Cambridge Health Alliance A COMMUNITY OF CARING	**INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH**

We try to make this form easy to understand. But it may have words or ideas that are not clear to you. Please ask the study doctor or study staff to explain anything you do not understand.

You may take this form home with you to discuss with family or friends before you decide whether to be in this study.

Study Title:
Mindful Self-Regulation fMRI Study (MindfulPCfMRI)

Funding Title:
Mindfulness Influences on Self-Regulation: Mental and Physical Health Implications (fMRI Study)

Your name (Participant):	**Today's Date:**

Not including the MINDFUL-PC study, are you taking part in any research now? ☐ **Yes** ☐ **No**

Name of Principal Investigator: Zev Schuman-Olivier, MD

NIH Common Fund Science of Behavior Change Collaboration -- Principal Investigators:
Eric Loucks, PhD; Willoughby Britton, PhD; Jean King, PhD

Name of Co-Investigator(s): Gaelle Desbordes, PhD; Vitaly Napadow, PhD; Michael Datko, PhD; Richa Gawande, PhD.

Consent form version date or number: Version 2

Name and telephone number of study contact to call with questions: **Michael Datko**
Tel: 619-851-7381

CHA IRB Number: CHA-IRB-1002/08/14 **IRB Approval Date:** January 25, 2019 **IRB Expiration Date:** October 8, 2019	**Study Sponsor(s):** NIH Science of Behavior Change Initiative/National Center for Complementary and Integrative Health (UH3AT009145)

About this Consent Form

Please read this form carefully. It tells you important information about an additional optional functional magnetic resonance neuroimaging study (fMRI study). The additional optional study is part of the study "Integrating Mindfulness into the Patient-Centered Medical Home" (MINDFUL-PC). The fMRI study is open to MINDFUL-PC participants who are eligible. If you have any questions about the research or about this form, please ask us.

If you decide to take part in this fMRI study, you will be asked to sign this form. You will be given a copy of the signed form. Please keep your copy for your records. It has information including important names and telephone numbers, for future reference.

Taking part in this study is voluntary. You can choose to take part or not. If you take part in the study, **you may leave the study at any time for any reason**. If you don't want to take part in the neuroimaging

study, you can still participate in the main MINDFUL-PC study and participate in the mindfulness group. Also, it does not change any of the standard health care you receive at Cambridge Health Alliance (CHA).

Introduction

Mindfulness is paying attention, on purpose, to the present moment in a non-judgmental way. Regular mindfulness practice has effects on the brain. This research aims to study the brain changes that may happen when a person takes part in a CHA mindfulness group

Only a small group of all MINDFUL-PC participants will participate in this study. We will perform brain scans at the Massachusetts General Hospital Athinoula A. Martinos Center for Biomedical Imaging (Martinos Center) located at 149 13th Street, Charlestown, MA.

The NIH Common Fund Science of Behavior Change Initiative and the National Center for Complementary and Integrative Health (NCCIH) is providing funding for this research. NCCIH is one of the centers within the National Institutes of Health (NIH).

Purpose of the Study

This study will look at the effects on the brain of the MINDFUL-PC program. We will use fMRI scans to compare brain activity before and after this program.

New Findings

We will tell you about new findings that may cause you to change your mind about being in this study.

Reasons why you have been invited to be in this study

You are currently a patient at Cambridge Health Alliance (CHA). You have been invited because your primary care provider is also participating in the MINDFUL-PC study and you are hoping to start an 8-week mindfulness group.

To take part in this study you will have to meet the following criteria:

- You are ages 21-60 years.
- You have been chosen to participate right away in the mindfulness group for the MINDFUL-PC study.
- You have no current meditation or yoga practice of more than 30 min a week.
- You also don't have previous meditation experience of more than either:
    - 10 minutes a day of current mindfulness meditation practice.
    - 200 hours of total lifetime meditation practice (non-Mindfulness-Based-Intervention (MBI)).
    - More than 63 lifetime hours of MBI-related mindfulness practice.
- You have a diagnosis of history of depression, dysthymia (a continuous long-term form of depression), generalized anxiety disorder, or current mild to moderate anxiety or depressive symptoms.
- You do not have a current severe panic disorder, active or severe post-traumatic disorder, psychosis, or suicidal thoughts.

We will review these criteria before the phone screening, based on the answers you provide as part of your participation in the MINDFUL-PC study

- You are able to abstain from drinking alcohol and using cannabis for at least 3 days prior to the fMRI measurements.
- You do not currently use cannabis in any form more than twice per month.
- You are able to not use any illicit drugs during the 12 weeks of this study.
- You do NOT have past severe head trauma.
- You have NOT had brain surgery.
- You have normal or corrected vision (contact lenses only).
- You are right handed.

