CONSENT TO PARTICIPATE IN
BIOMEDICAL RESEARCH

Magnetic Resonance Imaging (MRI) and Magnetoencephalography (MEG) Study of Voice in Major Depressive Disorder (MDD)

MDD Subject

You are asked to participate in a research study conducted by Satrajit Ghosh, Ph.D., from the McGovern Institute for Brain Research at the Massachusetts Institute of Technology (M.I.T). You have been asked to participate in this study because you are an adult diagnosed with Major Depressive Disorder (MDD). This study will include about 150 participants total. You should read the information below, and ask questions about anything you do not understand, before deciding whether or not to participate.

- PARTICIPATION AND WITHDRAWAL

Your participation in this research is completely VOLUNTARY. If you choose to participate you may subsequently withdraw from the study at any time without penalty or consequences of any kind. If you choose not to participate, that will not affect your relationship with M.I.T., or your right to health care or other services to which you are otherwise entitled.

- PURPOSE OF THE STUDY

The purpose of this study is to investigate which differences in brain activity are associated with voice quality differences seen in people with major depressive disorder (MDD).
PROCEDURES

If you volunteer to participate in this study, we would ask you to do the following things: be interviewed by a clinical staff member, take part in an MRI scan, and take part in an MEG recording. Before beginning each session the experimenter will describe the procedure to you. A description of each session is also included in the following paragraphs.

You may be asked to perform each of these study events multiple times over the course of one year. All of these study events will take place at MIT Building 46.

☐ Clinical Interview
During this part of the study, a clinical staff member will ask you questions about your personal experiences and emotions and will record your responses. Please communicate with the interviewer as openly and honestly as possible; we are not looking for specific answers but rather hope to receive truthful responses that provide the experimenter with a sense of who you are and your current mental state. The interview should take 60-90 minutes, although any given interview may take more or less time.

Subject Initials_______ Date ____________

☐ Magnetic Resonance Imaging (MRI)
This portion of the experiment will allow us to capture high-resolution images of your brain while you rest or perform various tasks. You will be asked to lie on a narrow bed which will be surrounded by the cylindrical MRI machine, which uses a strong magnet and radio waves to make images of the inside of your body. The procedure is similar to an x-ray CT scan, but MRI does not expose you to x-rays. Instead, the machine uses a magnetic field and radiofrequency magnetic fields, neither of which you will feel. However, you will hear tapping or beeping sounds from the MR scanner, which can be quite loud. You will be provided with hearing protection and must wear this hearing protection during the experiment.

The space inside the magnet in which you will lie is somewhat confined, but we have taken many steps to make it as comfortable as possible to prevent any “claustrophobic” sensations. Let the experimenter know if you do feel uncomfortable, and he or she will work with you to make the session as comfortable as possible.

During some parts of the MRI scan, you will be asked to lie still but be given no other tasks. During other parts of the scan, you will be shown images or hear sounds, and the experimenter may ask you to respond to the pictures or sounds orally or by pressing a button. Your vocal responses may be recorded digitally with a microphone located in the scanner room. This will allow us to look at the brain activity during various vocalizations.

The MRI session should take about 60 minutes.

Subject Initials_______ Date ____________

AMENDMENT APPROVED 27-FEB-2015
☐ Magnetoencephalography (MEG)
This portion of the study allows us to capture brain activity at very high speeds while you perform similar tasks as in the MRI portion of the study. Like the MR scanner, MEG consists of a large machine in its own room. However, unlike with the MR scanner, only the top of your head will be inside the MEG machine. MEG is also extremely quiet, so you will not need to wear hearing protection during this portion of the study. You will be given earphones, through which you will hear sounds as well as the experimenter during breaks in testing. You will also be able to see a screen which may have images presented on it. You will perform various tasks, during which you will observe images or hear sounds. You may be asked to respond to these images or sounds orally or by pressing a button. Your vocal responses may be recorded digitally with a microphone located in the scanner room. This will allow us to look at the brain activity during various vocalizations.

The MEG session should take about 60 minutes.

Subject Initials _______ Date ______________

☐ Mobile Phone- or Computer-Based Survey
In between visits to MIT for MRI and MEG recordings, you may be asked to complete mobile phone- or computer-based surveys. These surveys will include questions about your environment, your physical state, and your mental and emotional states. In addition, the survey may ask you to record yourself saying certain phrases and utterances using the device’s built-in microphone and camera.

