Internet-based Mind-Body Training for Brain Health (iMBT)

ClinicalTrials Identifier: NCT07019402

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The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**Internet-based Mind-Body Training (iMBT) for Brain Health**
Principal Investigator:	**Dr. Ruchika S. Prakash, Ph.D.**
Sponsor:	**National Institutes of Health**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study and that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

- The Clinical Neuroscience Laboratory at Ohio State University is conducting a pilot study to explore whether two different types of mind-body interventions can improve brain and cognitive health as well as reduce protein biomarkers associated with Alzheimer's disease. Participants who meet full criteria will be randomly assigned, like the flip of a coin, to one of two groups: an online mindfulness-based stress reduction group or an online lifestyle education group. Both programs were

developed by a team of psychologists, contemplative scholars, instructional designers, and adults aged 50 and older with concerns about their cognitive health.

- Participation in the study involves one in-person screening session, four in-person assessment sessions (two before training and two after training), and an online, self-paced, eight-week mind-body training program. All screening and assessment sessions will take place in the Department of Psychology at Ohio State University. The training will be offered through Ohio State's online ScarletCanvas platform, and you can complete it at your own pace.
- You will be compensated $15 per hour for completing any in-person assessments. Between the two assessment sessions, you will receive a smartphone to complete brief daily check-ins for five days. Each check-in will take about 10 minutes. For every day you complete the check-ins, you will earn an additional $10. You can earn up to $100 for completing all of the check-ins. Upon completing all assessments, you may receive a maximum total of $310. All participants will be compensated after completing their respective assessment session. Additionally, you will receive the mind-body training at no cost and will be provided with a Fitbit, which you can keep after the study is completed. Parking will be covered for all in-person sessions. We will also cover $40 each way in Lyft rides to and from The Ohio State University.

1. Why is this study being done?

Mind-body trainings are a group of practices aimed at improving physical, mental, and brain health. Recently, more people have come to recognize the strong connection between the mind and body. Research shows that these types of interventions can help reduce cognitive decline and boost brain health. However, many of these programs are only available in-person, and the number of trained professionals to lead them is limited. Because of this, there is a growing need to develop and test online mind-body programs that are fully self-paced.

Our team—which includes psychologists, contemplative scholars, instructional designers, and adults ages 50 and older with memory concerns—has developed two online mind-body programs: an online lifestyle education course and an online mindfulness-based stress reduction program. In this study, we aim to test whether these programs are practical and enjoyable for middle-aged and older adults who have cognitive concerns.

If you decide to participate and meet the eligibility requirements, you will complete a set of assessments before being randomly assigned (like the flip of a coin) to one of two groups. You will then receive access to your program through Ohio State's online ScarletCanvas platform used for distanced learning. The program is fully self-paced, and each week you will get new materials and activities. We expect participants to spend up to five hours per week, but you can choose when to fit that into your schedule. You will not need to come to campus for any part of the training. After eight weeks,

we will schedule follow-up assessments to see how the program has impacted your brain health.

2. How many people will take part in this study?

About 250 participants will be involved in this study. Individuals who participate in the study will be aged 50 years and older.

3. What will happen if I take part in this study?

We will begin by confirming that you meet the eligibility criteria to participate. You have already completed the web- and phone-based screening, and today, we will conduct the in-person screening. After this, you will complete two assessment sessions, which will be repeated after the eight weeks of training. Below is a detailed overview of the study components:

Screening and Assessments:
To measure the effects of the two mind-body trainings, all participants will complete assessments that examine thinking abilities, physical activity, blood-based changes in proteins implicated in Alzheimer's disease, and brain structure and function, both before and after the trainings. During these assessments, we will audio-record your voice while you complete some tasks to ensure accuracy in data collection. All efforts will be made to keep your study-related information confidential. There are three types of assessment sessions:

