PROTOCOL TITLE	Network Control TMS fMRI
IRB PROTOCOL NUMBER	830174
PRINCIPAL INVESTIGATOR	Desmond J. Oathes, PhD. Department of Psychiatry University of Pennsylvania
FUNDING SPONSOR(S)	National Institutes of Health
INVESTIGATIONAL PRODUCT	Transcranial magnetic stimulation (TMS) device that can stimulate brain regions noninvasively. • MagVenture X100 Stimulator • Cool-B65 Butterfly TMS Coil • MRI-B91 TMS Coil
INFORMED CONSENT FORM VERSION	V10
DATED	6/15/2023
CLINICALTRIALS.GOV NUMBER	NCT05736458

UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT FORM AND HIPAA AUTHORIZATION FORM

Protocol Title: RF1: Network Control TMS fMRI

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 transcranial magnetic stimulation (TMS) to different brain regions. First, magnetic resonance imagining (MRI) scan sequences will be collected to generate individualized TMS targets. These targets will be used in the subsequent TMS/fMRI visits, in which TMS is administered while functional MRI (fMRI) sequences are acquired. During TMS/fMRI, participants will complete a memory working task to study the effect of TMS in task performance.

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 7-12.5 hours over 4-5 experimental sessions, but there may be possible delays (~2 weeks) due to scheduling availability, MRI 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.

➢ 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 are recruiting approximately 95 young adults, aged 18-28 years old, to participate in our study. Specifically, we are looking for 45 subjects with symptoms of attention-deficit/ hyperactivity disorder (ADHD) and 50 asymptomatic subjects.

This consent form describes what this study is about, the possible risks and benefits of being in this study, and what we will ask you to do. The research team will explain the study and answer any questions you may have. You may also discuss it with your family, friends, or doctor. You may find some of the medical language difficult to understand, so please ask the research team about anything you would like to know. If you decide to participate, you will be asked to sign this form.

➢ What is the purpose of this research study?

The purpose of this research study is to use different types of MRI scans to find individualized TMS targets and compare how the brain responds. We are also interested in using TMS during a working memory test to see how it affects task performance.

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.

In addition, the data from the clinical assessments and computerized tasks performed in this study will be shared with the Neurodevelopment & Psychosis Section and Children's Hospital of Philadelphia (CHOP) to standardize our intake procedures and determine eligibility for other studies within our section.

➢ How long will I be in the study?

If you agree to take part in this study and you are found eligible, your involvement will include 4 or 5 study visits:

- **Visit 1: ICF, Screening Visit.** This screening will take approximately 2-3 hours and it will be done both remotely 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. If you meet the eligibility criteria of these remote procedures, you will be invited for 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. This in-person visit should take approximately 30 min.

- **Visit 2: Baseline MRI Scan, Assessments & Computerized Tasks.** You will complete a 1-hour baseline MRI scan. We will use this scan to create personalized TMS targets used during subsequent visits. This visit will also involve multiple questionnaires and computerized tasks. These procedures will be conducted remotely and may take 1-3 hours.

- **Visits 3 and 4: MRI Scans with TMS**. Two MRI scans will be performed with concurrent TMS procedures. We will first spend about 30 minutes on preparation,

then we will have a 1-hour MRI scan during which TMS will be administered. A memory task will also be administered during this scan.

- **Visit 5 (OPTIONAL): Task MRI Scan.** This visit will only take place if the task is available, and you want to complete it. This visit will take place over a 1-hour fMRI scan. During the scan you will complete attention and memory tasks. We will meet for 1-hour before the scan to practice the tasks.

In some instances, if you have already completed these screening and/or neurocognitive assessments through the Neurodevelopment & Psychosis Section at the University of Pennsylvania, you may not be required to repeat these measures. Similarly, if you are also participating in one of our other studies at the CNDS, then the same MRI may be used for both studies; in this case, these procedures would not need to be repeated.

Procedure	**Visit 1:** ICF & Screening (2-3 hours)	**Visit 2:** Baseline MRI & Assessments (2-4 hours)	**Visit 3:** MRI + TMS Scan 1 (1.5-2 hours)	**Visit 4:** MRI + TMS Scan 2 (1.5-2 hours)	**Optional Visit 5:** Task MRI Scan (2 hours)
Informed Consent & Clinical Interview	X				
Questionnaires	X	X	X	X	X
Computerized Tasks		X	X	X	X
MRI		X	X	X	X
TMS	X (demo)		X	X	

➢ What am I being asked to do?

- **Questionnaires:** You will be asked to answer questions regarding your medical history, demographics, mood, behaviors, and eligibility to receive MRI and TMS.

- **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.

- **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.

- **Computerized Tasks:** We will conduct memory tests to assess your attention, concentration, and memory. These activities may include vocabulary, abstract thinking, emotion, spatial relations and speed tasks. Some of these tasks will be conducted inside the MRI scanner.

- **MRI scans:** We will ask you to complete 4 MRI scans of your brain. For the MRI, you will 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.