The survey should take about 30 minutes.

Subject Initials _______ Date ______________

• POTENTIAL RISKS AND DISCOMFORTS

Clinical Interview
The clinical interview consists of questions about your past experiences, past and present feelings, and other topics. While there is little risk involved in this part of the study, the clinical staff member will ask personal, subjective questions that could be uncomfortable to answer for some people. As truthful responses are very important for conducting accurate research, please do your best to communicate honestly and openly with the clinical staff member. If at any point you do feel stressed or anxious, let the interviewer know, and he or she will work with you to make the session as comfortable as possible.

MRI Scan
Magnetic resonance imaging (MRI) does not rely on harmful radiation, and the magnetic fields it creates does not cause harmful effects at the levels used in the MRI machine. However, because the MR scanner is a strong magnet, it will attract some metals and affect some electronic devices. It is important that you tell the experimenter if you have

AMENDMENT APPROVED 27-FEB-2015

any biomedical device in your body, such as a cochlear implant or cardiac pacemaker. It is also important that you inform the experimenter if you have or suspect you may have a metallic object on or in your body; if possible, you should remove any metallic objects before entering the magnet room. If the implant or object cannot be removed, it may mean that you should not have an MRI performed. Other electronic and metallic objects such as wristwatches and credit cards may be damaged by the magnetic fields in the MRI room and should be removed before entering the room. Please notify the experimenter if you have a history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant.

Some participants may experience a localized twitching sensation in the MRI scanner due to changing magnetic fields associated with the scan. These are not unexpected and should not be painful. Some of the software, devices, and radio frequency coils used in the MRI procedure have not been approved by the FDA but are similar to counterparts that have been approved by the FDA. There is a small risk of heating from the cables connecting these devices; if you feel any heating sensation, tell the experimenter immediately. Some participants may feel dizzy or nauseous if they move while in the scanner. The experimenter will give you pillows and a blanket to help you feel as comfortable as possible for the duration of the MRI procedure. The experimenter will also give you hearing protection to minimize the loudness of the MR scanner.

INFORM THE OPERATOR IF YOU FEEL ANY DISCOMFORT. YOU CAN END THE TESTING SESSION AT ANY TIME.

MEG Recording
Unlike MR scanners, MEG machines do not produce strong magnetic fields. Instead, they pick up extremely small magnetic fields, including those generated by brain activity. Thus, the MEG machine does not pose the same risks for individuals with implanted devices or metallic objects on or in their bodies. However, for your comfort during the testing session and the safety of the sensitive machine, please remove any magnetic or electronic devices before entering the MEG machine room. The MEG machine is extremely quiet and is housed in an acoustically and magnetically shielded room, so there is little risk of discomfort from noise levels. If at any point you feel any discomfort, inform the operator and he or she will work to make you as comfortable as possible. You can end your participation in the examination at any time.

The treatment or procedure may involve risks that are currently unforeseeable.

Mobile Phone- or Computer-Based Survey
We do not anticipate any risks or discomforts from completion of mobile phone- or computer-based surveys and voice recordings. At the beginning of the survey, the application will remind you to go to a quiet, distraction-free location where you will be able to speak out loud. It is best to complete the surveys in a room without any other people. This will limit any noises or distractions and will also provide you with the most privacy and comfort when responding to survey questions with touchscreen or audio/video recordings.

AMENDMENT APPROVED 27-FEB-2015
Incidental Findings
The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and the Martinos Imaging Center are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the finding merits further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and the Martinos Imaging Center are not responsible for any examination or treatment that you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

- ANTICIPATED BENEFITS TO SUBJECTS

Subjects can expect no personal benefit from participating in the study beyond insight into the process of brain imaging and recording research.

- ANTICIPATED BENEFITS TO SOCIETY

Society will greatly benefit from the knowledge gained by studying the brain mechanisms underlying voice and MDD for the first time. While previous studies have investigated the relationship between voice and MDD from voice recordings alone, this study will be the first to use MRI and MEG to provide insight into the brain mechanisms affecting voice quality in patients with MDD and during MDEs. Additionally, this study will further investigate the mechanisms and structures associated with voicing and MDD separately, which, although both (especially MDD) have been the focus of much brain imaging research, are still not well understood at the level of cortical systems.

