study population
- Inclusion/Exclusion criteria

For a list of minor changes that do not require IRB review, please see Purdue HRPP Standard Operating Procedure 305. (Link appears in the "?" button above.) Also, see www.irb.purdue.edu for additional changes not requiring modification during the COVID-19 pandemic.

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*required

What type of change(s) would you like to make?

IMPORTANT:

All revisions to the protocol must be made to the relevant sections of your study in the sidebar. Please note, that more than one section may require change. For non-exempt protocols, please review your current consent form and edit language as needed.

Remember to review any advertisements, scripts, information sheets and consent forms. Attach them to the relevant sections of your protocol. Please title any attachments with dates or version control numbering in the file name to assist with review.

Personnel

Study Procedures

Change to the recruitment and/or data collection status.

✓ *(For example, click here if you are finished with data collection and would like to notify the IRB that the study will only analyze the collected data.)*

*required

Please briefly describe the change in status.

We had difficulty gaining enough participants for the study so we contacted the Provost's office so that our study flyer could be sent out to student, faculty, and staff listservs. This change has been noted in the "Recruitment" section. We have also added our research study coordinator to the flyer as a contact person for those that might be interested in the study. The new flyer is uploaded. Under Protocol Description we have also specified the following "Most of the MBSR and SME courses will be offered online via Zoom. There is one Saturday class for each of the interventions that we will try to hold in person on the Hammond campus." We have not changed any of the Mindfulness Based Stress Reduction (MBSR) or Stress Management Education (SME) classes or content, only that the courses could be offered through Zoom because our MBSR instructor cannot travel frequently from the upper peninsula of MI to Hammond. Both the MBSR and SME courses can be offered through Zoom, and we have done so previously while I was employed at Michigan Tech near the beginning of COVID-19.

Something else (e.g. participant compensation amounts)

(For resuming on-campus in-person research)- COVID-19 Research Space Standard Operating Procedure approval.

(For resuming off-campus in-person research)- COVID-19 off-campus research certification of practices outlined in the EVPRP Guidance for Off-Campus Research Activities

*required

Study Personnel

In this section you will name all staff who will participate in the study.

*required

A Principal Investigator (PI) is responsible for all aspects of a research study.
STUDENTS ARE NOT AUTHORIZED TO BE PRINCIPAL INVESTIGATORS

Provide the name of the Principal Investigator of this study.
All faculty (tenured, tenure-track, research and clinical) are eligible to be Principal Investigators. Others requesting to submit proposals as the Principal Investigator for the first time must obtain special approval.

Once the name is selected, training courses from the CITI system should appear when you click "View". If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.
Name: John Durocher
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: jjduroch@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

*required

Please check your Purdue University PI classification.

- ✓ Faculty (tenured, tenure-track, research and clinical)
- Student
- Purdue non-faculty staff member granted special PI status.

*required

Primary Contact

Provide the name of the Primary Contact of this study. The Primary Contact will be copied on all correspondence regarding the IRB review. Note that the Primary Contact and the Principal Investigator may be the same. The Primary Contact must be a current Purdue University faculty, staff, postdoc, or student and must have a role as Key Personnel on the study.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: John Durocher
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: jjduroch@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

If you wish to provide a campus phone number for the Primary Contact, you may list it here.

This field is optional. Most correspondences from the IRB will arrive via the Cayuse system.
219-989-2625

*required

Key Personnel

Below is a definition of Key Personnel. Please read the definition and decide who will need to be listed as Key Personnel on the study. The PI defines the roles of each staff member based on the definition below.

Key personnel: The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

*required

Does your study have additional Key Personnel besides the PI and Point of Contact?

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

✓ Yes

*required

Where are the Key Personnel from?

Check all that apply.

✓ I have key personnel from Purdue University.

I have key personnel from another external site (outside of Purdue).

No, the only personnel on the project are the PI and Point of Contact.

Key Personnel From Purdue University

- *The Principal Investigator and Primary Contact are considered Key Personnel. You do not need to list these names again.*
- *Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.*
- *If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.*

Name: Colleen Toorongian
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: ctoorong@purdue.edu

Name: Grant Thivierge
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: gthivier@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. For researchers outside of Purdue university, please use the next section and click "external investigators".

(First Name: Last Name: Purdue e-mail address)

*required

Provide a brief description of each person's position at Purdue (e.g. student, staff, faculty) and their role in the study.

Examples:
Prof. Principal (faculty) will oversee all aspects of the study design and conduct
John Researcher (graduate student) will recruit and consent participants and collect data
Purdue Pete (staff) will analyze collected study data.

John Durocher is the PI and tenured associate professor that will oversee all aspects of the study.
Grant Thivierge is a Research Study Coordinator and will assist with data collection, analyses, and dissemination of results.
Colleen Toorongian is an MS student in Biological Sciences that will assist with data collection, analyses, and dissemination of results.
Brigitte Morin MS is a senior lecturer at Michigan Tech that has been involved with teaching the MBSR class since the start of this project. She recently agree to teach the 8-week course one more time in the spring of 2022 and will conduct most of the sessions via Zoom. She may also fly down to lead the 1-day silent retreat that is part of the MBSR class.

Research Sites

*required

Where will the study take place?

✓ Purdue University

*required

Please check the following locations.

West Lafayette

✓ Regional Campus (PFW, PNW, IUPUI)

*required

Select the regional campus

✓ Hammond

Fort Wayne

Westville

Indianapolis

Polytechnic Institute Statewide Sites

Extension Sites

*required

Please provide a brief description of the Purdue University location(s).

Provide building names, course titles, event names as applicable.

Gyte Building - Room 6 (Clinical and Applied Human Physiology Laboratory)

External Site (non Purdue University)

Getting started with your submission

*required

Welcome to the submission system for the Purdue HRPP/IRB. Before you begin, you should be familiar with the framework of human research protections and how they relate to your proposed study. The materials to help you appear on our website.

Be certain that all personnel have completed online training prior to submitting the protocol.

Helpful Tip: Use the Create PDF button at the top of the page if you need to share a PDF version of this protocol for discussion with a reviewer outside of the Cayuse system.

The choices you make on the first two sections will help populate the required sections for your submission. Please look through the options and make the choice closest to your research. You can always seek assistance by scheduling an appointment with the HRPP Office or reviewing the materials at www.irb.purdue.edu.

Exempt study

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

Non-exempt study

✓ *Research that does not fit into an exempt category typically involves the collection of new data from a participant.*

Just-in-time

I have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but my application to the IRB is dependent on other factors such as:

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible at the time of the sponsor request, please do not select this option. The research team should affirm that their sponsor will accept documentation for a development protocol.

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

Quality Improvement

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

I need to know if my project is considered "Human Subjects Research"

I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).

When Purdue University will be engaged in human subject research with one or more institutions, investigators may submit a Request for Deferral asking that the review be deferred to one institution's Institutional Review Board (IRB).

Research Classification and Special Considerations

Would you determine that this research is predominately social or biomedical in nature

When you provide an answer to this question, a series of additional questions will display, and checking on each of these questions will generate a new form to the left that you will need to complete. These forms will ask the questions we used to ask, but in a clearer and more organized way, which will help the reviewer, as well as the investigator.

✓ **Biomedical**
My research has a biomedical focus.

Social / Behavioral
My research has a social or behavioral focus.

A combination of social science and biomedical, or I'm not sure.

*required

Please check any of the following that apply to the proposed research.

Each of these involves special considerations in the IRB review. If none of these items apply, click on "None of These" and continue forward in the application.

Potentially Vulnerable Populations
Examples: Children, Pregnant Women/Fetuses, Prisoners, those that lack capacity to consent), economically disadvantaged persons, minorities.

Use of an Experimental Drug
A substance manufactured via chemical process and intended for use in the diagnosis, cure, mitigation, than food) intended to affect the structure or any function of the body of man.

Note: Studies of this nature are considered Applicable Clinical Trials and may require an Investigational and Drug Administration and involvement of a physician investigator.
https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/investigational-new-d

Use of an Investigational Medical Device
An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or

or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, m in man or other animals, OR intended to affect the structure or any function of the body of man or other primary intended purposes through chemical action within or on the body of man or other animals and v metabolized for the achievement of its primary intended purposes.

Note: Studies of this nature are considered Applicable Clinical Trials and may require an Investigationa Drug Administration and involvement of a physician investigator.
https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/investigational-new-d

Clinical Trial
PLEASE READ THIS DEFINITION CLOSELY.

✓ *NIH defines a Clinical Trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."*

If this determination applies, please check this box.

Research with Food
Articles used for food or drink (or for components of such articles) and NOT intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

Radiation and/or Imaging
X-ray, CT, PET scans, nuclear medicine procedures, and MRI scans.
This protocol requires for research purposes 1) radiological assessments and procedures that involve radiation exposure (X-ray, CT, PET scans) 2) nuclear medicine procedures (imaging or therapeutic) or 3) MRI scans.

Nursing or Study Physician Resources
This protocol will have Nursing or Study Physician Resources

Blood Collection for Research Purposes
This protocol involves collection of blood samples other than discarded specimens. Examples are collections involving finger stick, venipuncture, or indwelling catheters.

Human Biological Specimen Repository
This protocol involves the establishment of a biological specimen repository.
Repositories are used for prospective collections of specimens that are processed, stored and

distributed to multiple investigators for use in research.

Gene Research Classification

The study will collect samples from individuals and look at a single gene, group of genes, or full genome for the purposes of research.

Stem Cells

This protocol includes an intervention with human subjects that involves either
a) the derivation of stem cells,
b) the implantation of stem cells.

International Research

This protocol includes research that is conducted at a non US location.

Data Controlled Under HIPAA and/or FERPA

Health Insurance Portability and Accountability Act (HIPAA) covers individually identifiable health information held or transmitted by a covered entity. This often involves healthcare providers and insurance companies.
AND/OR
Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records.

Biological Product

A substance manufactured via biological process and otherwise meets the above definition of a drug; includes a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

Dietary Supplement

A product taken by mouth that is intended to supplement the diet and that contains one or more dietary ingredients.

Community-engaged research

This is community-engaged research. For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.

Incidental Findings

Incidental findings are discoveries of individual-level findings that are unrelated to the goals of the study. (e.g. genetic data, MRI or test results).

Deception or incomplete disclosure

Deception occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.

Incomplete Disclosure occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

None of the above apply.

Protocol Description

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

Tell the IRB what specific trait(s), function(s) or behavior(s) you would like to study. Give a brief summary of your study in simple terms.

Describe why you are conducting the study. Identify the research question(s).

More than 50% of U.S. adults have elevated blood pressure or hypertension which increases the risk of cardiovascular disease (CVD). Early detection of elevated blood pressure or stage 1 hypertension offers a window of opportunity to prevent progression to overt hypertension and CVD through behavioral modification. Sympathetic activation and arterial stiffness are both deleterious factors that concomitantly contribute to elevated blood pressure. Mindfulness-Based Stress Reduction (MBSR) programs have been shown to reduce blood pressure in adults, but the mechanisms for the reduction remain speculative.

*required

Specific Aims/Objectives

Give the IRB an example of potential discoveries you hope to make or insight you hope to share. For example, outline a disease state, social characteristic or behavior that might benefit from the study results.

We will systematically examine 24-hour blood pressure regulation and two potential mechanisms for the anti- hypertensive effects of MBSR by directly assessing muscle sympathetic nerve activity (MSNA) and arterial stiffness. Aim 1 will determine if MBSR improves 24-hour blood pressure regulation, aim 2 will determine if MBSR reduces sympathetic neural activity, and aim 3 will determine if MBSR will decrease arterial stiffness in prehypertensive adults. This project will also provide advanced research opportunities to undergraduate and graduate students in health-related fields at Purdue University Northwest, consistent with the goals of the Academic Research Enhancement Award (R15) mission.

*required

Background and Significance

Include how previous research studies and their results support your study or how you will build upon existing information.

The proposed research is relevant to public health because over 50% of adults in the U.S. have elevated blood pressure or hypertension. The project is relevant to NIH's mission because it will provide rigorous investigation on Mindfulness-Based Stress Reduction as a proactive anti-hypertensive lifestyle intervention that may improve blood pressure regulation through sympathetic nerve control and arterial stiffness.

*required

Research Hypotheses

Please list any relevant study hypothesis/hypotheses. If this does not apply, type "Not Applicable".

Our central hypothesis is that MBSR will: 1) improve nocturnal blood pressure dipping and / or reduce early-morning surges, 2) reduce resting MSNA and attenuate the neural cardiovascular responses to acute stress, and 3) decrease arterial stiffness. We will utilize a parallel, randomized, control design (MBSR vs. active control) that includes gold-standard techniques for measuring blood pressure (24-hour ambulatory assessment), MSNA (microneurography), and arterial stiffness (applanation tonometry).

*required

How long will participants be asked to be in the study?

List the approximate duration in the fashion below.

- *Number of Visits =*
- *Minutes or Hours per visit =*
- *Single Day or Multiple Days?*
- *Total number of months until all data are collected =*

Potential participants visit the laboratory on three non-consecutive days for screening visits that take approximately 15 minutes each. We have included 3 pre-screening blood pressures to ensure that participants meet the primary requirement for elevated blood pressure. This procedure was proposed in

the original NIH proposal, has been used throughout this study so far, and has been used in previous projects we had funded through the NIH.

