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STUDY INFORMATION:

Study Title: Deep Brain Stimulation for Bipolar Depression: Assessing the safety and use of Intracranial neurophenotyping of state switches

Study site(s): Icahn School of Medicine at Mount Sinai, Mount Sinai Hospital, Mount Sinai West, The Clinical Neurosciences Center (part of Mount Sinai network)

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SUMMARY OF THIS RESEARCH STUDY

This form explains a research study you may choose to join. Joining is your choice. Your care at Mount Sinai will stay the same if you join or if you do not join. Before you decide, make sure you understand what the study is about. Make sure all your questions are answered. If you join, the study team will tell you about any new information that could change your choice to stay in the study.
This study is testing a new treatment for bipolar disorder. It is for people whose depression has not improved with usual treatments. The researchers are testing a treatment called Subcallosal Cingulate Cortex Deep Brain Stimulation (SCC DBS). SCC DBS uses small electrical signals to affect a brain area linked to depression. They want to see if it can help treat bipolar I depression without causing mania.

Mania is a common side effect of many antidepressant drugs. The team will measure brain activity in two brain areas. These areas are called the SCC and the amygdala. This will help them learn how the treatment works. It will also help them look for early signs of a mood change. If this method helps, it may help scientists learn more about how the brain controls mood in bipolar disorder. Because of this study, doctors may be able to watch brain signals in real time in the future. They may then change treatment when needed. You are being asked to join because you have treatment-resistant depression and Bipolar I disorder and are on stable medications to control your manias.

If you choose to take part, you will be asked to:



- Receive DBS to a part of your brain called the subcallosal cingulate (SCC) with monitoring of brain activity from the SCC and a second region, the amygdala (amg)
- Come to Mount Sinai West, the Clinical Neurosciences Center, and/or the Icahn School of Medicine for several visits
- Share your medical records with us to confirm your eligibility to participate
- Have a treating psychiatrist throughout the study to monitor and manage your bipolar disorder
- Allow the study team to share information with your treating psychiatrist and permit them to share information with us
- Agree to have two contacts (family member or friend) available to be reached in case you cannot be contacted
- Stay on your current anti-mania medication regimen and any other psychiatric medications for a minimum of 4 weeks before and throughout the year of the study,
- Perform assessments of your mood and brain activity every day for 1 year
- Know how to use and maintain your device and accessories
- Have several neuroimaging procedures
- Pay for your battery replacement surgery at a later date as needed and any clinical care outside of the study. We will work with you and your insurance company prior to receiving the surgery to address coverage of your clinical expenses
- You will not be financially compensated for participating in this study, though you may request reimbursement for a portion of your travel expenses of research-related appointments

If you choose to take part, the main risks to you are related to the DBS device implantation surgery or subsequent device-related complications. Known complications of the surgery and/or the anesthesia used during the procedure can be minor (such as discomfort/pain at the surgical sites) or major (including brain hemorrhage, stroke, or, rarely, even death). Secondary complications have been observed due to device failure, which can result in clinical worsening or additional procedures to replace device components. A complete list of all reasonably foreseeable risks associated with participating in this study is included later in this form.

You may benefit from participating in this research if your depression symptoms improve. However, this is a possibility and not a certainty; you may not benefit from taking part in this research, or you may get DBS induced side effects. Deep Brain Simulation is not an FDA approved treatment for bipolar depression.

Instead of participating in this research, you may pursue other forms of treatment that you have not tried before. You should discuss other treatment alternatives with your psychiatrist before choosing to

participate in this study. If you are interested in learning more about this study, please continue to read below.

STUDY PARTICIPATION:

You may qualify to take part in this research study because you are between the ages of 22 and 70, have treatment resistant depression, a diagnosis of bipolar 1 disorder, and you have expressed interest in receiving Deep Brain Stimulation (DBS).

You must be under the care of a psychiatrist who manages your bipolar disorder medications to be in this study, and you must be willing to allow the study team and your psychiatrist to share information. You must be healthy enough to have general anesthesia and brain surgery. You must be willing and able to comply with all study procedures and proper use of the DBS device. You must also be able to reside in the New York Metropolitan area during the first 12 months of the study or willing/able to travel weekly to the study site.

Your participation in this research study is expected to last about 3 years; the most demanding data collection will occur in the first year of participation. There are 5 people expected to participate in this research study at Mount Sinai.

Funds for conducting this research study are provided by Breakthrough Discoveries for thriving with Bipolar Disorder (BD^2).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

DESCRIPTION OF WHAT IS INVOLVED:

What is an Electronic Health Record?

An Electronic Health Record (EHR) is a digital version of a patient's medical chart. If you join this research study and you are not already a Mount Sinai patient, an EHR will be created for you. The EHR will include personal and health information needed for the study.

What information may be in the EHR?

Information from this research study, such as lab results, notes, imaging, and procedures, will be added to your EHR.

• Your EHR may not include all of the information collected during the research study.
• Mount Sinai staff who are not part of the research team may see your EHR.
• Your EHR may be shared with authorized groups outside of Mount Sinai, including insurance or disability providers.

Will I have access to my information in the EHR?

The 21st Century Cures Act gives patients and research participants more access to their EHR. The law allows some research information not to be shared. In this study, some research information will not be shared with you.

If you agree to take part in this research study, here is what may be involved:

- Screening and presurgical evaluation
- Baseline assessments 1 month prior to surgery
- DBS implantation surgeries staged over two surgical procedures one month apart
- 4-week daily brain and home recordings without any stimulation received
- 52-week active stimulation phase with in-person appointments and home recordings
- An approximate 3-year naturalistic follow-up phase with psychiatric care as usual and ongoing DBS

These stages are described in detail below. The procedures that take place in this study will be conducted at the Clinical Neurosciences Science, Mount Sinai West, and/or the Icahn School of Medicine.