- Screening: In this session, you will complete computerized and paper-and-pencil tests to determine eligibility. If you do not meet the criteria, you will be notified and will not proceed with the study. This session will last approximately 3 hours.
- Assessment Session 1: In this session, a certified nurse from Ohio State's Clinical Research Center will collect blood (about four teaspoons, or 20 ml per visit) at two points: 1) before beginning the training, and 2) after completing the training. In total, you will provide about eight teaspoons (40 ml) of blood for the study. You will also complete questionnaires about your health behaviors, brain health, and quality of life. We will additionally administer computerized cognitive tasks to assess your thinking skills. You will also receive a smartphone to complete four brief daily assessments for five consecutive days between assessment sessions 1 and 2 for up to 10 minutes per assessment. The study coordinator will provide detailed instructions. This session will last 2 hours before training and 3 hours after training.
- Assessment Session 2: This session will include an MRI assessment to measure brain structure and function. Before the scan, you will have

completed a screening questionnaire to ensure there are no safety risks (such as pacemakers or implants). A trained MRI technician will collect your brain images using functional magnetic resonance imaging (fMRI), which measures blood flow changes related to brain activity, in addition to MRI scans showing brain structure. You will practice the tasks you will complete during the scan, and while inside the MRI, sensors will be attached to measure your pulse and breathing. This scan will last about 3 hours. Please note that the MRI scan does not use X-rays, contrast dyes, or radiation, and it is not meant to replace a clinical diagnostic scan reviewed by a radiologist. FDA safety guidelines for the MRI will be followed.

- After the scan, you will be randomly assigned to one of the two mind-body interventions. Additionally, we will provide you with a Fitbit to track your physical activity during the intervention, with instructions on how to use it. Your Fitbit data will be collected via the Fitabase platform. This session will last about 3 hours.

Summary of Assessment Sessions:
Participants will complete a total of four assessment sessions. Once eligibility is confirmed after the screening, participants will complete assessments both before and after the eight-week mind-body training. All assessment sessions will take place at The Ohio State University. Behavioral assessments will occur at the Clinical Neuroscience Laboratory, MRI scans at the Center for Cognitive and Behavioral Brain Imaging, and blood draws at the Psychology Building. Training sessions will be virtual through the online platform assigned to you.

Mind-Body Training Programs: Participants who qualify for the study will be randomly assigned to one of two intervention groups: iMBSR (internet-based Mindfulness-Based Stress Reduction) or iLifeEd (internet-based Lifestyle Education). Both programs are delivered through ScarletCanvas, Ohio State's online distanced learning platform. Each program consists of eight modules, designed to take about 2.5 hours per week. You can complete these modules at your own pace.

Additionally, we offer optional 30-minute "drop-in" Zoom/Teams sessions, where you can join a group conversation with a doctoral student in clinical psychology to ask questions and discuss the material. The modules combine educational content, hands-on practices, and opportunities for social support and community-building activities. You will also be encouraged to engage in homework using the online platform.

An important part of these programs is building community. You will be grouped with at least three other participants, called "buddies," to support each other during

the study. Although the trainings are self-paced, you can interact with your buddies through discussion boards in the online modules. You may also have the chance to attend the "drop-in" hours with them.

Below is a description of each program:

- **Internet-based Lifestyle Education Program (iLifeEd):** The iLifeEd program is an educational series that presents the latest research on healthy living and wellness, with a focus on supporting brain health as we age. Each week, participants will explore key topics such as reducing sedentary behavior, increasing physical activity, engaging in mentally stimulating activities, building social support, improving sleep, managing stress, and optimizing nutrition and hydration.

  In addition to the educational content, participants will be introduced to light stretching and toning exercises, included in the 2.5-hour weekly modules. These exercises, designed by a certified yoga instructor, aim to promote flexibility and overall well-being.

  To reinforce what you learn, participants will complete homework assignments, including:
    - Light stretching and toning exercises.
    - Watching one or two short videos and answering related questions.

- **Internet-based Mindfulness-Based Stress Reduction (iMBSR):** The iMBSR program is based on the renowned MBSR approach developed by Jon Kabat-Zinn. This eight-week series introduces key mindfulness practices aimed at cultivating present-moment awareness and promoting an attitude of acceptance and non-judgment. The MBSR program has been used successfully worldwide to improve mental health, cognitive function, and brain health.

