Principal Investigator: David Vago **Revision Date: 01/06/2020**
Study Title: Mechanisms of Mindfulness-Based Interventions
Institution/Hospital: VUMC

This informed consent applies to adults currently registered *for* MBCT or MBSR aged 18-55 years old.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

1. What is the purpose of this study?

You are being asked to take part in this study because you have shown interest in a mind and body health treatment with a focus on learning mindfulness skills. The state of mindfulness can be described as a form of present-moment awareness that is open to whatever emotion or thought arises with curiosity, and without getting stuck on any thought or emotion with judgement. Mindfulness-based Interventions (MBIs) are a family of group-based treatments that focus on learning mindfulness skills and have effectively been applied in a variety of medical settings for a wide range of problems and types of people. The current study aims to study how MBIs may function to address health outcomes using surveys, computer testing, brain imaging, and markers for inflammation (e.g., body infection) found in blood.

2. What will happen and how long will you be in the study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any of the following study procedures. You maintain the right to withdraw from the study at any time for any reason. Following your consent to participate in all aspects of this study in which you qualify, we will ask you to take part in a number of tasks that could involve: 1) computer testing involving attention, memory, social interaction and how you experience emotion; 2) surveys that ask questions about health and well-being; 3) brain scanning using functional magnetic resonance imaging (fMRI) or electroencephalography (EEG); and 4) providing blood samples at the Center for Clinical Research at the Vanderbilt University Medical Center. Testing will happen prior to and following your mindfulness-based intervention (MBI).. All procedures will be handled by professional staff within the Clinical Research Center.

You should have already completed our pre-screen survey via email. This pre-screening survey has allowed us to determine which of the following parts of the study you qualify for. If you qualify for the MRI Testing please continue reading the section, “MRI Testing”. If you qualify for the EEG testing, please continue reading the section, “EEG testing”. If you qualify for the Behavioral Testing, please continue reading the section, “Behavioral Testing”.
As part of this study, you will receive appointment cards at the end of each visit and will get a reminder call the day before your scheduled study appointment. If you do not show up for your appointment, the study coordinator will contact you to reschedule. A minimum of three attempts will be made to reschedule missed study appointments. If you unexpectedly miss a session, a research team member and/or the MBI instructor will call you to discuss any issues that have appeared to prevent you from attending the session. To support you and your completion of this study, we will request contact information from one member of your family and one close friend so they may help encourage you to complete the study and we may reach out to them if we are unable to contact you during the course of the study.

Mindfulness-based Intervention

As part of this study, you have elected to participate in and complete* a mind and body health treatment that will involve:

- A group pre-program orientation session (2-2.5 hrs)
- A brief individual interview (5-10 min)
- Eight weekly group classes 2- hrs in duration
- An all-day class during the sixth week of the program (7.5 hrs)
- Learning “formal” Meditation practices
    - Body scan Meditation – while lying down
    - Gentle Yoga – some stretching while following breath
    - Sitting Meditation – some practice that focuses on breath, some practice that focuses on thoughts, feelings, and sensation
    - Walking Meditation – practice paying attention to experience while walking
- Learning “Informal” Meditation practices – skills for everyday life
    - Noting pleasant and unpleasant events
    - Becoming aware of breathing, and routine activities like eating, driving, walking, conversations
    - Daily homework assignments, including about 30-45 minutes of formal practices, 5-15 minutes of informal practices
    - Individual and group dialogue discussing home assignments and any problems

Total in class contact Time: 30+ hours
Total home assignments: 42-48 hours
Total group orientation Session time: 2-2.5 hours

*It is expected that at least 5 of the 8 in-person classes of your treatment be attended in order to qualify for study completion

Self-report Questionnaires
All Subjects in this study will participate in answering our surveys prior to and following the intervention. There will be surveys we will send to you on a weekly basis and some of you may be asked to fill out the same battery of survey questions once again.

Pre-/Post-intervention Survey Battery (About 25 min)
Stress- and emotion-related survey questions will record any changes from pre- to post-mindfulness training.

Daily Survey (About 1-2 min)
Home Meditation Practice [daily during intervention]: You will be asked to record the frequency and duration of formal home practice sessions, which will take roughly 1-2 minutes to complete daily for eight weeks.

