INFORMED CONSENT FORM

PROTOCOL TITLE	Individualized Closed Loop TMS for Working Memory Enhancement
IRB PROTOCOL NUMBER	832891
PRINCIPAL INVESTIGATOR	Desmond J. Oathes, PhD. Department of Psychiatry University of Pennsylvania
FUNDING SPONSOR(S)	National Institutes of Health (NIH)
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UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT FORM

Protocol Title:	Optimizing Neuromodulation through Individualized Stimulation Frequencies
Study Sponsor:	National Institute of Health
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Emergency Contact:	If you have a study related medical emergency, please contact 911 and/or contact the study staff.

Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to investigate the brain and behavioral effects of different transcranial magnetic stimulation (TMS) frequencies. Using a combination of TMS and functional MRI (TMS/fMRI), we will determine optimal and the least optimal TMS stimulation frequency. These two frequencies will be tested in two 3-day rTMS neuromodulation sessions to explore whether optimal stimulation frequency will lead to more robust brain and behavior responses to repetitive TMS (rTMS).

If you agree to join the study, you will be asked to complete questionnaires, a clinical interview, computerized tasks, and MRI scans with and without TMS.

Your participation will last for approximately 13.5-20 hours over 9 experimental sessions, but there may be possible delays (~2-3 weeks) due to scheduling availability, fMRI scanner

availability, or other unforeseen circumstances.

This study is being conducted for research purposes and not for clinical treatment. There are no direct benefits to you for your participation in this study.

Possible risks of participation include discomfort and claustrophobia during the MRI procedures. You may also experience emotional discomfort when answering questions of the clinical interview and/or questionnaires. TMS may cause a mild headache and localized pain from the muscle activation. We will test TMS at the initial visit to ensure it is tolerable for you. More rare risks (1/100,000 sessions) include a seizure from TMS administration.

This is a voluntary study. If you choose not to participate, it will not affect your treatment or the care given by your health provider, your insurance payment or enrollment in any health plans, or any benefits to which you are entitled.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

I. Why am I being asked to volunteer?

You are being invited to participate in a research study. We are contacting you because you may have an interest in participating. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. We will be recruiting about 38 subjects without psychiatric history who are 18-60 years old to participate.

Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the investigator and/or the research team about anything you do not understand. If you decide to participate, you will be asked to sign this form. Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

II. What is the purpose of this research study?

The purpose of this research study is to investigate if we can improve the efficacy of TMS through precise TMS targeting and optimal TMS delivery tailored for individuals. We hope to use this information to better understand variability in response to TMS and potentially enhance the capabilities of the existing device. This approach may be critical to developing novel treatment

protocols for psychiatric conditions.

TMS involves a procedure during which your brain will be non-invasively (i.e. from the scalp) stimulated by magnetic pulses, and MRI scans are used to take pictures of your brain. In this study, we administer TMS inside of the MRI scanner so we can see how the stimulation affects the rest of the brain.

III. How long will I be in the study?

If you agree to take part in this study, your involvement will take place over approximately eight weeks and will include the following study visits:

- **Visit 1: Initial Screening Session (1-3hrs).** This visit be done both remote and in-person. During the remote visit, we will review this informed consent form and you will be given an electronic copy. If you agree to participate, you will be asked to electronically sign the end of this form. Enrolled subjects will be asked to complete a remote consent attestation form followed by multiple questionnaires and a clinical interview. Subjects who recently completed the clinical interview through another study at the Center for Neuromodulation in Depression and Stress may not need to repeat it. If you meet the eligibility criteria of the remote procedures, you will be invited for an in-person visit. During the in-person visit, you will undergo a TMS demonstration. We will also identify the minimum TMS stimulation intensity needed to induce activity specifically for your brain. The in-person visit should take approximately 30min.

- **Visit 2: Baseline MRI (1.5hrs).** This visit will involve several questionnaires and a 1-hour MRI scan. During the scan, we will ask you to complete multiple computerized tasks.

- **Visit 3: MRI Scan with TMS (2-2.5hrs).** A second MRI scan will be done with concurrent TMS procedures. We will spend approximately 30 minutes marking sites on a swim cap, and then we will spend an additional 1.5-2 hours in the MRI scanner where TMS will also be administered. During this scan, we will ask you to complete multiple computerized tasks.

- **Visit 4-6: TMS Visits (1-1.5hrs each).** At each visit, we will administer TMS and ask you to complete multiple computerized tasks and questionnaires.

- **Visit 7: MRI Scan with TMS (1.5-2hrs).** This visit will be a shorter version of Visit 3. After spending ~30 minutes marking sites on a swim cap, you will undergo a 1-hour MRI scan with TMS while you will complete computerized tasks.

- **Visit 8-10: TMS Visits (1-1.5hrs each).** These visits will mirror Visit 4-6. We will administer TMS and you will be asked to complete multiple computerized tasks and questionnaires. Visit 8 will be scheduled at least 1 week after Visit 7.

- **Visit 11: MRI Scan with TMS (1.5-2hrs).** This visit will mirror Visit 7. There will be a 1-hour MRI scan with TMS while you complete computerized tasks.

Visit #3-Visit #7 will be scheduled within the same work week, such as Visit #3 is on Monday, Visits #4-7 are Tuesday/Wednesday/Thursday, respectively, and Visit #7 is on Friday. Similarly, Visit #8-Visit #10 will be scheduled 4 work-days in a row, either Monday-Thursday or Tuesday-

Friday. See chart below with a summary of the visit schedule:

Procedure	Visit #1: Screening (1-3 hours)	Visit #2: Baseline MRI (1.5 hours)	Visit #3: TMS/fMRI (2-2.5 hours)	Visit #4-6: TMS (1-1.5 hours each) Neuromodulation 1st Session	Visit #7: TMS/fMRI (1.5-2 hours)	NO VISITS- 1 WEEK *(at least)*	Visit #8-10: TMS (1-1.5 hours each) Neuromodulation 2nd Session	Visit #11: TMS/fMRI (1.5-2 hours)
Informed Consent	X							
Clinical Interview	X							
Questionnaires	X	X	X	X	X		X	X
Computerized Tasks		X	X	X	X		X	X
MRI		X	X		X			X
TMS	X (demo)			X	X		X	X
			CONSECUTIVE VISITS *(5 workdays in a row)*				**CONSECUTIVE VISITS** *(4 workdays in a row)*	

IV. What am I being asked to do?

- **Clinical Interview**: You will be asked questions by a trained interviewer about your life experiences (such as your medical, social, emotional, work history, and drug/alcohol use), mood, feelings, thoughts, and behaviors as well as your family members.
- **Questionnaires:** You will be asked to answer questions regarding your medical history, demographics, mood, behaviors, and eligibility to receive MRI and TMS.
- **Computerized Tasks:** We will conduct memory tests to assess your attention, concentration, and memory. These activities may be incentive-based and include vocabulary, abstract thinking, emotion, spatial relations and speed tasks. During some of the tasks we may ask you to wear a passive eye-tracking device to record the location of your gaze at any particular time. Some of these tasks will be conducted inside the MRI scanner.
- **TMS demo:** We will administer a TMS pulse to further determine your eligibility to participate in the study. To determine the TMS stimulation level, we will change the intensity of the stimulation until it causes your thumb or finger to twitch (when the coil is placed over the part of the brain controlling movement on the other side of the body). This calibration is done to ensure that stimulation intensity is sufficient, but not excessive, for each individual.
- **MRI Scan:** We will ask you to undergo multiple MRI scans of your brain. For an MRI, you will be asked to lie still on a padded table in the scanner while images of your brain are obtained. We will provide you with ear plugs to wear during the MRI to protect your hearing.
- **TMS with MRI:** TMS involves a procedure during which your brain will be non- invasively (i.e. from the scalp) stimulated by magnetic pulses. For this procedure, you will lie down in the MRI machine and will wear earplugs to protect your hearing. You may be asked to wear

a swim cap for making measurements of your head. A plastic-coated magnetic coil will be held against your scalp. You will hear a clicking noise as magnetic pulses are produced in the TMS coil. These magnetic pulses induce very brief activity in brain areas underlying the TMS coil. Stimulation intensity will be calibrated according to the amount of energy needed in the coil to induce activity specifically for your brain. To determine the stimulation level, the researchers will move the intensity of the stimulation until it causes your thumb or finger to twitch (when the coil is placed over the part of the brain controlling movement on the other side of the body). This calibration is done to ensure that stimulation intensity is sufficient, but not excessive, for each individual.

- **TMS without MRI (Neuromodulation Sessions):** Visits 4-6 and Visit 8-10 will use TMS without MRI. We will ask you to sit still for approximately 10-14 minutes at a time when TMS is administered. The duration of the TMS administration will depend on your results from Visit 3.

V. What are the possible risks or discomforts?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. If you are injured, you should inform your treating physician that you are participating in this study.

Clinical interview, computerized tasks & questionnaires: Participants may experience emotional discomfort when answering some questions in the clinical interview and/or questionnaires. You may choose not to answer any of the questions and to terminate their participation. You may also become tired during the interview or computerized activities. You can ask for a break during any activity.

MRI scan: Because the MRI scanner is a narrow space, you may experience claustrophobia, or a fear of enclosed spaces and/or anxious feelings accompanied by fast heart rate or shortness of breath. Additionally, the scanner produces a loud repetitive knocking noise during the study that some people find bothersome. To lessen the noise, earplugs will be provided. If you have any problem with feeling uncomfortable while inside the scanner, you may stop this study at any time. Rare risks from MRI scan:

- Medical Implants and Foreign Bodies: The MRI scanner has a strong magnet which attracts certain metals. **As a result, the MRI will not be performed on anyone having these types of metal in their body**. This includes metallic fragments and certain implanted medical devices, such as: Pacemakers, Internal Cardiac Defibrillators, Insulin Pumps, and other medical devices. Implanted medical devices and metallic foreign fragments inside your body may pose a risk if you were to enter the MRI magnet room. Therefore, questions regarding medical and work history will be asked prior to your exam to ensure you do not have any of these metallic fragments in your body.
- Flying Objects: The known risks associated with this study are minimal. The greatest risk is a magnetic object flying through the air toward the magnet and hitting you. To reduce this risk, we require that all people involved with the study remove all magnetic metal from their clothing and all magnetic metal objects from their pockets. No magnetic metal objects are allowed to be brought into the magnet room at any time except by approved personnel. To prevent any injury to patients and staff and any damage to the MRI scanner, you will be asked to remove all jewelry and clothing containing metal before you enter the MRI

scan room. Also, since the MRI magnet will erase credit cards, they must not be taken into the scan room. In addition, once you are in the magnet, the door to the room will be closed so that no one inadvertently walks into the room.

- Some dyes in tattoos and permanent eyeliner contain metals which may heat up during the MRI scan. This can cause the area with the tattoo to become irritated and swollen.
- This MRI is not a clinical scan. It is possible that during the course of the research study, the research staff may notice an unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the PI will inform you if necessary. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician.
- Although there are no known risks related to MRI on pregnant women or a fetus, there is a possibility of yet undiscovered pregnancy related risks. Since there is no possible benefit from participating in this protocol for a pregnant woman, we will exclude pregnant women. All women of childbearing potential will be asked to confirm before entering the MRI scanner that they are not pregnant at the time. Implantable contraceptives are generally very safe for MRI, but the MRI technician may ask you additional questions before entering the MRI suite to ensure your safety.

Some of the MRI pulse sequences and equipment used are not FDA-approved but are considered to pose no more than minimal risk.

TMS: TMS is considered to be a low-risk procedure. There are no known significant risks with this procedure at this time because the magnetic fields at the strengths used are thought to be without harm. While there are no known long-term adverse effects reported with the use of this device, there may be unforeseen risks in the long-term that are currently unknown. The most common side effect of TMS is a mild headache, which approximately 25% of patients experience. We will demonstrate TMS at the initial screening visit to make sure you are comfortable receiving this procedure. Rare risks of TMS:

- You may experience temporary and local bruising, swelling or pain from the swim cap and/ or muscle activation by TMS. This muscle activation may induce jaw or eyebrow movement during the TMS stimulation. If the TMS target is near the eye muscles, TMS stimulation may induce tear formation.
- Although uncommon, some subjects have experienced nausea during the experiment. In patients with epilepsy, TMS could result in a seizure. Patients with stroke may also be at increased risk for a seizure due to brain scarring. Therefore, those with history of epilepsy or stroke will be excluded from TMS studies. For a typical healthy person, producing a seizure from TMS in this experiment is very unlikely.
- Repetitive TMS carries a standardized seizure risk of 1/100,000 sessions for those without identifiable risk factors and 67/100,000 sessions for those already at increased risk for seizures.
- The TMS device produces a clicking sound. Although studies have found no hearing impairments as a result of this sound, some subjects' experience a mild temporary effect on their hearing. To minimize this possibility, you will be given protective earplugs.
- The effects of TMS on a fetus are unknown. Therefore, we require that females of child-bearing potential attest at the time of participation that they are not pregnant. If you are or

could be pregnant, you will be excluded from this study.

The TMS that will be used in this research is not expected to carry any more than the limited potential for these risks listed above and there is no evidence of increased risk for using TMS on healthy individuals.

Risk of Breach of Confidentiality: There is a rare risk of breach of confidentiality. Breaches in confidentiality could impact future insurability and/or employability. An exception to confidentiality is if a participant reports child abuse or neglect, or if they report suicidal or homicidal ideation or intent to the research team. Any information about child abuse or intent to harm oneself or others will be reported to authorities, as required by law.

VI. What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

VII. What are the possible benefits of the study?

There are no direct benefits to you for your participation in this study. However, the knowledge gained may advance the field of psychiatry.

VIII. What other choices do I have if I do not participate?

This is a voluntary study. If you choose not to participate, you may seek information about other alternatives available by discussing options with your personal physician.

IX. Will I be paid for being in this study?

Your study compensation is based on the following schedule:

- Visit 1: Clinical Interview = $20.00
- Visit 2: Baseline MRI = $50.00
- Visit 3: TMS/fMRI = $150.00
- Visit 4-6: TMS = $50.00 each x 3 = $ 150.00
- Visit 7: TMS/fMRI = $100.00
- Visit 8-10: TMS = $50.00 each x 3 = $ 150.00
- Visit 11: TMS/fMRI = $100.00

Also, you may receive additional compensation during the neuromodulation visits, depending on the choices you make during an incentive-based task. We will explain the details of the compensation before you begin the task. Your final compensation will be based on the length of your participation as outlined above and task results.

If you previously completed procedures through another study at the Center for Neuromodulation in Depression and Stress at the University of Pennsylvania, you may not need to repeat these measures and therefore, will not be compensated again.

Your payments will be given to you in the form of a Greenphire ClinCard. This is a reloadable prepaid card (similar to a debit/ credit card) which allows funds to be available immediately.

You can use it for in-store or online purchases by selecting the "Credit" option at check-out, or it can be cashed out by presenting to a teller at any MasterCard member bank (look for a MC logo on the bank window). Study staff will provide you with a "ClinCard Cardholder FAQ: US" document to help answer any additional questions you may have.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

X. Will I have to pay for anything?

You will not have any costs for participating in this research study. The administration of all procedures will be covered by the study.

XI. Will I receive the results of research testing?

Many of the tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare. As discussed in the MRI scan risks section above, it is possible that during the course of the research study, the research staff may notice an unexpected finding(s). Should this occur, the finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician.

XII. What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

This research may involve risks that are currently unforeseeable. University of Pennsylvania investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator, Dr. Desmond Oathes at (215)- 573-9390.

XIII. When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. Your personal participation in the study may last approximately 8 weeks. This study may be stopped by you or your physician at any time. It may also be stopped by the Principal Investigator, the study Sponsor, or the Food and Drug Administration (FDA) without your consent if:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.

- The Sponsor or the study Principal Investigator has decided to stop the study.
- Other administrative reasons
- Unanticipated circumstances

If you decide to participate, you are free to leave the study at any time. There are no medical risks involved in the early termination of this study.

XIV. How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy.

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Hospital or University representatives, to complete Hospital or University responsibilities
- University Pennsylvania's Institutional Review Board (a committee that oversees the conduct of research involving human participants.) The Institutional Review Board has reviewed and approved this study.
- Representatives from collaborating institutions

To help protect your confidentiality, your data will only be transported by qualified study team members, and only during actual subject participation. Once all hard copy records are collected, they will be kept in a double- locked environment. Data collected during the study will be entered and stored in a password-protected database, accessible only to engaged study members. Electronic records will not be transported via external drives or any other means. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part

in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form.

XV. Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored

for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

XVI. What information about me may be collected, used, or shared with others?

During your participation, you will be asked to provide your name, address, telephone number, email address, and your social security number (so that we may issue you a check to compensate you for participation). We will also collect information about dates directly related to you (e.g. birthday). This identifiable information will be held in strict confidence and will be kept in password protected files behind locked doors. Your personally identifying information will not be linked to any of the data that is analyzed and reported. All data will be de- identified when reported. You will also be asked to answer questions about your medical history including questions about your physical and mental health. Results from the research assessments will be part of the research record. All research data will be de-identified and assigned a randomly generated research identification number. All information obtained will be kept completely confidential and will be in locked files behind locked doors. Electronic data will be encrypted and password protected.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental illness to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

During and after the study, the researchers will send de-identified information about your health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your de-identified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental illnesses so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information.

However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://data-archive.nimh.gov.

XVII. What may happen to my information collected on this study?

The future use of your information only applies to information collected on this study. Your information will be assigned a unique identifier number to all of your collected data. The unique identifier assigned to you will be the only identifying information linked to collected data accessible to future use in research. Your coded information may be stored and used for future research purposes for an indefinite amount of time. This can be done without again seeking your consent in the future, as permitted by law. There are no plans to tell you about any of the specific research that will be done. Possible future research may include studies related to brain scans and mood disorders. We may share your coded information with other researchers within Penn, other research institutions, as well as pharmaceutical, device, or biotechnology companies. We will not follow up with you to tell you about the specific research that will be done. We will not give you any results from these studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

You will likely not directly benefit from future research with your coded information. Research with your coded information may help other by improving our understanding of health and disease, improving healthcare and making safer or more effective medical therapies, and developing new scientific knowledge.

If you have questions about the storage of your information, or have changed you mind, you can contact the principal investigator, Dr. Desmond J. Oathes at 215-573-4561. You may withdraw or take away your permission to use and disclose your de-identified information at any time. You do this by sending written notice to the investigator for the study.

XVIII. What is an Electronic Medical Record?

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within a health system. An EMR is simply a computerized version of a paper medical record. For the purpose of this study, we will not utilize Penn Medicine healthcare related services and will not create or edit your EMR.

What may be placed in the EMR?
For the purpose of this study, we will not utilize Penn Medicine healthcare related services and will not create or edit your EMR. None of the information related to this study will be in the EMR.

XIX. Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- Do the research
- Oversee the research
- To see if the research was done correctly.

XX. How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

XXI. Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

XXII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject Informed Consent Form and HIPAA Authorization describing your confidentiality and privacy rights for this study. By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above. If you do not sign this form, you will not be able to participate in the study.

If you decide not to participate, it will not affect:

- Your treatment or the care given by your health provider.
- Your insurance payment or enrollment in any health plans.
- Any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research.
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information.

If you revoke your authorization:

- The research team may only use and share information already collected for the study.
- Your information may still be used and shared if necessary for safety reasons.
- You will not be allowed to continue to participate in the study.

XXIII. Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

For general questions or for scheduling, please call the Center for Neuroscience of Depression and Stress at 215-746-2637. If you have concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, please call 215-746-2637. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215)898-2614.

XXIV. How will I be contacted?

We would like to contact you by phone or email in order to arrange your appointments. Some of these messages may contain information that identifies you. We will also be contacting you in the future, after the conclusion of the study, in order to follow up on your status. Please provide us with contact information for an additional individual who knows where to find you in the event that we cannot reach you.

We would like your permission to contact you about future studies to see if you are interested in participating in them. May we contact you to invite you to participate in future studies if we determine that you may be eligible for them?

☐ Yes ☐ No

If you choose to participate in future studies at the Center for Neuromodulation in Depression and Stress, may research staff have access to and use your data that is collected as a part of this study?

☐ Yes ☐ No

If you have previously participated in a study at the Center for Neuromodulation in Depression and Stress, may research staff have access to and use your data as collected as a part of that study for the current study?

☐ Yes ☐ No

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A electronic copy of this consent form will be given to you.

Name of Subject (Please Print)

Signature of Subject Date

Name of Person Obtaining consent (Please Print)

Signature Date