- ALTERNATIVES TO PARTICIPATION

The alternative to participation in this study is to not participate. If, at any point during the study, you would like to end your participation, please let an experimenter know.

- PAYMENT FOR PARTICIPATION

You will receive $30 per hour of scanning, prorated to $15 per half hour of participation in scanning. In person, on-site behavioral assessments will be paid at $15.00 per hour prorated to $7.50 per half hour. If you choose to withdraw at any time, you will be compensated for the amount of the study completed.

- FINANCIAL OBLIGATION

AMENDMENT APPROVED 27-FEB-2015
There is no financial obligation to you for participating in this research study.

- PRIVACY AND CONFIDENTIALITY

The only people who will know that you are a research subject are members of the research team and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research will be disclosed to others without your written permission, except: if necessary to protect your rights or welfare, or if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audio-tape recordings of you will be used for educational purposes, your identity will be protected or disguised.

Audio recordings made during the testing procedure will be coded numerically and stored separate from any personally identifying health information for the duration of the study. The recordings will only be accessible to the experimenters for research purposes.

If any data are shared with investigators outside the team, they will be stripped of any Health Insurance Portability, and Accountability Act (HIPAA) identifiers. As infrastructure permits, participants may have access to their own data and will be able to share that data without our permission.

I withdrawal of participation by the investigator

The investigator may withdraw you from participating in this research if circumstances arise which warrant doing so. If if you become ill during the research, you may have to drop out, even if you would like to continue. The investigator, Satrajit Ghosh, Ph.D., will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, or because it is part of the research plan that people who develop certain conditions may not continue to participate.

If you must drop out because the investigator asks you to or because you have decided on your own to withdraw, you will be paid for the amount of the study already completed.

- NEW FINDINGS

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

AMENDMENT APPROVED 27-FEB-2015
• **EMERGENCY CARE AND COMPENSATION FOR INJURY**

If you feel you have suffered an injury, which may include emotional trauma, as a result of participating in this study, please contact the person in charge of the study as soon as possible.

In the event you suffer such an injury, M.I.T. may provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed, or reimbursement for such medical services. M.I.T. does not provide any other form of compensation for injury. In any case, neither the offer to provide medical assistance, nor the actual provision of medical services shall be considered an admission of fault or acceptance of liability. Questions regarding this policy may be directed to MIT’s Insurance Office, (617) 253-2823. Your insurance carrier may be billed for the cost of emergency transport or medical treatment, if such services are determined not to be directly related to your participation in this study.

• **IDENTIFICATION OF INVESTIGATORS**

In the event of a research related injury or if you experience an adverse reaction, please immediately contact one of the investigators listed below. If you have any questions about the research, please feel free to contact:

- Satrajit Ghosh, Ph.D.
  - 617-324-3544
  - MIT Building 46-4033f, 43 Vassar St., Cambridge, MA 02139
- Thomas F. Quatieri, Ph.D.
  - 781-981-8994
  - MIT Lincoln Laboratory, 244 Wood St, Lexington, MA 02421
- Diego A. Pizzagalli, Ph.D.
  - 617-855-4230
  - McLean Hospital, de Marneffe Building, Room 233C, Mailstop 331, 115 Mill Street, Belmont, MA 02478-9106

• **RIGHTS OF RESEARCH SUBJECTS**

You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, M.I.T., Room E25-143B, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787.

☐ **ABLE TO BE RECONTACTED FOR FUTURE STUDIES**

The study investigators may contact you in the future regarding additional studies.

**AMENDMENT APPROVED 27-FEB-2015**

SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE
I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

___________________________
Name of Subject

___________________________
Name of Legal Representative (if applicable)

___________________________
Signature of Subject or Legal Representative

___________________________
Date

SIGNATURE OF INVESTIGATOR
I have explained the research to the subject or his/her legal representative, and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

___________________________
Name of Investigator

___________________________
Signature of Investigator

___________________________
Date (must be the same as subject’s)

SIGNATURE OF WITNESS (If required by COUHES)
My signature as witness certified that the subject or his/her legal representative signed this consent form in my presence as his/her voluntary act and deed.

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Name of Witness

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AMENDMENT APPROVED 27-FEB-2015