Qualified participants visit the lab two more times, once before and once after the 8-week intervention (within 10 days of the start and finish). Each of those visits take about 3 hours. The mindfulness-based stress reduction (MBSR) and stress management education (SME) classes (interventions) meet once per week for 2 to 2.5 hours. There is also one Saturday requirement at the end of the 6th week for about 7-8 hours. At home daily practice for participants in the two classes ranges from 30-45 minutes. The entire study with pre- and post-testing is approximately 10 weeks.

We specifically set up these courses for the research study. However, eight week mindfulness-based stress reduction courses are offered around the world by qualified instructors. We plan to have one of our previous instructors (Brigitte Morin) offer the course to the final cohort of participants in the spring of 2022. I will assist my graduate student Colleen Toorongian to offer the 8-week stress management education course. The SME course is traditionally used as an active control course for meditation studies, and to my knowledge it is not offered as an independent course like MBSR. Most of the MBSR and SME courses will be offered online via Zoom. There is one Saturday class for each of the interventions that we will try to hold in person on the Hammond campus.

*required

Specific Study Procedures

Describe in detail what a research participant will be asked to do.

- Prior to the start of the 8-week program, a 24-hour blood pressure reading will be taken. The device is compact and easily attached to a belt. Participants will also be fitted with a wrist accelerometer (similar to a Fitbit) that will track sleep-wake cycle for five consecutive nights. Participants will also complete questionnaires for anxiety, five-facets of mindfulness, and the ability to decenter.

- Following the accelerometer recordings, nervous system functions will be tested with microneurography (small electrode needle that can measure electrical activity in nerves) in a baseline setting along with a mental stress test (doing mental math calculations). Nerve activity will be continuously measured during the baseline and mental stress test. In addition to the nerve recordings, heart rate will be recorded with 3-lead electrocardiography, and continuous blood pressure with a small cuff on the middle finger. We will also estimate arterial stiffness with a small probe that will be placed at the radial (wrist), carotid (neck), and femoral (groin) pulse sites. We can also estimate breathing rate with an elastic pneumobelt that goes around the rib cage (fits gently outside of the participant's clothing). Breathing rate is not considered a primary variable, but we may report breathing rate (breaths per minute) if we calculate results for heart rate variability.

- With the programs outlined, participants will then proceed with the 8-week program to which they were randomly assigned. It is requested that you do not change your normal exercise schedule or eating habits. Both the MBSR and active stress management control programs will require a once

weekly group meeting and at home exercises. The home practice for MBSR participants includes things like breathing awareness, body scanning, and gentle Yoga. The home practice for SME participants includes daily reading from the book "Why Zebras Don't Get Ulcers" and gentle resistance band training. We have free copies of the required book that are lent out to participants during the 8-week class.

- Once the 8-week program is completed, participants will once more complete the questionnaires, 24- hour blood pressure readings, accelerometry, microneurography, heart rate, blood pressure, and arterial stiffness readings.

- Related to our laboratory safety, our new Tuttnauer 1730M autoclave is 20+ feet away from where participant testing would take place, and will never be used while a participant is in the laboratory. We have used this same autoclave for more than 15 years, and it has a very secure door latch. We have always worn neoprene gloves when prepping the electrodes to be autoclaved and when removing the electrodes from the autoclave in the sterilized pouches. We will use 3.5" x 10" self seal sterilization pouches made by PlastCare USA, that have an indicator strip that changes from blue to brown during the autovclaving process. We will follow additional PPE protocols during the COVID pandemic such as wearing a facemask during the autoclaving procedure.

In long term studies, a visual representation of a timeline is helpful. You may upload a visual representation as a Word (.docx) or PDF file here.

MBSR Conceptual Overview.pdf

Attach any surveys, questionnaires, assessments

For purposes of recordkeeping, the HRPP/IRB will need to have a Word or PDF version of any Qualtrics or electronic survey questionnaires. Please include more than a link to the survey.
MBSR Study Questionnaires.pdf

UFI_Pneumotrace_Datasheet.pdf

Actiwatch Spectrum PRO Brochure.pdf

Flow charts, schemas

MBSR Conceptual Overview.pdf

References

Below are references that we cite in our complete IRB proposal:

- 1.**Baer RA, Carmody J, and Hunsinger M**. Weekly change in mindfulness and perceived stress in a mindfulness-based stress reduction program. *Journal of clinical psychology* 68: 755- 765, 2012.
- 2.**Baer RA, Smith GT, Lykins E, Button D, Krietemeyer J, Sauer S, Walsh E, Duggan D, and Williams JM**. Construct validity of the five facet mindfulness questionnaire in meditating and nonmeditating samples. *Assessment* 15: 329-342, 2008.
- 3.**Brguljan-Hitij J, Thijs L, Li Y, Hansen TW, Boggia J, Liu YP, Asayama K, Wei FF, Bjorklund-Bodegard K, Gu YM, Ohkubo T, Jeppesen J, Torp-Pedersen C, Dolan E, Kuznetsova T, Katarzyna SS, Tikhonoff V, Malyutina S, Casiglia E, Nikitin Y, Lind L, Sandoya E, Kawecka-Jaszcz K, Filipovsky J, Imai Y, Wang J, O'Brien E, Staessen JA, and International Database on Ambulatory Blood Pressure in Relation to Cardiovascular Outcome I**. Risk stratification by ambulatory blood pressure monitoring across JNC classes of conventional blood pressure. *Am J Hypertens* 27: 956-965, 2014.
- 4.**Callister R, Suwarno NO, and Seals DR**. Sympathetic activity is influenced by task difficulty and stress perception during mental challenge in humans. *The Journal of Physiology* 454: 373-387, 1992.
- 5.**Cardoso CR, and Salles GF**. Prognostic Importance of Ambulatory Blood Pressure Monitoring in Resistant Hypertension: Is It All that Matters? *Curr Hypertens Rep* 18: 85, 2016.
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- 7.**Carter JR, Durocher JJ, Larson RA, DellaValla JP, and Yang H**. Sympathetic neural responses to 24-hour sleep deprivation in humans: sex differences. *Am J Physiol Heart Circ Physiol* 302: H1991-1997, 2012.
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- 11.**Egan BM, Nesbitt SD, and Julius S**. Prehypertension: should we be treating with pharmacologic therapy? *Ther Adv Cardiovasc Dis* 2: 305-314, 2008.

- 12.**Fresco DM, Moore MT, van Dulmen MH, Segal ZV, Ma SH, Teasdale JD, and Williams JM**. Initial psychometric properties of the experiences questionnaire: validation of a self-report measure of decentering. *Behav Ther* 38: 234-246, 2007.
- 13.**Fuchs FD, de Mello RB, and Fuchs SC**. Preventing the progression of prehypertension to hypertension: role of antihypertensives. *Curr Hypertens Rep* 17: 505, 2015.
- 14.**Gainey A, Himathongkam T, Tanaka H, and Suksom D**. Effects of Buddhist walking meditation on glycemic control and vascular function in patients with type 2 diabetes. *Complement Ther Med* 26: 92-97, 2016.
- 15.**Hoge EA, Bui E, Goetter E, Robinaugh DJ, Ojserkis RA, Fresco DM, and Simon NM**. Change in Decentering Mediates Improvement in Anxiety in Mindfulness-Based Stress Reduction for Generalized Anxiety Disorder. *Cognit Ther Res* 39: 228-235, 2015.
- 16.**Hoge EA, Bui E, Marques L, Metcalf CA, Morris LK, Robinaugh DJ, Worthington JJ, Pollack MH, and Simon NM**. Randomized controlled trial of mindfulness meditation for generalized anxiety disorder: effects on anxiety and stress reactivity. *J Clin Psychiatry* 74: 786- 792, 2013.
- 17.**Hughes JW, Fresco DM, Myerscough R, van Dulmen MH, Carlson LE, and Josephson R**. Randomized controlled trial of mindfulness-based stress reduction for prehypertension. *Psychosomatic medicine* 75: 721-728, 2013.
- 18.**Joyner MJ, and Green DJ**. Exercise protects the cardiovascular system: effects beyond traditional risk factors. *The Journal of physiology* 587: 5551-5558, 2009.
- 19.**Kario K**. Morning surge in blood pressure and cardiovascular risk: evidence and perspectives. *Hypertension* 56: 765-773, 2010.
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- 21.**Nehra DK, Nehra S, and Dogra R**. Positive psychological functioning with mindfulness based stress reduction (MBSR) program. *Biopsychosocial issues in positive health Delhi: Global Vision Publishing House,* 2012.
- 22.**Nejati S, Zahiroddin A, Afrookhteh G, Rahmani S, and Hoveida S**. Effect of Group Mindfulness-Based Stress-Reduction Program and Conscious Yoga on Lifestyle, Coping Strategies, and Systolic and Diastolic Blood Pressures in Patients with Hypertension. *J Tehran Heart Cent* 10: 140-148, 2015.
- 23.**Park J, Lyles RH, and Bauer-Wu S**. Mindfulness meditation lowers muscle sympathetic nerve activity and blood pressure in African-American males with chronic kidney disease. *Am J Physiol Regul Integr Comp Physiol* 307: R93-R101, 2014.

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- 25.**Pickering TG, Hall JE, Appel LJ, Falkner BE, Graves J, Hill MN, Jones DW, Kurtz T, Sheps SG, Roccella EJ, Subcommittee of P, and Public Education of the American Heart Association Council on High Blood Pressure R**. 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. *Hypertension* 45: 142-161, 2005.
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- 27.**Spielberger CD, and Gorsuch RL**. *State-trait anxiety inventory for adults: Manual, instrument, and scoring guide*. Mind Garden, Incorporated, 1983.
- 28.**Vlachopoulos C, Aznaouridis K, and Stefanadis C**. Prediction of cardiovascular events and all-cause mortality with arterial stiffness: a systematic review and meta-analysis. *J Am Coll Cardiol* 55: 1318-1327, 2010.
- 29.**Wang Y, and Wang QJ**. The prevalence of prehypertension and hypertension among US adults according to the new joint national committee guidelines: new challenges of the old problem. *Arch Intern Med* 164: 2126-2134, 2004.

Participant Information

*required

Total Study Enrollment

Please enter the number of subjects that will be enrolled at all sites, that are required to complete data analysis. Include the rationale for this number (e.g. statistical analyses, population composition). If at a later time it becomes apparent you need to increase your sample size, you will need to submit a Revision Request.

In the first two years of the award (while at Michigan Tech), we have randomized 43 participants into either the 8-week mindfulness-based stress reduction (MBSR) class or the stress management education (SME) active control course. We unfortunately lost our ability to post-test 19 participants in the spring of 2020 due to COVID-19 concerns. Our total project enrollment goal for NIH was 60 participants, but due to lost data on many participants we would like to be able to enroll and test up to 30 more participants at Purdue University Northwest.

*required

Attrition Considerations

If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through Purdue University. Please describe the rationale.

Consider:

- *Whether the withdrawal of the subjects might result from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and*
- *Whether the withdrawal might occur from all components of the research study or just the primary interventional component.*

Based on our previous cohorts we have lost up to 20% of enrolled participants during the longitudinal study. We have set a target to complete 24 more participants through the longitudinal study, so enrolling 30 new participants should help us to meet that objective.

*required

Age(s) of Participants in Study Population

Please include an age range for subjects, if relevant. If the research has multiple subject groups, describe the requirements for each separately.

Newborn to less than 10 years old

10 years old and less than 18 years old

✓ 18 to 65 years old

Enter specific age range if the target population age is less than 65.

18 to 55 years old

65 years and older

Unknown- Data are deidentified of any age or date of birth

*required

Inclusion criteria - Please identify the population that you would like to study.

Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study.

Age between 18 and 55 years
Must have an average seated clinical blood pressure >120 mmHg systolic and / or >80 mmHg diastolic
Must have a body mass index < 30 kg / sq. m
Not be taking any cardiovascular medication

*required

Exclusion criteria - Please identify the characteristics that do not represent your intended study population.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition. Please provide information about why the group will need to be excluded.

For NIH funded protocols: If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

Anyone with signs, symptoms, or diagnosis of COVID-19
Pregnant women
Taking cardiovascular medication
History of autonomic dysfunction such as postural orthostatic tachycardia syndrome (POTS) or syncope (fainting)
Smokers or those that use vaporized nicotine
Diabetics
Those with a pacemaker
Those with a history of MRSA, neuropathy, or illicit substance abuse

Please consider the population being studied. Are there any other safeguards that you are putting in place to address participant protections?

We will follow strict guidelines in regard to COVID-19.

Recruitment

*required

Recruitment Processes

How will people find out about your study? It's common for studies to be advertised on flyers, social media, or ads. The IRB must know what language and materials are used to recruit participants.

*required

Does your study use a known group of participants or records to recruit up-front? Check any of the following sources of information which will be used to identify potential subjects

Yes, a known group or subject pool.

✓ No, only the general population

Both a known group AND also the general population.

*required

Do the researchers hold any authority over the targeted population?
Examples:

- Teacher/student
- Supervisor/Employee

Please keep in mind the researcher that conducts recruitment, collects, and analyzes identifiable data cannot have authority over the potential participant due to the potential for undue influence. If necessary, a third party (listed as key personnel) who does not have authority over the targeted population must conduct recruitment and strip all identifiers prior to researchers/authority figures have access to the data.

✓ Yes

*required

Please detail how the study will prevent against undue influence or coercion to participate.

