

## UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**Study Title:** EMBODY Study-Evaluating Multivariate MRI Maps of Body Awareness: A pilot functional magnetic resonance imaging (fMRI) investigation (consent for Phase 2: fMRI Session)

Helen Weng, Ph.D., and Frederick Hecht, M.D at the UCSF Osher Center for Integrative Medicine and Adam Gazzaley, M.D., Ph.D. at the UCSF Neuroscience Imaging Center are conducting a research study to measure body awareness (paying attention to sensations in the body) using brain imaging. The study researchers will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers. You should only participate in the study if you really want to.

You are being asked to take part in this study because you are a healthy adult volunteer (18 years or older), are interested in having a brain scan, and may or may not have experience with mind-body practices such as meditation or yoga.

### **Why is this study being done?**

The purpose of this study is to develop a new task using functional magnetic resonance imaging (fMRI) to measure when people are paying attention to sensations in their bodies and when they are thinking about something else.

The study is being paid for by internal UCSF funds and/or a grant from the National Institutes of Health.

### **How many people will take part in this study?**

About 15 people will take part in this phase of the study to test a fMRI thinking and feeling task.

### **What will happen if I take part in this research study?**

If you agree, the following procedures will occur:

- Procedures that have already been completed include completing the online screening questionnaire and/or the phone screening, and the pre-visit online questionnaires.
- **Study Visit: Magnetic Resonance Imaging (MRI) session.** You will take part in a fMRI testing session at the UCSF Neuroscience Imaging Center (NIC) at the Mission Bay campus. Upon arriving at the NIC, we will go over study procedures with you again, and you will provide verbal and written consent to participate in the study. We will train you on instructions to pay attention to body sensations and on other cognitive tasks. The kinds of tasks you will engage in include 1) listening to audio instructions and sounds, 2)

viewing pictures of words, letters, and/or symbols, 3) paying attention to sensations in your body, 4) performing cognitive tasks such as a memory task with letters, 4) thinking about whatever is going on in your mind, 5) thinking about what you have going on for the day. During some tasks, you will be asked to respond by pressing a button.

In the fMRI study, we will use a magnet to measure blood flow to your brain. We use the fMRI to study which parts of your brain are most active while you do different cognitive tasks. You will be asked to lie down on a platform that can be slid into the middle of a magnet. A plastic MRI imaging coil will be placed around your head. You will not come into contact with the coil during the experiment. Before you enter the scanner, you will wear 1) headphones during the experiment to hear the instructions and so that we may communicate with you, 2) a Velcro belt around your stomach to measure your breathing, 3) a rubber ring on your finger to measure your heart rate, and 4) be given a ball you can squeeze if you need to stop the experiment at any time. Foam pads will be placed around your head to limit head movement during the experiment. We will then slide you into the magnet. During the scan, you will be instructed to rest with your eyes opened or closed, or will be asked to do the tasks from the training session. It will take about 90 to 120 minutes. After the fMRI scans, we may ask you additional interview questions about your experience doing the tasks. The interview will be audio recorded and securely stored. The entire session should last no more than three and one-half hours.

### **How long will I be in the study?**

Participation in the study will take a total of about 4.5 hours (15-min online screening (for some participants), 30-min phone screen, 30-min online questionnaires, 3-hour fMRI session) over a period of 2-4 weeks.

### **Can I stop being in the study?**

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study. Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

### **What side effects or risks can I expect from being in the study?**

- Questionnaires, interviews about experience in the scanner, and self-assessment: Some of the questions may make you uncomfortable. This may potentially bring up upsetting feelings, and you are free to decline any questions you do not wish to answer. You may feel tired, frustrated or bored when filling out the forms.
- Body sensation tasks: Some people may notice discomfort in certain body areas when asked to pay attention to those areas. You are free to stop the task at any time. Some people may experience boredom or sleepiness.
- Cognitive Tasks: You may experience mental fatigue or boredom as minor risks.
- fMRI: The levels of energy used to make fMRI measurements are far less than are used in a single X-ray, and many patients have been safely studied using MRI techniques. While there