  Each week, participants will access a 2.5-hour module through the online platform. These modules include a blend of mindfulness exercises, educational lessons on stress reduction, and gentle movement practices. The movement exercises, led by certified mindfulness instructors, encourage participants to incorporate mindfulness into their daily routines.

  To reinforce the lessons, participants will be invited to complete the following weekly homework practices:
    - Guided meditation
    - Reflecting on and answering questions related to mindfulness concepts.

4. How long will I be in the study?

Study participation will take place over a period of up to six months. The time commitment before the mind-body training includes: screening session (3 hours), pre-training assessment session I (2 hours), and pre-training assessment session II (3 hours).

After completing the training, the assessments will include: post-training assessment session I (3 hours) and post-training assessment session II (3 hours).

In total, you will spend approximately 14 hours on screening and assessment sessions. You will be compensated $15 per hour for your time during these sessions.

The two 8-week mind-body programs will consist of weekly 2.5-hour training sessions, totaling 20 hours. The training programs are provided at no cost to you. However, please note that you will not receive compensation for participating in the training sessions.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

The overall risks of participating in this study are considered minimal. However, as with any research, there are some potential risks involved. Below, we outline these risks to ensure you are fully informed about what to expect during the study.

Screening & Assessment Sessions: During the screening and assessment sessions, we will collect protected health information, including biometric data and details about psychiatric history and substance use. While we take every measure to protect your privacy, there is a potential risk to your reputation or legal standing if this information is accidentally disclosed. To minimize this risk, all confidential information will be stored securely, and only key research personnel, trained in research ethics, will have access to your data. Your identity will be removed from all research information and replaced with a code to protect your confidentiality.

Some of the tasks or questionnaires may touch on sensitive or personal topics, which could cause discomfort or stress. If, during the study, it is determined that you may need medical attention, we will provide appropriate referral information. Although this study does not specifically assess suicide risk, if you disclose thoughts of self-harm or suicide, we are required to break confidentiality to ensure your safety. We will first talk to you about your options, such as therapy or voluntary hospitalization. In cases of severe risk, involuntary hospitalization may be considered, but this would only happen after discussing all available options with you.

Additionally, some participants may experience temporary discomfort and mental fatigue when responding to the daily assessments of cognition.

Blood Draw: During the blood draw sessions, the risks are minimal but include slight pain from the needle and the potential for a bruise at the puncture site. In rare cases, fainting or infection may occur. A trained phlebotomist or registered nurse will follow sterile procedures to minimize these risks.

MRI Scans: There are no known significant risks associated with the standard MRI procedure at this time. There are strict federal guidelines for radio wave exposure, and our examinations comply with these guidelines. We believe these levels are safe and present less risk than a comparable X-ray or computed tomography (CT) scan. Ambient noise from the MRI scanner can reach approximately 130 decibels. To reduce the risk of potential hearing shifts, you will be provided with hearing protection (e.g., disposable earplugs), and padding will be placed around your head to reduce scanner noise. Proper insertion of earplugs is strongly recommended to limit any potential risk of long-term hearing shifts. Participants with hearing issues (e.g., tinnitus) should discuss their condition with the research staff before completing an MRI scan.

However, there are certain conditions that will make a participant ineligible for the MRI due to safety concerns. Because metallic objects are strongly attracted to the magnet, it is critical that you inform us of any metal objects, devices, or implants that are in or on your body before entering the magnet room. This includes biomedical devices such as pacemakers or cochlear implants, as well as any metal fragments from previous injuries (e.g., bullets, buckshot, shrapnel) or work involving metal. All other metallic objects must be removed from your body before entering the magnet room to prevent them from being pulled by the magnet. These items include keys, jewelry, pocketknives, money clips, paper clips, safety pins, hairpins, and barrettes. Additionally, objects such as watches, credit cards, and hearing aids may be damaged by the magnetic field. A locker will be provided to secure your items and valuables. It is important that you notify us of any metal objects, devices, or implants that cannot be removed. These include:

Certain medical implants containing metal, such as a cardiac pacemaker or metallic clips (e.g., aneurysm clips in the brain).

