INFORMED CONSENT FORM- HEALTHY VOLUNTEERS

Official title: Elucidating the Neurocircuitry of Irritability with High-Field Neuroimaging to Identify Novel Therapeutic Targets

NCT number: NCT05046184

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Title of Study: Elucidating the Neurocircuitry of Irritability with High-Field Neuroimaging to Identify Novel Therapeutic Targets

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center

Key Information about this Study

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the UT Southwestern Health System.

The goal of this research is to understand how patterns of brain functioning relate to irritability which is an important yet understudied symptom in adults with psychiatric disorders such as major depressive disorder (MDD). This study will investigate irritability in people with MDD as compared to control subjects, identify patterns of brain functioning dysfunctions in brain circuits that are associated with irritability, and determine how improvements in irritability with treatment in people with MDD relate to changes in patterns of brain functioning.

If you choose to participate, you will be asked to complete up to 2 in-person visits, each lasting roughly 2-4 hours. During the visits you will complete interviews and questionnaires. One of these visits will also involve an MRI scan lasting no more than 1.5 hours and will include a cognitive task. Costs may arise because of your participation in the study such as costs for transportation, childcare, lost wages. There may be compensation for your study participation. Your care at UT Southwestern Medical Center will not depend on whether you participate in this study.

The main risks to you if you choose to participate are: psychological stress of answering questions, undergoing medical work-up (such as blood draw), and undergoing magnetic resonance imaging (MRI) scans.

Participating in this research will not benefit you. Instead of participating in this research, if you are looking for a psychiatric evaluation, you may receive this care through providers at UT Southwestern and in the community.

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study. Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

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General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Manish K. Jha, MBBS, Department of Psychiatry at UT Southwestern Medical Center.

Research Site
All research visits will take place at UT Southwestern Center for Depression Research and Clinical Care (CDRC) and UT Southwestern Advanced Imaging Research Center (AIRC). The CDRC will be where general study procedures and labs will be completed and is located at1440 Empire Central Drive, Level 3 Mood Disorders, Dallas, Texas, 75247. The AIRC is where the MRIs will be completed and is located at 2201 Inwood Rd. Dallas, TX 75390.

Funding
National Institute of Mental Health, a federal agency that promotes scientific research, is funding this study. This organization is providing money UT Southwestern Medical Center so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

You are asked to participate in this research study of irritability in people with major depressive disorder (MDD). This study will investigate irritability in people with MDD as compared to control subjects, identify patterns of brain functioning dysfunctions in brain circuits that are associated with irritability, and determine how improvements in irritability with treatment in people with MDD relate to changes in patterns of brain functioning.

The researchers hope to learn how patterns of brain functioning relate to irritability which is an important yet understudied symptom in adults with psychiatric disorders such as MDD.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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 time.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are a healthy individual who has never suffered from mental disorders.

How many people are expected to take part in this study?
This study will enroll approximately 60 healthy adults and 140 people with MDD between the ages of 18 and 65.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend approximately 2 visits with the researchers or study staff.

Screening – After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study; this is called screening. We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will be told which results we will obtain and which procedures will not have to be repeated. All study procedures are completed for research purposes only.

Screening Procedures (Approximately 2 hours 30 minutes)
You will first come to the study site for a screening visit or complete part of the screening visit remotely via UTSW BlueJeans TeleHealth platform that you can access through MyChart. At this visit, you will first provide informed consent by signing this document [either in person or remotely via Telehealth utillizing Docusign]. Afterwards, the following procedures will be completed:

- Psychiatric evaluation, including psychiatric and medical history, work and education history, family history, treatment history, sociodemographic information
- Questionnaires about your mood, beliefs, how you think, and events during your lifetime
- Physical exam and blood work (up to 3 tablespoons or 45 mL), urine test (including urine pregnancy test if applicable), and vital signs for general health
- Electrocardiogram (ECG), which consists of putting stickers on your chest that are able to detect details of your heartbeat
- Urine drug screen
- As part of screening assessment, we may also ask you for access to your mental health records, alcohol and/or substance abuse records, and psychotherapy notes to assist with making a psychiatric diagnosis.

Typically, the questionnaires will be completed on a secured computer/tablet, however you may request a paper copy of these questionnaires if you do not feel comfortable completing them on the computer/tablet. Screening procedures, which include psychiatric assessments and surveys, may be conducted remotely via UTSW BlueJeans TeleHealth platform and RedCap for self-report questionnaires.

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you.