There is a chance that a student from one of my courses might volunteer as a participant, but they would not be the primary targeted population. Participation in this study is voluntary and participants may withdraw at any time without any penalty. Please let me know if you would prefer to have my department chair or someone from the Purdue University Northwest Faculty Research Board to monitor and mitigate this potential risk.

No

*required

How will you recruit the intended participants from the general population for your study?

It's common for studies to be advertised on fliers, ads, or social media. The IRB must know how people will find out about the study.
Points to consider:

- *Is the setting, location and timing of recruitment appropriate for the research being conducted?*
- *Are recruitment methods well defined and appropriate for the population?*
- *Are all recruitment materials non-coercive, and easily understood?*

We will include a study flyer as part of our submission. In the past we have shared the flyers by posting them around campus, and have also posted them in local newspapers and on social media. We will respond to interested potential participants by email, but will not use list serves unless we gain approval from the manager of the list serve and then the Purdue University IRB. The PI has completed NIH Good Clinical Practice training recently so that the flyer will not be coercive (for example, in regard to monetary compensation).

*required

Privacy During Recruitment

Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).

Examples of issues:
Potential subjects may not want to be approached for research purposes by someone they do not know.
Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc. If your study is not anticipated to generate privacy concerns during recruitment, please state this below.

The study PI and all students that help on the project will have completed the appropriate CITI training courses. The PI has been a leader of human participant research for more than 15 years. We will not access medical records, and will store any electronic study data on a password protected computer with non-identifiable data. Any paper data will be stored in a locked file cabinet in the PI's lab on the Hammond campus (in Gyte 6).

*required

Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?

✓ Yes

*required

Please describe how frequently and in what manner individuals will be contacted. Indicate the endpoint for contact.

Participants may be contacted by phone or text message, but the preferred method of contact will be via email listserves. The endpoint for contact will be the PI (John Durocher).

No

*required

Check any of the following recruitment materials which will be used to contact potential subjects.

✓ Direct mail/email

*required

Upload the recruitment letter that will be used.

MBSR Recruitment Email -2.pdf

MBSR Flyer Updated-Feb. 22.pdf

✓ Flyers/Brochures

*required

Upload the text or draft of this flyer or brochure.

MBSR Recruitment Email -2.pdf

MBSR Flyer Updated-Feb. 22.pdf

Published Advertisements

Verbal Scripts

Website

Social Media

✓ Other

*required

Describe the method used and how you will access information needed to contact or recruit potential participants. Please be specific.

We have gained approval to have our flyer sent out to campus listservs for students, faculty, and staff through Provost Chris Holford's office. I met with him on Zoom yesterday. His email is cholford@pnw.edu if you need to verify this approval.

Upload scripts/text and additional documents if needed.

MBSR Recruitment Email -2.pdf

MBSR Flyer Updated-Feb. 22.pdf

None of the above

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research. Describe the likelihood and seriousness of each risk.

Participation in research is voluntary. Consider the risks that a participant might encounter if they participate in the study. Risks may be physical, psychological, social, legal, etc. Please note that all research exposes to subjects to some risk.

For example, if the only foreseeable risk is breach of confidentiality, please describe the potential consequences to the participant's reputation, lifestyle, employability, or legal status that might occur if it became known that they participated in the study.

Potential Risks or Discomforts:

Measurement of Blood Pressure: *Blood pressure will be measured similar to a similar doctor's office visit. There are no known risks with this procedure. If discomfort is experienced the cuff can be deflated.*

24-Hour Blood Pressure Recording (ABPM): *It is possible for 24-hour blood pressure recordings to interfere with normal activity and sleep habits. We will try to minimize disruption to normal habits by gaining snapshots of 24-hour blood pressures once before, and once after, the 8-week intervention. We will record on a work or school day according to previous recommendations. To enhance user comfort, our ABPM devices are very compact, lightweight, and can be easily attached to a belt. We will collect only two readings per hour at night to help reduce the chance of sleep interference.*

Questionnaires: *We do not anticipate risk or discomfort in regard to questionnaires, but if a participant feels uncomfortable with any question, or any questionnaire, they can leave it blank.*

Microneurography: *There is a potential risk of infection after insertion of the leg electrode. Sterile techniques will be used to help prevent infection. We have never had any participants report infection after the procedure. Also, about 7% of subjects experience some aching or "pins and needles" sensations for a few days after the procedure. There is no specific treatment for these sensations, which are believed to be the result of tissue inflammation. Study volunteers who have experienced these sensations report they*

have disappeared spontaneously and completely without treatment within a few days. Dr. Durocher has safely performed over 300 successful microneurography sessions since 2010. We will mention to qualified participants during the screening visits that they should wear a pair of shorts underneath their clothing, or bring a pair of shorts, for the autonomic testing days. We have a private room in the lab with a locking door where participants can change into shorts. We have blue medical exam shorts that will be provided to participants that do not bring a pair of shorts with them. Microneurography (a small electrode needle that can measure electrical activity in nerves) will be completed prior to a 10-minute baseline and the mental stress test (doing mental math calculations) protocol. Nerve activity will be continuously measured during the baseline and mental stress test. The microneurography electrode would remain inserted for approximately 1 hour, and does not typically cause any discomfort after the initial insertion. We use a tungsten microelectrode behind the right knee as the recording electrode and a small acupuncture electrode about 3 cm away as the ground.

ECG: *There is a risk of skin irritation from the electrodes used for ECG. This is unusual, but we can stop the experiment if this irritation occurs. To date, we have never had a problem with our electrodes.*

Finger Cuff*: Rarely, some people experience mild discomfort in the fingers from the blood pressure cuff. If this occurs, we will stop the finger cuff.*

Arterial Stiffness: *This is a non-invasive procedure that is comparable to someone checking your radial (wrist) or carotid (neck) pulse via finger. A buildup of fats on artery walls are known as plaques. The use of a tonometry device could cause hardened plaques to dislodge. If aortic pulse pressure is 50 mmHg or greater, as estimated from the radial (wrist) pulse site with the tonometer, then we will not proceed with carotid (neck) or femoral (groin) pulse recordings. Individuals with aortic pulse pressures greater than 50 mmHg may have an increased risk for arterial plaques, and potentially disrupting these plaques could increase the risk for a cerebrovascular event such as a stroke. We will inform participants if they have an aortic pulse pressure greater than or equal to 50 mmHg, and explain that elevated pulse pressure has been associated with an increased risk of arterial plaques in one previous study. We would suggest that the participant could visit their primary care physician if they have any concerns about the elevated value. We use this cutoff out of an abundance of caution to not press on the carotid artery for the arterial stiffness measurements, which is why we would exclude the participant from carotid to femoral pulse wave velocity measurements if they have an elevated aortic pulse pressure.*

These measurements will be led by John Durocher, PhD who has more than 15 years of experience with this type of research. Some of the non-invasive measurements such as blood pressure or ECG may also be led by graduate student Colleen Toorongian. Colleen has worked with Dr. Durocher for several years in his previous laboratory that had nearly identical equipment, and she holds a BS in Exercise Science.

Breach of confidentiality: *This is always a risk with data, but we will take precautions to minimize this risk as described in the confidentiality section.*
Under Indiana law, Purdue researchers must report any suspected child abuse or neglect to law enforcement or to the Department of Child Services hotline.
Under federal law, Purdue researchers must report all incidents of discrimination, harassment, and/or retaliation in the Purdue workplace and/or educational environment to the Title IX Coordinator or Equal Opportunity/Affirmative Action Officer. "Harassment" includes sexual harassment, sexual violence, rape, and any non-consensual sexual act. If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

*required

Describe how risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

Points to Consider

- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*
- *Are medical or psychological resources available that participants might require as a consequence of the research?*

The PI of the Clinical and Applied Human Physiology Laboratory at Purdue University Northwest has an extensive history of research with human participants for more than the past 15 years. The current project is supported by NIH, and study data has been collected for the last 2+ years at Michigan Technological University. The laboratory will continue to consider the following to minimize risks:
1. All laboratory staff will complete CITI training to promote responsible conduct of research in regard to safety and confidentiality.
2. Strict protocols will be followed for techniques such as the microneurography procedure, such as autoclaving one-time use tungsten microelectrodes in a sterile pouch, wearing protective gloves during the procedure, and using alcohol wipes to thoroughly clean the site before starting insertion of any recording or reference electrode.
3. Arterial stiffness measurements always start with the pulse wave analysis (PWA) technique at the radial pulse site to ensure that aortic pulse pressure is less than 50 mmHg before proceeding to a more delicate pulse site such as the carotid artery. For participants with an estimated aortic pulse pressure greater than 50 mmHg, we will not proceed to any pulse wave velocity (PWV) recordings.
4. The PI will continually monitor the participant throughout the autonomic testing sessions.

*required

Please provide the risk level that you believe applies to the study.

In addition to the population being studied, consider the this definition:

Minimal Risk: *Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.*

The researchers believe the study is no greater than minimal risk.

✓ The researchers believe the study is greater than minimal risk.

*required

Are there potential direct benefits to a participant or benefits to society from your research?

The IRB must consider the risk/benefit ratio of each study.
Please note that payment for participation is not considered a benefit. If there are no direct benefits, please state this fact.

✓ Yes, there are potential benefit(s) to be gained by the individual subject/participant.
*required

Please list the potential benefit(s) to the individual.

There are numerous potential benefits to participating in this study, but nothing is guaranteed. You may learn how to better manage the stress in your life and your cardiovascular risk could be lowered.

✓ Yes, there are potential benefits to be gained by society.
*required

Please list the potential benefit(s) to society.

The findings of this study may help to indicate how adults could lower their cardiovascular risk through mindfulness-based stress reduction or stress management education.

No, there are no benefits.

*required

How does the investigator evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

Please provide an assessment of the risk:benefit ratio associated with your study. The HRPP/IRB must assess that the risks and benefits are appropriate . This is a crucial consideration for your study.

I consider this study to be more than minimal risk due to the invasive microneurography procedure. The PI has completed over 300 successful sessions independently and has also served as a participant for muscle sympathetic nerve activity (MSNA) recordings at least a dozen times. We have not had any serious adverse events in the hundreds of sessions that we have conducted, but there is some discomfort during the procedure during the first few seconds when the electrode makes contact with the peroneal (common fibular nerve) and there is a chance for some pins and needles sensations for a few days after the procedure. We will also make clear recommendations to each participant to not undertake any heavy exercise with the legs for at least 48 hours after the procedure to reduce the chance of pins and needles or feelings of discomfort. The risk for this procedure is very small with and experienced microneurographer and sterile techniques. Microneurography is the only method to directly assess post-ganglionic sympathetic activity in humans, and MSNA provides crucial insight into autonomic regulation of blood pressure. To explain briefly, higher MSNA induces vasoconstriction which increases blood pressure, while lowering MSNA induces vasodilation to lower blood pressure. Thus, the benefits of the measurement is very high, and provides significant mechanistic insight to the causes underlying hypertension, cardiovascular, and cerebrovascular disease.

Privacy and Confidentiality

*required

Privacy During Data Collection

Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant?s ability to privately provide information used for your study.

Privacy refers to a person's desire to control access of others to themselves.Participants must be able to control their right to participate in research (such as the timing and location of data collection. Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study. Subjects may not want to be seen in areas that may stigmatize them or at times when they are working or competing other tasks).

The pre- and post-testing sessions for this study will be held in private in the Gyte 6 laboratory. There will only be a single participant in the lab at a time at a designated desk for questionnaire data collection, and at a designated seat and / or on the laboratory tilt table for other cardiovascular assessments. The small window on the lab door is covered so that no one can see into the room during data collection.

We will treat your identity with professional standards of confidentiality. The information obtained in this study may be published, but your identity will not be revealed. Subject information and corresponding six digit alphanumeric codes will be stored in a secured file cabinet in Dr. Durocher’s laboratory (Gyte 6). This study is funded by the National Institutes of Health. The project's research records may be reviewed by the National Institutes of Health, Food and Drug Administration (if FDA regulated), US DHHS Office for Human Research Protections, and by departments at Purdue University responsible for regulatory and research oversight. Summary (but not individual) results will be registered and published at ClinicalTrials.gov in accordance with requirements from the National Institutes of Health.

*required

Confidentiality

Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.

- *For identifiable data in electronic format, describe the system that will be used.*
- *For identifiable data in hard copy or tangible format, describe methods on how to secure the data*

Hard copy data will be stored in a locked file cabinet in the PI's laboratory. Only the PI will have a key for the cabinet, but approved student researchers will be able to access the data during normal approved working hours.
Electronic data will be stored on a password protected computer on a specialized laboratory R drive that was created by the PNW Information Services Department only for Dr. Durocher and graduate student Colleen Toorongian, and electronic data will not include any participant's name.

*required

Provide a plan to protect the identifiers from improper use and disclosure.

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.

*required

Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers.

Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes. For protocols that may be subject to future continuing and secondary data analysis, the IRB needs to have the justification for not destroying identifiers permanently.

We will keep the hard copy data for a minimum of 3 years beyond the completion of this NIH project. No identified data will be stored electronically or used for a future study or analysis. If hard copy data were to be destroyed it would be via a confidential shredding process.

*required

Will a Certificate of Confidentiality be obtained from NIH for this research?

What is a Certificate of Confidentiality?

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are automatically granted for NIH-funded research (as of 2017). The IRB may request that the investigator seek a CoC if disclosure of identifiable sensitive information.