Screening and Pre-Surgical Evaluation (at least 8 weeks prior to surgery)
After you have signed this consent form indicating that you want to participate in the study, you will be screened to see if you are eligible to participate and complete the study procedures. To ensure that you qualify for this study, you will have a comprehensive evaluation. You will be asked, both in interviews and with questionnaires, about your current and past physical and mental health, as well as information about your use of drugs and alcohol. Individuals who are currently using substances that can increase the risk of DBS surgery or who are pregnant or breast feeding will not be able to participate in this study. It is possible that after completing the screening, you might not be eligible to participate. If so, you will not complete any further testing or assessments

Release of Information.
You must allow us to review the last 5 years of your medical records to confirm your eligibility to participate, including your psychiatrics and pharmacy records, records regarding any prior hospitalizations if applicable, and any relevant medical or neurological conditions. This is to document the previous treatments you have received for your symptoms, when you received them, and any effect they had on your symptoms.



Psychiatric Examination
The clinical rater (a research staff member specifically trained to administer study assessments) and study psychiatrist will interview you about your medical and psychiatric history. This will include a detailed psychiatric interview and rating of your depressive symptoms and confirmation of your Bipolar I diagnosis with TRD. A second psychiatric evaluation will be done to confirm the diagnosis of Bipolar I Disorder. This will last about 3 hours in total over different days and will include the Structured Clinical Interview for DSM Disorders (SCID), the Mini-International Neuropsychiatric Interview (MINI), the Antidepressant Treatment History Form Short Form (ATHF-SF), the Young Mania Rating Scale (YMRS), the Hamilton Depression Rating Scale (HDRS), the Montgomery-Asberg Depression Rating Scale (MADRS), the Mood Disorder Questionnaire (MDQ), the Quick Inventory of Depressive Symptomatology Clinician Rating (QIDS-C), and the Columbia-Suicide Severity Rating Scale (C-SSRS).

Self-Administered Scales
You will be asked to complete several self-administered scales during this screening process to determine your eligibility. These scales will include PHQ-9, PMQ, BDI, and PANAS.

Neurosurgical Examination
You will also meet with the study neurosurgeon and their staff, who will explain the planned surgery to you. As a part of the preoperative assessment, your medical history will be reviewed, and a detailed physical examination will be performed. Also, a small amount of blood (about 3-4 tablespoons or 44-60mL) will be drawn and used to test for medical illnesses, and a urine sample will be collected to test for medical illnesses, pregnancy, and evidence of drug use. An electrocardiogram (EKG) will also be performed, which uses sensors placed on your chest to record your heart's electrical activity and rhythm. The neurosurgeon will review your examination and test results to make sure that you are medically healthy enough to undergo brain surgery to implant the DBS device. This appointment will last approximately one hour.

Important Requirements
Please remember that as a part of this research study, you are required to continue to have a treating psychiatrist to manage ongoing non-depression DBS treatments for bipolar disorder (and mood stabilizers) throughout the study. You allow us to discuss your treatment and communicate with us throughout this study. You must also identify 2 family members and/or friends to serve as a point of contact throughout the study in case we are unable to reach you.

Baseline Assessments (4 weeks prior to surgery)
After you have been deemed eligible to participate and have decided to receive DBS in the study, you will complete the following study-related procedures:

Clinical Ratings



Every week during the 4-week pre-surgery period, you will meet with the clinical rater and/or study psychiatrist, who will rate your depression symptoms and monitor your condition. This will be done with several questionnaires including the HDRS, MADRS, YMRS, and C-SSRS with video/audio recording. These visits will take between one to two hours each.

Home-Based Assessments
Beginning 4 weeks prior to surgery, you will begin completing assessments from home. Once per day, you will receive an email to complete an assessment called the Computerized Adaptative Test of Mental Health (CAT-MH) which will ask you questions about your mood, behavior, suicidal thoughts, and quality of life. This should take only a few minutes a day to complete.

Twice a day, you will also be asked to record a short video diary on your smartphone and upload it as instructed via a HIPAA compliant platform. Data will not be monitored in real time, so you should not use the video diaries to relay any urgent information to the team. ***If you need assistance, such as if you are having thoughts of self-ham, you should call 911 and notify the study psychiatrist immediately.***

In-Lab Data Collection
Once a week, you will be asked to come to the QLab to conduct different experiments aimed at characterizing your depression prior to DBS. These will include electrophysiological measurements, video captures of your face, as well as behavioral tasks.

Pre-Surgical Magnetic Resonance Imaging (MRI) Scan
Prior to surgery, you will undergo a magnetic resonance imaging (MRI) scan, which will be done under general anesthesia. The MRI scan helps us plan where the electrodes will be placed during your surgery.

Medications
You must stay on your current medication regimen at the same dose for at least 4 weeks prior to surgery and for the first year following surgery (unless your symptoms worsen or you develop any side effects). This must include stable anti-mania medication. We will work with you and your psychiatrist as needed.

DBS Implantation Surgery
Components of the DBS system include:

- An **electrode**, which consists of insulated wires with four electrical contacts to deliver stimulation
- An **Implantable Pulse Generator (IPG)**, which is the power source and sensor for the device
- An **extension cable**, which connects the electrode to the IPG (power source)

The IPG is a metal “can” about 2 inches in diameter and about ½ inch thick that is inserted like a pacemaker under the skin of your chest. It contains a small battery that both produces the electrical impulses needed for stimulation of your brain as well as the sensor that measures the electrical activity around the neurons (brain cells) near the site of stimulation, called local field potentials or LFPs. There is also a cable placed under the skin in your neck that connects the IPG in your chest and the electrodes under your scalp.

Once you have completed all baseline testing procedures, you will have the Percept RC system implanted by the study neurosurgeon.

Your surgical procedure will be staged over two separate surgeries one month apart.

You will be admitted to the Mount Sinai West hospital on the morning of surgery. First, under local anesthesia, a frame required for the operation will be secured to your head to ensure accurate, stable positioning of your head throughout the procedure. Once the frame is placed, you will be moved to the operating room table and put to sleep. Once you are asleep, an X-ray Computed Tomography (CT) scan will be performed. Then, 2 incisions will be drilled in your skull on one side of your head. The neurosurgeon will then insert two small electrodes into predefined locations. Once both electrode leads are in place, the location will be confirmed by another CT scan. When you are completely awake, you will undergo about 30 minutes of behavioral and device safety testing with electrophysiology recordings.