Weekly Survey (About 1-3 min)
Treatment Regimen Check-In [weekly during intervention, posttest visit]: You will be asked to report whether your depression and/or anxiety medication regimen has changed or if any new, additional treatments have been initiated within the past week, which will take roughly 1-3 minutes to complete once weekly for eight weeks.

fMRI protocol. (About 90 min)
If you qualify for brain scan testing using "functional Magnetic Resonance Imaging" (fMRI), you will be scheduled to participate in scanning sessions taking place at the imaging center (Vanderbilt University Institute of Imaging Science) on the Vanderbilt University Medical Center campus. The fMRI testing will take about 60 minutes before and after your mindfulness training.

An fMRI scan is taken in a large machine (the MRI) that is shaped like a tunnel. This scan does not use x-rays. Instead, they use a strong magnet and radio waves, like those used in an AM/FM radio to make pictures of your body. The MRI scan should not cause you any pain. The MRI scan is not known to have any significant effect on health. The MRI technologist will have you complete a safety questionnaire to make sure that you don't have any device, implants, certain tattoos, etc., that make it unsafe for you to have an MRI scan.

You may not be able to have this scan if you have a device in your body such as aneurysm clips in the brain, heart pacemakers or defibrillators, and cochlear Implants. Also, you may not be able to have this scan if you have an iron-based tattoos, pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye).

Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the machine or may be pulled away from the body when you are getting the scan. Also, metal can sometimes cause poor pictures if it is close to the part of the body being scanned. For these reasons, you will be asked to remove these objects before going into the room for the scan.

The scanner is a noisy environment. You will be given earplugs to reduce the noise. You will also be told how to alert the staff if you need them.

During the scan, the MRI staff is able to hear and talk to you. You will also be able to hear the staff. They will be talking to you during your scan and may ask you to lie very still throughout the scan, or other simple tasks that measure your attention or response to emotional stimuli like pictures or words.

In this study, the MRI scan is for research only. But, if we see something that is not normal, you will be told and asked to consult your doctor.

The first scanning session will involve a task that requires and tests attention and "rest" task where you will be asked to lie still, stay awake, and let your mind freely wander while you lay on a table in the magnetic resonance imaging (MRI) scanner room. The MRI allows us to take detailed 3-D pictures of your brain. The scanning procedures should take no longer than two hours.

The attention task will involve the presentation of emotional words in which you will be asked to respond with a button press to each word unless the word is in italics. In the case where a word is in italics, you will be asked to withhold a response. A brief assessment will follow the scanning session. The assessment will include rating the emotional value of certain words and a memory task.

After the first scanning session is complete, you will complete an 8-week long training in an MBI at the Osher Center for Integrative Medicine before being scheduled for your second scanning session in the MRI. During your second visit, the same procedures will be repeated. During these visits, you will have an opportunity to ask questions about the study and receive help following completion of the study to continue your meditation practice if you would like.

EEG protocol. (About 90 – 120 minutes)

EEG data will be collected in special testing space in the Contemplative Neuroscience & Integrative Medicine (CNIM) lab at the Osher Center. The EEG testing space has a one-way mirror to a control room to help observe subject testing and to separate computer equipment from the testing room. The proposed research will use CNIM's state-of-the-art EEG equipment. EEG measures the electrical activity, or 'firing', of the synapses within the brain, and reveals how the brain 'communicates' information. Brain activity is measured using a special cap that is placed on the subjects' head. The cap looks like a swimming cap with many wires. We fill small plastic discs with metal contacts (electrodes) attached to the cap, with a gel, which allows us to measure brain activity better. The application of the electrodes will take about 15 – 30 minutes. We will begin testing

with a quiet rest period of 6 minutes where we will get a snapshot of your resting brain. Following the resting baseline, we will ask you to complete 4 computer tasks while wearing the EEG cap and we continue to watch your brain waves. Each of these tasks take between 15 – 35 minutes. The tasks will involve responding via button presses to different emotional words, pictures, or videos.

Computer Testing. (About 45 minutes)
If you are taking MBSR, you may only qualify for the computer testing part of this study. You will be asked to complete two tasks as a measure of memory, attention, and impulse control. In the first task, you will be asked to respond (e.g., button press) to a non-target letter and to withhold your response to a target letter. In the second task, you will be asked to respond (e.g., button press) to a non-target emotional word and to withhold your response to the target emotional word. To perform well, you must keep attention to your responses, such that, at the appearance of a target word, you can ignore the normal impulse to respond and instead withhold button press, a difficult task to do rapidly.

