UNIVERSITY OF CALIFORNIA, SAN DIEGO
CONSENT TO PARTICIPATE IN RESEARCH

1. **Title:** Mindfulness Engaged Neurostimulation for Depression (MEND) IRB # 809712

2. **Principal Investigator**: Dr. Jyoti Mishra, PhD MBA
   PI Contact Number: 858-232-2855

3. **Research Team Phone Number:** 858-249-2625
   Emergency Contact Number: 858-232-2855

4. **Sponsor:** The National Institutes of Health (NIH), the study sponsor, is paying UC San Diego to conduct this research study**.**

5. **Study Overview**

Dr. Jyoti Mishra, PhD MBA, is conducting this research to investigate a multimodal treatment that combines mindfulness training administered digitally with intermittent theta burst stimulation, a type of FDA-cleared transcranial magnetic stimulation (TMS); we refer to this combination as Medi-TBS. The research is specifically investigating whether the treatment changes brain activity in a specific way and is associated with changes in cognition and depressive symptoms among those with treatment-resistant depression. You are invited to take part in this study because you have been diagnosed with Major Depressive Disorder (MDD) that has been resistant to treatment.

This section provides a summary of important information. The rest of the form offers additional details so you may make an informed decision about participating.

- Research is voluntary - whether or not you participate is your decision. You can discuss your decision with others (such as family, friends, or another physician).
- You can say yes, but change your mind later.
- If you say no, we will not hold your decision against you.
- You can say no even if the person inviting you is part of your healthcare team.
- Your decision will not affect your health care or other benefits you may be entitled to.
- Please ask the study doctor or study team questions about anything unclear, and feel free to ask questions and mention concerns before, during, and after the research.
- You may consult with friends, family, a personal doctor, or anyone else before deciding whether or not to be in the study.
- You will be given a copy of this consent form and the Participant's Bill of Rights.

This research study aims to test the Medi-TBS multimodal treatment that combines mindfulness training administered digitally with intermittent theta burst stimulation, a type of FDA-cleared brain stimulation for treatment-resistant depression (TRD). In simple terms, this research study is trying to find a new way to help people with depression that hasn't responded well to other treatments.

You'll go through some clinical interviews to see if you're a good fit for the study. This includes answering questions about your medical history and ensuring you don't have any contraindications to participating in this clinical trial.

If you qualify for the study, you will undergo various tests and procedures. This includes getting an MRI (brain imaging), getting electroencephalography (EEG) and undergoing tests to measure different aspects of your cognitive abilities. After these tests you will be 'randomized' into one of two study groups described below. The two groups, Medi1-TBS, or Medi3-TBS test different types of mindfulness trainings. It is a blinded study so you will not know whether you are offered the active mindfulness training or a control mindfulness training. Based on prior research the active training includes consistent attentive focus on breathing while the control training includes deep breathing but does not require consistent attention. Hence, these trainings may offer different benefits and show different effects on the brain, and we are studying if the active training is superior to control. Both groups will receive the standard intermittent theta burst brain stimulation. All assigned trainings will happen immediately after the brain stimulation session at the clinic for 20 sessions that must be completed over 3-5 days per week over 4-7 weeks. It is recommended that you attend 5 treatment sessions/week over 4 weeks but if this schedule is not convenient in any week then you must complete at least 3 sessions/week and complete all 20 treatment sessions within 7 weeks. Pre and post-treatment assessment procedures will also be performed at the clinical site to ensure you are safe and to measure how well the treatment is working.

This study's most common risks or discomforts are mild headaches and scalp discomfort.

The most serious risks include seizure and hearing loss. The risk of seizure for healthy participants is very unlikely. However, participants with a history of seizures or stroke are at an increased risk of seizure.

A complete listing of possible risks and discomforts associated with this study can be found in Section 9.