Finally, after the electrodes are placed and tested, you will be put back to sleep to complete the implantation of the rest of the DBS system. The *extension cables that connect the electrodes to the battery will be tunneled under the skin behind your ear and connected to the IPG. The IPG will be placed in your chest wall below your collarbone, just under the skin. This portion of the procedure will take approximately 1 hour.*

The procedure explained above will be repeated one month later for the other side. After both surgeries, you will have a total of four electrodes and two batteries implanted.

Following each surgery, you will have another CT scan to check your brain for any unexpected events that may have occurred during surgery (e.g. bleeding in your brain). You will receive routine postoperative care, including pain medication and wound care. You will meet with the neurosurgical staff and study psychiatrists each day you are in the hospital.

4-Weeek Non-Stimulation Phase



This phase will begin immediately following your final staged surgical procedure for complete implantation of the DBS system and will last for one month. You will not receive any stimulation during this phase.

Postoperative MRI and CT scans/Neurosurgical Follow-Ups
Two weeks after you leave the hospital, you will have a CT scan. The scan will be the same as the other CT scan you received before the implantation surgery, which is described in detail later in this document.

Additionally, you will have neurosurgical follow ups as needed and/or clinically indicated.

Home-Based Assessments
Once per day, you will continue to receive an email to complete the CAT-MH assessment which will ask you questions about your mood, anxiety, suicidal thoughts, and quality of life. This should take only a few minutes a day to complete.

Twice a day, you will also be asked to record a short video diary on your smartphone and upload it as instructed via a HIPAA compliant platform. Data will not be monitored in real time, so you should not use the video diaries to relay any urgent information to the team. ***If you need assistance, such as if you are having thoughts of self-ham, you should call 911 and notify the study psychiatrist immediately.***

52-Week Active Stimulation Phase
This phase will begin immediately after your 4-week period of receiving no stimulation.

Postoperative MRI Scans
One week after active stimulation, you will have an MRI scan to see what changes, if any, have occurred in your brain activity after device implantation and DBS stimulation exposure. This will also be done again one month, 3 months, 6 months, and 12 months after active stimulation is started. These scans will be like the MRI scan you received before surgery, though you will be awake the whole time for these scans. They are described in detail later in this document.

In-Lab Data Collection
Once a week, you will be asked to come to the QLab to have your data downloaded from your device, as well as conduct different experiments aimed at understanding and tracking changes in your depression. These will include electrophysiological measurements, video captures of your face, as well as behavioral tasks.

Clinical Ratings
Every week, you will meet with the clinical rater and/or study psychiatrist, who will rate your depression symptoms and monitor your condition. This will be done with several questionnaires



including the HDRS, MADRS, YMRS, BDI-II, and C-SSRS with video/audio recording. These visits will take between one to two hours each.

Medtronic Percept RC System Accessories
You will be provided with equipment for use in the study, which will allow you to record your mood and brain signals. You will need to keep the various components charged and in working order at all times. The study team will show you these items during your preoperative visits, and you will be taught how to use them before you leave the hospital.

Event Recording
The device we are using in this study provides the opportunity to gather information about what your brain is doing when you experience emotional events in daily life and any momentary changes in your mood. If something happens during your day that you feel is important for us to know about, you can capture data about this event. This process will be taught to you before you leave the hospital. You will be asked to record twice daily at minimum with extra event recordings as needed.

Home-Based Assessments
Once per day, you will continue to receive an email to complete the CAT-MH assessment which will ask you questions about your mood, anxiety, suicidal thoughts, and quality of life. This should take only a few minutes a day to complete.

Twice a day, you will also be asked to record a short video diary on your smartphone and upload it as instructed via a HIPAA compliant platform. Data will not be monitored in real time, so you should not use the video diaries to relay any urgent information to the team. ***If you need assistance, such as if you are having thoughts of self-harm, you should call 911 and notify the study psychiatrist immediately.***

Long-Term Follow-Up Phase (3 years)
This phase will begin once you have completed the 52-week active stimulation phase and will last about 3 years. If no clinical benefit is seen at the 1-year mark, and/or you decide not to continue treatment, you will be scheduled for explantation of your DBS system. This will require the surgical removal of the DBS system (done in one procedure). You would have a conversation with the study psychiatrist and study neurosurgeon to determine if this is the best option for you and schedule the surgical procedure for removal if deemed medically indicated for your safety based on the outcome of the year of data collection. We will turn the device off for a recommended period of 12 weeks to assess if this is the best option for you. If you do not want to wait 12 weeks, we will discontinue your DBS system until your explant procedure can be arranged. You are free to change your mind if your symptoms return and you wish to resume stimulation.

If there is clinical benefit and you want to continue treatment, you will continue the activities described below and keep the DBS system implanted.

Event Recording
You will be asked to record daily at minimum with extra event recordings as needed throughout your long-term follow-up.

Home-Based Assessments
Once per day, you will continue to receive an email to complete the CAT-MH assessment which will ask you questions about your mood, anxiety, suicidal thoughts, and quality of life. This should take only a few minutes a day to complete.

You will also be asked to record a short video diary once a day on your smartphone and upload it as instructed via a HIPAA compliant platform. Data will not be monitored in real time, so you should not use the video diaries to relay any urgent information to the team. ***If you need assistance, such as if you are having thoughts of self-ham, you should call 911 and notify the study psychiatrist immediately.***

Clinical Ratings
Every 3 months, you will meet with the clinical rater and/or study psychiatrist, who will rate your depression symptoms and monitor your condition. This will be done with several questionnaires including the HDRS, MADRS, YMRS, BDI-II, and C-SSRS with video/audio recording. These visits will take between one to two hours each.