Consider this option if your study may place participants at risk due to the potential to identify situations such as disease state or criminal activity.

Please note that if a CoC applies, the consent form must have appropriate language (found in our template).

✓ Yes, the study is funded by an NIH grant or subaward and therefore automatically has CoC protections.

Yes, our team will seek a CoC from NIH if approval is granted for this IRB application. I will amend the study if this CoC is granted by attaching the document here.

No, this study will not require a CoC.

Data and Safety Monitoring

*required

Which individual or group will be responsible for monitoring the data and safety for this study?

- ✓ Principal Investigator/Research Team
- Independent Study Monitor(s)
- Internal Committee
- Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Independent of PI and Sponsor
- Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Not Independent of PI and Sponsor
- Other

*required

Describe the provisions for monitoring the data to ensure the safety of subjects.

The individual responsible for data safety and monitoring will be the principal investigator (PI), Dr. John J. Durocher. The greater than minimal risk activities include microneurography. Risks and safeguards for the procedure have been previously discussed (see microneurography attachment). If abnormal signs are detected during testing (ex. abnormal cardiac rhythm) or participants experience post-procedure adverse effects such as infection or prolonged paresthesia (i.e. beyond 48 hours) they will be referred to their primary care physician. In the event of a medical emergency, or detection of a hypertensive crisis (resting blood pressure 180 / 120 mmHg or higher and associated symptoms such as chest pain or shortness of breath), Dr. Durocher or research staff would immediately dial 911. Abnormal or adverse events will be documented by Dr. Durocher and reported as outlined below.

Throughout this study, Dr. Durocher will monitor the participants for adverse events. Events determined by the PI to be unanticipated problems involving risks to subjects or others (UPIRTSOs) will be reported by the PI to the IRB (via written memo) within 5 days per policy (SOP 409) for serious adverse events and within 14 days for other unanticipated problems (according to SOP 409). Additionally, in accordance with the National Institutes of Health (NIH) policy, the UPIRTSOs will be reported to the program official within 30 calendar days. All studies will be suspended in the laboratory until the issue has been resolved between the PI, IRB, and NIH. Adverse events that are determined by the PI to not be UPIRTSOs will be reported per IRB policy at the time of continuing review (i.e., annual review). All subjects and study staff

members will be informed by Dr. Durocher (via written memo) about any UPIRTSOs. If any protocol changes are needed, the PI will submit a modification request to the IRB. Protocol changes will not be implemented prior to IRB approval.

We will keep an electronic and printed copy of the Purdue University Unanticipated Problems and Adverse Event Reporting SOP 409 within the laboratory.

*required

Provide a description of the individuals who will be responsible for data safety monitoring

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Include the following details:
(1) association with the research and/or study sponsor;
(2) nature of their expertise and;
(3) whether they are independent of the commercial sponsor

If those monitoring the study are not independent of the sponsor, please describe how any potential conflicts of interest or biases will be avoided.

1) John Durocher the PI will be responsible for data safety monitoring.
2) Dr. Durocher has a PhD in Biological Sciences - Exercise Physiology, is a certified Exercise Physiologist through the American College of Sports Medicine, and certified Strength and Conditioning Specialist through the National Strength and Conditioning Association. Dr. Durocher was extensively trained in microneurography by two leading experts (William Cooke, PhD at Michigan Tech and Jason Carter, PhD at Montana State University) and has been leading the technique independently for more than a decade.
3) The PI is independent of the government sponsor.

Upload CVs

John Durocher's PNW Curriculum Vitae (2021).pdf

*required

What data will be reviewed?

Provide a description of the parameters that will be evaluated to ensure safety.

- ✓ Adverse events/Unanticipated problems
- ✓ Aggregate data
- ✓ Enrollment numbers
- ✓ Individual subject data/case report forms
- Protocol violations/deviations
- ✓ Subject withdrawals/terminations
- Other

*required

How often will data and safety monitoring be performed?

Please specify if this is a specific number of times, at defined time points, after a certain number of subjects have been recruited or as needed (i.e. every 6 months, every SAE, every 5 subjects, etc.)

As needed if there is an SAE.

*required

Describe the responsibilities that have been given to the data and safety monitoring function.

This should include a discussion of whether the data and safety monitoring plan includes a charter, whether stopping rules will be developed, and if any interim analysis will be performed (if so, on what basis). If this information is in protocol, please specify where relevant information is located.

Dr. Durocher will complete an annual report detailing the study progress, subject status, adverse events, and any protocol deviations. He has completed the first two annual reports that have already been submitted to the NIH.

*required

If this protocol is for a multi-center trial what mechanisms are in place to either receive or distribute results of the data and safety monitoring function in a prompt manner.

Describe each site's role in contributing to the data and safety monitoring.

This study will be conducted on the Hammond campus of Purdue University Northwest, and not at any other locations.

If a DSM Board charter exists, please upload it.

A charter includes identification and description of individuals responsible for monitoring the trial (their roles, qualifications, and the frequency of the monitoring activities. The proposed membership and assurances should be described within the document to ensure that there are no conflicts of interest with the study team or proposed institutions.

John Durocher's PNW Curriculum Vitae (2021).pdf

Compensation for Research Participation

Describe any compensation that subjects will receive when they participate in your study. Consider what happens to the compensation amount if the participant withdraws or is disqualified from the study. If course credit will be offered, please provide the amount and the percentage of the total grade.

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*required

Will subjects be compensated for their participation in the study?

Will the study provide (money/gift cards/inducements/discounts/entry into a drawing/course credit) in exchange for a person's participation in the study? Please note that Purdue University policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

✓ Yes

*required

Describe the payment arrangement, including amount and timing of disbursement.

If the compensation includes a lottery or raffle-style drawing, please provide the approximate odds of winning (number of prizes, anticipated number of participants).

If course credit will be offered, please provide the amount and the percentage of the total grade. Extra credit should be no more than 3% of the course grade in order to avoid undue influence.

Participants will receive the following: 1) $50 for each microneurography (autonomic) session completed; and 2) $200 for the completion of the 8-week MBSR or SME course (prorated as $25 per week completed if there is any need to withdraw before the completion of the 8-week course). The maximum payment that you can receive from this study is $300. According to the rules of the Internal Revenue Service (IRS), payments that are made as a result of participation in a study may be considered taxable income. Participants will be asked to

provide their full name, address, and social security number for our Human Subject Invoice Log so that our Business Office at Purdue University Northwest can process and send a payment to the participant.

We did not have any budgeted funds through NIH for the screening visits, and have already screened 139 potential participants while at Michigan Tech that did not receive payment for screening. Thus, it would not be feasible or ethical to add payments for screening at this point.

*required

Justify the proposed payment arrangement described above, specifically why payment does not provide undue influence for subject participation

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Explain how the amount is reasonable for the study.

The proposed $50 payment for each microneurography session is consistent with what is paid at other institutions. This amount is thought to compensate the participant for their time. The proposed $25 per week for the MBSR or SME classes is designed to compensate participants for their time investment to the intervention. The compensation provides some compensation for the investment of time in the study, and potentially something towards transportation to and from the laboratory or class site, but not enough to be coercive to simply participate in the study for financial gain.

*required

Will partial payment be provided if the subject withdraws or is disqualified prior to completion of the study?

For example, are there starting and stopping points where the participation will be pro-rated?

✓ Yes

*required

Explain the plan for providing partial payment.

Participants will receive a prorated $25 for each week completed for the MBSR or SME courses if there is any need to withdraw before the completion of the 8-week course.

No

No

Informed Consent Process Section title

Informed consent is more than a form; it's a process and a responsibility.

Please answer all questions regarding the ways that participants will provide informed consent to participate in your study.

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*required

Identify which subjects will consent to participate in the research.

- ✓ All subjects (or their legally authorized representative) will consent to participate in the research.
- Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.
- No subjects (or their legally authorized representative) will consent to participate in the research.

*required

For subjects who will consent to participate, choose whether the consent process will be documented by a **signature** from subjects.

Please note that you may request a waiver of the signature requirement if this study is minimal risk OR if the only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality.

- ✓ All consented subjects will provide a written signature as documentation of consent
- Some subjects will provide a signature as documentation of consent, and some subjects will not.
- No subjects will provide a signature as documentation of consent.

*required

Indicate in what language(s) the consent conversation will be conducted.

✓ English

Language(s) other than English

*required

Will subjects participate in any study activity prior to signing a consent document?

For example, some studies require subjects to fast, to refrain from drinking or smoking, pass a phone screening process or keep a journal/log prior to enrollment in the study.

✓ Yes

*required

List the activities in which subjects will participate prior to signing the consent document. Each activity must present no more than minimal risk of harm to subjects AND involve no activities for which written consent is normally required outside of the research. Please note that subjects should provide verbal consent to these activities.

Participants will be asked to refrain from eating for 3 hours, and from exercise, caffeine, and alcohol for 12 hours prior to seated blood pressure screenings.

No

Waiver of Informed Consent or Signed Consent

If any or all subjects will not provide written, signed informed consent for all parts of the study. Please complete the following information to request either a waiver of consent or a waiver of *signed* consent.

---

*required

Does the research pose greater than minimal risk to subjects (greater than everyday activities)?

This study is considered more than minimal risk due to the microneurography procedure, so we will not ask for any waiver of informed consent.

*required

Will the waiver adversely affect subjects? rights and welfare? Please justify.

---

not applicable.

Why would the research be impracticable without the waiver?

---

*required

How will pertinent information be reported to subjects, if appropriate, at a later date?

Through peer-reviewed publications for the overall study outcomes.

*required

Will any other materials (videos, brochure, drug/device information, etc) be used to present information to potential subjects?

Yes

✓ No

*required

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

The informed consent would be provided as an option at the end of the 3rd blood pressure screening visit for qualified participants.

*required

Consent form Elements

The following components are required for informed consent forms. If any of these elements are missing, you must provide justification for the reasoning.
Please confirm that all elements of informed consent are present. Use the Purdue IRB template found on the Purdue HRPP/IRB website

BASIC REQUIRED ELEMENTS OF INFORMED CONSENT
Please confirm that all elements of informed consent are present.

- Key Information at the beginning of the consent form
- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others that may reasonably be expected
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained
- A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

---

*required

Please confirm that all basic elements of consent appear in your draft consent form.

✓ The research team has drafted a consent form and affirmed that it contains all of these basic considerations of informed consent.

Our research team is omitting a basic section from the consent form.

Our research team requested a complete waiver of informed consent and will not be attaching a consent form to this submission.

SPECIAL REQUIRED ELEMENTS OF INFORMED CONSENT

Please check if these items apply and are addressed in the draft consent form.

If any of these elements apply, but are missing, you must provide justification for the reason(s) to omit this information.

- *A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.*
- *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*
- *Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.*
- *Any additional costs to the subject that may result from participation in the research.*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

- *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
- *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- *Disclosure of any conflicts of interest.*
- *Registration of the trial on Clinicaltrials.gov*
- *NIH Certificate of Confidentiality coverage.*
- *Future uses of identifiable or deidentified data.*

---

*required

Please confirm that all items that apply to your study have been addressed in the consent form.

You must review the study-specific parameters that were discussed within your application in previous sections. Please refer to the sections on the left for any items that may apply.

✓ The research team has drafted a consent form and affirmed that it contains all special considerations of informed consent applicable to our study.

Our research team is omitting an applicable section from the consent form.

Our research team requested a complete waiver of informed consent and will not be attaching a consent form to this submission.

*required

Please attach all versions of your consent form here.

Consent forms should follow the structure of the template on the IRB website.
MBSR Pre-Screening Consent.pdf

MBSR Pre-Screening Consent.docx

MBSR Consent-9.docx

MBSR Consent-9.pdf

Funding Source(s)

*required

CURRENT Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI's responsibility to update funding sources as a modification to the protocol and associated forms (such as the consent form) when funding changes.

Please list any sources of funding that are **confirmed** by contract, agreement, or other support of a sponsor.
You will list any pending sources in the next question.

If the research is funded by a subcontract, please add both the subcontract source and the prime sponsor.

✓ Externally sponsored (federal, state, corporate, foundations, industry, donor)

Please search for the sponsor(s) here. Be certain to include any funding that originates or includes US federal sources.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

US Department of Health and Human Services - DHHS

If you do not see the name of the funding source using the "Find Sponsors" button above, please enter the full sponsor name in the text box below.

Please use the full name of the sponsor and include any subcontracted efforts.

National Institutes of Health - National Heart, Lung, and Blood Institute

Internal Purdue University Funds (Includes departmental funds, start-up funds.)
(Note, this does not include Purdue Research Foundation or Purdue Research Park companies-please list as external sponsor above).

None - There are no confirmed funding sources at this time.

ANTICIPATED Funding Source(s) - Required

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

Please list any sources of funding where sponsorship is **anticipated** or pending a final decision.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

There are no pending funding sources at this time.

Conflict of Interest and/or Outside Activities Disclosure

Conflicts of Interest or outside activities must be disclosed and managed prior to IRB approval. For more information about these policies, please consult the resources listed in the question marks in each section.

The IRB may request confirmation of proper disclosures.

---

*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ I attest that I understand the outside activities policy and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Receiving more than $5,000 in compensation from, or having ownership interests in, outside entities, constitute Significant Financial Interests that need to be disclosed. Definitions of SFI, Investigator and Institutional Responsibilities, can be found at https://www.purdue.edu/policies/ethics/iiib2.html#definitions.