Assignment to Study Groups
When it is determined that you are eligible for the study, you will complete the study procedures described below. The data collected from you in this study will be used to compare to individuals with Major Depressive Disorder who are also enrolled in the study.

Study Procedures - as a participant, you will undergo the following procedures:
If you are eligible for this research study, you will be asked to complete a baseline visit within 3 weeks of the screening visit. During this visit with the study team, the following procedures will be completed:

- Complete questionnaires about your mood and beliefs
- Vital signs
- Urine pregnancy test and drug screen
- Magnetic resonance imaging (MRI) scans for brain imaging data. MRI set up may last approximately 1 hour and the 3T MRI scan will not last longer than 1.5 hours. You will be asked to complete cognitive tasks both out-of-scanner and within scanner.

For the MRI procedure, you will lie still inside a large, doughnut-shaped magnet, also called the MRI scanner. The MRI technician can see and hear you during the procedure. You will also be given a squeeze ball to use for communication. You will be inside the MRI scanner for no longer than 75 minutes. MRI scans will be completed at the Advanced Imaging Research Center (AIRC) at UT Southwestern Medical Center. The MRI uses a strong magnet to create images without using radiation that can cause an atom to become charged or ionized, x-rays or injection or any contrast agent (e.g., dyes). You will lie inside the scanner and rest and perform a task, which will be fully explained to you before scanning. The MRI scanner produces loud noises so you will be provided with earplugs or headphones. The MRI technician and/or designated study team member will wrap a breathing belt around your waist in order to measure your breathing rate throughout the scan. They will also attach a heart rate monitor and electrodes for ECG to better understand your physiology while in

scanner. You will be given button boxes that you will utilize for tasks. You may choose to stop the scan at any time for any reason and will not have to explain why and will not lose any reimbursement.

MRI Tasks
During most of the MRI scan you will be lying still and passively while the scanner takes different types of images of the brain. For one part of the scan you will be asked to watch a cross on a screen for about 10 minutes and think of nothing in particular. This is called a 'resting-state' scan. For another part of the scan you will do a computerized task, lasting about 25 minutes. During this task you will be asked to play a game where you have to select responses accurately and quickly. During this task, you may notice changes in how you feel and will be asked to rating your feelings at periodic intervals of the scan. You will earn money while playing this game which will be given to you after completion of the study visit. The aim of this is to see how the brain activates when anticipating and/or experiencing frustration. During the task you will be asked to rate how happy/frustrated you feel using button response pads attached to your hand. It is important to note that although this task is designed to elicit frustration that it should not cause intolerable distress. You can stop the scan at any point if the task is intolerable.

It is possible that the results of these scans might indicate a finding in which it would be informative for you to undergo further evaluation. If abnormalities are found, you may be requested to return for further imaging or evaluation. A physician will be consulted to verify whether any findings merit further investigation, in which case the investigator will contact you and inform you of these findings. The investigators, any consulting physicians, and UT Southwestern Medical Center are not responsible for the cost of any examination or treatment that you may choose to undertake based on any findings resulting from your study participation.

Because this project involves the use of MRI scans, it is necessary that we make a note of your participation in the electronic medical record. That way anyone treating you will be aware of your participation and may be able to avoid any unfortunate outcomes that could arise if your research participation were unknown.

End of Study Plan
At the end of the second visit, a qualified study team member will debrief you and you will be able to ask questions. However, if you feel too uncomfortable or distressed at any point during this visit, the study procedures will be stopped, and you will be exited from the study. A study clinician will discuss your post-study participation treatment options with you. If applicable, the study team will ask if they can reach out to your mental health provider to aid in the transition of care. If you don't have a current mental health provider, a clinical referral can be provided.

Your responsibilities if you take part in this research study:
If you decide to take part in this research study, you will be responsible for the following things:

- coming into our program for research study visits,
- using birth control methods as described in described in the Description of What's Involved section
- avoiding the use of psychotropic medications during study
- following the instructions of the principal investigator and study staff.
- telling the principal investigator or research study staff about any side effects, doctor visits, or hospitalizations that you may have because of the MRI or other procedures.
- telling the principal investigator or research staff if you believe you might be pregnant. Pregnant patients will be excluded from participation, due to potential and potentially unknown contraindications with MRI procedure.
- telling the principal investigator or research staff if you have any type of implanted electrical device (such as a cardiac pacemaker). If so, you will not be allowed to participate in this study.
- asking questions as you think of them.
- telling the principal investigator or research staff if you change your mind about staying in the study.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If data have been stored as part of the research study, they too can be destroyed without your consent. Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. Any clinically relevant results of the research will be communicated to you. Clinically relevant means that the information indicates that you may be at risk for a serious illness known at the time of testing to be treatable and it can be confirmed. In that case, we will attempt to notify you using the contact information you have provided.