Please note that depending on the results of the above activities and how you are doing clinically, you may be asked to be seen more frequently by the study team.

Upon completion of study participation, if you have a device implanted (be it active, inert, or partially explanted), you will be provided contact information for clinicians who can provide ongoing management of the device, including a neurosurgeon. Increasing stimulation parameters beyond those used during the course of the study is discouraged as the safety of such parameters have not been evaluated.

If you are stable after completion of study participation after 3 years, you can exit the study and receive clinical care through you or a third-party payer (health insurance) as you will have a commercial device. This can be through our team if you wish or another provider you will be given contact information as stated above).

Pregnancy

The risk to an unborn fetus from DBS treatment in general or from the specific device used in this study is not known at this time. Since you are participating in a research study that involves experimental treatment with potential risks to a developing fetus, it is recommended, for your protection, that you not become pregnant for the duration of the study. If you can possibly get pregnant, a urine pregnancy test will be done before you begin the study and will be repeated throughout the study, as indicated. You cannot be included in the study if you are or become pregnant, as the study device could harm your fetus. You also should not be in the study if you are producing milk to feed a child as the study device and/or procedures could harm your baby. Unless you are at least one year past menopause or have had a successful operation to make pregnancy impossible,
you should use effective birth control during the first year of the study. Unless you are sexually abstinent (not having genital sex) the recommended methods of birth control are:

- The consistent use of an approved hormonal birth control (pill, patches, rings),
- An intrauterine device (IUD),
- Contraceptive injection (Depo-Provera),
- Double barrier methods (Diaphragm with spermicidal gel or condoms with contraceptive foam)
- Sexual abstinence (no sexual intercourse), or
- Sterilization (a vasectomy, getting tubes tied, or a hysterectomy).

All birth control methods (other than abstinence and sterilization) are only effective if you use them properly, start them at least one month before you begin the research study, and continue using them throughout the research study and for one month after the research study ends. If you are unsure whether the method of birth control you use is approved to use while you are in this study, you should ask the Lead Researcher before you begin the study. You should ask your study doctor if you should continue birth control for longer than 30 days after the end of the study. If you are less than one-year post-menopausal, you could still become pregnant. If you or your partner becomes pregnant, or may be pregnant, at any time during the study, you must tell a person from the research team immediately. The team may stop the device trial procedure and refer you/your partner to an obstetrician/gynecologist for follow-up. If you plan to become pregnant in the year following a clinical trial, speak with your study doctor. Should you/your partner become pregnant, whether or not you/your partner have the baby, the people funding and overseeing the research may ask for information on the pregnancy, even if you are no longer part of the study. You/your partner will be asked for additional written consent to share this information if that happens.

Future Contact:

The researchers may wish to use your personal contact information to contact you in the future. Do you give the researchers permission to **contact you** in the future to request the collection of

additional information about you, discuss how your private information, study data and/or samples might be used, or discuss possible participation in another research study?

Please initial your choice: Yes_____ No_____

If “Yes”, please indicate your preferred method of contact: (initial all that apply)

[ ] Email [ ] Phone [ ] Letter [ ] Text

USE OF YOUR DATA AND/OR SAMPLES:

The researchers would like your permission to keep your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) to use or share in future studies. You can still be part of the study if you do not allow us to use or share them. Please select Yes or No to each of the questions below. To decline all future uses/sharing please select ‘No’ each time.

(1) Will you allow the researchers to store your data and/or samples to use in future research studies?

Please initial your choice: Yes_____ No_____

If you select No, please stop here and move to the next section, '**Your Responsibilities If You Take Part in This Research**' section below."

If yes, please continue to the next question and tell us how your personal information, study data and/or samples may be used in future research studies.

(2) The researchers can store your data and/or samples in one of two ways:

a) Anonymously (no one will know who the data and/or samples came from). If you choose this option, you can’t change your mind. So, if you wanted to have your data and/or samples destroyed in the future, the team could not do it as they would not know which data and/or samples were yours.
b) Linked to your identity (using a code that can show the information came from you personally). In this case you could ask for your data and/or samples to be destroyed in the future if you want that to happen.

How would you like your data and/or samples stored? Please initial **ONE** choice below:



I would like my data and/or samples stored anonymously _____

I would like my data and/or samples stored with a link to my identity through the use of a code_____

(3) Do you give the researchers permission to keep the data and/or samples, so they could use them in future studies that are **directly related** to the purpose of the current study?

Please initial your choice: Yes_____ No_____

(4) Do you give the researchers permission to keep the data and/or samples indefinitely, so they could use them for future studies that are **not related** to the purpose of the current study (for example a different area of research)?

Please initial your choice: Yes_____ No_____

(4.1) From time to time, researchers outside of medicine and related sciences would like to use data and/or samples. This might be in the fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your data and/or samples?

Please initial your choice: Yes_____ No_____

a. If the future research in a different area can be done without having to know that the data and/or samples came from you personally, that will be done.
b. If the future research in a different area requires that it is known specifically who the data and/or samples came from, then one of the following will be done:
   I. If you allowed the researchers to contact you in the future, they may be able to contact you to explain why your data and/or samples is needed and what will be done with it. Your permission will be asked to use your data and/or samples in that research project.
   II. If you do not give permission to be contacted in the future, or if it is found that contacting you is not practical (for example, because you have moved), your data and/or samples may still be used. The Institutional Review Board (IRB) will be asked for permission to use the data and/or samples linked to your identity. The IRB can give permission for researchers to use and share identifiable health information without contacting you, but only if it determines that sharing the data and/or samples will not be more than minimal risk to you or your privacy. The IRB is a committee of doctors and scientists and nonscientists, including people not associated with this hospital or medical school, whose job it is to protect people who participate in research.



(5) Do you give permission to have your data and/or samples given **to other researchers,** including those at Mount Sinai, other medical or scientific institutions and for-profit companies, for use in research within the limits you have chosen above?