We cannot promise any benefit to you or to others from you participating in this research. However, possible benefits to you include receiving a treatment that might improve your symptoms of depression. In addition, the findings from this study will 1) potentially benefit others with depression and related mood disorders in the future, 2) lead to better treatment for depression, and 3) improve understanding of the biology of depression. The alternative to being in the study is to not participate and potentially consider alternative treatment pathways. This might include other treatments as prescribed by your current psychiatrist outside the context of this study, which may include other combinations of psychotherapy and medications, clinical TMS, electroconvulsive therapy, ketamine treatment or hospitalization. You may also consider participating in other clinical trials offered at the UCSD Interventional Psychiatry clinic: www.ucsdtms.com

6. **Whom can I talk to if I have questions?**

If you have questions or concerns during your participation in the study, or if you think the research has hurt you, contact the research team at the numbers listed in Section 3 on the first page of this form.

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You should only agree to participate in this study once the research team has answered any questions about the study, including information in this form.

If before or during your participation in the study, you have questions about your rights as a research participant, or you want to talk to someone outside the research team, please contact:

- UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu

7. **How many people will take part?**

We aim to recruit 120 to enroll in this study at UCSD.

8. **What happens if I take part in the research?**

Here is what will happen to you if you agree to be in the study -

Screening: Visit 1
The screening visit should take approximately 2 hours. During this visit, we will ask questions and collect information to see if you qualify to participate in this research study. This visit will take place at UCSD or there is also the option of completing the visit via UCSD Health Zoom. This visit will first consist of reviewing and signing the consent form. After consenting, you will complete forms, clinical questionnaires, and an interview with a research coordinator. The study doctor will review the results of these this assessment to determine if you are eligible to participate.

At this visit, we will:
- Ask about your medical history and any medications you may be taking.
- Ask about your psychiatric history and review how you have recently felt.
- Review what antidepressant treatments you have tried and may currently be taking, including medications, psychotherapy, etc.
- Ask you questions about your current method of birth control to ensure you have an adequate method to prevent pregnancy throughout the trial.
- Review your ability to receive brain stimulation, especially any history of seizures or nonremovable metal objects in or around your head and body.
- Review your ability to receive an magnetic resonance imaging (MRI) scan using an MRI safety form.
- Ask you to complete some questionnaires about your mood.
- If you are a woman of childbearing potential, we will provide a pregnancy test and make sure it reads negative before beginning the research study.
- Complete a COVID-19 safety screen.

Pre-Treatment Imaging: Visit 2

The pre-treatment imaging visit will occur at the UC San Diego Center for Functional MRI (9500 Gilman Drive, La Jolla, CA 92093, MC 0677) and should take approximately 30 minutes to 1 hour. At the beginning of the imaging visit, you will be asked to retake the MRI safety form to ensure everything has stayed the same. We will also check for additional items that may be attracted to or impacted by the scanner's magnetic field. These include watches, credit cards (in your pockets, etc.), removable or irremovable jewelry, and tattoos. To establish safety, the researchers might need to ask you about the specifics of these items (e.g., for tattoos, how big they are, how old they are, where on the body, what colors they have, etc.). You will be provided a way to secure these items, such as watches and credit cards. Once you are cleared, you will lie on a long narrow couch for approximately 30 minutes to 1 hour while the MRI machine takes pictures of the inside of your brain. You will not feel anything while the data is being collected. You will also hear tapping noises that are from the MRI scanner. You may choose to forego the MRI visit if you underwent an MRI scan for one of our clinical trials within the UCSD Interventional Psychiatry program within the last 6 months and are willing to use those scans for this trial.

The scan performed in this study is for specific research purposes and is not optimized to find medical abnormalities. The investigators and MRI center are not responsible for failing to find abnormalities with this MRI scan. However, the investigator may occasionally notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings merit further investigation, in which case the investigator will contact you and your primary care physician and inform you of the result. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators and the consulting physician are not responsible for any examination or treatment you undertake based on these findings. Because the images collected in this study may not comprise a proper clinical diagnosis, the MRI scans will not be made available for diagnostic purposes.

The study MRI will be uploaded to a secure server under your assigned subject ID that will be used to identify you. This unique identifier will be used to identify you in places where your doctor, research coordinator, or MRI technician would typically enter your First and Last name to identify you.

At this visit we will also determine your Resting Motor Threshold (RMT). The RMT is determined by placing the magnetic stimulation coil on the head over the cortical representation ("hot spot") of the right thumb muscle and then sending a magnetic pulse to evoke movement in the thumb muscle. The hot spot will be found by moving the coil around the scalp and using TMS intensities that can evoke visual detection of the muscle in the hand. You can also opt for this assessment visit to occur on the same day as your first treatment visit, right before your first treatment.

Pre-Treatment Assessments: Visit 3

The pre-and post-treatment assessment visits will occur at the UCSD Interventional Psychiatry Clinic. The pre-treatment visit will begin with a COVID-19 screen; then you will complete a clinical symptoms interview and self-administered symptom and behavior scales. These symptom scales will primarily ask you about mental health symptoms (depression and anxiety), medications and mindfulness. You will also engage in game-like cognitive assessments. During the cognitive

assessments, your brain activity will be measured with EEG (electroencephalography). For the EEG measurement, you will sit on a chair and wear a cap that allows us to collect information about electrical signals produced by different parts of your brain. All data collected will be de-identified. This visit may last approximately 2 hours and you can take breaks as needed. The RMT assessment may also occur at this visit instead of at visit 2 above, if needed.

Randomization

You will be 'randomized' into one of two study groups. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers choose which group you will be in. You will have a 50%, or 1 in 2 chance of being placed in a specific group. Neither you nor the researchers will know which group you are in. These groups (Medi1-TBS or Medi3-TBS) will test different types of mindfulness training delivered over a software. The mindfulness training software is considered an investigational device that has not yet been approved by the Food and Drug Administration (FDA). The effectiveness of the device is being tested.

Treatment (4-7 weeks): Visits 4-23

Repetitive Transcranial Magnetic Stimulation (rTMS). All participants in this study will receive brain stimulation using rTMS. Transcranial magnetic stimulation (TMS) is a procedure that uses magnetic fields to stimulate nerve cells in the brain to improve symptoms of major depression. It's called a "noninvasive" procedure because it's done without using surgery or cutting the skin. Approved by the U.S. Food and Drug Administration (FDA), TMS usually is used only when other depression treatments haven't been effective. There are several protocols that are cleared by the FDA for the treatment of depression. We will be using one FDA-cleared protocol, termed intermittent Theta Burst Stimulation (iTBS). This protocol delivers specific patterns of stimulation. Participants will receive 20 TMS treatments in this study. These 20 visits will occur ideally daily i.e. 5 days per week or at least 3 days per week over four to seven weeks. The intermittent theta burst stimulation component is common to all treatment groups lasting approximately 3-4 minutes per session, with an additional 5-10 minutes that may be required for coil placement and adjustments for dosing precision.

After the theta burst stimulation, you will be provided a digital tablet to login and complete your assigned mindfulness training for the day that will last up to 10 minutes per session. This mindfulness training will involve exercises related to breathing. Once a week you will complete depression and anxiety symptom scales and we will also ask about any changes in medications. The expected total duration of each of these treatment visits is no longer than one hour including all TMS and digital training procedures, symptom evaluations and any rest breaks.

At the start of each treatment visit, a COVID-19 screen will be administered. During treatment, you will sit in a comfortable chair. The coil will be positioned using neuro-navigation that demonstrates the distance from the coil to the treatment location on your head as determined by your treating physician. While brain stimulation can feel different for everyone, you may experience a pulsing sensation at the treatment site. TMS pulses create a clicking sound that will be limited with the use of earplugs. RMT (as described in Visit 3 above) may be redone during treatment visits if there is a need to recalibrate the stimulation intensity.

Post-Treatment Assessments: Visit 24
This visit will be identical to the pre-treatment assessments visit (visit 3). You can also opt for this assessment visit to occur on the same day as your last treatment visit, right after your last treatment.

Four-week follow-up: Visit 25
At approximately 4-weeks post-treatment, you will either come to one of our clinics or have the option of doing this assessment remotely via UCSD Health Zoom. During this visit, concomitant medications will be collected. You will complete clinical symptom assessments.

9. **What are the risks and possible discomforts?**

Risks of rTMS. In this study you are receiving the intermittent theta burst form of TMS brain stimulation. There are no known long-term adverse effects reported with the use of this TMS. As with any technique, though, there may be long-term risks due to currently unknown TMS.

- **Certain Medical Diagnoses**: For participants with epilepsy, brain activation by TMS could also cause a seizure. Participants with stroke may also be at increased risk for a seizure due to brain scarring. For a typical physically healthy person, a TMS-induced seizure in this experiment is very unlikely.
- **Headache:** A mild headache is the most common side effect of TMS (approximately 65 out of 100 participants reported it at some point in time during their course of rTMS). This does not typically occur after every treatment and is usually manageable by those receiving TMS. Participants can discontinue treatment if they experience significant discomfort during the study.
- **Noise:** The TMS device produces a clicking sound. To minimize discomfort and prevent any associated damage to hearing associated with this sound you will be given protective earplugs.
- **Nausea/Dizziness:** Although uncommon, approximately 10 out of 100 participants may experience nausea or dizziness during the course of TMS. This typically resolves with time. Participants can discontinue treatment if they experience significant discomfort during the study.
- **Discomfort/Pain During Stimulation:** It is common to experience temporary pain or discomfort from muscle activation by TMS during treatments. This is typically manageable by those receiving TMS. Participants can discontinue treatment if they experience significant discomfort during the study.
- **Pregnancy:** The TMS treatments used in this study may affect a baby, before or after the baby is born. As a result, those able to become pregnant should not be in this study if they are:

• pregnant

• trying to become pregnant.

If you are able to become pregnant, you should use birth control for the entire time you are in the study. Hormonal methods (birth control pill, etc.), double-barrier methods (condoms with spermicidal, sponge with spermicidal, or diaphragm with spermicidal), or not having sex may be used. Your doctor will discuss these with you.

If you become pregnant or think you might be pregnant during study treatment or within 2 weeks after completing TMS treatments, you must inform the Study Doctor immediately. Your Study Doctor will discontinue treatments and want to follow the pregnancy and collect information about the outcome of the pregnancy.

Risks with Clinical and Cognitive Assessments and EEG.
Some discomfort, such as fatigue, may be associated with clinical and cognitive assessments and self-report questionnaires. Participants may experience mild physical discomfort because of the tight fit of the EEG cap.

Risks with Magnetic Resonance Imaging
MRI machines use a strong magnet to make pictures of the inside of your body. During the scanning, you will lie on a long narrow couch for *up to 60 minutes* while the machine gathers data. You will not feel anything while the data is being collected. You will also hear tapping noises that are from the MRI scanner.

Since the MRI scanner is a magnet, metal objects will be attracted to the scanner. It is very important that you tell the researcher about any metal objects, devices or implants that are in or on your body before you enter the scanner room. All metal objects must be removed before entering the magnet room. In some cases, having those devices may mean that you should not have an MRI scan. In some cases, having those devices in your body may mean that you should not have an MRI scan.

Possible risks of MRI include:

- **Claustrophobia**: Participants may experience claustrophobia (fear of enclosed spaces and anxious feelings accompanied by fast heart rate or shortness of breath) within the MRI scanner. An MRI scan requires you to be in a partially enclosed space inside the scanner. Some people may find this to be uncomfortable and claustrophobic. Participants need to inform the doctor ordering the scan, or the study staff, if they suffer from claustrophobia.
- **Magnetic Fields:** No known health risk is associated with exposure to magnetic fields during an MRI. There are minimal risks from the loud noise associated with the MRI scanner and the discomfort of lying on a hard surface. We shall provide protective earplugs as necessary and make every attempt to ensure comfort with blankets, etc., during the time in the scanner.
- **Flying Objects:** The most significant risk of MRI is a magnetic object flying through the air toward the magnet and hitting you. To reduce this risk, we require that all people involved in the study remove all magnetic metal from their clothing and all magnetic metal objects from their pockets. No magnetic metal objects are allowed to be brought into the magnet room at any time; you undergo extensive screening immediately prior to entering the scanner room.
- **Medical Implants and Foreign Bodies**: There is also a potential risk of MRI for participants with medical implants or other metallic objects in their body. All participants undergoing MRI scanning must complete a screening evaluation risk in advance of the study for the presence of medical implants or other foreign bodies that could pose an injury
- **Pregnancy:** Although there are no known risks related to MRI on pregnant women or a fetus, there is a possibility of yet undiscovered pregnancy-related risks.

Risk of Worsening of Depression Symptoms
While participating in this study, if symptoms worsen to the point of needing psychological or medical support, you will be given resources to emergency services. If your symptoms require urgent attention, call 911 and present to the nearest emergency room or contact: The University of California San Diego at (619) 543-6400. UCSD hotlines are staffed 24 hours a day, 7 days per week. For similar hotlines outside of the San Diego area, you can consult www.suicide.org.

Risks of Collection of Sensitive Information: Some of the questions we will ask you are personal. You may feel embarrassed or stressed. You may request to see the questions before deciding whether to participate in this study. You may skip any question that you do not want to answer. If the questions make you very upset, we will help you find a counselor, refer you to an appropriate clinic for follow-up, or contact the research manager.

Risks of Loss of Confidential Information: There is also a risk that information about you could be released to an unauthorized party. To minimize this risk, we will make every reasonable effort to keep your records confidential. All information collected will be coded with a non-identifying study ID number and stored on a password protected computer. All direct identifying information such as name, contact, date of birth and medical record number will be stored separately in a different location in a password protected file; only this one file will link your name with the study ID number and only authorized research staff will have access to this file.

Risks of Incidental Findings: Although the testing you will have in this study is being undertaken for research purposes only and should not be considered a substitute for normal medical care, it is possible that the doctors may notice something that may be serious or could affect your life. If so, we will contact you to explain what was observed. If you so desire, we will also talk with your primary care physician. If you do not have a primary care physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.

Possible Unknown Risks: In addition, there might be risks that we cannot predict at this time. These unknown risks may be temporary, mild, and last only while you actively participate in the research, or they may be serious, or long-lasting. You will be informed of any new findings that might affect your health or welfare or might affect your willingness to continue in the research.

10. **How will my information be protected?**
Information about you is protected by a federal Certificate of Confidentiality. This means that we cannot be forced to release your information about you for any legal proceeding, even if a court of law asks.

The Certificate allows us to use your information about you for purposes of this research or to disclose it for other research when allowed by law. The Certificate requires other researchers also to protect the information we share with them.

There are limits to this protection. The Certificate does not protect your information when:

- You or your family voluntarily release information about yourselves.
- You consent to release of information (for example, the uses described in this form or if you sign release forms for employment, insurance, or medical care).
- A federal agency audits or evaluates research that it funds.
- Researchers are required to report possible intent to harm themselves or others, child abuse, elder abuse, or infectious disease cases.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult, or elder, including physical, sexual, emotional, and financial abuse or neglect. In addition, if researchers are made aware that a subject has certain communicable diseases, including sexually transmitted diseases/infections (STDs/STIs), hepatitis, and HIV, this must be reported. If any investigator has or is given such information, they may be required to report such information to the appropriate authorities.

Research records will be kept confidential to the extent allowed by law. While we cannot guarantee complete confidentiality, we will limit access to information about you. Only people who need to review your information, documents, or specimens will have access. These people might include:

- Members of the research team and other staff or representatives of UCSD whose work is related to the research or to protecting your rights and safety.
- Representatives of the study sponsor or product manufacturer
- Representatives of Federal and other regulatory agencies who ensure the study is done correctly and your rights and safety are protected.

All study information will be labeled with a code instead of your name or other information that can easily identify you. The record linking your identifying information (name, address, etc.) and the code will be kept separate from the rest of the study information.

Your UC San Diego Health record will note this consent form and some details of your study participation. If you do not currently have a UC San Diego Health record, one will be created for you. People involved with your medical care and insurance may become aware of these details. UC San Diego also participates in Health Information Exchange (HIE) with other health systems. Sharing your electronic Health Record (EHR) with other health systems is only allowed when they are involved in your medical care. Study details included in your EHR will also be shared. For more information about HIE, including how you can opt out of sharing, ask the study team.

Federal and state privacy laws give participants the right to access information about their care and treatment in their EHR. During this study, you may only be able to access certain information related to this study in your UC San Diego Health record once the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you also agree to this possible temporary withholding of your research records.

The results of this study may be published once the study is completed. However, we will keep your name and other identifying information fully confidential. We expect this study will be completed in 5 years. This is only an estimate, and the actual time to complete the study may be longer or shorter depending on several factors.

You will be asked to sign a separate UC Health Insurance Portability and Accountability Act (HIPAA) Research Authorization form to use and disclose (share) your health information that identifies you for the purposes of this research study (see the separate authorization form for more details). Your permission, as described in this informed consent and authorization form, does not have an automatic expiration date.

11. **Will I need to pay to participate in the research?**

The treatment under study will be supplied at no cost while you participate in this study. The cost of getting the treatment ready and giving it to you is also provided at no charge. It is possible that the treatment may not continue to be offered to you while you are in the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your general condition while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no cost. Before you decide to be in the study, you should check with your health plan/insurance company to find out exactly what they will pay for.

12. **What if I agree to participate but change my mind later?**

You can stop participating anytime for any reason, and it will not be held against you. Your choice will not affect your treatment relationship with healthcare providers at UC San Diego Health or any services you receive from them. No matter what you decide, there will be no penalty towards you. You will not lose medical care or any legal rights. We also may be unable to remove the information we have already collected about you.

If any new information that may affect your health, welfare, or choice to stay in the research is found, we will notify you. In addition, you may be withdrawn from the study without your consent for the following reasons:

- A study physician believes it is in your best interest not to continue the study.
- You begin to pose a serious threat to your life or another's life.
- You feel unmanageable pain/discomfort at any point throughout the study.
- You no longer wish to participate in the remainder of the study in its entirety.
- You may also be withdrawn from the study if you do not follow the instructions given to you by the study personnel.
- Your clinical symptoms do not remain stable between screening and the start of treatment.

If you stop early, please get in touch with us immediately. We will ask you to complete some study termination assessments.

13. **What will happen to the information collected from me?**

The data we collect with your identifiable information (for example, your name, medical record number, or date of birth) as a part of this study may be used to answer other research questions or may be shared with other investigators for other research. In addition, data that have been de-identified may be uploaded for other researchers to access and use. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask for your consent to use or share your data in other research.

While your privacy and confidentiality are very important to us, and we will use safety measures to protect them, we cannot guarantee that your identity will never become known.

14. **What are my responsibilities if I take part in this research?**
If you participate in this research, you will be responsible for attending and completing all the research-required visits.

15. **Will I be compensated for participating in the research?**
If you agree to take part in this research, we will provide you $300 for your travel, time and effort. All compensation will be given as an Amazon e-gift card. If you decide to voluntarily withdraw at any stage of the study, pro-rated compensation will be provided to you based on the assessments completed until that point.

16. **What else is important for me to know?**
You will not be provided a summary of the research findings. It is possible that during the research study, the research staff may notice unexpected results in your MRI images. Should this occur, the PI will consider the results and inform you if necessary for medical follow-up. These possible findings will only be disclosed to you if deemed necessary by the PI and reviewing radiologist.

The study PI is the owner of the UCSD copyright to the cognitive assessment and training software that is being used for this study. The research may have significant therapeutic or commercial value. There are no plans to provide any compensation to you for potential commercial values. You are consenting to such uses.

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide you with any other form of compensation if you are injured. You may call the Office of IRB Administration at 858-246-4777 or irb@ucsd.edu for more information about this, to inquire about your rights as a research participant, or to report research-related problems.

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

This study has been explained to you, and your questions have been answered. If you have other questions or research-related problems, you may reach Dr. Jyoti Mishra and/or an authorized

research staff personnel who has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach us at braine@ucsd.edu or call Dr. Jyoti Mishra at (858) 232-2855.

You may also call the Office of IRB Administration at 858-246-4777 or irb@ucsd.eduto inquire about your rights as a research subject or to report research-related problems.

17. **What are my rights when providing electronic consent.**
California law provides specific rights when you are asked to provide electronic consent:

- You have the right to obtain a copy of the consent document in a non-electronic format.
- You have the right to provide consent in a non-electronic format.
- If you change your mind about electronic consent, you have the right to request your electronic consent to be withdrawn and you can then provide consent in a non-electronic format; however, a copy of your electronic consent will be maintained for regulatory purposes. If you wish to withdraw your electronic consent please tell the study team.

This agreement for electronic consent applies only to your consent to participate in this research study.

18. **Additional Choices to Consider**
Sharing your deidentified study data helps researchers learn new and important things about mental health and behavior more quickly than before. You may decide now or later that you do not want your study data to be shared. You can still participate in this research study even if you decide that you do not want your data to be shared. If you know now that you do not want your data shared, please indicate below. If you decide any time after today that you do not want your data shared, call or email the study staff who conducted this study. Once your data is already shared, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind.

_____ YES, you may share my de-identified data

_____ NO, you may not share my de-identified data

The study team would like your permission to contact you about participating in future studies. You may still join this study even if you do not permit future contact. You may also change your mind about this choice. Please initial your choice below:

YES, you may contact me

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_____

_____ NO, you may NOT contact me

If you completed an MRI for one of our clinical trials at the UCSD Interventional Psychiatry program within the last 6 months, we can use the data collected from the scan as part of this trial. The MRI data previously collected from you would have been stored with a unique ID in place of your first and last name. Our study team would use your previous unique ID to identify your MRI records and transfer them to the unique ID associated with this clinical trial. Any MRI data shared for future research will not include any personally identifiable information, including your name, address, birthday, etc.; only your unique ID will be shared. Will you allow us to use this data instead of the pre-treatment MRI? Please initial your choice below:

_____ YES _____ NO

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Signature Block for Adults Able to Provide Consent

Participant
I have received a copy of this consent document and a copy of the "Experimental Participant's Bill of Rights" to keep. I agree to participate in the research described in this form. _____ Printed Name of Participant _____ Signature of Participant Date
Person Obtaining Consent
I document that: • *I (or another research team member) have fully explained this research to the participant.* • *I have personally evaluated the participant's understanding of the research and obtained their voluntary agreement.* _____ Printed Name of Person Obtaining Consent _____ Signature of Person Obtaining Consent Date

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Witness (if applicable)
I document that the information in this form (and any other written information) was accurately explained to the participant. The participant appears to have understood and freely given consent to join the research.
Printed Name of Witness
Signature of Witness Date

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Experimental Participant's Bill of Rights

Every individual asked to participate in a research study has the right to be:

1. Informed about the nature and purpose of the study.

2. Provided an explanation of the procedures to be followed in the research study and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.

5. Informed about any alternative procedures, drugs, or devices that might be helpful and their risks and benefits compared to the proposed procedures, drugs, or devices.

6. Told of the types of medical treatment, if any, available if complications should arise.

7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.

9. Provided a copy of the signed and dated written consent form and a copy of this form.

10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study, contact the researchers listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:

UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777