We will review these criteria with you during the phone screening to make sure you can safely be scanned in the MRI scanner:

- You do not have Meniere's disease, epilepsy, or strong claustrophobia.
- You do not have a cardiac pacemaker, prosthetic heart valve, neurostimulator, cochlear implants, or surgical aneurysm clips.
- Have NO metal in your body or your eye from working with metal or from an injury.
- You have NO metal rods, plates, screws or other metal implants in your body.
- Women: You are NOT currently pregnant or breastfeeding or planning to conceive or breastfeed during the study.
- You do not use an IUD containing metal.

Dentures and some types of metal implants are safe for fMRI. We will review these devices with you during the phone screening. We will then assess the safety of the device with the fMRI physicist at the Martinos Center. We will then let you know if it is safe for you to undergo the fMRI.

If your weight is greater than 250 lbs, the scanner might be too tight to scan you. We will decide with you, based on additional measures, like head circumference.

If you have a vascular disease in your leg(s), or a severe skin disease, the equipment used for the experiment might not be safe for you to be in the fMRI study. We will review the disease with you and let you know if it is safe for you to participate.

Tattoos and transdermal patches containing metal are not safe for fMRI scans. We will discuss this during the phone screening.

You should be able to complete the tasks required during the fMRI scan. These are described below.

We may have limited schedule times for the fMRI study. In these cases, we will invite interested participants to participate in the fMRI study based on their availability for scheduling.

Period of Participation (how long you will be in this study)

If you choose to be part of this fMRI research study, **you will participate for 10-12 weeks**.

You will have an imaging appointment **1-2 weeks before** and **1-2 weeks after** the mindfulness group.

This fMRI study will be in addition to the MINDFUL-PC study. This means you will also fill out all questionnaires related to the main MINDFUL-PC study. The period of participation for the main study is 6 months.

Procedures (what will happen during this study)

In this study, you will have been randomly selected to participate in a **mindfulness group**, and you will have an fMRI scan at the Martinos Center before the group starts and after it ends. Each scan will last 1.5 hours. You will perform 3 different types of tasks in the scanner. The tasks will be explained to you before each scan. They are related to attention and emotions.

One task will involve short periods of harmless pain stimulation (medium intensity). This pain simulation will involve a pressure cuff being placed on your leg.

During and after the scan, you will also answer questions related to your experience with the tasks.

Participation is voluntary. If you are not interested, you may still participate in the mindfulness group. If you feel you need to stop, then you can stop at any time.

We ask you NOT to participate if you expect to be hospitalized in the next 2 months for a health problem. We will ask you NOT to participate if you expect to go to jail in the next 2 months. We will ask you NOT to participate if you are breastfeeding, pregnant or trying to become pregnant within 12 weeks of enrolling in this study**.**

Pre-Group Scan:

The pre-group fMRI appointment will take about 2.5 hours.

- The first 30 minutes will involve preparation. During this time we will explain the procedure to you, perform a salivary drug test, ask you to take a pregnancy test if you are a woman of childbearing age, and prepare you for the scan. If any test is positive, you will not be able to participate in this study. Individuals who have had a surgical implant to prevent pregnancy (tubal ligation, IUD) or who are post-menopausal will not be asked to take a pregnancy test.
- We will ask you to lie in the MRI scanner while we take pictures (called scans) of your brain. You will lie on a table. Your upper body will be placed in a narrow horizontal cylinder inside a large magnet. We will ask you to lie as still as possible during the scans.
- You will wear earplugs to protect you from the noise that the MRI scanner makes.
- Several sensors will be attached to your body. These sensors will measure your heart beat, blood oxygen level, skin temperature, skin conductance, and breathing rate. These sensors include electrocarciogram (ECG) electrodes (stickers placed on your skin that are easily removed). These sensors also include electrodes attached to your finger to measure your pulse. There will be other sensors attached to your fingers (skin conductance sensors, skin temperature sensors). There will also be a belt around your belly or chest designed to measure your breathing movements.
- The time you will spend inside the MRI scanner will be up to 1.5 hours.
    - We will ask you to perform several thinking tasks in the scanner. We will give you detailed directions about how to perform these tasks.
    - One of the tasks will be to alternate between paying attention to your heart beat and paying attention to images on the screen.
    - Another task will be to read about critical situations and to imagine yourself being self-critical or self-reassuring in these situations.
    - Another task will give you short, medium-painful pressure pain on the leg using a leg cuff. This is similar to cuffs used for measuring blood pressure. Pain will last for periods of 30 seconds. The pain is of medium intensity and harmless.
    - At times, you will simply rest with your eyes open while doing nothing in particular.

After-Group Scan:

After the mindfulness group, you will have another fMRI appointment. The screenings and tasks will be the same as during the pre-group scan.