- Any previous work with metal or a history of having metal removed from the eye(s).
- The presence of shrapnel, bullets, or buckshot in the body.
- Any other metallic objects that cannot be removed (e.g., jewelry).
- If you are pregnant or trying to become pregnant, you will not be eligible for the MRI as the effects of the scan on a fetus are unknown. Female participants who agree to complete the study will self-report their pregnancy status.

There are several additional risks associated with the MRI environment. The experimenter and/or MRI technician will check in with you regularly to ensure your comfort. You will also be given a call button to stop the scan at any time if you experience any discomfort.

- There is a risk of heating metal objects, such as wires, due to radio wave exposure. Please report any heating or burning sensations immediately.
- You may experience localized twitching sensations caused by magnetic field changes during the scan. This is not unexpected and should not be painful.
- Dizziness or nausea may occur briefly when your head moves in or out of the scanner tunnel. This sensation typically fades quickly.
- You may experience claustrophobia, a fear of being enclosed or having no escape.

Incidental Findings:

All imaging hardware and software used at the Center for Cognitive and Behavioral Brain Imaging at OSU are FDA-approved for medical applications. The MRI scans you will receive during this study are strictly for research purposes. These are not clinical scans and are not intended for diagnostic or therapeutic purposes, meaning they cannot rule out subtle or faint medical issues. The Center for Cognitive and Behavioral Brain Imaging is a research facility, not a clinical MRI center. Please note that the Principal Investigator (PI), Co-Is, and students involved in the study are not trained neuroradiologists, so the MRI scans do not replace any necessary clinical MRIs.

However, one structural scan obtained from each research participant will be sent to an off-site neuroradiologist for review. If the neuroradiologist detects any abnormalities, the Center staff will forward the findings to the primary care physician (PCP) you provided on the screening form within one month of the scan. You and your PCP will receive letters alerting you to any significant abnormalities. If you receive such a letter, it is important to follow up with your PCP. The neuroradiologist

will be available to consult with your PCP if necessary. Any costs associated with seeing your PCP will be your responsibility. If you cannot designate a PCP, you will not be able to participate in the study. Please provide the following contact information for your primary care physician:

Name: _____

Phone number: _____

Address:

_____

_____

_____

_____

Normal scan results will be processed within one month after the study and will not be communicated to your primary care physician.

If you are planning to obtain or change health insurance coverage in the future, you should be aware that in the unlikely event an incidental finding is detected (an unknown condition not recognized as part of any current neurological condition), the discovery of a previously unknown condition may be considered a "pre-existing condition" by the health care provider or insurer. For this reason, you may choose to opt out of the study.

Training Sessions:
Training sessions are conducted online through Ohio State's ScarletCanvas platform, where although you will complete weekly modules on your own, you will have access to discussion forums and Zoom/Teams "drop-in" hours, where you will engage with other participants in the study. While we encourage a sense of community, there is a risk to confidentiality since we cannot fully guarantee that other participants will maintain privacy. However, all participants are asked to respect each other's confidentiality as outlined in the consent form.

7. What benefits can I expect from being in the study?

During the training sessions, you will be exposed to information regarding lifestyle change to promote brain health that may be useful in your daily life. Additionally, you are allowed to keep the Fitbit that you are provided for the study.

The information gained from this study will also be helpful in providing valuable knowledge about the basic cognitive and emotional effects related to different mind-body practices. Your participation is critical for our understanding of the human brain, which in turn, will help us design interventions to help protect against the cognitive and emotional changes that may come along with aging.

However, we cannot and do not guarantee or promise that you will receive any benefits from this study.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no anticipated costs to you for participating in the study. The activities of the study are provided to you at no cost. Should medical attention be necessary, such services will be made available to you, but payment for those services will be your responsibility and/or that of your insurance carrier.

10. Will I be paid for taking part in this study?

You will be compensated for all screening and assessment sessions at $15/hour. We are anticipating pre-training assessments to be roughly around 8 hours, totaling to $120. Additionally, for post-training assessments, you will be compensated for 6 hours, totaling to $90.

Between the two assessment sessions, you will receive a smartphone to complete brief daily check-ins for five days. Each check-in will take about 10 minutes. For every day you complete the check-ins, you will earn an additional $10. We will be doing these check-ins before the mind-body training and after the mind-body training. You can earn up to $100 for completing all of the check-ins.

We will also provide free parking for all sessions. We will also cover Lyft rides from our OSU Lyft account up to $40 each way to attend in-person screening and assessment sessions.

You will additionally receive one of the two mind-body intervention programs for free of cost and receive a Fitbit that you are free to keep once the study is completed.

After you have been enrolled into our study, you can refer a potentially eligible friend or family member to the study for an additional $5. If the person you refer to our study completes the eligibility survey, you will receive an additional $5 up to a maximum limit of $35 in referral payments.

You are also free to withdraw from the study at any time and are entitled to receive the incentives that have built up to the time of your withdrawal. By law, payments to participants are considered taxable income.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, deidentified information will be used or shared with other researchers without your additional informed consent. The NIH has issued a Data Management and Sharing (DMS), effective January 25, 2023, to promote the sharing of scientific data.

There are multiple benefits to sharing scientific data, and ultimately this will facilitate the development of treatments and products that improve human health. All de-identified participant-level data, including data collected during assessment sessions, including but not limited to paper-and-pencil measures, daily activity data, questionnaire data, MRI data, and protein data extracted from the blood will be made available on a publicly accessible open data repository. NO identifying data will be made available, and no reflections collected during the training programs will be shared. Your blood sample will be stored for future potential analyses related to Alzheimer's disease that are within the scope of this study and kept indefinitely until they are used up. Additional tests may be performed on the samples and neither you nor any future legally authorized representative will ever be told of the results of this future analysis performed on your blood sample.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The National Institutes of Health (NIH) and its authorized representatives;
- Your insurance company (if charges are billed to insurance).

If we find information that significantly impacts your health, we will share it with you. If the neuroradiologist detects any abnormalities when reviewing your structural MRI scan, the Center staff will forward the findings to the primary care physician (PCP) you provided on the screening form within one month of the scan. You and your PCP will receive letters alerting you to any significant abnormalities. If you receive such a letter, it is important to follow up with your PCP.

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

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
  - The diagnosis and treatment of a mental health condition
- Records about any study drug you received;
- Records about the study device

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;
- Others:
  - Health care facilities, research site(s), researchers, health care providers, or study monitors involved in this study. To process the blood data for this study, we will be sharing blood samples with Dr. Elizabeth Head, a professor at University of California at Irvine.
  - The research sponsor and companies owned or connected with the sponsor: National Institutes of Health.

- Contract Research Organization(s): University of California at Irvine
- Your primary care physician or a physician that may have performed any kind of surgery on you that involved placement of metallic/non-metallic implants in your body. This is done to ensure that you are in fact safe to be scanned in an MRI scanner. Please provide name and phone number below of any physician that we may need to contact directly to obtain your medical records.

The information that is shared with those listed above may no longer be protected by federal privacy rules.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact *Ruchika Prakash, Ph.D. at Prakash.30@osu.edu or a member of her research staff at (614) 292-9568 or ra_cnl@osu.edu.* Dr. Prakash is the Principal Investigator for this study.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the *Office of Compliance and Integrity, The Ohio State University Medical Center, privacyoffice@osumc.edu, 614-685-3765*

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact *Ruchika Prakash, Ph.D. at Prakash.30@osu.edu or a member of her research staff at (614) 292-9568 or ra_cnl@osu.edu.*

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM**
	Date and time

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time