Yes

✓ No

*required

Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?

Yes

✓ No

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

Other attachments

*required

Do you have any other supporting documents to attach?

You may attach COVID-19 Research Space Standard Operating Procedures here if this is a new protocol submitted during the COVID-19 pandemic.

Investigators are invited to submit reference lists, study instruments, supporting information, training data, device pictures, or other relevant items for their study that were not addressed in the application.

✓ Yes

Attach any other documents. Please use a file name that describes the document.

You may attach multiple files to this entry.

PLEASE DO NOT UPLOAD PARTICIPANT DATA OR IDENTIFIABLE RESEARCH DATA.

citiCompletionReport1728324-Durocher Certificate.pdf

citiCompletionReport1728324RCR-Durocher Certificate.pdf

Previously Approved IRB Proposal from Michigan Tech - includes appendix on microneurography.docx

citiCompletionReport6623673-Toorongian.pdf

signed Durocher Data Transfer Memo.pdf

COVID-19 Prevention and SOPs for PNW Clinical and Applied Human Physiology Laboratory - Gyte 6.pdf

Data Transfer and Use Request - Durocher.pdf

No

Modification Submission

Modification/Amendment to a Protocol

Changes to a study must be approved by the HRPP/IRB.

Examples include (but are not limited to) changes in:

- Recruitment methods
- Screening materials
- Intended study population
- Inclusion/Exclusion criteria

For a list of minor changes that do not require IRB review, please see Purdue HRPP Standard Operating Procedure 305. (Link appears in the "?" button above.) Also, see www.irb.purdue.edu for additional changes not requiring modification during the COVID-19 pandemic.

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*required

What type of change(s) would you like to make?

IMPORTANT:
All revisions to the protocol must be made to the relevant sections of your study in the sidebar. Please note, that more than one section may require change. For non-exempt protocols, please review your current consent form and edit language as needed.

Remember to review any advertisements, scripts, information sheets and consent forms. Attach them to the relevant sections of your protocol. Please title any attachments with dates or version control numbering in the file name to assist with review.

✓ Personnel

*required

Are you changing the Principal Investigator?

Yes

✓ No

Study Procedures

Change to the recruitment and/or data collection status.
(For example, click here if you are finished with data collection and would like to notify the IRB that the study will only analyze the collected data.)

Something else (e.g. participant compensation amounts)

(For resuming on-campus in-person research)- COVID-19 Research Space Standard Operating Procedure approval.

(For resuming off-campus in-person research)- COVID-19 off-campus research certification of practices outlined in the EVPRP Guidance for Off-Campus Research Activities

*required

Study Personnel

In this section you will name all staff who will participate in the study.

*required

A Principal Investigator (PI) is responsible for all aspects of a research study.
STUDENTS ARE NOT AUTHORIZED TO BE PRINCIPAL INVESTIGATORS

Provide the name of the Principal Investigator of this study.
All faculty (tenured, tenure-track, research and clinical) are eligible to be Principal Investigators. Others requesting to submit proposals as the Principal Investigator for the first time must obtain special approval.

Once the name is selected, training courses from the CITI system should appear when you click "View". If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.
Name: John Durocher
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: jjduroch@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

*required

Please check your Purdue University PI classification.

- ✓ Faculty (tenured, tenure-track, research and clinical)
- Student
- Purdue non-faculty staff member granted special PI status.

*required

Primary Contact

Provide the name of the Primary Contact of this study. The Primary Contact will be copied on all correspondence regarding the IRB review. Note that the Primary Contact and the Principal Investigator may be the same. The Primary Contact must be a current Purdue University faculty, staff, postdoc, or student and must have a role as Key Personnel on the study.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: John Durocher
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: jjduroch@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

If you wish to provide a campus phone number for the Primary Contact, you may list it here.

This field is optional. Most correspondences from the IRB will arrive via the Cayuse system.
219-989-2625

*required

Key Personnel

Below is a definition of Key Personnel. Please read the definition and decide who will need to be listed as Key Personnel on the study. The PI defines the roles of each staff member based on the definition below.

Key personnel: The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

*required

Does your study have additional Key Personnel besides the PI and Point of Contact?

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

✓ Yes

*required

Where are the Key Personnel from?

Check all that apply.

✓ I have key personnel from Purdue University.

✓ I have key personnel from another external site (outside of Purdue).

No, the only personnel on the project are the PI and Point of Contact.

Key Personnel From Purdue University

- *The Principal Investigator and Primary Contact are considered Key Personnel. You do not need to list these names again.*
- *Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.*
- *If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.*

Name: Colleen Toorongian
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: ctoorong@purdue.edu

Name: Grant Thivierge
Organization: PNW BIOLOGICAL SCIENCES
Address:
Phone:
Email: gthivier@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. For researchers outside of Purdue university, please use the next section and click "external investigators".

(First Name: Last Name: Purdue e-mail address)

Key Personnel Outside Purdue University

If any external investigators outside of Purdue University personnel or specialized staff (physician, nurse, psychiatrist) will be collaborating or overseeing safety of the study. Please indicate their roles here.

Study Physician/Nursing Staff/Counseling Staff

✓ External (Non Purdue) individuals engaged in data collection or analyses.

How many external investigators will be included?

✓ One

Two

Three

More than three external collaborating coinvestigators.

External collaborator #1

Please enter the name of the external collaborator.

(First Name: Last Name: Affiliation: E-mail address)
Robert Larson: ralarson@mtu.edu

Will this external collaborator collect or analyze data on behalf of the research team?

✓ Yes, this person will work on behalf of the study team to collect and/or analyze data for the study.

No, this person will only help recruit participants or give permission to access the site for research.

Is this person affiliated with an institution that has an IRB?

The Purdue HRPP may request that one IRB be responsible for the study if appropriate.

✓ Yes, this person works at an institution that has an IRB.

Name the institution

Michigan Technological University

Non-Purdue personnel must have human subjects research training documentation. Please upload the external investigator's CITI training certificate or other equivalent training.

citiCompletionCertificate_Robert Larson.pdf

No, this person works at an institution that does not have an IRB.

Please submit a signed Independent Investigator Agreement (IIA) and documentation of CITI training and any other relevant certifications, licenses, etc. The IIA is located under

"External Collaborators" here:
https://www.irb.purdue.edu/application-forms/additional-forms.php.

Are you requesting that Purdue University serves as the Reviewing IRB for the entire study (including the non-Purdue sites?)

✓ Yes, this study involves activity at Purdue University and at the collaborating institutions. The research team would like Purdue to be the Reviewing IRB.

No, the researcher at this site will have their own IRB review.

*required

Provide a brief description of each person's position at Purdue (e.g. student, staff, faculty) and their role in the study.

Examples:
Prof. Principal (faculty) will oversee all aspects of the study design and conduct
John Researcher (graduate student) will recruit and consent participants and collect data
Purdue Pete (staff) will analyze collected study data.

John Durocher is the PI and tenured associate professor that will oversee all aspects of the study.
Grant Thivierge is a Research Study Coordinator and will assist with data collection, analyses, and dissemination of results.
Colleen Toorongian is an MS student in Biological Sciences that will assist with data collection, analyses, and dissemination of results.
Brigitte Morin MS is a senior lecturer at Michigan Tech that has been involved with teaching the MBSR class since the start of this project. She recently agree to teach the 8-week course one more time in the spring of 2022 and will conduct most of the sessions via Zoom. She may also fly down to lead the 1-day silent retreat that is part of the MBSR class.
Robert Larson, PhD is an assistant professor in Biological Sciences at Michigan Technological University. He has a long record of collaboration with John Durocher and took over as the PI on the NIH R15 grant for this project when John moved to Purdue University Northwest. Robert will assist with data analyses on this project and with completion and approval of the final report to NIH.

Research Sites

*required

Where will the study take place?

✓ Purdue University

*required

Please check the following locations.

West Lafayette

✓ Regional Campus (PFW, PNW, IUPUI)

*required

Select the regional campus

✓ Hammond

Fort Wayne

Westville

Indianapolis

Polytechnic Institute Statewide Sites

Extension Sites

*required

Please provide a brief description of the Purdue University location(s).

Provide building names, course titles, event names as applicable.

Gyte Building - Room 6 (Clinical and Applied Human Physiology Laboratory)

External Site (non Purdue University)

Getting started with your submission

*required

Welcome to the submission system for the Purdue HRPP/IRB. Before you begin, you should be familiar with the framework of human research protections and how they relate to your proposed study. The materials to help you appear on our website.

Be certain that all personnel have completed online training prior to submitting the protocol.

Helpful Tip: Use the Create PDF button at the top of the page if you need to share a PDF version of this protocol for discussion with a reviewer outside of the Cayuse system.

The choices you make on the first two sections will help populate the required sections for your submission. Please look through the options and make the choice closest to your research. You can always seek assistance by scheduling an appointment with the HRPP Office or reviewing the materials at www.irb.purdue.edu.

Exempt study

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

Non-exempt study

✓ *Research that does not fit into an exempt category typically involves the collection of new data from a participant.*

Just-in-time

I have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but my application to the IRB is dependent on other factors such as:

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible at the time of the sponsor request, please do not select this option. The research team should affirm that their sponsor will accept documentation for a development protocol.

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

Quality Improvement

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

I need to know if my project is considered "Human Subjects Research"

I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).

When Purdue University will be engaged in human subject research with one or more institutions, investigators may submit a Request for Deferral asking that the review be deferred to one institution's Institutional Review Board (IRB).

Research Classification and Special Considerations

Would you determine that this research is predominately social or biomedical in nature

When you provide an answer to this question, a series of additional questions will display, and checking on each of these questions will generate a new form to the left that you will need to complete. These forms will ask the questions we used to ask, but in a clearer and more organized way, which will help the reviewer, as well as the investigator.

✓ **Biomedical**
My research has a biomedical focus.

Social / Behavioral
My research has a social or behavioral focus.

A combination of social science and biomedical, or I'm not sure.

*required

Please check any of the following that apply to the proposed research.

Each of these involves special considerations in the IRB review. If none of these items apply, click on "None of These" and continue forward in the application.

Potentially Vulnerable Populations
Examples: Children, Pregnant Women/Fetuses, Prisoners, those that lack capacity to consent), economically disadvantaged persons, minorities.

Use of an Experimental Drug
A substance manufactured via chemical process and intended for use in the diagnosis, cure, mitigation, than food) intended to affect the structure or any function of the body of man.

Note: Studies of this nature are considered Applicable Clinical Trials and may require an Investigational and Drug Administration and involvement of a physician investigator.
https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/investigational-new-d

Use of an Investigational Medical Device
An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or

or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, m in man or other animals, OR intended to affect the structure or any function of the body of man or other primary intended purposes through chemical action within or on the body of man or other animals and v metabolized for the achievement of its primary intended purposes.

Note: Studies of this nature are considered Applicable Clinical Trials and may require an Investigationa Drug Administration and involvement of a physician investigator.
https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/investigational-new-d

Clinical Trial
PLEASE READ THIS DEFINITION CLOSELY.

✓ *NIH defines a Clinical Trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."*

If this determination applies, please check this box.

Research with Food
Articles used for food or drink (or for components of such articles) and NOT intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

Radiation and/or Imaging
X-ray, CT, PET scans, nuclear medicine procedures, and MRI scans.
This protocol requires for research purposes 1) radiological assessments and procedures that involve radiation exposure (X-ray, CT, PET scans) 2) nuclear medicine procedures (imaging or therapeutic) or 3) MRI scans.

Nursing or Study Physician Resources
This protocol will have Nursing or Study Physician Resources

Blood Collection for Research Purposes
This protocol involves collection of blood samples other than discarded specimens. Examples are collections involving finger stick, venipuncture, or indwelling catheters.

Human Biological Specimen Repository
This protocol involves the establishment of a biological specimen repository.
Repositories are used for prospective collections of specimens that are processed, stored and

distributed to multiple investigators for use in research.

Gene Research Classification

The study will collect samples from individuals and look at a single gene, group of genes, or full genome for the purposes of research.

Stem Cells

This protocol includes an intervention with human subjects that involves either
a) the derivation of stem cells,
b) the implantation of stem cells.

International Research

This protocol includes research that is conducted at a non US location.

Data Controlled Under HIPAA and/or FERPA

Health Insurance Portability and Accountability Act (HIPAA) covers individually identifiable health information held or transmitted by a covered entity. This often involves healthcare providers and insurance companies.
AND/OR
Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records.

Biological Product

A substance manufactured via biological process and otherwise meets the above definition of a drug; includes a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

Dietary Supplement

A product taken by mouth that is intended to supplement the diet and that contains one or more dietary ingredients.

Community-engaged research

This is community-engaged research. For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.

Incidental Findings

Incidental findings are discoveries of individual-level findings that are unrelated to the goals of the study. (e.g. genetic data, MRI or test results).

Deception or incomplete disclosure

Deception occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.

Incomplete Disclosure occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

None of the above apply.

Protocol Description

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

Tell the IRB what specific trait(s), function(s) or behavior(s) you would like to study. Give a brief summary of your study in simple terms.

Describe why you are conducting the study. Identify the research question(s).

More than 50% of U.S. adults have elevated blood pressure or hypertension which increases the risk of cardiovascular disease (CVD). Early detection of elevated blood pressure or stage 1 hypertension offers a window of opportunity to prevent progression to overt hypertension and CVD through behavioral modification. Sympathetic activation and arterial stiffness are both deleterious factors that concomitantly contribute to elevated blood pressure. Mindfulness-Based Stress Reduction (MBSR) programs have been shown to reduce blood pressure in adults, but the mechanisms for the reduction remain speculative.

*required

Specific Aims/Objectives

Give the IRB an example of potential discoveries you hope to make or insight you hope to share. For example, outline a disease state, social characteristic or behavior that might benefit from the study results.

We will systematically examine 24-hour blood pressure regulation and two potential mechanisms for the anti- hypertensive effects of MBSR by directly assessing muscle sympathetic nerve activity (MSNA) and arterial stiffness. Aim 1 will determine if MBSR improves 24-hour blood pressure regulation, aim 2 will determine if MBSR reduces sympathetic neural activity, and aim 3 will determine if MBSR will decrease arterial stiffness in prehypertensive adults. This project will also provide advanced research opportunities to undergraduate and graduate students in health-related fields at Purdue University Northwest, consistent with the goals of the Academic Research Enhancement Award (R15) mission.

*required

Background and Significance

Include how previous research studies and their results support your study or how you will build upon existing information.

The proposed research is relevant to public health because over 50% of adults in the U.S. have elevated blood pressure or hypertension. The project is relevant to NIH's mission because it will provide rigorous investigation on Mindfulness-Based Stress Reduction as a proactive anti-hypertensive lifestyle intervention that may improve blood pressure regulation through sympathetic nerve control and arterial stiffness.

*required

Research Hypotheses

Please list any relevant study hypothesis/hypotheses. If this does not apply, type "Not Applicable".

Our central hypothesis is that MBSR will: 1) improve nocturnal blood pressure dipping and / or reduce early-morning surges, 2) reduce resting MSNA and attenuate the neural cardiovascular responses to acute stress, and 3) decrease arterial stiffness. We will utilize a parallel, randomized, control design (MBSR vs. active control) that includes gold-standard techniques for measuring blood pressure (24-hour ambulatory assessment), MSNA (microneurography), and arterial stiffness (applanation tonometry).

*required

How long will participants be asked to be in the study?

List the approximate duration in the fashion below.

- *Number of Visits =*
- *Minutes or Hours per visit =*
- *Single Day or Multiple Days?*
- *Total number of months until all data are collected =*

Potential participants visit the laboratory on three non-consecutive days for screening visits that take approximately 15 minutes each. We have included 3 pre-screening blood pressures to ensure that participants meet the primary requirement for elevated blood pressure. This procedure was proposed in

the original NIH proposal, has been used throughout this study so far, and has been used in previous projects we had funded through the NIH.

Qualified participants visit the lab two more times, once before and once after the 8-week intervention (within 10 days of the start and finish). Each of those visits take about 3 hours. The mindfulness-based stress reduction (MBSR) and stress management education (SME) classes (interventions) meet once per week for 2 to 2.5 hours. There is also one Saturday requirement at the end of the 6th week for about 7-8 hours. At home daily practice for participants in the two classes ranges from 30-45 minutes. The entire study with pre- and post-testing is approximately 10 weeks.

We specifically set up these courses for the research study. However, eight week mindfulness-based stress reduction courses are offered around the world by qualified instructors. We plan to have one of our previous instructors (Brigitte Morin) offer the course to the final cohort of participants in the spring of 2022. I will assist my graduate student Colleen Toorongian to offer the 8-week stress management education course. The SME course is traditionally used as an active control course for meditation studies, and to my knowledge it is not offered as an independent course like MBSR. Most of the MBSR and SME courses will be offered online via Zoom. There is one Saturday class for each of the interventions that we will try to hold in person on the Hammond campus.

*required

Specific Study Procedures

Describe in detail what a research participant will be asked to do.

- Prior to the start of the 8-week program, a 24-hour blood pressure reading will be taken. The device is compact and easily attached to a belt. Participants will also be fitted with a wrist accelerometer (similar to a Fitbit) that will track sleep-wake cycle for five consecutive nights. Participants will also complete questionnaires for anxiety, five-facets of mindfulness, and the ability to decenter.

- Following the accelerometer recordings, nervous system functions will be tested with microneurography (small electrode needle that can measure electrical activity in nerves) in a baseline setting along with a mental stress test (doing mental math calculations). Nerve activity will be continuously measured during the baseline and mental stress test. In addition to the nerve recordings, heart rate will be recorded with 3-lead electrocardiography, and continuous blood pressure with a small cuff on the middle finger. We will also estimate arterial stiffness with a small probe that will be placed at the radial (wrist), carotid (neck), and femoral (groin) pulse sites. We can also estimate breathing rate with an elastic pneumobelt that goes around the rib cage (fits gently outside of the participant's clothing). Breathing rate is not considered a primary variable, but we may report breathing rate (breaths per minute) if we calculate results for heart rate variability.

- With the programs outlined, participants will then proceed with the 8-week program to which they were randomly assigned. It is requested that you do not change your normal exercise schedule or eating habits. Both the MBSR and active stress management control programs will require a once

weekly group meeting and at home exercises. The home practice for MBSR participants includes things like breathing awareness, body scanning, and gentle Yoga. The home practice for SME participants includes daily reading from the book "Why Zebras Don't Get Ulcers" and gentle resistance band training. We have free copies of the required book that are lent out to participants during the 8-week class.

- Once the 8-week program is completed, participants will once more complete the questionnaires, 24- hour blood pressure readings, accelerometry, microneurography, heart rate, blood pressure, and arterial stiffness readings.

- Related to our laboratory safety, our new Tuttnauer 1730M autoclave is 20+ feet away from where participant testing would take place, and will never be used while a participant is in the laboratory. We have used this same autoclave for more than 15 years, and it has a very secure door latch. We have always worn neoprene gloves when prepping the electrodes to be autoclaved and when removing the electrodes from the autoclave in the sterilized pouches. We will use 3.5" x 10" self seal sterilization pouches made by PlastCare USA, that have an indicator strip that changes from blue to brown during the autovclaving process. We will follow additional PPE protocols during the COVID pandemic such as wearing a facemask during the autoclaving procedure.

In long term studies, a visual representation of a timeline is helpful. You may upload a visual representation as a Word (.docx) or PDF file here.

MBSR Conceptual Overview.pdf

Attach any surveys, questionnaires, assessments

For purposes of recordkeeping, the HRPP/IRB will need to have a Word or PDF version of any Qualtrics or electronic survey questionnaires. Please include more than a link to the survey.
MBSR Study Questionnaires.pdf

UFI_Pneumotrace_Datasheet.pdf

Actiwatch Spectrum PRO Brochure.pdf

Flow charts, schemas

MBSR Conceptual Overview.pdf

References

Below are references that we cite in our complete IRB proposal:

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Participant Information

*required

Total Study Enrollment

Please enter the number of subjects that will be enrolled at all sites, that are required to complete data analysis. Include the rationale for this number (e.g. statistical analyses, population composition). If at a later time it becomes apparent you need to increase your sample size, you will need to submit a Revision Request.

In the first two years of the award (while at Michigan Tech), we have randomized 43 participants into either the 8-week mindfulness-based stress reduction (MBSR) class or the stress management education (SME) active control course. We unfortunately lost our ability to post-test 19 participants in the spring of 2020 due to COVID-19 concerns. Our total project enrollment goal for NIH was 60 participants, but due to lost data on many participants we would like to be able to enroll and test up to 30 more participants at Purdue University Northwest.

*required

Attrition Considerations

If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through Purdue University. Please describe the rationale.

Consider:

- *Whether the withdrawal of the subjects might result from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and*
- *Whether the withdrawal might occur from all components of the research study or just the primary interventional component.*

Based on our previous cohorts we have lost up to 20% of enrolled participants during the longitudinal study. We have set a target to complete 24 more participants through the longitudinal study, so enrolling 30 new participants should help us to meet that objective.

*required

Age(s) of Participants in Study Population

Please include an age range for subjects, if relevant. If the research has multiple subject groups, describe the requirements for each separately.

Newborn to less than 10 years old

10 years old and less than 18 years old

✓ 18 to 65 years old

Enter specific age range if the target population age is less than 65.

18 to 55 years old

65 years and older

Unknown- Data are deidentified of any age or date of birth

*required

Inclusion criteria - Please identify the population that you would like to study.

Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study.

Age between 18 and 55 years
Must have an average seated clinical blood pressure >120 mmHg systolic and / or >80 mmHg diastolic
Must have a body mass index < 30 kg / sq. m
Not be taking any cardiovascular medication

*required

Exclusion criteria - Please identify the characteristics that do not represent your intended study population.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition. Please provide information about why the group will need to be excluded.

For NIH funded protocols: If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

Anyone with signs, symptoms, or diagnosis of COVID-19
Pregnant women
Taking cardiovascular medication
History of autonomic dysfunction such as postural orthostatic tachycardia syndrome (POTS) or syncope (fainting)
Smokers or those that use vaporized nicotine
Diabetics
Those with a pacemaker
Those with a history of MRSA, neuropathy, or illicit substance abuse

Please consider the population being studied. Are there any other safeguards that you are putting in place to address participant protections?

We will follow strict guidelines in regard to COVID-19.

Recruitment

*required

Recruitment Processes

How will people find out about your study? It's common for studies to be advertised on flyers, social media, or ads. The IRB must know what language and materials are used to recruit participants.

*required

Does your study use a known group of participants or records to recruit up-front? Check any of the following sources of information which will be used to identify potential subjects

Yes, a known group or subject pool.

✓ No, only the general population

Both a known group AND also the general population.

*required

Do the researchers hold any authority over the targeted population?
Examples:

- Teacher/student
- Supervisor/Employee

Please keep in mind the researcher that conducts recruitment, collects, and analyzes identifiable data cannot have authority over the potential participant due to the potential for undue influence. If necessary, a third party (listed as key personnel) who does not have authority over the targeted population must conduct recruitment and strip all identifiers prior to researchers/authority figures have access to the data.

✓ Yes

*required

Please detail how the study will prevent against undue influence or coercion to participate.

There is a chance that a student from one of my courses might volunteer as a participant, but they would not be the primary targeted population. Participation in this study is voluntary and participants may withdraw at any time without any penalty. Please let me know if you would prefer to have my department chair or someone from the Purdue University Northwest Faculty Research Board to monitor and mitigate this potential risk.

No

*required

How will you recruit the intended participants from the general population for your study?

It's common for studies to be advertised on fliers, ads, or social media. The IRB must know how people will find out about the study.
Points to consider:

- *Is the setting, location and timing of recruitment appropriate for the research being conducted?*
- *Are recruitment methods well defined and appropriate for the population?*
- *Are all recruitment materials non-coercive, and easily understood?*

We will include a study flyer as part of our submission. In the past we have shared the flyers by posting them around campus, and have also posted them in local newspapers and on social media. We will respond to interested potential participants by email, but will not use list serves unless we gain approval from the manager of the list serve and then the Purdue University IRB. The PI has completed NIH Good Clinical Practice training recently so that the flyer will not be coercive (for example, in regard to monetary compensation).

*required

Privacy During Recruitment

Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).

Examples of issues:
Potential subjects may not want to be approached for research purposes by someone they do not know.
Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc. If your study is not anticipated to generate privacy concerns during recruitment, please state this below.

The study PI and all students that help on the project will have completed the appropriate CITI training courses. The PI has been a leader of human participant research for more than 15 years. We will not access medical records, and will store any electronic study data on a password protected computer with non-identifiable data. Any paper data will be stored in a locked file cabinet in the PI's lab on the Hammond campus (in Gyte 6).

*required

Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?

✓ Yes

*required

Please describe how frequently and in what manner individuals will be contacted. Indicate the endpoint for contact.

Participants may be contacted by phone or text message, but the preferred method of contact will be via email listserves. The endpoint for contact will be the PI (John Durocher).

No

*required

Check any of the following recruitment materials which will be used to contact potential subjects.

✓ Direct mail/email

*required

Upload the recruitment letter that will be used.

MBSR Recruitment Email -2.pdf

MBSR Flyer Updated-Feb. 22.pdf

✓ Flyers/Brochures

*required

Upload the text or draft of this flyer or brochure.

MBSR Recruitment Email -2.pdf

MBSR Flyer Updated-Feb. 22.pdf

Published Advertisements

Verbal Scripts

Website

Social Media

✓ Other

*required

Describe the method used and how you will access information needed to contact or recruit potential participants. Please be specific.

We have gained approval to have our flyer sent out to campus listservs for students, faculty, and staff through Provost Chris Holford's office. I met with him on Zoom yesterday. His email is cholford@pnw.edu if you need to verify this approval.

Upload scripts/text and additional documents if needed.

MBSR Recruitment Email -2.pdf

MBSR Flyer Updated-Feb. 22.pdf

None of the above

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research. Describe the likelihood and seriousness of each risk.

Participation in research is voluntary. Consider the risks that a participant might encounter if they participate in the study. Risks may be physical, psychological, social, legal, etc. Please note that all research exposes to subjects to some risk.

For example, if the only foreseeable risk is breach of confidentiality, please describe the potential consequences to the participant's reputation, lifestyle, employability, or legal status that might occur if it became known that they participated in the study.

Potential Risks or Discomforts:

Measurement of Blood Pressure: *Blood pressure will be measured similar to a similar doctor's office visit. There are no known risks with this procedure. If discomfort is experienced the cuff can be deflated.*

24-Hour Blood Pressure Recording (ABPM): *It is possible for 24-hour blood pressure recordings to interfere with normal activity and sleep habits. We will try to minimize disruption to normal habits by gaining snapshots of 24-hour blood pressures once before, and once after, the 8-week intervention. We will record on a work or school day according to previous recommendations. To enhance user comfort, our ABPM devices are very compact, lightweight, and can be easily attached to a belt. We will collect only two readings per hour at night to help reduce the chance of sleep interference.*

Questionnaires: *We do not anticipate risk or discomfort in regard to questionnaires, but if a participant feels uncomfortable with any question, or any questionnaire, they can leave it blank.*

Microneurography: *There is a potential risk of infection after insertion of the leg electrode. Sterile techniques will be used to help prevent infection. We have never had any participants report infection after the procedure. Also, about 7% of subjects experience some aching or "pins and needles" sensations for a few days after the procedure. There is no specific treatment for these sensations, which are believed to be the result of tissue inflammation. Study volunteers who have experienced these sensations report they*

have disappeared spontaneously and completely without treatment within a few days. Dr. Durocher has safely performed over 300 successful microneurography sessions since 2010. We will mention to qualified participants during the screening visits that they should wear a pair of shorts underneath their clothing, or bring a pair of shorts, for the autonomic testing days. We have a private room in the lab with a locking door where participants can change into shorts. We have blue medical exam shorts that will be provided to participants that do not bring a pair of shorts with them. Microneurography (a small electrode needle that can measure electrical activity in nerves) will be completed prior to a 10-minute baseline and the mental stress test (doing mental math calculations) protocol. Nerve activity will be continuously measured during the baseline and mental stress test. The microneurography electrode would remain inserted for approximately 1 hour, and does not typically cause any discomfort after the initial insertion. We use a tungsten microelectrode behind the right knee as the recording electrode and a small acupuncture electrode about 3 cm away as the ground.

ECG: *There is a risk of skin irritation from the electrodes used for ECG. This is unusual, but we can stop the experiment if this irritation occurs. To date, we have never had a problem with our electrodes.*

Finger Cuff*: Rarely, some people experience mild discomfort in the fingers from the blood pressure cuff. If this occurs, we will stop the finger cuff.*

Arterial Stiffness: *This is a non-invasive procedure that is comparable to someone checking your radial (wrist) or carotid (neck) pulse via finger. A buildup of fats on artery walls are known as plaques. The use of a tonometry device could cause hardened plaques to dislodge. If aortic pulse pressure is 50 mmHg or greater, as estimated from the radial (wrist) pulse site with the tonometer, then we will not proceed with carotid (neck) or femoral (groin) pulse recordings. Individuals with aortic pulse pressures greater than 50 mmHg may have an increased risk for arterial plaques, and potentially disrupting these plaques could increase the risk for a cerebrovascular event such as a stroke. We will inform participants if they have an aortic pulse pressure greater than or equal to 50 mmHg, and explain that elevated pulse pressure has been associated with an increased risk of arterial plaques in one previous study. We would suggest that the participant could visit their primary care physician if they have any concerns about the elevated value. We use this cutoff out of an abundance of caution to not press on the carotid artery for the arterial stiffness measurements, which is why we would exclude the participant from carotid to femoral pulse wave velocity measurements if they have an elevated aortic pulse pressure.*

These measurements will be led by John Durocher, PhD who has more than 15 years of experience with this type of research. Some of the non-invasive measurements such as blood pressure or ECG may also be led by graduate student Colleen Toorongian. Colleen has worked with Dr. Durocher for several years in his previous laboratory that had nearly identical equipment, and she holds a BS in Exercise Science.

Breach of confidentiality: *This is always a risk with data, but we will take precautions to minimize this risk as described in the confidentiality section.*
Under Indiana law, Purdue researchers must report any suspected child abuse or neglect to law enforcement or to the Department of Child Services hotline.
Under federal law, Purdue researchers must report all incidents of discrimination, harassment, and/or retaliation in the Purdue workplace and/or educational environment to the Title IX Coordinator or Equal Opportunity/Affirmative Action Officer. "Harassment" includes sexual harassment, sexual violence, rape, and any non-consensual sexual act. If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

*required

Describe how risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

Points to Consider

- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*
- *Are medical or psychological resources available that participants might require as a consequence of the research?*

The PI of the Clinical and Applied Human Physiology Laboratory at Purdue University Northwest has an extensive history of research with human participants for more than the past 15 years. The current project is supported by NIH, and study data has been collected for the last 2+ years at Michigan Technological University. The laboratory will continue to consider the following to minimize risks:
1. All laboratory staff will complete CITI training to promote responsible conduct of research in regard to safety and confidentiality.
2. Strict protocols will be followed for techniques such as the microneurography procedure, such as autoclaving one-time use tungsten microelectrodes in a sterile pouch, wearing protective gloves during the procedure, and using alcohol wipes to thoroughly clean the site before starting insertion of any recording or reference electrode.
3. Arterial stiffness measurements always start with the pulse wave analysis (PWA) technique at the radial pulse site to ensure that aortic pulse pressure is less than 50 mmHg before proceeding to a more delicate pulse site such as the carotid artery. For participants with an estimated aortic pulse pressure greater than 50 mmHg, we will not proceed to any pulse wave velocity (PWV) recordings.
4. The PI will continually monitor the participant throughout the autonomic testing sessions.

*required

Please provide the risk level that you believe applies to the study.

In addition to the population being studied, consider the this definition:

Minimal Risk: *Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.*

The researchers believe the study is no greater than minimal risk.

✓ The researchers believe the study is greater than minimal risk.

*required

Are there potential direct benefits to a participant or benefits to society from your research?

The IRB must consider the risk/benefit ratio of each study.
Please note that payment for participation is not considered a benefit. If there are no direct benefits, please state this fact.

✓ Yes, there are potential benefit(s) to be gained by the individual subject/participant.
*required

Please list the potential benefit(s) to the individual.

There are numerous potential benefits to participating in this study, but nothing is guaranteed. You may learn how to better manage the stress in your life and your cardiovascular risk could be lowered.

✓ Yes, there are potential benefits to be gained by society.
*required

Please list the potential benefit(s) to society.

The findings of this study may help to indicate how adults could lower their cardiovascular risk through mindfulness-based stress reduction or stress management education.

No, there are no benefits.

*required

How does the investigator evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

Please provide an assessment of the risk:benefit ratio associated with your study. The HRPP/IRB must assess that the risks and benefits are appropriate . This is a crucial consideration for your study.

I consider this study to be more than minimal risk due to the invasive microneurography procedure. The PI has completed over 300 successful sessions independently and has also served as a participant for muscle sympathetic nerve activity (MSNA) recordings at least a dozen times. We have not had any serious adverse events in the hundreds of sessions that we have conducted, but there is some discomfort during the procedure during the first few seconds when the electrode makes contact with the peroneal (common fibular nerve) and there is a chance for some pins and needles sensations for a few days after the procedure. We will also make clear recommendations to each participant to not undertake any heavy exercise with the legs for at least 48 hours after the procedure to reduce the chance of pins and needles or feelings of discomfort. The risk for this procedure is very small with and experienced microneurographer and sterile techniques. Microneurography is the only method to directly assess post-ganglionic sympathetic activity in humans, and MSNA provides crucial insight into autonomic regulation of blood pressure. To explain briefly, higher MSNA induces vasoconstriction which increases blood pressure, while lowering MSNA induces vasodilation to lower blood pressure. Thus, the benefits of the measurement is very high, and provides significant mechanistic insight to the causes underlying hypertension, cardiovascular, and cerebrovascular disease.

Privacy and Confidentiality

*required

Privacy During Data Collection

Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant?s ability to privately provide information used for your study.

Privacy refers to a person's desire to control access of others to themselves.Participants must be able to control their right to participate in research (such as the timing and location of data collection. Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study. Subjects may not want to be seen in areas that may stigmatize them or at times when they are working or competing other tasks).

The pre- and post-testing sessions for this study will be held in private in the Gyte 6 laboratory. There will only be a single participant in the lab at a time at a designated desk for questionnaire data collection, and at a designated seat and / or on the laboratory tilt table for other cardiovascular assessments. The small window on the lab door is covered so that no one can see into the room during data collection.

We will treat your identity with professional standards of confidentiality. The information obtained in this study may be published, but your identity will not be revealed. Subject information and corresponding six digit alphanumeric codes will be stored in a secured file cabinet in Dr. Durocher’s laboratory (Gyte 6). This study is funded by the National Institutes of Health. The project's research records may be reviewed by the National Institutes of Health, Food and Drug Administration (if FDA regulated), US DHHS Office for Human Research Protections, and by departments at Purdue University responsible for regulatory and research oversight. Summary (but not individual) results will be registered and published at ClinicalTrials.gov in accordance with requirements from the National Institutes of Health.

*required

Confidentiality

Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.

- *For identifiable data in electronic format, describe the system that will be used.*
- *For identifiable data in hard copy or tangible format, describe methods on how to secure the data*

Hard copy data will be stored in a locked file cabinet in the PI's laboratory. Only the PI will have a key for the cabinet, but approved student researchers will be able to access the data during normal approved working hours.
Electronic data will be stored on a password protected computer on a specialized laboratory R drive that was created by the PNW Information Services Department only for Dr. Durocher and graduate student Colleen Toorongian, and electronic data will not include any participant's name.

*required

Provide a plan to protect the identifiers from improper use and disclosure.

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.

*required

Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers.

Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes. For protocols that may be subject to future continuing and secondary data analysis, the IRB needs to have the justification for not destroying identifiers permanently.

We will keep the hard copy data for a minimum of 3 years beyond the completion of this NIH project. No identified data will be stored electronically or used for a future study or analysis. If hard copy data were to be destroyed it would be via a confidential shredding process.

*required

Will a Certificate of Confidentiality be obtained from NIH for this research?

What is a Certificate of Confidentiality?

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are automatically granted for NIH-funded research (as of 2017). The IRB may request that the investigator seek a CoC if disclosure of identifiable sensitive information.

Consider this option if your study may place participants at risk due to the potential to identify situations such as disease state or criminal activity.

Please note that if a CoC applies, the consent form must have appropriate language (found in our template).

✓ Yes, the study is funded by an NIH grant or subaward and therefore automatically has CoC protections.

Yes, our team will seek a CoC from NIH if approval is granted for this IRB application. I will amend the study if this CoC is granted by attaching the document here.

No, this study will not require a CoC.

Data and Safety Monitoring

*required

Which individual or group will be responsible for monitoring the data and safety for this study?

- ✓ Principal Investigator/Research Team
- Independent Study Monitor(s)
- Internal Committee
- Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Independent of PI and Sponsor
- Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Not Independent of PI and Sponsor
- Other

*required

Describe the provisions for monitoring the data to ensure the safety of subjects.

The individual responsible for data safety and monitoring will be the principal investigator (PI), Dr. John J. Durocher. The greater than minimal risk activities include microneurography. Risks and safeguards for the procedure have been previously discussed (see microneurography attachment). If abnormal signs are detected during testing (ex. abnormal cardiac rhythm) or participants experience post-procedure adverse effects such as infection or prolonged paresthesia (i.e. beyond 48 hours) they will be referred to their primary care physician. In the event of a medical emergency, or detection of a hypertensive crisis (resting blood pressure 180 / 120 mmHg or higher and associated symptoms such as chest pain or shortness of breath), Dr. Durocher or research staff would immediately dial 911. Abnormal or adverse events will be documented by Dr. Durocher and reported as outlined below.

Throughout this study, Dr. Durocher will monitor the participants for adverse events. Events determined by the PI to be unanticipated problems involving risks to subjects or others (UPIRTSOs) will be reported by the PI to the IRB (via written memo) within 5 days per policy (SOP 409) for serious adverse events and within 14 days for other unanticipated problems (according to SOP 409). Additionally, in accordance with the National Institutes of Health (NIH) policy, the UPIRTSOs will be reported to the program official within 30 calendar days. All studies will be suspended in the laboratory until the issue has been resolved between the PI, IRB, and NIH. Adverse events that are determined by the PI to not be UPIRTSOs will be reported per IRB policy at the time of continuing review (i.e., annual review). All subjects and study staff

members will be informed by Dr. Durocher (via written memo) about any UPIRTSOs. If any protocol changes are needed, the PI will submit a modification request to the IRB. Protocol changes will not be implemented prior to IRB approval.

We will keep an electronic and printed copy of the Purdue University Unanticipated Problems and Adverse Event Reporting SOP 409 within the laboratory.

*required

Provide a description of the individuals who will be responsible for data safety monitoring

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Include the following details:
(1) association with the research and/or study sponsor;
(2) nature of their expertise and;
(3) whether they are independent of the commercial sponsor

If those monitoring the study are not independent of the sponsor, please describe how any potential conflicts of interest or biases will be avoided.

1) John Durocher the PI will be responsible for data safety monitoring.
2) Dr. Durocher has a PhD in Biological Sciences - Exercise Physiology, is a certified Exercise Physiologist through the American College of Sports Medicine, and certified Strength and Conditioning Specialist through the National Strength and Conditioning Association. Dr. Durocher was extensively trained in microneurography by two leading experts (William Cooke, PhD at Michigan Tech and Jason Carter, PhD at Montana State University) and has been leading the technique independently for more than a decade.
3) The PI is independent of the government sponsor.

Upload CVs

John Durocher's PNW Curriculum Vitae (2021).pdf

*required

What data will be reviewed?

Provide a description of the parameters that will be evaluated to ensure safety.

- ✓ Adverse events/Unanticipated problems
- ✓ Aggregate data
- ✓ Enrollment numbers
- ✓ Individual subject data/case report forms
- Protocol violations/deviations
- ✓ Subject withdrawals/terminations
- Other

*required

How often will data and safety monitoring be performed?

Please specify if this is a specific number of times, at defined time points, after a certain number of subjects have been recruited or as needed (i.e. every 6 months, every SAE, every 5 subjects, etc.)

As needed if there is an SAE.

*required

Describe the responsibilities that have been given to the data and safety monitoring function.

This should include a discussion of whether the data and safety monitoring plan includes a charter, whether stopping rules will be developed, and if any interim analysis will be performed (if so, on what basis). If this information is in protocol, please specify where relevant information is located.

Dr. Durocher will complete an annual report detailing the study progress, subject status, adverse events, and any protocol deviations. He has completed the first two annual reports that have already been submitted to the NIH.

*required

If this protocol is for a multi-center trial what mechanisms are in place to either receive or distribute results of the data and safety monitoring function in a prompt manner.

Describe each site's role in contributing to the data and safety monitoring.

This study will be conducted on the Hammond campus of Purdue University Northwest, and not at any other locations.

If a DSM Board charter exists, please upload it.

A charter includes identification and description of individuals responsible for monitoring the trial (their roles, qualifications, and the frequency of the monitoring activities. The proposed membership and assurances should be described within the document to ensure that there are no conflicts of interest with the study team or proposed institutions.

John Durocher's PNW Curriculum Vitae (2021).pdf

Compensation for Research Participation

Describe any compensation that subjects will receive when they participate in your study. Consider what happens to the compensation amount if the participant withdraws or is disqualified from the study. If course credit will be offered, please provide the amount and the percentage of the total grade.

---

*required

Will subjects be compensated for their participation in the study?

Will the study provide (money/gift cards/inducements/discounts/entry into a drawing/course credit) in exchange for a person's participation in the study? Please note that Purdue University policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

✓ Yes

*required

Describe the payment arrangement, including amount and timing of disbursement.

If the compensation includes a lottery or raffle-style drawing, please provide the approximate odds of winning (number of prizes, anticipated number of participants).

If course credit will be offered, please provide the amount and the percentage of the total grade. Extra credit should be no more than 3% of the course grade in order to avoid undue influence.

Participants will receive the following: 1) $50 for each microneurography (autonomic) session completed; and 2) $200 for the completion of the 8-week MBSR or SME course (prorated as $25 per week completed if there is any need to withdraw before the completion of the 8-week course). The maximum payment that you can receive from this study is $300. According to the rules of the Internal Revenue Service (IRS), payments that are made as a result of participation in a study may be considered taxable income. Participants will be asked to

provide their full name, address, and social security number for our Human Subject Invoice Log so that our Business Office at Purdue University Northwest can process and send a payment to the participant.

We did not have any budgeted funds through NIH for the screening visits, and have already screened 139 potential participants while at Michigan Tech that did not receive payment for screening. Thus, it would not be feasible or ethical to add payments for screening at this point.

*required

Justify the proposed payment arrangement described above, specifically why payment does not provide undue influence for subject participation

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Explain how the amount is reasonable for the study.

The proposed $50 payment for each microneurography session is consistent with what is paid at other institutions. This amount is thought to compensate the participant for their time. The proposed $25 per week for the MBSR or SME classes is designed to compensate participants for their time investment to the intervention. The compensation provides some compensation for the investment of time in the study, and potentially something towards transportation to and from the laboratory or class site, but not enough to be coercive to simply participate in the study for financial gain.

*required

Will partial payment be provided if the subject withdraws or is disqualified prior to completion of the study?

For example, are there starting and stopping points where the participation will be pro-rated?

✓ Yes

*required

Explain the plan for providing partial payment.

Participants will receive a prorated $25 for each week completed for the MBSR or SME courses if there is any need to withdraw before the completion of the 8-week course.

No

No

Informed Consent Process Section title

Informed consent is more than a form; it's a process and a responsibility.

Please answer all questions regarding the ways that participants will provide informed consent to participate in your study.

---

*required

Identify which subjects will consent to participate in the research.

- ✓ All subjects (or their legally authorized representative) will consent to participate in the research.
- Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.
- No subjects (or their legally authorized representative) will consent to participate in the research.

*required

For subjects who will consent to participate, choose whether the consent process will be documented by a **signature** from subjects.

Please note that you may request a waiver of the signature requirement if this study is minimal risk OR if the only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality.

- ✓ All consented subjects will provide a written signature as documentation of consent
- Some subjects will provide a signature as documentation of consent, and some subjects will not.
- No subjects will provide a signature as documentation of consent.

*required

Indicate in what language(s) the consent conversation will be conducted.

✓ English

Language(s) other than English

*required

Will subjects participate in any study activity prior to signing a consent document?

For example, some studies require subjects to fast, to refrain from drinking or smoking, pass a phone screening process or keep a journal/log prior to enrollment in the study.

✓ Yes

*required

List the activities in which subjects will participate prior to signing the consent document. Each activity must present no more than minimal risk of harm to subjects AND involve no activities for which written consent is normally required outside of the research. Please note that subjects should provide verbal consent to these activities.

Participants will be asked to refrain from eating for 3 hours, and from exercise, caffeine, and alcohol for 12 hours prior to seated blood pressure screenings.

No

Waiver of Informed Consent or Signed Consent

If any or all subjects will not provide written, signed informed consent for all parts of the study. Please complete the following information to request either a waiver of consent or a waiver of *signed* consent.

---

*required

Does the research pose greater than minimal risk to subjects (greater than everyday activities)?

This study is considered more than minimal risk due to the microneurography procedure, so we will not ask for any waiver of informed consent.

*required

Will the waiver adversely affect subjects? rights and welfare? Please justify.

---

not applicable.

Why would the research be impracticable without the waiver?

---

*required

How will pertinent information be reported to subjects, if appropriate, at a later date?

Through peer-reviewed publications for the overall study outcomes.

*required

Will any other materials (videos, brochure, drug/device information, etc) be used to present information to potential subjects?

Yes

✓ No

*required

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

The informed consent would be provided as an option at the end of the 3rd blood pressure screening visit for qualified participants.

*required

Consent form Elements

The following components are required for informed consent forms. If any of these elements are missing, you must provide justification for the reasoning.
Please confirm that all elements of informed consent are present. Use the Purdue IRB template found on the Purdue HRPP/IRB website

BASIC REQUIRED ELEMENTS OF INFORMED CONSENT
Please confirm that all elements of informed consent are present.

- Key Information at the beginning of the consent form
- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others that may reasonably be expected
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained
- A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

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*required

Please confirm that all basic elements of consent appear in your draft consent form.

✓ The research team has drafted a consent form and affirmed that it contains all of these basic considerations of informed consent.

Our research team is omitting a basic section from the consent form.

Our research team requested a complete waiver of informed consent and will not be attaching a consent form to this submission.

SPECIAL REQUIRED ELEMENTS OF INFORMED CONSENT

Please check if these items apply and are addressed in the draft consent form.

If any of these elements apply, but are missing, you must provide justification for the reason(s) to omit this information.

- *A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.*
- *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*
- *Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.*
- *Any additional costs to the subject that may result from participation in the research.*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

- *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
- *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- *Disclosure of any conflicts of interest.*
- *Registration of the trial on Clinicaltrials.gov*
- *NIH Certificate of Confidentiality coverage.*
- *Future uses of identifiable or deidentified data.*

---

*required

Please confirm that all items that apply to your study have been addressed in the consent form.

You must review the study-specific parameters that were discussed within your application in previous sections. Please refer to the sections on the left for any items that may apply.

✓ The research team has drafted a consent form and affirmed that it contains all special considerations of informed consent applicable to our study.

Our research team is omitting an applicable section from the consent form.

Our research team requested a complete waiver of informed consent and will not be attaching a consent form to this submission.

*required

Please attach all versions of your consent form here.

Consent forms should follow the structure of the template on the IRB website.
MBSR Pre-Screening Consent.pdf

MBSR Pre-Screening Consent.docx

MBSR Consent-9.docx

MBSR Consent-9.pdf

Funding Source(s)

*required

CURRENT Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI's responsibility to update funding sources as a modification to the protocol and associated forms (such as the consent form) when funding changes.

Please list any sources of funding that are **confirmed** by contract, agreement, or other support of a sponsor.
You will list any pending sources in the next question.

If the research is funded by a subcontract, please add both the subcontract source and the prime sponsor.

✓ Externally sponsored (federal, state, corporate, foundations, industry, donor)

Please search for the sponsor(s) here. Be certain to include any funding that originates or includes US federal sources.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

US Department of Health and Human Services - DHHS

If you do not see the name of the funding source using the "Find Sponsors" button above, please enter the full sponsor name in the text box below.

Please use the full name of the sponsor and include any subcontracted efforts.

National Institutes of Health - National Heart, Lung, and Blood Institute

Internal Purdue University Funds (Includes departmental funds, start-up funds.)
(Note, this does not include Purdue Research Foundation or Purdue Research Park companies-please list as external sponsor above).

None - There are no confirmed funding sources at this time.

ANTICIPATED Funding Source(s) - Required

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

Please list any sources of funding where sponsorship is **anticipated** or pending a final decision.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

There are no pending funding sources at this time.

Conflict of Interest and/or Outside Activities Disclosure

Conflicts of Interest or outside activities must be disclosed and managed prior to IRB approval. For more information about these policies, please consult the resources listed in the question marks in each section.

The IRB may request confirmation of proper disclosures.

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*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ I attest that I understand the outside activities policy and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Receiving more than $5,000 in compensation from, or having ownership interests in, outside entities, constitute Significant Financial Interests that need to be disclosed. Definitions of SFI, Investigator and Institutional Responsibilities, can be found at https://www.purdue.edu/policies/ethics/iiib2.html#definitions.

Yes

✓ No

*required

Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?

Yes

✓ No

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

Other attachments

*required

Do you have any other supporting documents to attach?

You may attach COVID-19 Research Space Standard Operating Procedures here if this is a new protocol submitted during the COVID-19 pandemic.

Investigators are invited to submit reference lists, study instruments, supporting information, training data, device pictures, or other relevant items for their study that were not addressed in the application.

✓ Yes

Attach any other documents. Please use a file name that describes the document.

You may attach multiple files to this entry.

PLEASE DO NOT UPLOAD PARTICIPANT DATA OR IDENTIFIABLE RESEARCH DATA.

citiCompletionReport1728324-Durocher Certificate.pdf

citiCompletionReport1728324RCR-Durocher Certificate.pdf

Previously Approved IRB Proposal from Michigan Tech - includes appendix on microneurography.docx

citiCompletionReport6623673-Toorongian.pdf

signed Durocher Data Transfer Memo.pdf

COVID-19 Prevention and SOPs for PNW Clinical and Applied Human Physiology Laboratory - Gyte 6.pdf

Data Transfer and Use Request - Durocher.pdf

No

Closure Submission

Information for Study Closure

*required

Please identify the reason(s) for study closure.

- ✓ Study is complete
- Principal Investigator is leaving Purdue.
- Study never began
- Other

Final study participant numbers

*required

Please enter the total number of participants who completed the study.

Eight.

If you have additional comments or numbers related to participant study completion, please include them here.

Eight adults with elevated blood pressure enrolled in this study.

To close this study, you must affirm all of the following protocol closure requirements.

Check the box next to each statement.

*required

✓ No further interventions/interactions with participants, no follow-ups, nor access to personally identifiable information for research purposes are occurring.

*required

✓ All data analysis involving the research site(s) under this study is complete.

*required

✓ Data have been de-identified. No direct identifiers or code key(s) (if data are coded) exist that would allow for the potential identification of participants.

*required

✓ The research team has plans to retain study documents in a secure manner for at least 3 years following the closure date, (6 years for studies involving HIPAA-protected data).

*required

Funding Status

What is the status of any funding associated with this study?

This study was never funded by an external sponsor (unfunded or internal funds).

✓ Grant funds associated with the study are expired or no longer being accessed.

An associated sponsored account remains active, but the human subject research activities have ended.

Since the last IRB approval, did any unanticipated problems involving risks to subjects or others, adverse events, protocol deviations, subject complaints or noncompliance occur that required prompted reporting to the IRB?

Yes

✓ No

Are there any final documents related to the study closure that you need to attach to this record.

Do not upload study data, consent forms, or identifiable data to this system.

Yes, I have final documents to attach.

✓ No

*required

Please acknowledge the closure statement below. Note that the Principal Investigator will also need to certify the submission.

✓ The information supplied to the Human Research Protection Program (HRPP) relevant to closure of this project is complete and accurate. I certify that I will retain study documents including, but not limited to, consent forms and data in a secure manner for at least 3 years following the closure date, (6 years for studies involving HIPAA-protected data). These records are subject to post approval monitoring practices. If I leave Purdue employment before this 3 (or 6) year record-keeping requirement has passed, the records for this study will either be left with a records custodian whose identity will be made known to the IRB prior to departure or transferred to a new institution by proper data transfer practices with the university.