Electronic Medical Records:

We will collect brain and brain-activation data. We will also collect breathing and heart rate and skin conductance. We may look at your prescribed medications and other health information to analyze the brain data. This information includes height and weight. This information also includes your health-related behaviors, your mood, and the visits that you made to the hospital and to your primary care provider. You can choose to leave the study and remove our access to your data at any time.

Possible Risks, Discomforts, Side Effects, and Inconveniences

Risks of MRI/fMRI scan

The MRI system will be operated in a manner accepted by the US Food and Drug Administration. There are no known or foreseeable risks or side effects associated with conventional MRI/fMRI procedures, except to individuals who have electrically, magnetically or mechanically activated implants, such as cardiac pacemakers, ear implants, shrapnel injuries, electronic implants, certain intra-cranial aneurysm clips and/or other types of metal or electronic devices in their body (including some surgical implants and some tattoos). You will be

screened for these conditions prior to entering the study, and again prior to each MRI/fMRI scan. During the MRI/fMRI scan you will lie on a table that slides into a horizontal cylinder that is slightly wider than your body. If you feel anxious or scared when in a tight space, these feelings could happen while in the MRI machine. Also, you might feel uncomfortable from the noise that the MRI scanner makes. Earplugs and additional padding around your ears will be provided to help reduce this noise. You will be able to communicate with the research staff at all times during the scan. If you become uncomfortable in the machine tell the researchers and the procedure will be stopped.

Risk of Incidental Findings

These scans are being performed for research purposes only. The results will not be used to make decisions related to your diagnosis or regular care. The MRI/fMRI scans being performed in this study are not designed to examine your brain medically. These scans are not a substitute for one a doctor would order. They may not show problems that would be picked up by a medical MRI scan. However, if we believe a scan shows a condition that could affect your health, we will ask a doctor who is trained in the reading of MRI scans, a radiologist, to help us review the scan. If the radiologist thinks that there may be an abnormality in your MRI scan, you will be contacted by us and referred for follow-up care. Also, sensors monitoring your heartbeat might show some abnormalities. In this case, you will be contacted and referred for follow-up care. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.

Risks related to the tasks in the scanner

During this study, you may experience pain while inflating the cuff device during the pain task. You may also experience mild bruising associated with inflation of the cuff. The pressure from this cuff is controlled to be within a safe and tolerable range. If you feel distress while wearing the cuff, you can tell the researchers to stop. If you have peripheral vascular disease, varicose veins or lymphedema in both your legs, you may not be able to take part in the study, or may need to have the cuff on the unaffected leg if you choose to participate in the study. If any of the pain you feel is too uncomfortable, you may stop this specific task immediately, or you may immediately withdraw your participation from the study and leave. If you have any discomfort or concerns after this task, you call the principal investigator, Dr. Zev Schuman-Olivier, at 617-591-6056 or contact the Behavioral Health Communication Center for CHA Psychological Services at 617- 665- 1560. To be clear: you may immediately end your participation if the task makes you feel too uncomfortable to continue.

Alternatives to Participation

Participating in this fMRI study is voluntary. You may choose not to participate in this optional study and continue to participate in the main mindfulness study. Whether or not you are enrolling in the study will not affect your health care at CHA.

Benefits (good that may come from being in this research)

Participation in the fMRI study will not help you directly. However, what we learn from brain research may help others in the future.

Costs

There are no costs to be in the fMRI study. The time related to study survey visits and procedures will be given to you at no cost.

Payment

You will be paid $5 in pre-paid card or gift card for completing the informed consent and drug screenings at the pre-group scan. You will be paid $5 in pre-paid card or gift card for completing the drug screenings at the post-group scan. You will be paid $50 in pre-paid card or gift card for the pre-group scan session. You will be paid $50 in pre-paid card or gift card for the post-group scan. You will also receive either free parking at Martinos or $10 in pre-paid card or gift card supporting public transport or taxi costs to the Martinos Center for each visit.

You will only be paid for each scan session that you complete and for completing informed consent and both drug screenings. You will be given your payment at the end of each scan session. If you complete the informed consent, the drug screenings and every scan session in this study, **you will be paid a total of $110 in** pre-paid card or gift card **for your time. You will also receive free parking or $20 in** pre-paid card or gift card **for transportation.**

Study-Related Injury

If you get hurt or get sick as a direct result of being in this study, emergency treatment will be given to you. All needed emergency care is available to you, just as it is to the general public. Any needed medical care is available to you at the usual cost. You or your insurance carrier will have to pay for any such medical care.

Cambridge Health Alliance has not set aside any money to pay for a research-related injury or illness. There are no plans to pay for your treatment if you get hurt or sick as part of this study.

Voluntary Participation

Taking part in this optional fMRI study is voluntary. If you do not take part you will not be punished or lose benefits that you have the right to receive. The quality of your medical care will be the same at Cambridge Health Alliance whether you take part in the study, refuse to take part, or decide to leave the study.

If you choose to take part and then decide to stop, tell a member of the research team. It may not be safe for you to suddenly stop being in this study. The study team will help you stop safely.

Any information collected from you before the date you leave the study will be used in the research study.

The research team may decide that you can no longer be in the study. This could be for several reasons, including:

1. You have had a bad reaction to the study.
2. You did not follow all the study rules.

Privacy / Confidentiality

There are laws (state and national) that protect your health information to keep it private. We follow those laws. Your identity, medical records, and study data will be kept confidential, except as required by law.

We will protect all of your health information, including your Protected Health Information or "PHI." Your PHI is your individually identifiable health information.

The MRI scans will not have your identifiable information (name, address, telephone number, etc.) in it. Instead, a unique study ID is used to store this data. However, we will add your year of birth to the data, as it would be relevant in case a radiologist reviews your scans.

If you take part in this study, you agree to let the research team at CHA and MGH/Martinos Center use your medical information. Do not take part in this study if you do not want the research team to access your health information.

We will follow these guides:

- The research team will view your health information only during this study.
- We will not include any information that could identify you in any publication.
- At the end of the study, we will remove all of your identifiable information (name, address, telephone number, *etc.*) from the study database.

We will make every effort to keep your information private, but we cannot guarantee it. The Cambridge Health Alliance Institutional Review Board (IRB) is responsible for protecting the safety and welfare of people who take part in research studies at our hospital. IRB staff may ask to look at any research records to make sure the study team is following the laws and rules to protect you. Certain government agencies, including the Office for Human Research Protections and the U.S. Food and Drug Administration (regulates drug and device studies), may also look at records that identify you.

Sometimes, we are required to share your study records with others, too, including:

- Other researchers conducting this study at CHA and MGH/Martinos Center,
- The study sponsor and any companies that the sponsor uses to oversee, manage, or conduct the study,
- Data and Safety Monitoring Board (this is an independent group of experts who monitor study participant data and safety while a study is taking place),
- Clinical staff not involved in the study, but involved in your regular treatment,
- Insurance companies.

If any of these groups ask to look at your information, then we cannot prevent it from being shared. Once information is shared, we cannot guarantee any further confidentiality and privacy.

Your drug screening results will have extra protection. We will not keep these results in your medical records. Orders for testing and results will only be retained in your research records. Further, we will apply for a Certificate of Confidentiality, which will allow us to withhold this information from subpoena.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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 t me.

Period of Authorization

Your authorization on this research project will expire 10 years after completion of data gathering for the study. If you change your mind and want to withdraw your authorization please tell a member of the study team or write to the HIPAA Privacy Officer for Research, Cambridge Health Alliance, 1493 Cambridge Street, Cambridge, MA 02139. If you withdraw your authorization, you may no longer be allowed to participate in the study described in this form.

Getting Help (Contacts)

If you have questions about this study please ask a member of the study team. Some questions people have:

- What are the risks and benefits of being in this study?
- What are my rights as a research participant?
- What should I do if I feel pressured to take part in this study?
- How is my health information used in this study?
- How will my health information be protected?

Call the study investigators for answers to any study-related questions or if you get hurt or sick as a result of being in this study. This is how to contact us Monday to Friday during regular business hours:

Zev Schuman-Olivier, MD (Principal Investigator)
My Ngoc To (Research Coordinator)
Richa Gawande, PhD (Program Manager)
MINDFULPC@challiance.org
617-591-6055

Michael Datko, PhD (Post-Doctoral Fellow - Neuroimaging)
mdatko@challiance.org
619-851-7381

If you have questions about your rights as a study participant please contact either the IRB office or the Patient Relations Department. The offices are open Monday to Friday (not holidays) from 8:30am until 5:00pm:

IRB Chair: Dr. Lior Givon
Telephone: 617-806-8702

Patient Relations Manager: Lorraine Vendetti
Telephone: 617-665-1398

Signature of Consent

I, the study participant, have read this form or it has been read to me. I understand my part in this study and have had my questions answered to my satisfaction. I agree to take part in this research study.

_____ _____
Participant's Signature Date

I have informed the study participant, _____ of:
Participant's Printed Name

- The procedures, purpose, and risks related to participation in the above-described study;
- How his/her health information may be used, shared, and reported, and;
- His/her privacy rights.

The study participant has been provided with a signed copy of this form.

_____ _____
Signature of Researcher Obtaining Consent Date

_____
Printed Name of Researcher Obtaining Consent

This form is valid only if it has the IRB stamp of approval.