You may also change your decision to participate in this research study at any time by calling 866-436-4710.

3. Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment received at the Osher Center. This includes treatments you would need even if you were not in this study. These costs will be billed to you and/or your insurance. You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study:

There are no severe or life-threatening side effects or risks in taking part in any part of this study. Below, we outline the risks with each type of methodology.

Surveys/Computer Testing:
The interview and questionnaires involve responding to questions that are personal about issues that may be considered sensitive and may be stressful. You do not have to answer questions that upset you. You may stop the interview at any point. During computer testing, some of the things we show on the screen will be emotional words and pictures. These tasks should not cause discomfort but can also be stopped at any point. You may feel that answering these questions truthfully is a possible invasion of privacy or probing of information which might be considered sensitive. You do not need to answer any questions that you would prefer not to answer.

EEG Testing:
The only inconvenience involving EEG will be some non-sticky, non-smelling, water-based, easily washable gel in your hair from the testing. We have areas at the Osher Center to wash your hair after the testing session. As part of testing, we ask you to please not use any hair products (i.e. hair-spray, gel) before coming in for the EEG testing session, since these products interfere with the quality of the testing. You will be asked to complete some experiments presented to you via a computer screen while we record your brain (EEG) activity. These tasks will involve showing emotional images or words on screen and you being asked to press a button in response, or to with-hold a response. You will be asked to press a button if you think a word is positive or negative, for example. These tasks are NOT tests and do not have right or wrong answers; rather, we are interested in what is happening within your brain at the when doing such tasks.

MRI Scanning:
There are no known major risks with an MRI scan. But, it is possible that harmful effects could be found out in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs.

If you use a transdermal patch (medicated patches applied to the skin), you may need to take it off during the MRI scan. Transdermal patches slowly deliver medicines through the skin. Some patches have metal in the layer of the patch that is not in contact with the skin (the backing). You may not be able to see the metal in the backing of these patches. Patches that contain metal can overheat during an MRI scan and cause skin burns in the immediate are of the patch. Tell the study doctor that you are using a patch and why you are using it (such as, for pain, smoking cessation, hormones). Ask your doctor for guidance about removing and disposing of the patch before having an MRI scan and replacing it after the procedure. Tell the MRI facility that you are using a patch. You should do this when making your appointment and during the health history questions you are asked when you arrive for your appointment.

There are no known risks of having MRI scans without contrast while pregnant. However, there may be risks that are unknown.

5. Payment in case you are injured because of this research study:

If Vanderbilt and the Investigator determine that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

6. Good effects that might result from this study:

As a result of this study, it is our hope that the research can provide useful information about the development of various clinical problems and the improvement of existing treatment methods. We further hope this research study will help us to improve our understanding of mindfulness and eventually lead to the use of mindfulness to treat patients and understand healthy mind-brain-body connections. As such, you will be helping others experiencing similar challenges as yourself, and contributing to improving integrative health care treatments.
You will not have any direct benefit from participating in this study. It will require your time to participate. We hope, however, that the research can provide you with information about meditation and some of the benefit of its practice for you. However, we cannot and do not guarantee that you will receive any benefit from this research study.

7. Payments for your time spent taking part in this study or expenses:

You will be provided compensation for your participation in this study.

If you are taking MBCT, you will earn a total between $140 -- $275 upon completion. You can earn $30 for completion of self-report surveys ($10 for pre-treatment self-report surveys, $10 for post-treatment survey completion, $10 for completion of follow-up surveys), $110 for fMRI ($50 for pre-treatment and $60 for post-treatment), and $110 for EEG ($50 for pre-treatment and $60 for post-treatment).

If you are taking MBSR you will earn a total up to $70–$ upon completion. You can earn $30 for completion of self-report surveys ($10 for pre-treatment self-report surveys, $10 for post-treatment survey completion, $10 for completion of follow-up

surveys), $30 for completion of pre/post-treatment and follow-up computer testing ($10 for pre-treatment, $10, for post-treatment testing, and $10 for follow-up).

Completion of the study earns an additional $10 for protocol associated with the MBSR course and $25. Completion involves attending at least 63% (5/8) of 8 weekly group classes and completion of at least 80% of daily and weekly self-report assessments throughout the 8-week intervention.

