MBT study

PI: Todd Braver
IRB ID #: 201701071

Project Details

1. Demographics

1.1 Project Title:
Neural Mechanisms of Mindfulness

1.2 Short Title (required):
MBT study

1.3 Project is primarily:
Biomedical

1.3.a Does this study require review under ICH-GCP?
No

1.4 Type of Study:
Other Interventional

1.4.a Is your research study one 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 (NIH clinical trial definition).
Yes

1.5 Select how you plan to obtain consent:
- Sign a consent document or a consent letter
- Script for use either in person or over the phone with no signature

2. Source(s) of Support

2.1 Source(s) of Support

Type/Source	Grant Title	Name of PI on Grant	Status
Federal Agency NIH/NCCIH	Neural Mechanisms of Mindfulness: a Discordant Twin Design	Braver	AWARDED

Attachment Name	Category	Version	Date Attached
1R21AT009483-01 Braver NCCIH JIT Letter.pdf	Notice of Just in Time (JIT) Documentation	1	01/17/17
compiled application.pdf	Grant from funding source or private foundation/association	1	01/17/17

3. Research Team

3.1 Principal Investigator

Name	E-mail	Title	School
Todd Braver	tbraver@email.wustl.edu	Professor of Psychological & Brain Sciences	Arts & Sciences

3.2 Team Members

Research Team Members

Role	Name	Role Desc	Student	Email	Title	School	Department	Contact	Consent Process Involvement	Epic Contact Person
PI	Todd Braver, MS, PHD, BS		No	tbraver@email.wustl.edu	Professor of Psychological & Brain Sciences	Arts & Sciences	Psychology - A&s	Yes	Yes	Yes
	Seth Adler, High School		No	sethadler@email.wustl.edu	Undergraduate Student-Notetaker	Arts & Sciences	Cornerstone - Disability Resources	No	Yes	No
	Kathleen Bucholz, PHD			bucholzk@psychiatry.wustl.edu	Prof of Psychiatry	School Of Medicine	Psychiatry	No	No	No
	Carol Cox, BA, BS			ccox@email.wustl.edu	Research Project Coordinator	Arts & Sciences	Psychology - A&s	Yes	Yes	No
	Joset Etzel, PHD			j.a.etzel@email.wustl.edu	Statistical Data Analyst III	Arts & Sciences	Psychology - A&s	No	Yes	No
	Michael Freund, BA			m.freund@wustl.edu	University Fellow	Arts & Sciences	Psychological & Brain Sciences	No	Yes	No
	Maria Gehred, BA			mgehred@go.wustl.edu	Research Tech II-Social Scienc	Arts & Sciences	Psychology - A&s	No	Yes	No
	Erin Gourley, BA			egourley@email.wustl.edu	Research Tech II-Social Scienc	Arts & Sciences	Psychology - A&s	No	Yes	No
	Brittany Haus, High School			bhaus@email.wustl.edu	Faculty Assistant	Arts & Sciences	Psychology - A&s	No	Yes	No
	Andrew Heath, DPhil			heatha@psychiatry.wustl.edu	Spencer T. Olin Prof of Psychology in Psych	School Of Medicine	Psychiatry	No	No	No
	Alexander Kizhner, BA			akizhner@email.wustl.edu	Research Tech I-Social Science	Arts & Sciences	Psychology - A&s	No	Yes	No

	Bidhan Lamichhane, PHD			bidhanlamichhane@email.wustl.edu	Postdoctoral Research Assoc	Arts & Sciences	Psychology - A&s	No	Yes	No
	Eric Lenze, MD			lenzee@psychiatry.wustl.edu	Prof of Psychiatry	School Of Medicine	Psychiatry	No	Yes	No
	Yichen Li, BA			yichen.li@email.wustl.edu	Undergraduate Student-Note Taker	Arts & Sciences	Cornerstone - Disability Resources	No	Yes	No
	Pamela Madden, PHD			maddenp@psychiatry.wustl.edu	Prof of Psychiatry	School Of Medicine	Psychiatry	No	No	No
	Casey Mason, High School			casey.mason@email.wustl.edu	Undergraduate Student-FWS	Arts & Sciences	Ra Payroll	No	Yes	No
	Jacob Noel, High School			jacob.noel@email.wustl.edu	Undergraduate Student	Arts & Sciences	Psychology - A&s	No	Yes	No
	Katya Noel, High School			katya.noel@email.wustl.edu	Undergraduate Student	Arts & Sciences	Psychology - A&s	No	Yes	No
	Kevin Oksanen, BA			kevinoksanen@email.wustl.edu	Research Tech II-Social Science	Arts & Sciences	Psychology - A&s	No	Yes	No
	Chunzi Peng, BA, MA, PHD		No	chunzi.peng@email.wustl.edu	Research Tech II-Social Scienc	Arts & Sciences	Psychology - A&s	No	Yes	No
	Alexandra Symes, none			asymes@go.wustl.edu	•Security Access Only	School Of Medicine	Psychiatry	No	Yes	No
	Rongxiang Tang, BS, MA			rongxiang@email.wustl.edu	University Fellow	Arts & Sciences	Psychology - A&s	No	Yes	No
	David Van Essen, PHD			vanessen@brainvis.wustl.edu	Alumni Endowed Prof of Neurobiology	School Of Medicine	Neuroscience	No	No	No
	Debbie Yee, BS			debbieyee@email.wustl.edu	A & S Graduate Fellowship	Arts & Sciences	Psychology - A&s	No	Yes	No

