

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 1 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

STUDY INFORMATION:

Study Title: Deep Brain Stimulation for Treatment Resistant Depression: Exploration of Local Field Potentials (LFPs) with the Medtronic Percept PC System

Study Sites: Icahn School of Medicine at Mount Sinai, Mount Sinai West

Principal Investigator (Lead Researcher): Helen S. Mayberg, MD

Physical Address: 521 West 57th Street, 6th Floor, New York, NY 10019 AND 1000 10th Avenue, New York, NY 10019

Mailing Address: 518 West 58th Street, New York, NY 10019

Phone: 646-493-1607

Alternate Study Contacts:

Ellie Rapp (Clinical Research Coordinator), 646-493-1607

Dr. Brian Kopell (Neurosurgery), 212-523-8340

Dr. Martijn Figee (Psychiatry), 212-523-8681

SUMMARY OF THIS RESEARCH STUDY:

This document explains a research study you might be interested in joining. Participation in the study is voluntary. You can agree to join or not. Your decision will not limit your ability to receive care at Mount Sinai. You should only agree to take part if you understand the study and if all of your questions about the research study are answered. If you do join the study, the research team must share any new information with you that may change your mind about taking part.

The purpose of this research study is to use a device, the Percept PC (Medtronic, Inc), to measure changes in the electrical patterns in your brain while you are receiving deep brain stimulation (DBS) for your treatment resistant Major Depressive Disorder (MDD). DBS involves a surgical procedure during which electrodes are placed in specific locations in your brain, and a device (called an IPG) containing a battery is implanted in your chest to power the device. The device produces electric currents that travel to the electrodes, which can stimulate the brain and change how it functions. We will use the information we obtain in this study to better understand how DBS affects the brain in people with depression, as well as how brain activity changes as your symptoms change over time. Once the Percept PC IPG battery is sufficiently drained, one additional surgery will be required to replace it with another, rechargeable one.

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 2 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

Your active participation in this research study is expected to last about 5 years as DBS for depression is not an approved treatment for depression. In addition to tracking your brain changes over time, it is necessary to monitor the safety of the device with long term use. You will have staged exams and data collection starting at the time of surgery: most regularly in the first 24 months, followed by less frequent clinical and device monitoring over the subsequent 3 years, as needed.

If you choose to participate, you will be asked to:

- Receive DBS to a part of your brain called the subcallosal cingulate (SCC)
- Come to Mount Sinai West for a number of visits, including weekly evaluations by the study team for the first 8 months of the study.
- Reside in the New York Metropolitan area for the first year of the study or be willing and able to travel to the study location for monthly visits
- Share your medical records with us to confirm your eligibility to participate
- Have a treating psychiatrist throughout the study
- Allow the study team to share information with your psychiatrist and permit him/her to share information with us
- Stay on your current medication regimen for at least the first 8 months of the study
- Perform assessments of your mood every day for 1 year
- Know how to use and maintain your device and accessories
- Have several neuroimaging procedures, which are all used to take pictures of your brain
- Wear a device (such as a watch) to track how much you move
- Provide blood and urine samples
- You or your third-party payer (i.e. your health insurance carrier) will be responsible for ALL surgical costs related to the study, including but not limited to the implantation surgery and implanted devices, pre and post-op scans, and lab tests, as well as battery replacement surgery at a later date as needed. 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 to research-related appointments.

If you are unwilling or unable to commit to ALL of these activities, you should not participate.

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 3 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

If you choose to take part, the main risks to you are related to the DBS device implantation 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 participation in this research if your depression symptoms improve with SCC DBS. However, this is a possibility and not a certainty; you may not benefit from taking part in this research. Deep Brain Stimulation is not an FDA approved treatment for 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, including other clinical trials of DBS for depression.

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

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you are between the ages of 25 and 70, have depression symptoms that have been resistant to treatment, and you have expressed interest in receiving deep brain stimulation (DBS). You may qualify to receive DBS if your depression has not improved with multiple treatments, including adequate trials of at least 4 different antidepressant treatments in your current episode (e.g. medications, psychotherapy, electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS), ketamine).

You must be under the care of a psychiatrist 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. Also, you must live in the New York City metro region within reasonable commuting to the study location to participate or be willing and able to travel to the study location for monthly visits. These procedures are described in detail below.

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 4 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

You cannot participate in this study if you have: bipolar disorder or other serious mental illnesses other than major depressive disorder (such as schizophrenia, posttraumatic stress disorder, panic attacks, borderline personality disorder), current drug/alcohol abuse, a neurological disorder (like Parkinson's, Alzheimer's disease, past stroke), have an unstable or life-threatening medical illness, or have an implanted electrical device (such as a pacemaker). You cannot participate if you are pregnant or planning to become pregnant during the study.

Your participation in this research study is expected to last about 5 years; the most demanding data collection will occur in the first year of participation, with staged exams thereafter during long term follow-up. There are 20 people expected to take part in this research study at the Icahn School of Medicine at Mount Sinai.

. 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 Web site will include a summary of the results. You can search this website at any time.

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 PC 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 Potential (LFP) recordings
- Taking your medications as prescribed (including using appropriate methods of birth control for females of childbearing capacity, as per the "Description of What's Involved" section)
- Informing the research team about any side effects, mood changes, or device issues in a timely fashion as they arise
- Transfer oversight of your psychiatric care (medications, psychotherapy) to the study team for the first year of the study
- Return to receiving your non-DBS, primary psychiatric care with a psychiatrist and therapist outside the research team after the first year of the study.

If you are unwilling or unable to commit to ALL of these activities, you should not participate.

DESCRIPTION OF WHAT'S INVOLVED:

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 5 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

If you agree to participate in this research study, here is what may be involved: This study will be carried out in several stages over 5 years. These are:

- Screening and Presurgical evaluation
- Baseline Assessments
- DBS implantation surgery
- Acute stimulation testing and in-person recordings
- A 52 week (approximately 12 month) chronic stimulation phase with monthly in person appointments
- A 1-week discontinuation of stimulation (i.e. stimulation OFF) with daily brain activity recordings (done after 6 months of ongoing DBS)
- After stimulation is turned back on, 1-year continuation phase with ongoing DBS and intermittent lab visits
- An approximate 3-year naturalistic follow-up phase with psychiatric care as usual (no restrictions on medication or therapy changes) and ongoing DBS

These stages are described in detail below. The procedures that take place in this study will be conducted at the Center for Advanced Circuit Therapeutics (C-ACT), a research unit at the Icahn School of Medicine located at Mount Sinai West, part of the Mount Sinai Health System.

Screening and Pre-surgical Evaluation (at least 4 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 or who are pregnant or breast feeding will not be able to participate in this study. This screening should take about one to two hours. 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 psychiatric and pharmacy records, records regarding prior hospitalizations and 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.

-----FOR IRB USE ONLY-----
ev 11.11.22



**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 6 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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. A second psychiatric evaluation will be done to confirm diagnosis of Major Depressive Disorder. This will last about 3 hours in total and may be conducted over several days if needed (e.g. if you cannot complete the assessment in one sitting due to fatigue, etc.).

Neurosurgical Examination

You also will meet with the study neurosurgeon and their staff, who will explain the planned surgery to you. As 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.

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:

Weekly Mood Ratings

Every week during the 4-week pre-surgery period, you will meet with the clinical rater and study psychiatrist, who will rate your depression symptoms and monitor your condition. Your mood will be measured with a number of questionnaires. These study visits will last approximately 2 to 3 hours each.

Pre-Surgical Magnetic Resonance Imaging (MRI) scan

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 7 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

Also, prior to surgery, you will undergo a magnetic resonance imaging (MRI) scan, which will be done under general anesthesia. After a portion of the scan is completed, medicines will be used to put you to sleep, so you do not move while the scan is completed. The MRI helps to plan where the electrodes will be placed during your surgery and should take about 2 hours. In addition, you will have several shorter MRI scans after surgery, which will be done while you are awake. These procedures are described in more detail below.

Activity Monitoring

You will be asked to wear a wrist-worn activity tracking monitor (Apple Watch) during the first year of the study. The watch will use an accelerometer to see how much you move, and monitor your heart rate, heart rate variability, sleep quality, respiration rate, and other physiological measures. We will use this data to see if changes in movement may be related to changes in depression symptoms and/or response to DBS. To protect your privacy, we will not record any GPS data on where you go or where you spend your time.

Home-based Assessments

Beginning 4 weeks prior to surgery, you will begin completing additional assessments from home. Once per day, you will receive an email to complete an assessment called the Computerized Adaptive Test of Mental Health, or CAT-MH, which will ask you questions about your mood, anxiety, suicidal feelings, and life quality. This should take about 5 minutes per day. Also, you will also be notified via email to complete additional questions about your mood and energy via our secure online Redcap database twice per day. At that time, you will also be asked to record a short video diary on your smartphone and upload as instructed. Data will not be monitored in real time, so you should not use the diaries to relay clinical information to the research team. If you need assistance, such as if you are having thoughts of self-harm, you should directly notify the research team immediately or call 911.

Medications

You may continue to take antidepressant and other medications during this study. You must stay on the same antidepressant(s) at the same doses for 4 weeks before surgery and at least the first 8 months following surgery (unless your depression worsens severely or you develop side effects). We will work with you and your psychiatrist to lower the dose or stop your use of certain medications before the DBS surgery, including stimulants, antipsychotic, and benzodiazepine medications.

Percept PC System

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 8 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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.

DBS Implantation Surgery

Once you have completed all baseline testing procedures, you will have the Percept PC system implanted by the study neurosurgeon, along with the researchers.

You will be admitted to 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 asleep, an X-ray Computed Tomography (CT) scan will be performed (described in detail later in this form). Then, two small incisions (about 2 inches each) will be made through your scalp, and two holes will be drilled in your skull (one on each side of your head). The neurosurgeon will then insert the two small electrodes into the predefined locations. Once both electrode leads are in place, the location will be confirmed by another CT scan. Then, you will be awakened from anesthesia in the operating room. 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. At this time, 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.

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 9 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

Following 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.

Acute Stimulation Testing Session & Initiation of Active Stimulation (1 to 2 days after surgery)

Acute Stimulation Testing Session

Before you are discharged from the hospital after your surgery, we will test different kinds of stimulation with your Percept PC device. This testing will last about 4 hours in total.

24 Week Active Stimulation Phase

After the acute testing session is complete, the DBS stimulator will be turned ON, and you will begin to receive continuous active brain stimulation. During this time, you will 1) continue to do the online questionnaires at home and 2) come to C-ACT for weekly visits with the research team.

Percept PC 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.

Weekly Study Visits: Active Stimulation Phase

Beginning the week after surgery, you will come to the research offices at Mount Sinai West once per week to have the brain recording data stored on the Percept PC IPG downloaded, as well as have your data downloaded from the Apple Watch you have been wearing. These sessions will take about an hour each. In addition, you will meet with the study psychiatrist and clinical rater to complete mood ratings and assessments every two weeks. These appointments will be conducted either in person or remotely and will be recorded. These sessions will take between 2 to 3 hours each.

-----FOR IRB USE ONLY-----
ev 11.11.22



**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 10 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

Postoperative MRI and CT scans

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.

Four weeks after you leave the hospital, you will have another 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 three months later (12 weeks after surgery) and 6 months after surgery. These scans will be similar to 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.

Stimulation-Off Testing (6 months after DBS ON)

At the end of the 6-month active stimulation phase, your DBS stimulator will be temporarily turned OFF for 1 week during a two-week period. The LFP sensor will still be ON, and you will continue to collect data from the device and about your mood twice daily. At the end of the OFF week, the device will turn itself back on, and DBS will resume using the previous settings. You will not be told when the device will be turned off. Though worsening of your depression symptoms is not expected with this short discontinuation, you need to inform study personnel as soon as possible of any noticeable changes in your clinical condition.

Two-Year Follow-up Phase (beginning 12 months after surgery)

Following the 6-month initial chronic stimulation phase, you will transition to the long-term follow-up phase of the study. Less frequent on-site visits will be performed. You will continue to meet with the study team and psychiatrist(s), and adjustments to the stimulator settings and your medications will be made based on how you are feeling. The frequency of office visits during this phase will depend on your condition; however, you will be seen at least: once a month for the first 6 months of this phase (up to 1 year after surgery), every 3 months for the next year (year 2), and every 6 months thereafter until the end of the study. At each visit, you will meet with the study psychiatrist, and the clinical rater will complete the mood ratings and assessments you previously completed weekly. These study visits will last approximately 2 to 3 hours each. Based on average stimulation parameters and the planned recordings, we anticipate that the original Percept PC IPG will remain active for approximately 2 years, at which time you will need another surgical procedure to have it replaced.

-----FOR IRB USE ONLY-----

ev 11.11.22



**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 11 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

Battery Replacement and Long-Term Naturalistic Follow up

When the battery in your device is sufficiently depleted, you will be scheduled for surgery to have it replaced. The Percept PC IPG implanted in your chest will be removed and replaced with another standard Medtronic IPG. The frequency of study visits during this phase will depend on your condition and depression symptoms, but you will be scheduled for in-person assessments at least once every 6 months. The costs of all battery replacement surgeries, including the replacement system components, will be the responsibility of you or your third-party payer (i.e., your health insurance carrier).

Additional Procedures

The procedures described below will be performed one or more times during the study. These include:

Magnetic Resonance Imaging (MRI) Scan

MRI uses strong magnetic fields and radio waves to obtain detailed images of your brain's structure and function. The preoperative MRI will take about 2 hours, though you will be under anesthesia (i.e. asleep) for most of this time. The postoperative MRI appointments will take about an hour each, but you will only be in the scanner for 30 minutes. You will be awake the whole time for these scans. The scans done after surgery will be done in accordance with the established safety guidelines for use of MRI in people implanted with the Percept PC device. Known risks associated with MRI scans are described below (page 17).

Having ANY METAL in your body that has not been deemed safe for use in the MRI will exclude you from having the MRIs, and, as a result, you will not be permitted to participate in the study. In this protocol, the preoperative MRI will be conducted under general anesthesia, as is the standard practice of the implanting neurosurgeon (Dr. Brian Kopell) for all his DBS cases performed at Mount Sinai West. The risks associated with general anesthesia are discussed later in this document ("Risks of Surgery, Anesthesia, and DBS Treatment", page 15).

High-Resolution Computed Tomography (CT) scan

Three CT scans will be performed in this study (before, during, and 1 month after surgery) to plan/perform the procedure and verify the final location of the DBS electrodes to select the optimal contacts to be used for your chronic stimulation. Each scan will last about 15 minutes. Known risks associated with these scans can be found in the "Risks of CT Scans" section of this document (page 18).

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 12 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

Interview and Survey Feedback

You might be asked to complete one semi-structured interview designed to explore your experiences with Deep Brain Stimulation (DBS) for Treatment-Resistant Depression (TRD) including perceived benefits, challenges, and overall impact throughout their journey and experience with this treatment. Interviews will follow a semi-structured interview to ensure consistency while allowing flexibility to explore individual perspectives as that is the aim of the interview and survey.

Survey questionnaires will be sent via email if you agree to participate. The interview questions will be conducted on Zoom by trained members of the research team. With your consent, interviews will be recorded (video and audio) to ensure accurate capture of responses. Recordings will be subjected to video analysis and thematic analysis. Survey questionnaires will be completed one time and should take no more than 30 minutes. The Zoom interview is expected to be 1-2 hours long. All data will be stored securely as described below:

The data will be stored securely on encrypted servers behind the Mount Sinai firewall, which comply with all applicable Mount Sinai policies and procedures including HIPAA and IT data integrity and security.

Video recordings will only be identified by study-specific subject ID. However, as videos will include full face images, it is not possible to fully deidentify this media.

Recordings will be transcribed verbatim. These transcripts will be de-identified prior to analysis, with any potentially identifying information removed or replaced with coded descriptors. Only de-identified transcripts will be used for analysis.

Some of the questions may bring feelings of discomfort as you share your experience with this treatment. You can end the interview or survey at any time.

Videotaping

To provide an audiovisual record of your appearance and behavior during this study, we will videotape a portion of every study visit in every phase of the study. We would like to see if there are changes in your facial expressions, vocal inflection, or word choice. Study investigators will analyze these video and audio recordings to determine if there are identifiable changes in your appearance and behavior due to DBS and compare them to your clinical ratings and LFP data, which may identify a potential

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 13 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

biomarker of early depression recovery that can help guide treatment decisions in the future. These videotapes will be maintained as part of your study record. Information about how this data will be stored and provisions to protect your privacy are listed below in the “Privacy Risks” and “Maintaining Confidentiality” sections of this document (pages 20 and 25, respectively).

Meetings with the Clinical Psychologist

During the first 6 months of the study, you will meet at defined intervals with the Center’s licensed clinical psychologist both before and after DBS surgery. This is a PhD-level mental health professional who will develop a cognitive behavioral therapeutic plan for you during the course of your DBS treatment. Long-term care after year 1 will be resumed by your private psychologist and psychiatrist. The research team will continue to manage your DBS treatment and device.

Blood Samples

As part of your neurosurgical evaluation, you will have a blood sample drawn (about 3-4 tablespoons or 44-60mL) to do tests to make sure you are healthy enough to have surgery and do not have any existing problems that may make the surgery and/or anesthesia used more dangerous for you.

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).

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 14 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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.

Privacy Considerations

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. In addition, the manufacturer of the Percept PC device (Medtronic, Inc) will have a limited amount of information about you, such as your name and device information, as your device will be registered in their system for their required submissions to the Food and Drug Administration (FDA). This is so they will be aware of any problems with your device and report them appropriately. If any problems occur, the FDA will be notified, and your identity may be shared with them, as well. This information is outlined in the “Maintaining Confidentiality” section of this document (page 25).

Additionally, in order to ensure your safety throughout the study, you must agree to provide the name and verifiable contact information (including email and mailing addresses, and home and work mobile and land-line phone numbers as applicable) of at least two persons $\geq$ age 22 who reside within a reasonably accessible distance of the patient’s residence. You must agree that in the event of a safety concern or even during study participation, research staff is at liberty to contact these individuals if we are unable to reach you.

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 15 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

Contraindications to DBS (Prohibited Procedures)

You will not be able to receive the following procedures once you are implanted with the Percept PC.

Diathermy (deep heat treatment).

Patients with DBS cannot receive shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy anywhere on your body. Energy from diathermy can be transferred through the DBS system, which can cause tissue damage and result in severe injury or death.

Electroconvulsive therapy (ECT)

The safety of ECT in patients who have an implanted DBS system has not been established. If your depression worsens and you choose to have ECT, we will discuss with you the potential risks of applying ECT to subjects with DBS devices or whether the DBS device should be removed beforehand.

Transcranial magnetic stimulation (TMS) therapy

The safety of TMS in patients who have an implanted DBS system has not been established at present. In addition, there is no established valid clinical reason for receiving TMS and DBS simultaneously. No additional or adjunctive antidepressant treatments of any kind should be initiated without receiving the explicit approval of the Principal Investigator or site clinical personnel.

Limited use of MRI with the Percept PC

Certain MRI procedures are not permitted in the presence of the Percept PC system. Thus, there are limitations of MRI use once you are implanted with the percept PC. If an MRI will be required for a clinical purpose, the study investigators should be contacted to discuss the type of scan proposed and evaluate its safety and alternatives will be proposed, if necessary.

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 (i.e. your health insurance carrier) will be responsible for ALL clinical costs related to the study, including but not limited to preoperative testing (labs, EKG, MRI), implantation surgery, postoperative surgical care, and postoperative CT scan. We will work with you and your insurance company prior to receiving the surgery to address coverage of your clinical expenses. We will provide you a list of procedures and fee

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 16 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

schedule for out-of-pocket costs before surgery so you will know what to expect. You or your third-party payer will also be responsible for the cost of the replacement device and the surgical costs of its implantation at the point of battery depletion.

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. Receipts must be submitted in order 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 Major Depressive Disorder.

It is important 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 may 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 understanding treatment resistant depression, how it effects the brain, and the effects of SCC DBS in this context.

POSSIBLE RISKS AND DISCOMFORTS:

Risks of Surgery, Anesthesia, and DBS Treatment

As with surgery for any medical problem, there are risks involved both from having the surgery and/or the anesthesia used during the procedure. The neurosurgeon, Dr. Kopell, and his staff will discuss any and all risks with you in detail and answer any questions you may have when you meet with them, as well as procedures to mitigate these risks, treatments available for given complications, and consequences of these effects should they occur. A summary of the known side effects and complications associated with DBS device implantation are listed below. The estimated rates of the

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 17 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

effects listed have largely been based on those experienced by patients receiving DBS for Parkinson's disease, which is the largest patient group receiving DBS at present. In addition, the specific experiences of patients receiving DBS for depression in research studies has also been provided in the study information sheet.

The complications of DBS surgery are well established and relate to 1) surgical complications at the time of implantation (such as hemorrhage, seizures, stroke) and 2) secondary complications due to failure of the device, infection, or stimulation of parts of the brain adjacent to the ones intended. The risk of death associated with the general anesthesia used for the preoperative MRI and implantation of the IPG is small (less than 1 in 20,000 people). More common risks of surgery are pain, discomfort, and/or swelling at the sites of the incisions in the head and chest, as well as at the sites where the pins of the stereotactic frame are placed. If these problems occur, they generally go away within one week for most people. These risks are the same for all patients receiving DBS surgery and are not specific to depression patients. There are no additional risks of the behavioral and safety testing with electrophysiological recordings done during the implantation surgery procedure.

Risk of Infection, Device Malfunction, Adverse Reaction to Device Components

It is possible that the device and/or its components may become infected. This could cause an infection not only in the area of the implanted device but also an infection that involves the whole body. Such an infection would require treatment with antibiotics and, possibly, surgery to remove the DBS system. The risk of infection or malfunction of the DBS device and/or IPG is about 10.6%. It is also possible that an implanted electrode may move, break, or become dislodged requiring another operation to correct. There is also a chance of having an allergic reaction to the device or any of its components requiring device explantation, as well as a risk that a component of the device may cause damage to your brain or other parts of your nervous system or cause tumors (benign or cancerous) due to materials that compose the leads.

Risk of Clinical Worsening / Onset of New Psychiatric Symptoms

As DBS is an experimental procedure for treatment resistant major depressive disorder, it is possible that the symptoms of your depression will not improve, or even become worse, with DBS. If your depression does not improve over time or you experience worsening of your psychiatric condition, the investigators will discuss with you the option of changing the dose of stimulation, the location being stimulated, making adjustments to your medications, discontinuing active stimulation, and/or removing the device. You should promptly inform study personnel as to any changes in your symptoms.

-----FOR IRB USE ONLY-----
ev 11.11.22



**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 18 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

Need for Additional Surgical Procedures

It may become necessary to remove the DBS device. Reasons for removing the device include damage to the device or infection that does not adequately respond to antibiotics. Removal of the device has a very low risk of serious complications (less than 1 in 1,000), but they are the same as those associated with surgical implantation of the device stated above.

Risks Associated with Battery Replacement(s)

The estimated IPG battery life of the Percept PC device using standard stimulation parameters is approximately 2 years from the time of implantation. Battery life may be shorter in this study due to the recordings from the sensor, which uses extra battery power. At the end of battery life, another minor surgical procedure, will be required to replace the IPG with the same or a similar unit when available. The risks of this procedure are similar to the risks of having the first IPG implanted in your chest, namely discomfort or pain at the site of the incision, infection, or risk associated with anesthesia.

Risks of Battery Depletion or Interruption of Stimulation.

If your DBS system is not working properly, it is possible that your depression symptoms can return. One reason that the device may not work properly is if the system is turned off. For this reason, it is **EXTREMELY IMPORTANT** that you that you monitor the status of your system on a regular basis. People who received DBS for depression with other devices had temporary discontinuation of their stimulation (lasting hours to days), and this was not associated with any noticeable symptomatic or behavioral changes. Controlled experiments of DBS discontinuation observe a slow decline that develops over several weeks characterized by decreased motivation, interest, and activities, followed by a late change in negative mood. Abrupt changes in sadness, anxiety, or sudden thoughts of suicide have not been observed to date. You should report changes in your symptoms or device problems to the study personnel as soon as possible.

Risks of Other Study Procedures

Risks of MRI

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

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 19 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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 risks associated with the general anesthesia used with the preoperative scan in this procedure are well known and have been discussed previously in this document ("Risks of Surgery, Anesthesia, and DBS Treatment," page 15). There are no additional risks of anesthesia use in this context, and all equipment used is compatible with the MRI. 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 PC 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 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

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 20 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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 similar to 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 Activity Monitoring

There are no known risks of wearing the activity monitoring watch. There are no known risks associated with the use of these wearable devices, as these are commercially available to the general public. Data from these devices will be stored with a unique study ID number, not your name, to protect your privacy.

Risks of Physiological Measures

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 21 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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

Risks of Interview and Survey Feedback

The main risks are emotional triggers associated with recounting their DBS treatment experience. The video/audio recording and privacy risks described below are also applicable.

Privacy Risks

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, video recordings) will be deidentified 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 (page 25). 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.

In order to protect your privacy, the devices provided to you as part of the study (iPhone, Apple Watch) 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. You should not log into any personal accounts, such as your email, download any applications, or make any phone calls with the study devices. Otherwise, that personal information will be stored on the device and will be available to the device manufacturer, Apple, Inc. Information shared with Apple, Inc cannot be retrieved, and your privacy cannot be guaranteed if information is shared. These devices must be returned to the research team after a specified amount of time, and the

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 22 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

Mount Sinai Information Technology Department will delete all data from the devices in accordance with their policies once they are no longer in use.

Economic risks

Taking part in this research study may lead to added costs to you. You and your third-party payer (i.e. your health insurance company) will be responsible for the costs of ALL clinical procedures related to the study, including but not limited to the implantation surgery and implanted devices, surgical follow-up appointments, and lab tests. 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 also be responsible for the cost of the replacement battery and the cost of its implantation when that is required. 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 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 and psychologist, 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.

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 23 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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 under the Description of What Is Involved section of this document (page 12).

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 POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you. For patients with TRD who qualify to participate in this study, alternative treatment options are limited, due to your past treatment failures. There is one FDA approved alternative surgical treatment for depression called vagus nerve stimulation (VNS), though 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, including other clinical trials of DBS for depression. The Study Psychiatrists will also discuss potential alternatives for treatment with you and your treating psychiatrist, if needed.

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.

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 24 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. 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 research 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 of this form. 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 to be used for research anymore, you can contact the researcher and ask to have your data withdrawn or labeled so that it will not be shared or used in new projects. If your data has already been shared with researchers, those researchers will be asked to stop

-----FOR IRB USE ONLY-----
ev 11.11.22



**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 25 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

using it. If any data have already been shared without your identity or a linking code, it won't be possible to retrieve it because no one will know who you are. Data that has already been used will not be affected by your decision. If your data has already been deposited in an external repository, the study team will request that your data be removed. However, it may not be possible to remove your data from the external database. Also, as long as you have the Percept PC 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. More possible reasons for removal from the study include noncompliance (refusal/inability to adhere to the study schedule or procedures), worsening of your medical or psychiatric health, clinically significant adverse effect of DBS, conditions or behaviors that may increase the risk of DBS, or pregnancy. 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. Helen Mayberg, at phone number 212-824-8278.

Alternate Study Contacts:

Ellie Rapp (Clinical Research Coordinator), 646-493-1607

Dr. Brian Kopell (Neurosurgery), 212-523-8340

Dr. Martijn Figee (Psychiatry), 212-523-8681

For medical or psychiatric emergencies during the study after business hours or on weekends:

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 26 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

- Call 911 and/or go to the nearest emergency room. Let the emergency room staff know you are in a research study so they can contact the Lead Researcher or study clinicians, if needed.
- Contact Dr. Kopell, Dr. Figee, and/or your treating psychiatrist, as appropriate (i.e. depending on the problem you are having)
- Inform the research team as soon as possible after the event

DISCLOSURE OF FINANCIAL INTERESTS:

Dr. Helen Mayberg (a lead researcher in this study) 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.

Dr. Mayberg and Dr. Ki Sueng Choi (a researcher 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, Dr. Choi, and other researchers in this study (Dr. Allison Waters and Mr. Stephen Heisig) are also 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. Brian Kopell (a researcher in this study) receives financial compensation as a paid consultant for Abbott Laboratories and Medtronic, Inc. (companies which manufacture Deep Brain Stimulation (DBS) products).

Dr. Fedor Panov (a researcher in this study) receives financial compensation as a paid consultant for Zimmer, Inc and NeuroPace (manufacturers of DBS devices).

Lucia Feldman (a researcher in this study) receives financial compensation as a paid consultant for Medtronic, Inc.

-----FOR IRB USE ONLY-----
ev 11.11.22



**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 27 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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.

What is protected health information (PHI)?

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 the description section of 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?

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 28 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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.
- If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Lead Researcher, study 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)
- Other collaborating research centers: Georgia Institute of Technology

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 29 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

Medtronic, the company that makes the device, will know your name at the time your Percept PC 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 confidentially 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. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. 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, 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

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 30 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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 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.

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.

-----FOR IRB USE ONLY-----

ev 11.11.22



**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 31 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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) 306-5070. These agencies are responsible for protecting your rights.

Certificate of Confidentiality

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your personal information, study data and/or samples with anyone who is not a member of the research team, including any family members or friends, other than those identified above. However, you should know that if it is learned that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the research team may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

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.

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 32 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 33 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

ADULT PARTICIPANT:

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

_____ Signature of subject	_____ Printed Name of Subject	_____ Date	_____ Time [required if used for FDA documentation purposes]
-------------------------------	----------------------------------	---------------	---

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____ Signature of consent delegate	_____ Printed Name of consent delegate	_____ Date	_____ Time
--	---	---------------	---------------

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 34 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

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

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 $\geq$ 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:

Name: _____

Relationship to you: _____

Address: _____

Mobile Phone Number: _____

Home Phone Number: _____

Email: _____

-----FOR IRB USE ONLY-----
ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027

**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 35 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

USE OF YOUR DATA

In addition to being used to complete this research study, your personal information (such as, name, address, date of birth, social security number) and study data may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed, and it will be replaced with a code. Researchers are not planning on giving you the details of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project. 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 You have the right to withdraw, at any time, your consent to future use of the data. If you wish to do so, please let the research staff know immediately or contact the Principal Investigator, Dr. Helen Mayberg (her contact information is listed on the first page of this form).

(1) Will you allow the researchers to store your information to use in future research studies?

Please initial your choice: Yes _____ No _____

If no, please stop here. 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 keep your information stored 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 information stored? Please initial **ONE** choice below:

I would like my information stored anonymously _____

I would like my information stored with a link to my identity through the use of a code _____

(3) Do you give the researchers permission to keep the information indefinitely and use it for future studies that are **directly related** to the purpose of the current study?

Please initial your choice:

Please initial your choice: Yes _____ No _____

-----FOR IRB USE ONLY-----
ev 11.11.22



**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 36 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

(4) Do you give the researchers permission to keep the information indefinitely so they can use it 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 this information. This might be in fields such as anthropology, human origins, mapping human migration patterns. Do you give permission for researchers **outside the field of medicine** to use your information?

Please initial your choice: Yes _____ No _____

(a) If the future research in a different area can be done without having to know that the information 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 information 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 identifiable information or specimen is needed and what will be done with it. Your permission will be asked to use your information 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 information may still be used. The Institutional Review Board (IRB) will be asked for permission to use the information 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 information will not be more than a minimal risk to you or your privacy. The Institutional Review Board (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 _____

(6) Do you give permission to have portions of your data and/or samples deposited in large public databases (repositories) for use in research with the limits you may have chosen above? Please read the paragraphs below which explains repositories, then initial your choice:

-----FOR IRB USE ONLY-----
ev 11.11.22



**THE MOUNT SINAI HEALTH SYSTEM
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION**

Page 37 of 37

STUDY ID#: 22-01731

Form Version Date: 16JUN2026

To do more powerful research, it is helpful for researchers to share information from the people they study. They do this by putting data and/or samples into a repository. A repository is where something is stored safely for a specified period of time. Data and/or samples from one study may be stored in a repository along with data and/or samples from other studies. Sample repositories are commonly called biobanks, while data repositories are commonly called databases. Researchers can then use the data and/or samples from multiple studies to learn even more about health and disease. If you agree to take part in this study, some of your health information might be placed into one or more scientific databases, but they will not share your direct identifiers (for example, name, address, date of birth). These databases are maintained by either Icahn School of Medicine at Mount Sinai, another institution, the federal government, or private companies. Any researcher who wants to do a study using data and/or samples from the repository must apply for permission. There are different ways of reviewing such requests. Researchers with an approved study may be able to see and use your data, along with that from many other people. Researchers may use your information for other experimental testing. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are always risks associated with data collection and sharing. They are described in more detail in the Risks section of this document.

Researchers will use a Global Unique Identifier, a computer-generated ID, which cannot be linked back to your identity. This is so any data collected from you is linked to one unique ID, so databases operated by the National Institutes of Health can make sure your data is secure and is not accidentally duplicated if you take part in research at multiple sites.

Please initial your choice: Yes _____ No _____

Whether or not you have allowed us to share your data and/or samples with these repositories, 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.

-----FOR IRB USE ONLY-----

ev 11.11.22



Effective Date: 7/7/2026
End Date: 1/5/2027