If you do not want to be notified of any of these incidental findings, please initial below.

_____ Please do not notify me of any incidental findings obtained from this research.

Risks – "What are the risks of participation in the research?"

Risks from the research

Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.

The following section will describe the risks related to each your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Risks and discomforts associated with MRI Scan:

- *Eye Discomfort*: On very rare occasions, you may feel some eye discomfort. The scanning will be stopped if this occurs. These symptoms, if present, will subside shortly after leaving the magnet.
- *Claustrophobia*: Please note that some subjects who are uncomfortable in small spaces have experienced claustrophobia, which is feeling discomfort in small, confined spaces, while in the MRI scanner. You may discontinue the scan at any time if you feel intolerable discomfort.
- *Twitching Sensations*: There is a possibility that you will experience a localized twitching sensation due to magnetic field changes during the scan. This is not unexpected and such sensations should not be painful. However, you may have the scan stopped at any time if this occurs.
- *Heat Sensations:* There is a risk of heating from radiofrequency imaging coils and their cables, button response boxes and their cables, and the cables from monitoring devices that record physiologic processes such as heart beats per minute or electrical activity of the brain. Please report any heating sensation immediately. You may have the scan stopped at any time if this occurs.
- *Dizziness or Nausea:* Dizziness and nausea will occur if you move quickly near the magnet or if your head moves within the bore of the magnet. You will be instructed on how to move through the MRI room to minimize any such dizziness and nausea.

- *Frustration or Stress:* The MRI task in this scan is designed to elicit frustration. The aim of this is to see how the brain activates when anticipating and/or experiencing frustration. It is important to note that his task should not cause intolerable distress. You can stop the scan at any point if the task is intolerable.

The procedure may involve risks that are currently unforeseeable. If you feel discomfort at any time, notify the operator and you can discontinue the exam at any time.

MRI scanning involves the use of a magnet and radio frequency energy. Therefore, patients who have implanted metal devices, such as pacemakers, certain aneurysm clips, or shrapnel or metal in the eye are at risk. If you have any question of metal in the body, you should inform the technologist or investigators before entering the magnet room. If you have metal in your body that you are unable to remove, you will not be able to participate in this study. Because of the strong magnetic field associated with the scanner, it is rare, but possible, that a metallic object could fly through the air toward the scanner and hit you. To reduce this risk, everyone in the vicinity of the magnet will remove all metal from their clothing or pockets when in the scanning environment.

MRI releases radio waves which are noisy but not harmful. To minimize any discomfort from this noise, you will be provided with disposable earplugs or headphones that help suppress external noise levels but do not eliminate the noise so that you can have voice communication with the scanner operator. During the MRI you may also experience discomfort and a feeling of claustrophobia (fear of being trapped in a narrow place). The machine may be stopped at any time during the scan upon your request.

Other risks of MRI that rarely occur include neurostimulation effects, such as muscle twitches and tingling sensations, due to the rapid switching of magnetic fields, and a slight increase in body temperature that may occur in the presence of radio frequency energy. These are very unlikely under current operational guidelines. In the very remote event that the magnet loses its magnetism, liquid helium in the magnet will escape. The room is designed with ventilation systems to prevent accumulation of these gases. Should this occur, you will immediately be brought out of the magnet room.

Risk of loss of private information: this risk always exists, but there are procedures in place to minimize the risk.

Psychological stress: During the clinical interviews, you may become tired or upset about the questions. If this happens, you should tell the interviewer/study personnel and he/she will stop the examination. Depending upon how you feel, you may then 1) take a rest period and resume later, 2) reschedule for a later appointment or 3) decide not to finish the exam.

Blood draw: The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

Potential for Abnormal Medical Findings: A limited research report will be sent to a radiologist for all scans. 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 a medical diagnosis. 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 findings merit 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 UT Southwestern Medical 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.

This MRI scan is not being done for your regular medical care. The machine settings used for this special MRI are not chosen to pick up structural changes in the brain, for example: masses or bleeds. It is possible that during the course of the research study, the research staff may notice an unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician and may result in additional cost to you.