Team Member Financial Interest

Name	Financial Interests
Todd Braver, MS, PHD, BS	none
Seth Adler, High School	none
Kathleen Bucholz, PHD	none
Carol Cox, BA, BS	none
Joset Etzel, PHD	none
Michael Freund, BA	none
Maria Gehred, BA	none
Erin Gourley, BA	none
Brittany Haus, High School	none
Andrew Heath, DPhil	none
Alexander Kizhner, BA	none
Bidhan Lamichhane, PHD	none
Eric Lenze, MD	none
Yichen Li, BA	none
Pamela Madden, PHD	none
Casey Mason, High School	none
Jacob Noel, High School	none
Katya Noel, High School	none
Kevin Oksanen, BA	none
Chunzi Peng, BA, MA, PHD	none
Alexandra Symes, none	none
Rongxiang Tang, BS, MA	none
David Van Essen, PHD	none
Debbie Yee, BS	none

4. Other Institutional Reviews/Requirements

4.1 Do any of the objectives of this study involve the diagnosis, prevention, screening, evaluation, treatment or support of cancer patients?
No

4.2 Are more than 30% of the patients involved in this study likely to have an active cancer diagnosis?
No

4.3 Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or radiopharmaceutical therapy)?
No

4.4 Does your study involve the administration of radiopharmaceuticals (radioactive drugs) for research purposes?
No

4.5 Will any participant be asked to undergo any of the following:

- a standard radiology procedure involving ionizing radiation (includes X-rays, fluoroscopy, DEXA, CT)
  OR
- a standard nuclear medicine examination with FDA-approved radioactive drugs (including bone scans, radionuclide ventriculogram (RVG or MUGA), myocardial perfusion imaging, FDG-PET)
- DO NOT include MRI or ultrasound

No

4.6 Will the study involve any of the following activity at WUSM or any BJC hospitals, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?

- Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or
- Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)

No

4.7 Does this project involve administration of recombinant DNA (gene therapy) or microorganisms?
No

4.8 Does this study involve the use of human embryonic stem cells or human induced pluripotent stem cells?
No

4.9 Does this study involve research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero?
No

4.10 Will a Certificate of confidentiality be used for this research?
No

4.11 Does this project need to be registered on ClinicalTrials.gov?
Yes

4.11.a Who is the Responsible Party for registering this study in ClinicalTrials.gov?
Principal Investigator

4.12 Title that should appear in Epic (and will be visible in the patient medical record):
N/A

4.13 Select one person from the study team that should appear in Epic as the contact person for this study:
Todd Braver

4.14 Do you want to request that an ordering tool be built for your study in Epic?
No

4.15 Would you like to submit a request for the Epic team to consider your study for the use of BPA (Best Practice Advisory) in Epic?
No

4.16 Would you like to submit a request for the Epic team to build your questionnaires in Epic for the purposes of recruitment?
No

4.17 Will any external monitors require access to this study in Epic?
No

4.19 Mark all that apply to your study:

1. Protocol

1.1 Is there a separate, written protocol that will be submitted in addition to this form? (Note: a grant application is not considered to be a protocol)
No

1.2 Select up to three key words below that best describe this research study:
- Psychology
- Clinical

1.3 Provide a short summary/abstract of the purpose and procedures of the study proposed in this IRB application.

- DO NOT include information on studies not proposed in this application.
- Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.
- DO NOT cut and paste technical abstracts from source of support applications that may not be understood by a general audience.

This project focuses on understanding the cognitive and neural mechanisms by which mindfulness training (MT) results in positive behavioral change and enhanced psychological well-being. Building upon research by the Human Connectome project and the Dual Mechanisms of Cognitive Control studies, we will recruit MZ and DZ twins and non twin siblings, to participate in fMRI sessions.
The subjects will be recruited in pairs, with one subject randomly assigned to the MT condition (mindfulness-based stress reduction, or MBSR; the most-validated and standardized form of MT instruction) and the other serving as a (wait-list) control. Each co-subject will undergo extensive behavioral and MRI neuroimaging assessments in a pre/post fashion, before and after the MT (or no-contact control) intervention, to test for specific MT-related effects.

1.4 Specify your research question(s), study aims or hypotheses:
We will use this design to investigate theoretically-focused hypotheses that stem from our guiding framework regarding the neural mechanisms of cognitive control. Specifically, using a newly developed cognitive control task battery, we will test the counterintuitive hypothesis that MT is produces an enhancement in the neural mechanism and circuits associated with reactive (rather than proactive) control. An additional subset of MZ twin participants will undergo retesting with the original HCP protocol, in order to provide a comprehensive assessment and comparison of MT effect sizes across multiple domains of cognitive and brain function. Success in this project will have high relevance for public health, by providing innovative experimental tools and a novel theoretical framework from which to empirically evaluate and better understand the potential impact of MT programs as lifestyle interventions for enhancing psychological well-being in healthy populations.

1.5 Background and significance and/or Preliminary studies related to this project:
Over the last decade, current understanding of the neural basis of complex psychological functions has shifted in emphasis from a focus on specific regions, to that of brain networks, while still highlighting the importance of key nodes within these networks. In terms of attentional and cognitive control, the lateral frontoparietal network(FPN) is generally agreed to be paramount. Within the FPN, dorsolateral prefrontal cortex (dlPFC) regions appear to function as critical hub nodes.
Strikingly, current cognitive neuroscience research has also associated MT with critical changes to each of these networks and key nodes. The FPN, and dlPFC in particular, show MT-related effects that appear to reflect both the state-changes associated with increased focusing of attention during meditative states, as well as potentially trait-related changes due to MT experience that result in more effective utilization of this network during attentional control tasks.
Building upon MZ and DZ research conducted by the HCP and current R37 study on dual mechanisms of cognitive control by Dr. Braver, we will utilize the tasks and build upon the data of these successful and ongoing studies.