MBSR PAYMENT				
Assessment	**Pretest Amount**	**Posttest Amount**	**Follow-up 16-24 weeks**	**Total**
Self-reports	$10	$10	$10	$30
Computer Testing	$10	$10	$10	$30

MBCT PAYMENT				
Assessment	**Pretest Amount**	**Posttest Amount**	**Follow-up 16-24 weeks**	**Total**
Self-reports	$10	$10	$10	$30
fMRI	$50	$60		$110
EEG	$50	$60		$110

8. Reasons why the study doctor may take you out of this study:

You will be removed from the study only for the following reasons:

1) Any mood disturbances requiring changes in medication dosage or type
2) Inpatient hospitalization or medication
3) If you become medically unstable which demands intensive medical intervention as determined by your primary physician
4) If you become suicidal as determined by MBI instructors and require inpatient hospitalization or more intensive treatment
5) If you miss more than 50% of MBI sessions (determined to be an adequate dose).

You can be removed from the study if there is a worsening of symptoms. You may participate again once you are medically and psychologically stable. You will be enrolled in a subsequent group at a later time.

9. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

10. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, **please feel free to contact the principal investigator (David Vago, PhD) at 615-875-9555** or email our research staff at cnimlab@vumc.org . If you cannot reach the research staff, please contact the Osher Center general number and they will find the appropriate clinical or research staff member at: 615-343-1554

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

11. Clinical Trials Registry.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

ClinicalTrials.gov Identifier: NCT03571386

12. Confidentiality:

Imaging data will be collected using the MRI machine at the Vanderbilt University Imaging Institute (VUIIS), part of the Biomedical Imaging Research Core. We will use the VUIIS secure data storage and access protection methods to ensure that images are analyzed in a consistent manner, a high-performance computing facility with a quality assurance framework.

EEG data will be collected in the Contemplative Neuroscience & Integrative Medicine (CNIM) lab dedicated to EEG testing at the Osher center. The CNIM lab offers plenty of space for protected storage of study data. The EEG equipment is specialized for collecting brain scanning data. The equipment is from Brain Products and analyses are conducted by our expert research staff on professional-grade software from internal lab computers that are password protected. Only relevant research staff will have access to the EEG and computer-based data.

Computer-based "Behavioral" data will be collected in the same testing room as EEG. Behavioral data will be securely stored on the Vanderbilt University Medical Center server, which is both firewall- and password-protected, and access is only to authorized research staff (as determined by the PI).

We will make every reasonable effort to protect your privacy and confidentiality interests through:

- Requiring that all key study personnel complete trainings in CITI Responsible Conduct of Research, CITI Human Subjects Protection, and Good Clinical Practice.
- Ensuring that data are collected in a secluded research-only area.
- Managing and disseminating data (including surveys, observations of the behavior from computer testing, fMRI scans, and blood samples) in a confidential manner.

Individually identifiable health information (IIHI; i.e., name, phone number, email address, address, date of birth, age, gender, race, ethnicity), Consent forms, identifiers (i.e., unique subject ID numbers) linking you to deidentified data, and all self-report data will be stored on REDCap (Research Electronic Data Capture) – a private, firewall-protected, HIPAA-compliant platform through which web-based information transmission is encrypted and through which users have unique IDs, passwords, role-specific access limitations, and audit trails. The PI (David Vago, Ph.D.) and study coordinator will grant and appropriately restrict access to these data by members of the research team on an as needed basis. After a participant verbally verifies his/her name and date of birth and completes relevant screening forms, behavioral observations, fMRI scans, EEG, and blood samples will be collected and maintained in a deidentified manner, separate from the key linking IIHI and subject ID numbers.

When findings from this study are disseminated, information will be presented in summary format such that no research participants can be individually identified.
Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr Vago and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

13. Authorization to Use/Disclose Protected Health Information
All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked laboratory tests (including fMRI data, EEG data, behavioral data, self-report data, blood-based biomarkers), as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, FOOD AND DRUG ADMINISTRATION, or NATIONAL INSTITUTES OF HEALTH. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Vago in writing and let him know that you withdraw your consent. Dr. Vago's mailing address is:

Osher Center for Integrative Medicine
3401 West End Ave. Nashville, TN 37212.

At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality. You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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I agree to provide permission for future contact in the event of follow-up research studies
☐ Yes ☐ No Initials _____

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date Signature of patient/volunteer

Consent obtained by:

Date Signature

Printed Name and Title Time