Please initial your choice: Yes_____ No_____

Whether or not you have allowed us to share your data and/or samples, the researchers at Mount Sinai will keep data and/or samples collected about you during this research study to use in future research studies consistent with the wishes you expressed above.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

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

- Attending all study-related appointments, as scheduled
- Operating the Percept RC DBS device and all accessories, as indicated
- Collecting data about your mood and activities daily
- Collecting brain activity recordings at home daily, also called Local Field Potentials (LFP) recordings
- Taking your medications as prescribed (including using appropriate methods of birth control for individuals of childbearing capacity, as described earlier in the document
- Informing the research team about any side effects, mood changes, or device issues in a timely manner if they arise

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

There may be costs to you by taking part in this study. You or your third-party payer will be responsible for the cost of the replacement device and the surgical costs of its implantation at the point of battery depletion. You will also be responsible for any clinical care outside of the study.

You will not receive compensation for being in this study, but you may request reimbursement for your travel to the study site for research-related appointments. The maximum amount to be reimbursed is $15 per visit, and a maximum of 50 visits will be reimbursed over the course of the study. The maximum total you may receive is $750. Receipts must be submitted to receive reimbursement, which will be provided in the form of checks issued no more than once per month. It can take up to 6 weeks to prepare and give you a check for study participation. If you do not get a check by then, you can first contact the research team. If further assistance is needed, please contact Mount Sinai's Program for the Protection of Human Subjects at (212) 824-8200.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as

applicable. Generally, this happens if you receive payments that equal $2,000 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.__

POSSIBLE BENEFITS:

Deep brain stimulation is NOT FDA approved for the treatment of bipolar depression. It is important for you to know that you may not get any benefit from taking part in this research. Others may not benefit either. There is a possibility that your depression symptoms improve with the SCC DBS received in this study. However, this is a possibility and not a certainty. The information obtained from this study will aid in assessing the therapeutic efficacy of continuous SCC-DBS for depression and developing novel safety biomarkers that can track impending bipolar mood state switches.

POSSIBLE RISKS AND DISCOMFORTS:

Risks of Surgery and Deep Brain Stimulation (DBS) Treatment

DBS implantation carries established neurosurgical risks, including intracranial hemorrhage, seizures, and stroke. Additional risks include postoperative infection, hardware failure, and unintended stimulation of structures adjacent to the target.

Adverse effects related to SCC25-DBS in depression differ from those reported for Parkinson's disease and obsessive–compulsive disorder due to differences in both anatomical targets and surgical technique. Although the acute and chronic effects of SCC25-DBS are better understood, important aspects of safety and response trajectories remain under investigation.

Our DBS surgeon will work with you should you need other medical procedures to ensure your safety.

Risks Associated with Battery Depletion, Lead Malfunction, or Interruption of Stimulation

- Inadequate stimulation may lead to a relatively slow return of depressive symptoms.
- Temporary discontinuation of stimulation, whether accidental or clinical procedures lasting hours to days, has not been associated with abrupt behavioral changes.
- Controlled discontinuation studies demonstrate a gradual progression of symptoms over several weeks, beginning with reduced motivation and activity followed by increased negative mood. Acute worsening of sadness, anxiety, or suicidal ideation has not been observed.
- Complete sustained failure to charge the battery depletion and /or hardware malfunctions (e.g., lead fracture) have been associated with symptom recurrence. Battery status and impedance is evaluated at each study visit, and additional monitoring occurs during blinded discontinuation conditions.

- The Percept RC device has an estimated battery life of approximately 15 years under standard therapeutic settings.

Additional Device-Related Risks and Contraindications

MRI Restrictions

Specific MRI procedures such as those requiring a full-body RF transmit coil, a receive-only head coil, or a head transmit coil extending over the chest, are contraindicated. Participants will be informed of these restrictions. To mitigate these risks, you will be provided with an MR device card denoting the MR conditional status of the device. You will also be informed to let the team know about any upcoming MRIs as applicable so we can plan safety precautions with you. The planned research protocols meet safety standards set by Medtronic. A Medtronic technical rep will be present for all research scans to ensure MRI protocols are performed. Any clinical MRI must be reviewed by study investigators in advance to ensure appropriate safety measures or alternative imaging plans.

Post-implant MRI will be conducted per the labeling (MR conditional status).

Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including coma, paralysis, or death. This is described in more detail below.

Abandoned Systems and Electromagnetic Interference (EMI) considerations - If any DBS system components (neurostimulator, lead, extension, or a fragment of a lead or extension) remain implanted in your body after a partial system explant, you are still susceptible to possible adverse effects from EMI. These effects include induced current and component heating, which may result in shocking or jolting you and tissue damage resulting in serious injury or death. If you have DBS system components implanted in your body, you are advised to notify all medical personnel that you have an implanted DBS system. MRI scan-type eligibility for patients with abandoned systems (ie, abandoned components no longer providing therapy) cannot be determined for MRI scanning purposes.

MRI scans using the full-body eligible MRI scan conditions with a neurostimulator implanted in locations other than the pectoral and abdominal regions are untested and may cause unintended stimulation, device damage, or excessive heating, which can result in serious and permanent injury including coma, paralysis, or death.

Exposure of the Medtronic DBS System to MRI at unapproved parameters guideline can induce significant heating at the lead electrodes or at breaks in the conductor wire (in the lead, extension, or pocket adaptor). Excessive heating may occur even if the lead and/or extension are the only part of the Medtronic DBS System that is implanted. Excessive heating can result in serious and permanent injury including coma, paralysis, or death

Heating – The MRI RF field induces currents onto the lead system that can produce significant heating effects at the lead-electrode-tissue interface or at the location of any breaks in the



neurostimulator lead system. Component heating from the MRI RF field is the most serious risk from MRI exposure. Failure to follow these MRI recommendations can result in thermal lesions, which could result in coma, paralysis, or death.

Diathermy Contraindication

Shortwave, microwave, and therapeutic ultrasound diathermy are strictly contraindicated in individuals implanted with a neurostimulation system. Diathermy may transfer energy through implanted leads, causing severe tissue injury or death and potentially damaging the DBS system, necessitating explantation. This risk applies regardless of whether the system is on or off. Participants will be explicitly instructed to avoid all forms of diathermy.