1.6 Literature cited/references (if attaching a grant enter N/A):
N/A

1.7 Describe EACH of your participant populations

- Include description of any control group(s)
- Specify the Inclusion/Exclusion criteria for EACH group

Participants are healthy young adults of age range 18 to 45 years, native English speakers with no contraindication for fMRI.
We will recruit a cohort of monozygotic (MZ) and dizogotic twins and siblings from Missouri family registries. We will target individuals that have completed study 201510077, Dual Mechanisms of Cognitive Control.

Any participant will be excluded for the following reasons: 1) taking any medication with potential cognitive effects (e.g., sleeping pills); 2) taking any psychotropic medications; 3) the presence of any clinically unstable medical disorder, or a medical disorder that affects cognitive or motor function (e.g., epilepsy, Parkinson's Disease); and 4) present or past head injury with documented neurological sequelae, and/or causing loss of consciousness. Additionally, subjects for the fMRI studies will also be excluded for: 1) pregnancy; 2) history of claustrophobia; 3) non-medically approved metallic objects in the body; and 4) history of heart rhythm abnormalities or presence of a heart pacemaker.

In addition, we will screen for premature births (for twin pairs, before 34 weeks; for other siblings, before 37 weeks, to avoid inclusion of individuals with atypical connectivity patterns resulting from very premature birth.

1.8 Check all materials/methods that will be used in recruiting participants:

- Telephone script
- Ads/Brochures/Posters/News Release/Fliers
- Email or letters
- Other Materials - prior participants in study 201510077 (Braver, PI) Dual Mechanisms of Cognitive Control
- Existing Registry/database
  - Other Research Study - prior participants in study 201510077 (Braver, PI) Dual Mechanisms of Cognitive Control
  - Other Existing Registry/database - Missouri Family Registry (twin database)
- Medical Records or Other PHI

Attachment Name	Category	Version	Date Attached
DMCC_MBSR_EMAIL.rtf	Recruitment: Other	1	05/02/17
priorparticipantflyer.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	05/15/17
newparticipantemailflyer.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	05/15/17

1.8.a List the individual data elements you will need to access/use from the patient or clinic records to identify potential participants for recruitment
For the telephone screen, we are generating PHI in the form of medical history and medications (see attached phone screen document).

1.8.b What is the plan for participant identifiers obtained to identify participants for recruitment?
Identifiers for those who do NOT enroll will be destroyed at the earliest opportunity, consistent with the conduct of the research (for example when recruitment and enrollment are completed.)

1.8.c Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule?
Yes

1.9 Will you use a screening log or other record that would include information on people who do not consent to participate in the study?
No

1.10 Describe where the consent discussion will occur (check all that apply):

- Private room or area
- By phone

1.11 Participants and/or their legally authorized representative will have (check all that apply to the consent process and explain process in Question 1.12 below):

- As much time as they desire to consider enrolling in the study, including:
  - An opportunity to thoroughly review the consent materials with knowledgeable members of the research team, and with family and/or friends as appropriate
  - Sufficient time to have all of their questions answered

1.12 Provide a description of the enrollment and consent process in sequential order and address EACH of the bulleted points below:

- Describe each study population separately including control population
- Describe when recruitment and consent materials are used
- Indicate how much time individuals will have to consider participation
- Use THIRD person active voice. For example, "the principal investigator will identify potential participants, the study coordinator will discuss the study with participants over the telephone and schedule the first study visit, etc..."
- Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process

We will recruit healthy young adult twin pairs. We will utilize the Missouri Twin registries.

Email: An email will be sent to former DMCC participants about the study.

Phone screen: A member of the research team will provide participants with information about the study and required elements of consent over the telephone (see attached telephone screen) prior to obtaining verbal consent to participate in the initial screening elements of the study. The initial phone screen will include questions about inclusion and exclusion criteria and the MR safety screening form, to ensure that we do not recruit participants who are unable to safely complete MR scans. An appointment will be set up with eligible subjects if they choose to participate.

In Lab:
If a participant is deemed eligible and agree to participation in the study, an appointment is scheduled. Upon arrival in the lab, the participant will be consented by an engaged research team member using the approved consent form. Participants will be
allowed ample time to read/review the consent form and to ask questions. Participants will then complete: an intake review form, an fMRI screening form, and a demographic form. If any contraindications or exclusion criteria, the participant will be withdrawn from the study and paid for their time. If the participant is found eligible, the experiment will begin.

We will take steps to minimize the possibility of coercion and/or undue influence during the consent process by reminding the participants that their participation is completely voluntary, and may be ended at any time for any reason.

All members of the research team will have completed human subjects and HIPAA training through Washington University before having participant contact.

1.13 Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.

Describe study populations separately if they will be participating in different procedures

DESCRIBE:

- Control populations, if applicable
- Any randomization, if applicable
- What participants will be asked to do/what happens in the study (in sequential order)
- The time period over which procedures will occur
- Long-term follow-up and how it occurs

SESSION I:
A. Intake: This will involve a brief interview and data on standard physiologic information (height, weight, blood pressure, and pulse). If blood pressure is considered high, participant will be given an information sheet at the end of their session. All participants will then be administered the MRI screening form and demographic form. If participant is deemed eligible, the
experiment will commence. If they are ineligible, they will be told why and will be withdrawn from the study.

B. Behavioral Practice Session (This will take approximately 2 hours.)
1. TASKS: Participant will complete 4 behavioral tasks (AXCPT, Stroop, Sternberg and Taskswitching) on a computer. Subjects will complete the Operational and Symmetry Span tasks, an 18 item Ravens Matrices task, a breath counting task, and a Letter Set task.
2. Questionnaires:
Subjects will also complete behavioral questionnaires during practice sessions, which include: Behavioral Inhibition System/Behavioral Approach System (BIS/BAS)
Need for Cognition Scale (NfC)
Generalized Reward and Punishment Expectancy Scales (GRAPES)
Mindful Attention Awareness Scale (MAAS)
Five Facet Mindfulness Questionnaire (FFMQ)
Pittsburgh Sleep Quality Index
State Trait Anxiety Inventory (STAI)
Domain Specific Risk Taking(DOSPERT)
The Positive and Negative Affect Schedule(PANAS)
Sensitivity to Reward and Punishment Questionnaire
Self-Scoring Self Control Scale (SCC)
Barratt Impulsiveness Scale (BIS)
Alcohol&Smoking Questionnaire
Neo FFI
Fordyce
Patient health questionnaire (PHQ0
Satisfaction with Life (SWL)
Self Compassion scale (scomp)
Pittsburch sleep quality index (PSQI)
Exit Satisfaction Survey
pre & post task questionnaires
C. Break
D. Scanning: In the scanner, participants will perform baseline session of the 4 tasks (AXCPT, Stroop, Task-switching and Sternberg) in a scanner. This will take approximately 2 hours. Blood pressure and pulse will be measured prior to scan. Scanning will consist of structural, functional and resting state acquisition.
E. Review of schedule for Scanning Session II.

Session II and Session III (can either be completed on the same day or broken into two sessions A&B&D, A,C,D):
A. Behavioral Practice Session: Participant will complete 4 behavioral tasks (AXCPT, Stroop, Sternberg and Task-switching) on a computer. Participants will practice the corresponding (counterbalanced order of proactive/reactive) condition of the tasks outside of the scanner before the scanning sessions. These practice sessions will last approximately 30 minutes each. If not completed, subjects will complete any questionnaires remaining from Session I Behavioral Practice.
B. Scanning Sessions:
Participant will perform two scanning sessions in Session II of the study. The sessions will be counterbalanced between the proactive and reactive conditions of the four tasks (AXCPT, Stroop, Task-switching and Sternberg) in a scanner. Scanning will consist of both functional (tasks) and resting state acquisition. Each scan will last approximately two hours. Blood pressure and pulse will be measured prior to the scan.
B: Break
C. Second Scanning Session (of counterbalance)
D. Exit Survey (post-task questionnaire)/Debriefing

One of the twin participants will be randomly selected to participate in an 8-week Mindfulness-based stress reduction (MBSR) program led by certified MBSR instructors at a dedicated facility, supervised by Dr. Eric Lenze. The MBSR program uses a combination of mindfulness meditation, body awareness, and yoga to help people become more mindful. The MBSR program is an eight-week workshop taught by certified trainers that entails weekly group meetings (two-hour classes) and a one-day retreat (six-hour mindfulness practice) between sessions six and seven, home practice, and instruction in three formal techniques: mindfulness meditation, body awareness, and simple yoga posture.

After the completion of the program, the twins will return for sessions three and four - a repeat/retest of Session I and II.
If participants that have completed or are enrolled in IRB 201510077, Dual Mechanisms of Cognitive Control (Braver, PI), they will not complete session one and two. They will be asked to begin at the mindfulness training and complete sessions three and four.

The twin that was not chosen to participate in the MBSR initially will be given the opportunity to voluntarily participate after the completion of the retest sessions.

Task descriptions:
AXCPT:
In the AXCPT task, a modified version of the continuous performance task, participants are told to make one response for the letter X when it was preceded by the letter A, and another response for all other stimuli. AX trials are "target trials"; in these types of trials a valid cue is followed by a valid probe. The 3 other trial types are "Nontarget trials" in which either a valid cue is followed by an invalid probe ("AY" type trials) or an invalid cue is followed by either a valid or invalid probe ("BX" or "BY" probes, respectively). Participants will be asked to respond by pushing a button. The baseline, proactive and reactive versions of the task will vary the number of AX, AY and BX and BY trials.

Sternberg:
In the Sternberg task, participants will be shown word lists on a computer monitor and will be asked to make judgments about them by pushing buttons. During each trial, participants will observe presentation of a list of items to memorize, followed by a memory maintenance period during which the subject must maintain the list of items in memory. The maintenance period is
terminated by the onset of a 'probe' letter, to which the subject must respond whether the item was in their memorized list of items or not. Participants will be asked to decide if the probe word appeared in the lists within the trial indicating yes or no via a button press. The baseline, proactive and reactive variants of the task will vary in the length of the word lists, i.e. short list 23 words, medium list 45 words, long list 67 words. The baseline, proactive and reactive conditions will vary the load and frequency of the lists.

Stroop:
In a Stroop task, participants name the color of ink a word is printed in (e.g., RED in blue ink [incongruent] or RED in red ink [congruent]) or the picture of an animal while ignoring a word (e.g., cat picture with word FISH superimposed [incongruent] or cat picture with word CAT superimposed [congruent]). Responses will be recorded as an audio .wav file
During the behavioral and the scanning session, each participant will complete 3 versions of the task as follows:
The baseline variant of this task will involve the presentation of mostly congruent items.
The proactive variant will involve the administration of mostly incongruent items, and the reactive version will involve the
administration of 50% congruent items.
The reactive version, half of the items (e.g., the words RED and BLUE or the pictures cat and fish) will be mostly congruent and the other half will be mostly incongruent, which is referred to as an item-specific variation.
Participants will be asked to respond aloud, with their voice used to mark reaction time. A recorded file will also be saved, de-identified and stored, to later record accuracy.

TaskSwitching:
In a task-switching task, participants are cued as to which of two tasks are relevant for a given trial, and are asked to respond to the stimuli following the cue. The two tasks that may be cued involved simple judgments such as vowel/consonant judgment (e.g., is E a vowel or consonant, digit judgment (e.g., is 3 smaller or larger than 5), word judgment (e.g., how many syllable in TORCH, or does the word refer to an object that is smaller or larger than a basketball), or picture judgment (e.g., does the picture reflect a mode of transportation that involves car/plane or bike/boat? In a mixed task block, both tasks are relevant and can be cued on a given trial, and sometimes one task is cued more frequently than the other. In a single task block, only one task is relevant at a time (i.e., can be cued). Participants respond by pressing designated keys on a keyboard. Reaction time and accuracy are recorded.
The baseline, proactive and reactive variants will involve intervals of varying length between stimuli and congruency.
Incentives (i.e., a cue indicating a trial is worth more points or other incentive) may be added to encourage proactive preparation of the cued task.