are no significant risks from fMRI as it is to be performed, the fMRI procedures can be risky for people with pacemakers or metal in their bodies. We will not ask you to participate in the fMRI if you have a pacemaker or any metal in your body that cannot be easily removed. Some people get claustrophobic in the MRI scanner. If you have a history of claustrophobia, we will not ask you to participate in the fMRI study. Because the fMRI scan makes loud noises, we will give you ear plugs to dampen the sound. You may also experience peripheral stimulation, which will feel like a gentle tap or sensation of mild electric shock. If you do not like being in the scanner for any reason, we will immediately stop the experiment.

- We do not know if the fMRI procedure is associated with risks to an unborn fetus. We ask that all women of child-bearing age take a pregnancy test before participating. This is an “over-the-counter” pregnancy test that identifies pregnancy through a urine sample. We will give you the test kit for you to take by yourself, in private, in the bathroom. If you are pregnant, it is important that you tell the experimenter that you cannot participate in the fMRI scan.
- Physiology Monitoring during fMRI scan: The procedure is not painful and will not cause you any physical harm. If you feel uncomfortable during the testing, you should tell the study staff, so that they can fix the problem or stop the testing.
- Study findings: Participants will have the option to obtain study results, including MRI scans and basic behavioral analysis. These data are collected for specific research purposes and are not optimized to find medical abnormalities; therefore, they should not be used for clinical decisions should you consult with your physician or other healthcare provider. The investigators and UCSF are not responsible for failure to find existing abnormalities with these MRI scans. The investigators and UCSF are not responsible for any examination or treatment that you undertake based on these findings.
- For more information about risks and side effects, ask one of the researchers.

**Are there benefits to taking part in the study?**

There will be no direct benefit to you from participating in this study. However, the information that you provide may help researchers better understand how mindfulness and body-based interventions may impact people’s ability to pay attention to body sensations.

**What other choices do I have if I do not take part in this study?**

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you.

**Will information about me be kept private?**

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include: UCSF's Committee on Human Research to University of California (for the protection of human subjects research).

Research records will be kept as confidentially as possible. All data collected will be coded with a study number (no names will be used). Questionnaire responses are confidential and will not be shared with people outside the study. Every reasonable effort will be made to keep your records confidential. All data will be stored in a locked file cabinet only accessible to the study team, and all electronic data will be stored on password-protected computers.

**What are the costs of taking part in this study?**

You will not be charged for any of the study treatments or procedures.

**Will I be paid for taking part in this study?**

In return for your time, effort and travel expenses, you will be compensated \$15 for completing online questionnaires, \$60 for the fMRI testing, and up to \$20 for travel and parking costs. You will be paid with a gift or debit card, or cash.

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

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you in any way.

**Who can answer my questions about the study?**

You can talk to the researchers about any questions, concerns, or complaints you have about this study. Contact the researcher Helen Weng, Ph.D at [Helen.Weng@ucsf.edu](mailto:Helen.Weng@ucsf.edu) or 415-514-8601.

If you have any questions, comments, or concerns about taking part in this study, first talk to the researcher above. If for any reason you do not wish to do this, or you still have concerns after doing so, you may contact the office of the Committee on Human Research, UCSF's Institutional Review Board (a group of people who review the research to protect your rights).

You can reach the CHR office at 415-476-1814, 8 am to 5 pm, Monday through Friday. Or you may write to: Committee on Human Research, Box 0962, University of California, San Francisco (UCSF), San Francisco, CA 94143.

**CONSENT**

You have been given a copy of this consent form to keep.

**PARTICIPATION IN RESEARCH IS VOLUNTARY.** You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Signature for Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent

Future contact with this study:

This consent form only covers study assessments up to 1 year. If researchers are able to follow up with participants in this study in future years, they will contact you if you check this box.

Future contact for other studies:

There are other studies that you may be eligible for in the future. UCSF may contact you to invite you to participate in other research studies if you check this box.