Electromagnetic Interference (EMI)

While typical household and workplace electronics do not pose a risk, certain high-intensity EMI sources may interfere with device function by altering stimulation parameters, powering the system on/off, inducing current surges, or heating tissue through voltage induction. Exposure to strong EMI may also damage the system and require surgical replacement.
Participants will be instructed to avoid or exercise caution around: theft-detection systems, airport/security screening devices, large magnetized speakers, electric arc welders, induction furnaces or heaters, high-voltage power lines, substations, and power generators.

Interaction With Other Implanted Electrical Devices

DBS neurostimulators may interfere with, or be affected by, cardiac pacemakers, implantable cardioverter-defibrillators, or other implanted electrical devices. Individuals with such devices are excluded from participation.

Additional Device Malfunction Risks

Loss of Sensing Capability

If the device loses sensing function, but stimulation remains intact, attempts will be made to restore sensing. If unsuccessful, no clinical intervention is required because sensing is used solely for research purposes. Participants would discontinue LFP data collection but continue all other aspects of the study.

Stimulation Outside Established Clinical Parameters

The Percept RC system includes safeguards to prevent unsafe stimulation delivery. Chronic stimulation parameters will be maintained at 130 Hz, 90 µs pulse width, and 2–8 mA current, consistent with established therapeutic ranges. Investigators will not exceed these limits, and patient-side software will prevent participants from intentionally or unintentionally modifying stimulation settings. There will be no stimulation of the amygdala; only recordings.

Risks of Other Study Procedures

Risks of MRI Scans



Pre-surgical scans. 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. You will complete a screening form to identify metals, but 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, the safety team will determine whether you will be able to undergo MRI scanning safely. 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. Additional risks of MRI have been outlined in the study information sheet that will be provided to you.

The procedure will be supervised by an anesthesiologist in its entirety to ensure your safety. During the evaluation process, you will be thoroughly screened for factors which may make having general anesthesia dangerous for you.

As it is also required for implantation of the DBS system IPG, individuals who cannot receive general anesthesia will be excluded from study.

Post-surgical scans. Postoperative MRI scans will be performed as per the established safety guidelines for using MRI in patients who have been implanted with the Percept RC system. As such, no additional risks are anticipated by having these scans done in the study. **However, since some MRIs are not considered safe to have after you are implanted with this device, please contact the research team if you need MRI scans performed for a clinical purpose outside the study.**

Risks of CT Scans

You will have several CT scans as part of the study and the DBS implantation process, so your participation in this research study includes exposure to radiation from x-rays and/or gamma rays. Since DBS is not an approved treatment for bipolar depression, this radiation exposure is for research purposes only and is in addition to any radiation needed for your medical care. However, the amount of radiation you will receive from the CT scans is the same as that of similar patients who receive DBS outside of a research study (i.e. if a patient receives DBS for Parkinson's disease at Mount Sinai West, this is the same type of scan he/she would receive). X-rays and/or gamma rays can damage the genetic material (DNA) in cells. At low doses, cells usually can repair this damage. Risk from radiation is believed to be related to the total lifetime exposure. For each research study we calculate an ""effective dose"" to estimate the effects or harm of the radiation on your organs. This quantity will help predict the effect of radiation on tissue. You should think about your own history of radiation exposure from tests (like x-rays or CT scans) in deciding about the radiation usage in this study. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor. To put your estimated effective dose in perspective, the radiation that you will get for this research study will be:



- more than the average person in the United States receives each year from natural sources (sun, outer space, air, food, and soil) and medical procedures

- less than the annual limit allowed by the federal government for radiation workers.

The scans we are using in this study will not use any additional contrast agents. As with MRIs, people can experience discomfort by being in the scanner or have trouble laying still during the scan, and some people can experience claustrophobia during the scan.

Risk of Collection of Biological Samples / Intravenous Catheter Placement

For most people, having blood drawn or an IV does not cause any serious problems. However, there is a risk of pain, bruising, and the slight possibility of infection at the place where the needle is inserted. If this happens, the effects usually go away in a few days on their own. Some people may feel dizzy or may faint during or after a blood draw. The risk of having blood drawn or an IV placed in this study is no different than what you would encounter with a routine blood test done at a doctor's office or an IV used for other medical purposes.

Risks of Screening and Assessments

The screening, interviews, and tests can be time consuming and tiring. As part of the psychiatric assessments, you will be asked sensitive questions, but the questions we will ask are like those you are asked during your routine psychiatric and medical care. It is possible you will feel upset, tired, bored, or anxious during the interviews. If you do, you can decide not to answer specific questions, ask for a break, or stop the interview or test.

Risks of Physiological Measures

There are no known risks associated with the heart/breathing rate, EKG, skin conductance, or oximetry monitors used during and/or after surgery.

Privacy Risks

Because this research study involves the use of an investigational medical device, a note must be included in your electronic medical record that you are taking part in the research. This way, anyone involved in your medical care will know that you are a study participant, and they can work to avoid any problems or negative outcomes that could arise if they do not know.

Your name and other information that could directly identify you (such as address or social security number) will never be placed into a scientific database. Your research data (such as rating scales, LFP measurements, activity monitoring, and video recordings) will be de-identified and stored in

physically and/or electronically secure locations in the research offices. Your name and other personally identifiable information will not be stored in conjunction with the videotapes of your study sessions.

Data will only be shared with co-investigators and collaborators working on this project, who will only view the minimal amount of data necessary to complete the scope of their work on this project. The data shared will not identify you by name, nor will any other personally identifiable information be connected to your data. Access to the key that can link your data to you personally will be limited to select members of the research staff. As with any time you share private and personal information, there is always a risk of loss of this private information, but there are procedures in place to minimize this risk and protect the information you share with us. These procedures are described in the "Maintaining Confidentiality" section of this document. If your private information was misused, it is possible you would experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

To protect your privacy, the devices provided to you as part of the study are to be used for research procedures only. These devices will be set up by the research team and will be linked only to your study ID, so that device accounts will not contain any personally identifiable information.

Economic Risks

Taking part in this research study may lead to added costs to you. We will work with you and your insurance company prior to receiving the surgery to address coverage of your surgery expenses. However, it is possible that you may have to pay money out of pocket, including co-pays and deductibles for medical expenses. You or your third-party payer will be responsible for the cost of the replacement battery and the cost of its implantation when that is required. You will also be responsible for the cost of explant if that is what you and the study team decide is the best option for you. As of 2026, this rate is approximately $31,000 without any insurance coverage. Also, if you lose your health insurance at any point, you will be responsible for all expenses as out of pocket expenses as described above. In addition, there may be other potential economic risks to you associated with study participation, such as missing work or school for study appointments.

Group Risks

Although your name will not be given to researchers, basic information such as your race, ethnic group, and sex may be shared. 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 discrimination.

Depression-related Risks



People with TRD can experience suicidal ideation. As a result, suicidal behaviors, including attempts and completed suicide (death), are possible risks associated with TRD. It is not yet known if Deep Brain Stimulation changes the risk for suicide in patients with bipolar depression. As done in all psychiatric care (including the care you have received for your depression outside of a research study), you will be asked about any suicidal thoughts and/or behaviors you may have been experiencing, as well as your intent to act upon them, as part of your visits with the study psychiatrist, as well as part of your clinical ratings. If you are having any of these thoughts and are at risk for acting on them at any time, please contact the research team immediately who will discuss additional treatment options with you as per your individual safety plan, which will be established prior to surgery.

Mania-related Risks

It is not yet known if Deep Brain Stimulation changes the risk for mania in patients with bipolar depression. As done in all psychiatric care (including the care you have received for your bipolar disorder outside of a research study), you will be asked about any mania symptoms or behaviors you may have been experiencing as part of your visits with the study psychiatrist, and your clinical ratings. If you are experiencing any manic symptoms, please contact the research team and your psychiatrist immediately who will discuss additional treatment options with you.

Pregnancy-related Risks

If you are pregnant or become pregnant, this research may hurt your baby or your pregnancy in ways that are unknown. The unknown risks could be minor or major (death) for the pregnancy. You should not become pregnant or get someone pregnant while you take part in this study. Please read the acceptable methods of birth control found earlier in the document.

Unforeseeable Risks

This study may involve risks to you that are currently unknown and unforeseeable. 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). DBS and/or use of this specific DBS stimulator may involve other risks that are not known at the present time. The long-term effects of DBS are not known. You will be informed of any and all additional risks to you as they are identified.

OTHER OPTIONS TO CONSIDER:

You may decide not to take part in this research study. If you decide not to take part, this will not affect the clinical care you receive at Mount Sinai. The choice is totally up to you. For patients with

bipolar I disorder with TRD who qualify to participate in this study, alternative treatment options are limited.Vagus nerve stimulation (VNS) could be an alternative option, but receiving VNS will make you ineligible to receive DBS in the future. You should discuss other treatment alternatives with your psychiatrist before choosing to participate in this study.

IN CASE OF INJURY DURING THIS RESEARCH STUDY

If you are injured or made sick from taking part in this research study, you will get medical care. Generally, it will be billed to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, copayments, and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. You can contact the Lead Researcher for more information.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this study at any time. No matter what you choose, your care and benefits through Mount Sinai will not be negatively impacted.

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. If you decide you want to withdraw from the study after the DBS device has been turned on, the study staff will meet with you to discuss this decision. The study investigators will discuss this option with you to determine if it is appropriate, including evaluating the improvement in and stability of your depression symptoms and your plan for receiving care outside of the study. If you decide that you want to have your DBS device removed for any reason, the stimulation will first be turned off for a minimum of 12 weeks, and the study personnel will then assess your condition. If at that time you continue to want the device removed, you will be scheduled to see the neurosurgeon and set up a time to have the device removed from your body. Regardless of your choice (replacement or removal), you will require an additional surgical procedure, and you will be financially responsible for the cost of this procedure and any device component(s). You will have the option of withdrawing completely from the study or staying in touch so your condition can be monitored in the future.

If you decide to stop being in the research study, you will return to treatment as usual with your existing psychiatrist. If you stop being in the research study, information already collected may not be removed from the research study database and will continue to be used to complete the research analysis. You may be asked whether the study doctor can collect information from your routine medical care. If you agree, this data will be handled the same as research data.

You may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page. Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected if that information is necessary to complete the research study. Your health



information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you stop being in the research study, the research team may not remove information they have already placed in the study database and may continue to use that data as part of this study. The research team may ask you whether they can continue to collect information from your medical record.

If you decide you don't want your data and/or samples to be used for research anymore, you can contact the researcher and ask to have your data and/or samples withdrawn or labeled so that they will not to be used in additional projects or shared. If your data and/or samples have already been shared with researchers, those researchers will be asked to stop using them. However, if any data and/or samples have already been shared without your identity or a linking code, it won't be possible to retrieve them. Data and/or samples that have already been used will not be affected by your decision. If your data and/or samples have already been deposited in an external repository, the study team will request that your data and/or samples be removed.

However, it may not be possible to remove your data from the external database. Also, as long as you have the Percept RC device implanted, both the manufacturer (Medtronic) and the FDA will be able to access to your information for safety and regulatory monitoring purposes (e.g. to ensure that you do not have any problems as a result of having the device, the device is functioning properly, they can provide any new information that you would need to know about the device).

Withdrawal without your consent

The Lead Researcher, the funder or Mount Sinai may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the research team have not been followed, the Lead Researcher believes it is in your best interest, or for any other reason. If data and/or samples have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT INFORMATION:

If you have any questions, concerns or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Lead Researcher, Dr. Mayberg at phone number 212-523-8276.

If there is an emergency, please call 911 or go to the emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher if needed.

DISCLOSURE OF FINANCIAL INTERESTS:

Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

Dr. Brian Kopell (a researcher in this study) receives financial compensation as a paid consultant for Medtronic, Inc (company that manufactures Deep Brain Stimulation (DBS) products). Dr. Kopell also receives financial compensation as a paid consultant for Abbott Laboratories (company that manufactures DBS products).

Dr. Ki Sueng Choi and Dr. Helen Mayberg (researchers in this study) are named co-inventors on a patent application that describes a method of determining the optimal electrode placement for deep brain stimulation for the treatment of depression. This technology is filed through Mount Sinai and currently unlicensed.

Dr. Mayberg and Dr. Choi are co-inventors on technology describing novel brain biomarkers for depression. This technology is filed through Mount Sinai and Medtronic holds a non-exclusive license.

Dr. Mayberg is a named co-inventor on a novel method for using deep brain stimulation (DBS) in a specific region of the brain (the subcallosal cingulate area) as therapy for treatment resistant depression. This method had been licensed to Abbott Laboratories and Dr. Mayberg has received and is entitled to receive future royalty payments from Functional Neuroscience related to this method.

Dr. Mayberg is a paid consultant for Abbott Laboratories for their clinical trials of DBS for depression.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

<u>What is protected health information (PHI)?</u>
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.



Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

What PHI is collected and used in this research study, and might also be shared with others?
As part of this study, the research team at the hospital(s) involved in the research will collect your name, address, telephone numbers, birthdate, dates of admission/discharge, e-mail address, social security number, medical record number(s), health plan numbers, device identifiers, and photographic images. The researchers will also get information from your medical record at Mount Sinai, from your current private doctor(s), and from other facilities where you received medical services (e.g. doctor's offices, hospitals) or medications (pharmacy records).

During the study the researchers will gather information by:

- Reviewing and/or taking your 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 this consent.
- Reviewing mental health records
- Reviewing alcohol and/or substance abuse records, if applicable
- Reviewing psychotherapy notes
- Reviewing general medical or neurological records, if applicable

Why is your PHI being used?
Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example:

- The Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants and may need to see your information.



- If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your PHI?
As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Lead Researcher.

- The United States Department of Health and Human Services (DHHS) and the Office of Human Research Protection (OHRP) (the government organization that is responsible for protecting human research participants).
- The device manufacturer and/or their representative (who will use the results for submissions to the Food and Drug Administration): Medtronic, Inc.
- A Data Safety Monitoring Board or other committee that will monitor the study on an ongoing basis for safety.
- The United States Food and Drug Administration (FDA)

Medtronic, the company that makes the device, will know your name at the time your Percept RC system is registered at the time of implantation surgery, which is done for regulatory and safety purposes. The company will not have access to any other information about you but will reserve the right to update the study team about any safety developments or updates about the device that impact your care. Medtronic may use your data confidential in accordance with all applicable laws and regulations. Any reports or publications about the study or any other research will not include your name or a description of you. Information received during the study will not be used to market to you; your name will not be placed on any mailing lists or sold to anyone for marketing purposes. You agree to allow Medtronic to use your data in these ways.

Results from study tests and procedures that are performed, analyzed and/or read at or for Mount Sinai Healthcare facilities that can be used for healthcare purposes will be placed in any medical record that you have with Mount Sinai Healthcare facilities. In addition, a copy of the informed consent form and HIPAA authorization form that you sign will be placed in any Mount Sinai Healthcare medical record you may have. Persons who have access to your medical record will be able to have access to all results and documents that are placed there, and the results/documents may be used by Mount Sinai Healthcare facilities to help provide you with medical care. Certain state and federal laws and regulations that may prevent the disclosure of research data do not cover any results and documents that are kept as part of your medical record. However, laws such as HIPAA that concern medical records will govern the confidentiality of the results and other documents in the medical record.
In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and



information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy.

Additionally, OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Lead Researcher will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board (IRB) allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, *OHRP, as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document you are authorizing this access.* The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?
Your authorization for the use of your PHI for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give the researchers permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment, or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

If you decide to stop being in the study, please contact the Lead Researcher or the research staff. The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 416-0197. These agencies are responsible for protecting your rights.

How the Institutional Review Board (IRB) can help you:

This research has been reviewed and approved by an Institutional Review Board (IRB). You may reach a representative of the Mount Sinai Program for Protection of Human Subjects at telephone number (212) 824-8200 during regular work hours (Monday-Friday, 9am-5pm, excluding holidays) for



any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research

Study ID: STUDY-26-00089
Form Version Date: 23APR2026

ADULT PARTICIPANT:
Your signature below documents your permission to take part in this research study and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____	_____	_____	_____
Signature of Participant	Printed Name of Participant	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of Consent Delegate	Printed Name of Consent Delegate	Date	Time

Emergency Contacts:
As mentioned earlier in the consent form, the researchers may have to contact the two individuals you list below (that reside within a reasonably accessible distance from your residence and are **≥** age 22) in the event that there is a safety concern or event during study participation or if we are not able to reach you. Please confirm that we may do so and indicate their name along with verifiable contact information as applicable below:

I give the researchers to contact the individuals below: Yes _____ No_____

Contact 1:
Name: _____
Relationship to you: _____
Address: _____
Mobile Phone Number: _____
Home Phone Number: _____
Email: -_____

Contact 2:



Study ID: STUDY-26-00089
Form Version Date: 23APR2026

Name: _____
Relationship to you: _____
Address: _____
Mobile Phone Number: _____
Home Phone Number: _____
Email: -_____

Treating Psychiatrist Information:
As mentioned earlier in the consent form, the researchers will have to communicate with your treating psychiatrist throughout the study as they manage your non-DBS treatment. Please complete the information below:

I give the researchers permission to contact my treating psychiatrist I indicated below:
Yes _____ No_____

Psychiatrist Information:
Name: _____
Address: _____
Phone Number: _____
Fax Number: _____
Email: -_____