Span Tasks:
Operational Span Task: measures general capacity for working memory. In this task, participants are asked to read and verify a simple math problem and then read a word after the operation (such as SNOW). After a series of problems and words has been presented, the participants recall the words that followed each operation. The number of operation word

strings in a sequence is increased and decreased to measure the participant's operation span. Operation span measures predict verbal abilities and reading comprehension even though the subjects are solving mathematical problems.

Symmetry Span tasks: The Symmetry span task is a complex span partner to the matrix span task. The participant is shown a series of grid locations onebyone form the 4x4 grid in the center of the screen. The participant must remember the grids and the order in which they appeared. After each grid is shown the participant is shown an 8x8 grid that has a number of grids filled
black to form a pattern. The pattern will either be symmetrical along the vertical axis or it will not and the participant must make this judgement using the left/right arrow keys before the next grid will be shown.

18 item Ravens Matrices: a nonverbal group test typically used in educational settings. It is usually a 60item test used in measuring abstract reasoning and regarded as a nonverbal
estimate of fluid intelligence

Letter Set task: presents series of letters in a pattern. Subject responds to which does or does not fit the pattern. This task is used as a measure of fluid intelligence.

Breath Counting task: Participants press a key for each exhale for breaths 1-8 and a separate key for 9 breath, then reset. If they lose track of breaths, they press a 3rd reset key.

Questionnaires:
1. Behavioral Inhibition System/Behavioral Approach System (BIS/BAS): A behavioral approach system (BAS) is believed to regulate appetitive motives, in which the goal is to move toward something desired. A behavioral avoidance (or inhibition) system (BIS) is said to regulate aversive motives, in which the goal is to move away from something unpleasant. We developed
the BIS/BAS scales to assess individual differences in the sensitivity of these systems.
2. The Need for Cognition Scale is an assessment instrument that quantitatively measures "the tendency for an individual to engage in and enjoy thinking" (Cacioppo & Petty, 1982, p. 116). The Need for Cognition Scale asks individuals to rate the extent to which they agree with statements about the satisfaction they gain from thinking.
3. Generalized Reward and Punishment Expectancy Scales (GRAPES): A scale to assess generalized reward and punishments
expectancies in individuals.
4. Mindfulness Attention Awareness Scale (MAAS): The trait MAAS is a 15item scale designed to assess a core characteristic of mindfulness, namely, a receptive state of mind in which attention, informed by a sensitive awareness of what is occurring in the present, simply observes what is taking place.
5. Five Facet Mindfulness Questionnaire (FFMQ):This instrument is based on a factor analytic study of five independently developed mindfulness questionnaires. The analysis yielded five factors that appear to represent elements of mindfulness as it is currently conceptualized. The five facets are observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience.
6. State Trait Anxiety Inventory (STAI): is a commonly used measure of trait and state anxiety at both poles of the normal affect curve (state vs. trait.
7. DomainSpecific RiskTaking (DOSPERT)is a psychometric scale that assesses risk taking in five content domains: financial decisions (separately for investing versus gambling), health/safety, recreational, ethical, and social decisions.
8. Self Scoring Self Control Scale (SCC): Measures self control.
9. The Positive and Negative Affect Schedule(PANAS: The Positive and Negative Affect Schedule (PANAS) comprises two mood scales, one that measures positive affect and the other which measures negative affect. Used as a psychometric scale, the PANAS can show relations between positive and negative affect with personality stats and traits. Ten descriptors are used for
each PA scale and NA to define their meanings.
10.Sensitivity to Reward and Punishment Questionnaire: The Sensitivity to Punishment and Sensitivity to Reward Questionnaire (SPSRQ) has been proposed as a measure of the behavioral approach system (BAS) and behavioral inhibition system (BIS).
11. Barratt Impulsiveness Scale (BIS) The BIS was designed to assess the personality trait of impulsiveness. It was intended to
be an improvement over previous versions of the BIS, including Barratt's (1959) original measure
13. Pittsburgh Sleep Quality Index (PSQI: The Pittsburgh Sleep Quality Index (PSQI) is an effective instrument used to measure
the quality and patterns of sleep in the older adult. It differentiates “poor” from “good” sleep by measuring seven domains: subjective sleep quality, sleep latency, sleep
duration, habitual sleep efficiency, sleep disturbances, use of sleep medication, and daytime dysfunction over the last month.
14. Alcohol and Smoking: used to gauge alcohol and tobacco use in subjects. Results compared with individual difference
measures.

1.14 Will participants be randomized?
Yes

1.15 Will any of the following be used to collect information from the participant or others?

- Screening questions or screening/eligibility questionnaires
- Surveys
- Questionnaires
- Stimuli
- Any other written assessments

Yes

Attachment Name	Category	Version	Date Attached
FFMQ_full.pdf	Subject Data Collection Instruments	1	01/17/17
BIS11English.pdf	Subject Data Collection Instruments	1	01/17/17
STAI.pdf	Subject Data Collection Instruments	1	01/17/17
Dospert.pdf	Subject Data Collection Instruments	1	01/17/17
Intake_PSQI_EON(1).pdf	Subject Data Collection Instruments	1	01/17/17
PANAS.pdf	Subject Data Collection Instruments	1	01/17/17
Exit_Satisfaction_Survey_NMM.doc	Subject Data Collection Instruments	1	01/17/17
MBSR-Alcohol.doc	Subject Data Collection Instruments	1	01/17/17
BISBAS.pdf	Subject Data Collection Instruments	1	01/17/17
ncogscale.pdf	Subject Data Collection Instruments	1	01/17/17
GRAPES-typed-clean.doc	Subject Data Collection Instruments	1	01/17/17
BJH_MRI-Screening_BJ_208-3343-2292_20EF_Proof.pdf	Subject Data Collection Instruments	1	01/17/17
01092013_briefscc.pdf	Subject Data Collection Instruments	1	01/17/17
NMM pre and post task.docx	Subject Data Collection Instruments	1	01/17/17
sprs (1).pdf	Subject Data Collection Instruments	1	01/17/17
MAAS trait research-ready + intro.pdf	Subject Data Collection Instruments	1	01/17/17
SWL.pdf	Subject Data Collection Instruments	1	08/14/17
fordycescale.pdf	Subject Data Collection Instruments	1	08/14/17
PHQ.pdf	Subject Data Collection Instruments	1	08/14/17
DEMOGRAPHIC FORM (2).docx	Subject Data Collection Instruments	1	01/25/17
NEO-FFI.pdf	Subject Data Collection Instruments	1	08/14/17
PSQI.pdf	Subject Data Collection Instruments	1	08/14/17
sComp.pdf	Subject Data Collection Instruments	1	08/14/17

1.16 Does this project involve creating any audio, video, or photographs?
Yes

1.17 Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?

Examples:

- Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.
- Participants will be provided with false information regarding the particular behaviors of interest in the research.
- Procedures include a confederate pretending to be another participant in the study.
- Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.
- Study is designed to introduce a new procedure (or task) that participants are not initially told about.

No

1.18 Indicate any payments or reimbursements to participants (check all that apply)
- Check

1.19 Does this study have a plan to have an individual or committee review combined data from all participants on a periodic basis (such as summary or aggregate safety and/or efficacy data)?
Yes, but it's not described in an attached protocol

Drs. Braver and Lenze and will have primary responsibility for the monitoring of subjects. Data to be reviewed will be coded with a subject number and will not contain identifiable information. Data will contain summary reporting. This will be shared on a annual basis with the sponsor, or as needed. All incidental findings will be reported to the IRB upon occurrence. All adverse or serious adverse events will be reported to the sponsor and the IRB shared upon occurrence. The investigators and the engaged research team will meet weekly, or as needed, to review accrued data (neuroimaging and behavioral results) and confirm confidentiality of data files.

1.20 What have you done to minimize any risks?
- No forseeable risks

1.21 What are the potential benefits related to this project for:

- the participant (if any)
- benefits to society (if any)

There are no direct benefits to participants in this study.

This project has high relevance for public health by providing a rigorous and comprehensive evaluation of the effects of mindfulness training on psychological and brain function in healthy young adults. Although mindfulness practices are rapidly gaining in popularity as a lifestyle intervention to enhance psychological health and well-being, the brain basis of their effects are still not well-understood, particularly in healthy populations. The knowledge gained from this project will promote greater understanding and more informed decision-making regarding the potential benefits to be gained from instruction and training in mindfulness.

1.22 Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.
Standard statistical analyses using a within subjects factorial ANOVA, t-test or regression. All data points will be included, which include experimental conditions (e.g., delay, target location). Dependent measure will be saccade accuracy.

1.23 Provide the rationale or power analysis to support the number of participants proposed to complete this study.
Estimates of power for all of our primary analyses are over 80% power to detect a medium or even small effect size with the proposed sample size. We are looking for extremely subtle effects in the data, including time-dependent changes in accuracy.

1.25 Will any data from this project be stored for use in future research studies?
Yes - contribution for future use is mandatory for participation in the study

1.26 Does this project involve the collection or use of biological samples?
No

1.27 Are you requesting institutional certification to contribute human data or samples to a repository or database for broad sharing (public or restricted access)?
No

2. Participants

2.1 Will there be any adult participants?
Yes

2.1.a How many adult participants do you expect to consent or enroll under a waiver for this project?
50

2.1.b What is the age of the youngest adult participant?
18.0

2.1.c What is the age of the oldest adult participant?
45.0

2.2 Will there be any minor participants?
No

2.3 Will there be any emancipated minor participants?
No

2.7 Do you plan to recruit/enroll non-English speaking people?
No

2.8 Do you propose to enroll any of the following in this study as participants?

- Employee of the PI or employee of a research team member
- Individual supervised by PI or supervised by member of research team
- Individual subordinate to the PI or subordinate to any member of the research team
- Student or trainee under the direction of the PI or under the direction of a member of the research team

No

2.9 Is this project about pregnant women?
No

2.10 Will this project involve fetuses?
No

2.11 Does this project involve the use of fetal tissue from any source?

No

2.12 Does this project recruit adult participants who may be incompetent or have limited decision-making capacity on initial enrollment into the study?
No

2.13 Does this project involve prisoners as participants?
No

3. Performance Sites

3.1 Indicate type of site(s) where research will occur (check all that apply):
- Academic Institution

3.2 Where will project procedures take place (check all that apply)?
- School of Medicine
- Danforth Campus

3.3 Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?
No

4. Drugs/Devices

4.1 Does this project involve:

Yes	No	
○	◉	Drug(s) (including radioisotopes)
○	◉	Use of contrast agent(s)
○	◉	Other substance injected, ingested, or applied to the body
○	◉	Testing a Device (Including companion devices, software, mobile health devices, assays, not FDA approved or outside approved indications, etc.)
○	◉	Combination product (as determined by the FDA - must have FDA documentation identifying this as a combination product)

4.2 Does this project involve a drug washout (asking participant to stop taking any drugs the participant is currently taking)?
No

4.3 Will any participants receive a placebo in place of standard therapy?
No

5. Privacy & Confidentiality

5.1 Indicate your plans to protect the privacy interests of the participants during the conduct of the study (check all that apply):
- Only the minimum necessary private information is collected for the purposes of the study
- Any procedures or interventions conducted as part of the study will be conducted in private setting to the extent possible
- Recruitment/consent will occur in a private setting
- Participants will be able to ask questions in a private setting

5.2 Are you collecting or using the Social Security Number of any participants for any purpose?
Yes

5.2.a Provide the intended usage of SSN:
- To provide compensation to participants

5.3 Project uses paper or hard copy consents, surveys, data collection forms, research subject binders, or other hard copy materials (check all that apply):
Yes
- All materials are stored in secured environment
- Access is limited to research team members only
- Other - identifiable records are stored separately from data; data is coded with subject number

5.4 Project collects, stores and/or transmits electronic data on mobile devices, desktop computers, servers including cloud servers, email, or any other information in electronic form (check all that apply):
Yes
- Password protected
- Access is limited to research team only
- Data are encrypted
- Data in Redcap
- Transmitted using recognized security for electronic submission
- Other - Virtual Private Network

5.5 Project collects or uses biologic specimens (check all that apply):
No

5.6 Identify any additional protections in place for data and or samples (check all that apply):
- No additional protections

Washington University in St. Louis

FOR IRB USE ONLY
IRB ID #: 201701071
APPROVAL DATE: 12/21/17
RELEASED DATE: 12/21/17
EXPIRATION DATE: 12/20/18

INFORMED CONSENT DOCUMENT

Project Title: Neural Mechanisms of Mindfulness

Principal Investigator: Todd Braver

Research Team Contact: Maria Gehred or Alexander Kizhner 314-935-8547

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are a healthy young adult that meets our inclusion criteria.

The purpose of this research study is to study the impact of Mindfulness Training (MT) on the neural mechanisms of cognitive control.

WHAT WILL HAPPEN DURING THIS STUDY?

This is a test – retest study. Your participation in the study will involve completing cognitive tasks in three to six separate neuroimaging sessions performed on different days. You may also be asked to complete a mindfulness training program (MT) completed either between the first three sessions (test) and last three sessions (retest), or at the conclusion of your neuroimaging sessions.

If you have completed or enrolled in Dr. Braver's research study 201510077, Dual Mechanisms of Cognitive Control, you will not participate in the first set of neuroimaging sessions, normally sessions 1-3.

I. Session One/Day 1:

1. You will complete a brief interview, physiological measurements, including blood pressure and pulse rate, which will be taken before and during sessions. You will also complete a screening form and demographic information.
2. You will complete four tasks on a computer. These are memory tasks in which you will be presented words, pictures, colors, faces or alphanumeric characters on a computer monitor and

will be asked to respond to them by either pushing buttons or by speaking into a microphone.
3. You will be asked to complete several questionnaires measuring individual differences and motivation. You are free to skip any questions you would prefer not to answer.
4. Break
5. You will complete four tasks completed earlier in the day inside of a magnetic resonance imaging (MRI) scanner.
   These are memory tasks in which you will be presented words, pictures, colors or alphanumeric characters on a computer monitor and will be asked to respond to them by either pushing buttons or by speaking into a microphone. We will scan your brain using magnets while you complete the task in the scanner. We will also scan your brain while you are resting.

   The MRI scanner is a large machine that contains a hollow tube. You will be asked to lie on your back on a special table that slides into the tube. The sides of the tube will be fairly close to your body and the scanner makes a loud hammering noise while you are inside. You will be able to talk to people in the room through a speaker system. We will monitor you closely while you are inside the scanner.

   An MRI scanner takes pictures of the inside of your body by sending out a magnetic field and radio waves. Because the MRI scanner contains a very strong magnet, you may not be able to have the MRI if you have certain kinds of metal in your body (for example, a heart pacemaker, a metal plate, certain types of heart valves or brain aneurysm clips). Someone will ask you questions about this before you have the MRI.

6. We will ask you to complete a short questionnaire after the scan.

   We estimate session one will take 4-6 hours to complete. You will be allowed to take breaks as needed throughout your time in the scanner.

II. Session Two and Three/Day 2 and Day 3:

1. You will complete four tasks on a computer outside of the scanner. These are memory tasks in which you will be presented words, pictures, colors or alphanumeric characters on a computer monitor and will be asked to respond to them by either pushing buttons or by speaking into a microphone. Physiological measurements of blood pressure and pulse rate will be taken before and during sessions. You will be complete four tasks completed earlier in the day inside of the MR scanner. These are memory tasks in which you will be presented words, pictures, colors or alphanumeric characters on a computer monitor and will be asked to respond to them by either pushing buttons or by speaking into a microphone. We will scan your brain using magnets while you complete the task in the scanner. We will also scan your brain while you are resting.
2. Break
3. You will complete four tasks on a computer outside of the scanner. These are memory tasks in which you will be presented words, pictures, colors or alphanumeric characters on a computer monitor and will be asked to respond to them by either pushing buttons or by speaking into a microphone.
4. You will complete four tasks completed earlier in the day inside of the MR scanner. These are memory tasks in which you will be presented words, pictures, colors or alphanumeric characters on a computer monitor and will be asked to respond to them by either pushing buttons or by

speaking into a microphone. We will scan your brain using magnets while you complete the task in the scanner. We will also scan your brain while you are resting.

5. We will ask you to complete a short questionnaire after the scan.
   We estimate session one will take 4-5 hours to complete. You will be allowed to take breaks as needed throughout your time in the scanner.

III. After the first set of neuroimaging sessions, you will be randomly assigned to the mindfulness training (MT) group or the control, non-training group.

The mindfulness training program will be based on the *Mindfulness-Based Stress Reduction Workbook* (Stahl and Goldstein 2010) , from the program developed by Jon Kabat-Zinn, Ph.D.'s group at the Center for Mindfulness in Medicine, Health Care, and Society at the University of Massachusetts. Content includes instruction in mindfulness meditation practices, gentle mindful movement, and exercises to enhance mindfulness in everyday life. You will be given daily home assignments along with CDs of practices. MBSR will be provided as 8 week, 2.5-hour classes plus one day-long class. Each class will be conducted at the Psychological Service Center on the west campus of Washington University in St. Louis.

IV. After the completion of the mindfulness training, you will complete the second set of neuroimaging sessions, normally 3-6, (retest sessions of the first set, as described above).

If you have not been chosen to participate in the mindfulness training first, you will be asked to complete the retest portion, neuroimaging sessions 3 through 6, first and then the mindfulness training.

You are free to skip any questions that you prefer not to answer.

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining questionnaire, MRI, and task response data from you. We would like to use this data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding the effects of mindfulness training, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Audio Recording/Video Recording/Photographs

One aspect of this study involves making audio recordings of you. The audio recordings are used to measure your response time during a cognitive task known as the Stroop task. The recordings will be

coded with a subject number and will only be available to engaged members of the research team. The recordings will be destroyed at the completion of data analysis.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 50 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for three to six sessions.
Each session will last approximately 4-5 hours, will be completed on different days, and will include breaks.

You will only be asked to complete the initial test portion, sessions one through three, if you have not participated in study 201510077, Dual Mechanisms of Cognitive Control.

If you are chosen to participate in the mindfulness training program, you will participate for 2.5 hours per week for 8 weeks and an additional half day meeting.

If you are not chosen to participate in the mindfulness training program, we will give you the opportunity to complete the training program after your completion of the retest portion, sessions three through six, at no cost to you.

WHAT ARE THE RISKS OF THIS STUDY?

Likely / Common:
Completing the questionnaires or tasks may cause boredom or fatigue.

Less Likely / Less Common:

Mindfulness Training: You may experience emotional discomfort or distress from undergoing a group intervention. Participants may experience discomfort while engaging in mindfulness exercises involving movement.

Functional Magnetic Resonance Imaging (fMRI):
During the fMRI, you may develop mild muscle aches and pains due to immobility and exposure to the acoustic noise of the MRI scanner. We will minimize the possibility of muscle aches and pains by providing appropriate cushions at pressure points and beneath the knees and ensuring you are as comfortable as possible.

You may be uncomfortable inside the MRI scanner if you do not like to be in closed spaces ("claustrophobia"). During the procedure, you will be able to talk with the MRI staff through a speaker system. You can tell them to stop the scan at any time.

The MRI scanner produces a loud hammering noise, which has caused hearing loss in a very small number of patients. You will be given earplugs to reduce this risk.

Tattoos: If you have a skin tattoo, including cosmetic tattoos (eye-liner, lip-liner) you could experience the following:

- irritation, swelling or heating in the area of the tattoos
- in rare instances a primary or secondary burn.

If you have a tattoo we will offer you a cold, wet washcloth to put over the tattoo to reduce this risk.

If you have a device such as a pacemaker, bone hardware, or device placed in your uterus there may be additional risks. We will review what device you have and inform you of these risks. In general, these risks could be:

- heating or movement of the device
- device malfunction
- damage to the tissue that surrounds the device.

The fMRI images you will have for this study are for specific research purposes and are not being used to evaluate your health or find medical abnormalities. However, if there is an incidental finding or abnormality discovered, we will refer the images to a consulting radiologist for review. The radiologist will contact you if warranted.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study if you participate in the mindfulness training.

However, we hope that, in the future, other people might benefit from this study because it will provide critical and detailed information regarding the brain basis of normal human variation in higher mental functions such as attention, memory, decision making, and intelligence and effects of mindfulness training on these functions. Such knowledge will be critical in helping to better understand the relationship between normal functioning and mental health disorders (such as schizophrenia, depression, addiction, ADHD), as well as risk vulnerability factors that may contribute to such disorders.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. Checks are normally processed within 5-10 working days. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

If you have not completed IRB study 201510077, you will receive $400 for the completion of Part I of

the study (session one and session two).
If you have enrolled in and/or completed IRB study 201510077, you will receive $400 for Part II of the study (sessions three and four).
Participants will not be paid a per diem or an hourly rate for their participation in the Mindfulness Training program (Part III, described above).
If you do not complete the study, your participation time will be prorated at $25 per hour.

WHO IS FUNDING THIS STUDY?

National Center for Complementary and Integrative Health/ National Institutes of Health is funding this research study. This means that Washington University is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator, Todd Braver at 314-935-5143 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The National Institutes of Health
- The National Center for Complementary and Integrative Health
- Your primary care physician or a consulting radiologist if a medical condition that needs urgent attention is discovered
- Hospital or University representatives, to complete Hospital or University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Data Safety Monitoring Board

To help protect your confidentiality, we will secure all of your information that contains identifiable data and keep it separate from your research data at all times. Research data records are coded with a subject number that will not be included on any form that contains identifiable information.
Paper records will be securely stored in locked cabinets in locked suites and accessible only to members of the research team. Electronic records will be stored on password-protected computers, on private networks and on secure database systems maintained by Washington University. No one outside of the

research team will have access to identifiable data.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu/participants//withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.

- Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
- You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at http://hrpo.wustl.edu/participants/ under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because you have developed contraindications for magnetic resonance imaging, or if it is unsafe for you to be in the study.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Todd Braver at 314-935-5143 or Maria Gehred or Alexander Kizhner at 314-935-8547. If you experience a research-related injury, please contact: Todd Braver at 314-935-5143.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.

- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 12/20/18.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)