In addition to these risks, this research may hurt you in ways that are not known. The unknown risks might be minor or might be major (death).

Group Risks: Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

Privacy Risks: Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database. In any research study there exists the potential for loss of your private information. However, there are strict procedures in place to minimize this risk.

For more information about risks and side effects, ask one of the researchers or study staff.

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

Are there Risks related to withdrawing from the study?
If you decide to withdraw from this study early, please discuss your decision with the principal investigator. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your data removed from future use. If any data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place.

Reproductive Risks -
Concerns for sexually active men and women: Women should not become pregnant and men should not father a baby while taking part in this research study because the MRI could possibly affect a man's sperm (for some drugs/procedures, the concern may be that the sperm might be affected and in some cases, drugs could being carried by the semen into the vagina and cause harm) or a fetus, if a woman becomes pregnant during the MRI. It is important that you talk to your doctor about avoiding pregnancy during this study. If you think you might have become pregnant or if you believe your female partner has become pregnant while you are in this study, you must tell one of the doctors right away so that management of the pregnancy and the possibility of stopping the study can be discussed.

If you become pregnant during your participation in this research study, the researchers would like to collect follow-up information regarding your pregnancy.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still

experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information at the end of this document. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

It is important to know that you may not receive any benefits from taking part in this research. Others may not benefit either. However, the information gathered from this study may contribute to the development and testing of new noninvasive brain imaging techniques (i.e., technology that does not rely on either surgery or on the use of drugs). These techniques may also contribute to isolating and describing suspected brain structure or function related to irritability, and/or improving our understanding of anatomy and function within these disorders.

Payments – Will there be any payments for participation?

If you agree to take part in this research study, you can earn up to a total of $250 for your time and effort. You will be paid $50 for the screening visit. Additionally, you will be paid $100 for completing the MRI and can earn up to $100 for the cognitive tasks completed both outside and within MRI scanner. You will be paid at the completion of each visit/MRI. If you do not complete the study, you will be paid for the visits that you have completed based on the following schedule:

Study visits	**Payment**
Screening visit	$50
MRI (baseline)	$100
Cognitive task performance	Up to $100
Possible Total for Study:	$250

You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of each visit (screening and baseline). Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year unless it's a reimbursement.

You should also know that it is possible that products may someday be developed with the help of your data, and there are no plans to share any profits from such products with you, regardless of whether your identifiable information is removed.

Costs – Will taking part in this study cost anything?

The sponsor will pay UT Southwestern for the procedures that are part of the study. You will not be reimbursed for your travel or time that may be required for study visits.

Taking part in this research study may lead to added costs to you such as those related to transportation, childcare, and missed wages. Payments for study visits are to help cover such costs.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Certificate of Confidentiality:

To help us further protect your information, the investigators will obtain a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;
- information regarding test results for certain communicable diseases to the Texas Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

How will my information be used?

With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

By agreeing to participate in this study, your information could be used for future research studies or sent to other investigators for future research studies without additional consent from you. The information that identifies you will first be removed from your information. If you do not want your information to be used for future research studies without your consent, you should not participate in this study.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include your: name, address, telephone/fax numbers, dates directly related to the individual (birth, admission, discharge, date of death, etc.), e-mail addresses, social security number, and medical records number.

The researchers will also get information from your medical record from your doctor, from UT Southwestern Medical Center, and by asking you to complete the tests, procedures, questionnaires and interviews explained in the description section of this consent.

All MRI scans will be saved indefinitely after the conclusion of the study.
During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- Reviewing mental health records
- Reviewing alcohol and/or substance abuse records
- Reviewing psychotherapy notes

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The Sponsor, National Institute of Health, funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- The members of the local treatment team
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- The Research offices at the University of Texas Southwestern Medical Center.
- The Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.

- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the Center for Depression Research and Clinical Care (CDRC) and AIRC for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Manish K. Jha, UT Southwestern, 1440 Empire Central Drive, Level 3 Mood Disorders, Dallas, Texas, 75247. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

During your participation in this study, you will not be able to access your medical records. This will be done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The investigator is not required to release to you research information that is not part of your medical record.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until October 2033. This permission to use your personal health information expires on the date noted above.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Manish K. Jha, MBBS can be reached at 214-648-0156 or Manish.Jha@UTSouthwestern.edu.

Secondary contact:
If Dr. Jha is unavailable, please contact:

Brindley House, MA at 469.602.3679 or Ann.House@UTSouthwestern.edu

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM

Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:

By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM