**Northwell Health**

**Campus: Zucker Hillside Hospital**

**Consent for Participation in a Research Study**

**Study Title:** Deep Brain Stimulation (DBS) Therapy for Treatment Resistant Depression (TRD)

**Principal Investigator:** Albert Fenoy, MD

**Sponsor:** Northwell Health, Zucker Hillside Hospital, Feinstein Institutes for Medical Research, National Institutes of Health (NIH)

**About this research**
You are being asked to participate in a research study.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

**Important Information**
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

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| **Why am I being asked to provide my consent?** | This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future. |
| **Do I have to join this research study?** | No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled. |
| **Why is this research study being done?** | This initial study at Northwell Health has the purpose to demonstrate the feasibility and safety of performing medial forebrain bundle (MFB) deep brain stimulation (DBS) as a treatment for treatment resistant depression (TRD) at Northwell Health. |
| **What will happen to me during the study?** | If you agree to participate, you will undergo surgery for implantation of the deep brain stimulation device. During the study you will be asked to complete several questionnaires, undergo several brain scans (MRI), one CT scan, blood and urine tests, and several PET scans. The details of each of these procedures are discussed in detail below.<br><br>At some points in the study DBS will be turned ON and OFF without your knowledge. When DBS is OFF there are associated risks which are discussed in detail below.<br><br>We will collect a 5 teaspoon blood sample from you at multiple timepoints in this study to check for various markers that may be possibly related to causing your depression. |

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| **How long will I participate?** | The study includes 60 study visits. Weekly visits will occur for 52 weeks with follow-up visits occurring at weeks 78, 104 (2 year), 130, 156 (3 year), 234, and 260 (5 year). The study will be for approximately 5 years. |
| **Will taking part expose me to risks?** | The major risks to patients are related to device implantation. Implanting the DBS system from Medtronic carries the same risks associated with any other brain surgery. The device is considered investigational for the purposes of this study.<br><br>**Possible common side effects of brain stimulation include:** Increased depressive symptoms/fluctuating results; Changes in mood (positive and negative); Diplopia (double vision); Gastrointestinal disturbances (changes indigestion) or nausea; and, Tingling sensation (paresthesia) . A complete list of possible risks and side effects can be found below in the detailed risk section.<br><br>The complete list of possible side effects and risks of the procedures can be found below in the detailed risk section of this consent form.<br><br>There is the potential for depression to worsen, including a potential increased risk for suicide. |
| **Are there any benefits to participation?** | Specific benefits to the subject include a potential improvement in clinical symptoms. |
| **What are my alternatives to participation?** | Alternative procedures or courses of treatment would be standard care. |

**Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.**

**Introduction**
You are being asked to join a research study. The purpose of a research study is to answer specific questions, sometimes about the safety of a drug or device and how well it works. Being in a research study is different from being a patient. When you are a patient, you and your doctor have freedom in making decisions about your healthcare. When you are in a research study, the researcher will follow the rules of the research study as closely as possible, while monitoring your health.

You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

**Financial Disclosure:** Albert Fenoy, MD is a consultant for Medtronic. There is a financial interest held by Dr. Fenoy that could be affected by the results of the study. This disclosure is made so that you can decide if this relationship may affect your willingness to participate in this study. You are not under any obligation to participate. If you have any questions, please ask the researcher or a member of the research team.

**Does the investigator of this study receive money if you take part?**
The investigators on this study receive money to conduct the study, but do not financially benefit from your participation. The money they receive is to pay them back for the costs of conducting the research study. Funding for this research study is provided by NIH. If your doctor is an investigator for this study he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

**Why is this research study being done?**
The purpose of this research study is to perform deep brain stimulation (DBS) in treatment resistant depression (TRD) patients targeting the medal forebrain bundle (MFB). Specifically, this investigation will assess the efficacy and safety of MFB DBS in treatment resistant depression and analyze the incurred changes in brain function.

**Why is this research?**
This is a research study because DBS in TRD is investigational, and is not approved by the Food and Drug Administration (FDA) for treatment of TRD. The device is manufactured by Medtronic.
The actual device is FDA-approved for use in diseases such as Parkinson's disease, essential tremor, dystonia, and obsessive compulsive disorder. This very same device has not yet been approved by the FDA for use in treatment resistant depression.

You are being asked to participate in this study because you have TRD and have not responded to previous treatments.

**How many people will take part in this study?**
This research study hopes to enroll 20 patients.

**How long will you be in this study?**
If you choose to take part in this study, the study will take approximately 5 years. The study includes 60 study visits. Weekly visits will occur for 52 weeks with follow-up visits occurring at weeks 78, 104 (2 year), 130, 156 (3 year), 234, and 260 (5 year). There will be a total of 15 MRI scans throughout the study. The screening visit is approximately 5-6 hours, the follow-up visits will be approximately 2-2.5 hours and the neurocognitive visits will be approximately 4-6 hours. Each MRI session will be approximately 1 hour.

**What will happen in this research study?**
Once a patient enrolls in this study, they will undergo imaging (pre-operative PET and MRI). DBS surgery will then occur. Briefly, you will be awake part of this surgery. Your head will be shaved. A stereotactic frame will be placed on your head. You will then be sedated. Incisions on your scalp will be made, followed by 2 holes drilled through your skull. Wires will then be passed through your brain down to the target area, and we will listen to your brain cells fire. Once we are at the target site, we will wake you up and place the stimulating electrode at the target and check for an effect. The PI Dr. Fenoy will be talking to you throughout this part of the procedure and asking you questions. Once we have checked for good effect and lack of side effect, we will verify location with imaging, secure the electrodes, and re-sedate you. We will close the incisions. The stereotactic head frame will be removed, and you will be intubated (a breathing tube will be placed by anesthesia) and re-positioned for the second part of the surgery. During this part of the surgery we will connect the brain electrodes to extension wires that will be passed from your scalp down under your skin to below your collar bone, where a battery pocket will be made and the battery placed. Following the placement of the battery, the incisions will be closed and you will be extubated (breathing tube removed) and taken to recovery, and stay overnight in the hospital on the normal neurosurgical monitoring floor. Most patients go home the next day.

Post-operative visits will occur weekly with the study psychiatrist for 52 weeks following surgery. These visits must be in-person at least every other week starting with post-op week 1; on the following week, you can begin alternating in-person and virtual visits, alternating every week, for 52 weeks. At these visits, the device will be manipulated and study physicians and their staff will assess your psychiatric and medical well-being. Virtual visits may be completed digitally using Northwell Health available online telemedicine appointments and platforms, or via a phone call if such platforms are not accessible you.

In-person visits with neurosurgery will be scheduled following DBS implantation at a minimum of 5 times during the first year. More frequent visits can be scheduled as needed.

In-person visits will be required in order to ensure your safety and that of the device, as well as make any necessary changes to the device. Visits that must be completed in person include: post-surgery Week 1, Week 12 (3 months), Week 24 (6 months), Week 38 (9 months), Week 42 (10 months), 52 (1yr), 104 (2yr), 156 (3yr), 208 (4yr), and 260 (5yr). After 52 weeks, if it does not work into your schedule for that exact week, in person visits may be scheduled as close to the required week as possible. Aside from safety reasons, these will be required in- person because the majority include components such as MRI scans, neuropsychological evaluation and blood sample collection.

A battery of tests will be completed at each weekly visit to measure your general health, depression symptoms, quality of life and side effects.

Your vital signs will also be collected at the weekly follow-up visits (in-person). Any of the questionnaires conducted at these appointments may also be conducted at any unscheduled visits requested by either you or the study team, clinical appointments with your study psychiatrist, or at appointments with Dr. Albert Fenoy and his team.

During the course of the study, each of the outpatient visits will last approximately two hours. On each day, we will do a brief clinical interview and obtain measures of depressive symptoms, mood and affect, possible side effects, and cognition.

During the course of this study, you will not know when the device will be turned on or off. We cannot let you know that it is on or off as there is a potential of a placebo effect that can occur, which means that you may think you are getting therapy but are not. Such a placebo effect is not helpful in science when we are trying to prove the effectiveness of the device, such as in this study, where it the true effectiveness is not yet proven. So for this reason we will not tell you whether the device is on or off until the end of the first year. However, we can tell you that it will be on for 70% of the time throughout the first year, and we will alert you of the discontinuation phase (below).

In this study you will be randomized. At the ninth month post DBS implantation, you will enter a discontinuation phase of a duration of 6 weeks. Unbeknownst to you, the stimulator will be switched off or will remain on. During this time, we will carefully monitor your well-being. After 6 weeks we will switch the DBS back on if it was turned off. Whether the stimulation is active or not, it will be double blinded. Double blinding is when neither the researcher nor the people in the study know which study group a person is in. It is used to make sure the study data will not be biased.

When the device is turned off, there is a potential for your depression to relapse (return or get worse). We will be closely monitor you during this discontinuation phase as well as other times that it may be turned off. You will be sent text messages daily to check in with the research staff, performing self-assessments, as well as

attending your in-person sessions. Should at any time there be a worrisome change in your depression, you will be called, brought in and / or sent to the psychiatric emergency room to prevent self-harm.

The research team will collect a 5 teaspoon blood sample from you at several time points: before surgery, 1 week after surgery, 4 months after surgery, and then at 1,2,3,4, and 5 years after surgery. Samples of blood will be used to analyze markers of inflammation and other factors that may be possibly related to causing your treatment resistant depression.

**MRI studies:**
MRI machines use a strong magnet to make pictures of the inside of your body. During the scanning, you will lie on a long narrow couch for 1 hour while the machine gathers data. You will not feel anything while the data is being collected. You will also hear tapping noises that are from the MRI scanner.

**Deep Brain Stimulation Device**
Implantation of all devices will be performed at a single surgery, as described above. DBS electrode implantation will take place under local anesthesia, after a head frame is placed on your head. Two electrodes, one for the left-sided and one for the right -sided medial forebrain bundle target in the brain, will be placed through holes drilled in your skull. Each will be fixed to the skull using a plastic securing device covering the hole through which it was drilled.

Once these are secured, you will be placed under general anesthesia, where two extension wires (one for each DBS electrode) will pass from the scalp area under skin to below your collarbone in your chest, where a battery will be placed. You will then be sent to recovery room after you wake up, and then admitted to the hospital where you will stay overnight. You would then most likely go home the next day only after the neurosurgery team see that you are able to do so.

Before you go home, you will have a CT to check for bleeding and a MRI performed to verify electrode placement.

**What are the risks of the research study? What could go wrong?**
Possible Device Complications:
You will sign a consent form on the day of surgery at North Shore University Hospital for these risks. Thus, risks of brain surgery include bleeding, infection, stroke, paralysis, death. The PI has performed over 700 such DBS procedures so as to minimize the chance of these risks. The frequency of these risks should be 1% but it is difficult to precisely determine since stimulation of the medial forebrain bundle for psychiatric disorders has been performed in only a limited number of patients (less than 100 total worldwide). No major complications have been reported in any of these cases.

Explantation of the DBS system and revision of DBS electrodes carries the same risks as implantation of DBS lead electrode system. Revision/replacement of pulse generator risks include hemorrhage or infection. There is additional surgical risk associated with pulse generator replacements; the maximum lifetime of the Percept PC battery is longer than 5 years, but actual duration is dependent on stimulation parameters. Since both leads are powered from one battery, sometimes replacement of the extension wires is required to make the proper connection to the new battery system. The extension wires are attached to the intracranial electrodes within the scalp. The proximal connection of the old extension wires to the intracranial electrodes must be undone, and new extension wires need to be attached and tunneled down

to the battery location. There is a less than 5% chance that this revision may result in damage to the intracranial electrodes, which would then require additional surgery to replace them. In the worst-case scenario, this would delay therapy and incur all the risk of intracranial electrode placement. Usually, what this extra step would mean is that there is an additional incision at the scalp in addition to the incision at the battery site, and there is a small risk that, relative to the usual replacement surgery, the scalp site would also be at risk for infection.

- There may be pain, lack of healing, or infection where the DBS parts are implanted.
- The DBS parts may erode through skin, which can cause an infection or scarring.
- The lead or lead/extension connector may move, requiring surgical re-adjustment.
- Components or parts of the DBS system may break or fail to work properly, requiring surgical repair or replacement.
- Stimulation could stop because of mechanical or electrical problems. Either of these would require surgery. The DBS implanted pulse generator (IPG) service life depends on individual use. The DBS PG service life for tremor typically ranges from 2-3 years.
- An allergic reaction to the DBS system may occur. The DBS system materials coming in contact with tissue include titanium, polyurethane, silicone, and nylon. Also, the body could reject the system (as a foreign body).
- There is the possibility of tissue damage resulting from the programming parameters or a malfunction of one of the parts of the DBS system.

Possible Effects/Risks when DBS is turned ON:

- Dizziness or lightheadedness (disequilibrium)
- Facial and limb muscle weakness or partial paralysis (paresis)
- Facial flushing (red or rosy facial color) or facial muscle contractions
- Jolting or shocking sensation
- Numbness (hypoesthesia)
- Increased heart rate
- Hyperactivity or euphoria (hypomania)
- Pain or discomfort
- Headaches
- Cognitive Changes
- Dry mouth
- Itching at the surgical site(s)
- Insomnia (trouble sleeping)
- Increased fatigue (feeling exhausted or moving slower than usual)
- Cognitive disturbance (“cloudy” thinking)
- Restlessness
- Weight gain or weight loss
- Double vision (diplopia)
- No change or increased/decreased depressive feelings/irritability
- No change or increased/decreased anxiety

Possible Effects/Risks when DBS is turned OFF:

- No change or increased depressive feelings/irritability
- No change or increased anxiety

**Suicide Risk**

There is the potential for depression to worsen, whether the device is ON or OFF, including a potential increased risk for suicide.

**Blood-Draws**

There are no major risks of having blood drawn. It can be uncomfortable and can sometimes cause a bruise. In rare cases, it can cause fainting. Only trained staff will draw your blood.

**Magnetic Resonance Imaging (MRI) Studies**

The magnetic resonance imaging (MRI) machine is a powerful magnet. It is very important that you tell the researcher about any metal objects, devices or implants that are in or on your body before you enter the scanner room. All metal objects must be removed before entering the magnet room. In some cases, having those devices may mean that you should not have an MRI scan. If you know of any metal in your body, you will need to tell the researcher right away. Otherwise, there are no known risks of MRI. Some people with claustrophobia (fear of closed spaces) may find the MRI scanner too confining. In that case, you can ask to be removed from the scanner and this will be done immediately. The MRI scanner makes a loud beeping sound. We may ask you to wear protective earplugs during scanning.

In addition, a gel marker will be placed on your head during the scan. These markers are routinely used and are MRI compatible. Because these markers are attached to the side of the head, they may cause slight skin irritation. On rare occasions, some subjects may experience one or more of the following: momentary dizziness, nausea, tingling sensations and/or muscle twitches. Please tell the investigator over the intercom if any of these sensations occur.

We are doing the MRI in this study to answer research questions, not to give you medical care. All scans are reviewed by a radiologist. If the radiologist thinks there might be a problem or the scan reveals a condition that could affect your health, you will be referred for the proper follow-up care to your primary care physician or another specialist. This MRI is not the same as one that your own doctor would order. It may or may not show problems that would be found on a standard MRI.

During the MRI, you may experience heating due to your implanted device, or an unusual sensation due to unintended stimulation. This is highly unlikely. If this does occur, please squeeze the call button in the MRI machine or tell the technician immediately and the MRI will be stopped.

**Radiation Risks**

PET Imaging: The scanning procedure itself is not painful and carries no risk. Some participants may experience discomfort lying in the PET scanner for a long period of time, but we reduce the discomfort with bolsters and blankets. The following list of events and the proper responses to them is based on our extensive experience with imaging studies of this kind.

a. Claustrophobia during PET scan (infrequent): if this occurs, we will stop the scan

b. Pain during IV placement – this pain is generally tolerable and transient, and minimized by experienced staff

c. Bruising during IV or catheter Insertion (infrequent) – Local site care as needed

d. Lightheadedness/Fainting during IV Insertion or blood draw (rare) – you will remain on unit for assessment until you feel well enough to be discharged

e. Infection at site of IV insertion (very rare) – Medical treatment as indicated
Since only trace amounts of radioactive compounds will be present, the procedure presents no risks in terms of toxicity. The planned activity to be administered in each scanning session is designed to maintain radiation doses within suggested FDA guidelines for research (dosimetry table provided as part of Radiation Safety submission).

You will be under continuous observation/monitoring during the PET scans. If you are pregnant or breastfeeding, you will be excluded from the study. Urine pregnancy testing will be conducted on all women of child-bearing potential within 30 days of PET scanning, and will be repeated as necessary. While PET is not geared toward detection of anything abnormal in the body, some abnormalities also show pathologic (bad) PET signal. If an abnormality is noted on the scans that are obtained, we will set up an appropriate referral for further evaluation for you, if you desire, and you may be provided with copies of the appropriate research records (e.g., scan image, scan report) relative to this evaluation. We will also check your blood sugar prior to each PET; if it is higher than the upper limit for PET, we will refer you to a specialist.

This research study involves exposure to radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The amount of radiation that you will receive as a result of participating in this study will be equivalent to less than 2 times the yearly background of radiation in the US This amount of radiation may involve a low risk of cancer. If you are pregnant or breast feeding, you cannot participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

**Incidental Findings**

Although the imaging you will have in this study is being undertaken for research purposes only, it is possible that doctors may notice something that could be important to your health. Although not likely, it is possible that the doctors may notice something that may be very serious and could immediately affect your life. If so, we will contact you to explain what was observed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.

**Unknown Side Effects**

As with any study, there might be side effects that are unknown at this time. You will be closely watched for side effects. You should report any unusual events to the study staff.

**Interviews/questionnaires/QOL assessments that discuss sensitive issues that may cause <u>emotional upset</u>, such as grieving:**

Some of these questions may seem very personal or embarrassing. They may upset you. You may skip any question that you do not want to answer.

**What are the benefits of this research study?**

You may or may not benefit from the deep brain stimulation. You may experience potential improvement in your depression.

**Will I receive my results?**

We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. You may need to meet with professionals with expertise. The study team/study will not cover the costs of any follow-up consultations or actions.

**If you do not want to take part in this research study, what are your other choices?**
You do not have to participate in the study to receive treatment.

If you do not join this study, you have other choices for treatment. Talk to your doctor about your choices. Your other choices may include:

- Another research treatment
- Standard treatment

**Are there any costs for being in this research study?**
The participant or his/her insurance carrier will be responsible for the tests, procedures, etc of the study. Taking part in the study may lead to increased costs to the participant or his insurance company.

**Will you receive any payments for participating in this research study?**
You may receive up to $6,834 for participating in the study. Compensation is only for the first year of participation. Compensation is as follows:

- $50 for each session of clinical assessments, 52 sessions total for $2,600
- $40 for travel fees for each in person weekly session, up to $2,080
- $300 for each outpatient PET scan, 2 sessions total for $600
- $100 for each outpatient MRI scan, 14 sessions total for $1,400
- $11 for parking fees at each outpatient MRI scan, 14 sessions total for $154

**What happens if you are injured while participating in this study?**
If you are hurt from being in the study, you will receive medical care and treatment as needed from Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage. Northwell Health is not offering to pay you for pain, worry, lost income, the cost of your medical care or non-medical care costs that might occur as a result of your taking part in the study. However, you do not waive any of your legal rights by signing this form.

**What are your rights as a research participant?**
Your participation in this study is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

**Could you be taken off the study before it is over?**
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected.

**What happens if new information is learned?**
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

**What will happen with the information we collect as part of this research study?**
Any study information about you will be kept private and will only be given out with your permission. If the results of this study are published, your name will not be used. Your research records will be private to the extent allowed by law. In order to make sure the research is done properly, the Human Research Protection Program (a group of people that oversees research at this institution) may need access to information about your participation in this study.

**What information will be collected and used for this study?**
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

**Who else will see your information?**
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

Investigators will share information collected from this research study with:
study sponsor (Northwell Health, Zucker Hillside Hospital, Feinstein Institutes for Medical Research, and National Institutes of Health (NIH)) and/or its agents,

- other researchers,
- accrediting agencies,
- data safety monitoring board,
- clinical staff not involved in the study who may be involved in participant's treatment,
- health insurers or payers

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies such as the Food and Drug Administration (FDA) and the National Institutes of Health (NIH)
- Representatives from Northwell Health's Human Research Protection Program (the group of people that oversee research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do, we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

**Will you be able to access your records?**
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

**How long will your health information be kept?**
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

**What happens if there are problems with the device?**
If there are problems that arise with the device, please contact Dr. Albert Fenoy at 516-550-2100. He and his team will best be able to help you find a solution.

**What will happen at the end of this study?**
If you choose to remain part of this study for 5 years after surgery, then you may elect to keep the device functioning as it is or has been. You are entitled to keep the device and use it as you have become accustomed. There are no planned study visits after study completion, however you are welcome to continue seeing your study doctor investigators as you desire. At the end of the study, the complete device system will remain in your body under your possession. If you want to have any part of the system removed, you will have to bear the costs of device removal. Drs. Fenoy and Argyelan will continue to see you as needed for routine check-ups. There may be other studies which may become available to you at that time.

**Can you change your mind?**
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Albert Fenoy, MD
805 Northern Blvd
Suite 100
Great Neck, New York 11021

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

**What will happen if I withdraw from the study?**
If you withdraw from the study, the study physicians can no longer monitor your disease and help you with your medications or your device. If you withdraw before surgery occurs, then there will be no harmful consequence to you. If you withdraw after surgery but before the study is over, there is a potential that we have not been able to find the best setting on the device to treat your depression. This means that you will have a device that is on and which is unattended, as well as medications that are not being monitored. This may result in significant relapse of depression. Aside from your depression not being treated, there are no known medical consequences

from withdrawing from the study. If you choose to withdraw from the study, the complete device system will remain in your body under your possession. If you want to have any part of the system removed, you will have to bear the costs of device removal.

**Will information about this study be available to the public?**
A description of this clinical trial will be available on http://www.Clinical Trials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

**Will my information be used for research in the future?**
Information or specimens [collected from you] for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your de-identified specimens and/or data to be used by future researchers without additional consent. Information or specimens collected from you will not be used for future research studies or shared with other researchers for future unspecified research.

**Does the investigator of this study receive money if you take part?**
The investigators on this study do not receive money for your participation in this study.

**Who can answer your questions about this study?**
If you have any questions about the study, you may call Dr. Albert Fenoy at (516) 550-2100 or Dr. Miklos Argyelan at (718) 470-8175. If you have questions about side effects or injury caused by research you should call Dr. Albert Fenoy. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, or concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910. A signed copy of this consent form will be given to you.

**[Signature Page Follows]**

**Summation/Signature**
You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Printed Name of Participant Date

_____
Signature of Participant Date

_____ _____ _____
Witness's Printed Name Witness's Signature Date
*(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)*

**Investigator's Statement**
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are/or may be associated with this study and to answer any further questions relating to it.

_____ _____ _____
Investigator's Printed Name Investigator's Signature Date