- **MRI with TMS:** We will ask you to complete two MRI scans during which you will receive TMS. During this scan, you will be asked to wear a swim cap on your head which will have marks on it to help study personnel know where to place the TMS device. A plastic-coated (i.e., MRI- safe) magnetic TMS 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 brief activity in the brain areas underlying the TMS coil. TMS intensity will be calibrated specifically for your brain. To determine the stimulation level, we will place the coil over the part of the brain that controls movement. We will then adjust the intensity of the stimulation until it causes your finger to have a small twitch. This calibration is done to ensure that sufficient stimulation intensity is used for each individual without excessive stimulation. Lastly, you will be performing a memory task while you receive TMS during the scan.

➢ 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.

Procedure	Risk
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 risks	<u>Likely/ Common:</u> ▪ 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.

MRI scan risks (cont.)	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. The MRI performed under this protocol is not for medical purposes, and the images are not planned to be interpreted by a physician. <u>Rare:</u> ▪ 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. Should this occur, the finding will be considered by the appropriate personnel and the PI will inform you. These possible findings may or may not be significant, but could lead to anxiety about your condition and to further evaluation by your physician.

MRI scan risks (cont.)	• 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.
TMS risks	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. Likely/ Common: 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: • Headache intensity following administration of TMS could vary in severity from mild to intense. The effects of a more intense headache could last into the next day. • You may experience temporary and local bruising, swelling or pain from the swim cap and/ or muscle activation by TMS. • Although uncommon, some subjects have experienced nausea, lightheadedness, and dizziness 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. Having first-degree relative with a history of seizures may be a risk factor for a TMS-induced seizure, but no cases have been reported. 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

TMS risks (cont.)	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.
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.

➢ 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.

➢ 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.

➢ 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 and treatments available by discussing options with your personal physician.

➢ Will I be paid for being in this study?

Your study compensation is based on the following schedule:

- **Visit 1: Screening Visit**
  - Clinical interview = $40
  - Test TMS Pulses = $10
- **Visit 2: Baseline Visit**
  - MRI Scan & Assessments = $60
  - Computerized Tasks = $80
- **Visit 3: TMS/ MRI Scan** $150

- **Visit 4: TMS/ MRI Scan 2** $150
- **Visit 5 (OPTIONAL): Task MRI Scan** $100

Your final compensation will be based on the length of your participation as outlined above. You will be compensated at the end of your study participation. If you complete Visits 1-4, you will be compensated $490. You may receive an additional $100 if the task for Visit 5 is available *while you are enrolled in the study,* and you would like to complete it. This means that if the task is not available by the time you complete Visit 4, your study participation will be considered complete and you will not receive the additional $100, even if you would like to complete the visit.

If you previously completed procedures through another study at the Center for Neuromodulation in Depression and Stress or the Neurodevelopment & Psychosis Section 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.

➢ 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.

➢ 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.

➢ 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. However, your personal participation in the study may last up to 3 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, the study Principal Investigator has decided to stop the study.

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.

➢ Who can see or use my information? How will my personal information be protected?

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
- Authorized members of the workforce at the University of Pennsylvania Health System and the School of Medicine
- University Pennsylvania's Institutional Review Board (a committee that oversees the conduct of research involving human participants).
- Representatives from collaborating institutions
- Dr. Raquel E. Gur and her study team who developed some of the clinical assessments and neurocognitive tasks performed in this study.
- Authorized staff members of the workforce at the Children's Hospital of Philadelphia (CHOP)

Other people or organizations may review or receive your identifiable identification. They need this information to conduct the research, assure the quality of the data or to analyze the data or samples. This information may be disclosed to:

- People from agencies and organizations that perform independent accreditation and/or oversight of research, such as:
    - The University of Pennsylvania Office of Human Research
    - The University of Pennsylvania Office of Regulatory Affairs
    - Department of Health and Human Services
    - Office for Human Research Protections at CHOP
- Groups monitoring the safety of this study, for example, the CHOP Lifespan Brain Institute Steering Committee
- Authorized employees of Greenphire

Once your personal health information is released to others outside the study, it may no longer be covered by federal privacy protection guidelines. You will be informed if any persons or agencies are added to the list above while you are actively participating in the study. Any additions will have to follow University of Pennsylvania guidelines set up to protect your privacy.

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.

If you have previously participated in research at the Neurodevelopment & Psychosis Section at the University of Pennsylvania and choose to participate in this study, study staff will have access to your information gathered from that study (for example, the interview you may have already completed).

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.

➢ 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.

➢ 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). 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. Information from your medical charts will be reviewed and documented for research purposes. Results from cognitive 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. At most, the website will include a summary of the results. You can search this website at any time.

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.

➢ What may happen to my information collected on this study?

Future Use of Data
Your information will be assigned a unique identifier number to all of your collected data. Your coded information will be stored for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to information collected on this study. The unique identifier number will be the only identifier that will be retained with your coded information. Your coded information may be stored and used for future research purposes for an indefinite amount of time. 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, or 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.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by removing all identifiers from your coded information except for the unique identifier number. All other identifiers will be retained with study records, but will be recorded in a password-protected document and not shared.

You will likely not directly benefit from future research with your coded information. Research with your coded information may help others 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.

➢ 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.

➢ 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

➢ 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.

➢ 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 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 decide not to sign this form, 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.

➢ How can we contact you?

We would like to contact you by phone, email, or mail 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.

➢ 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.

➢ Will I receive the results of research testing that may be relevant to my health?

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.

➢ 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.

May we contact you to invite you to participate in future studies within our section 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 collected as a part of that study for the current study?

☐ Yes ☐ No

For this study we may need to contact you via email to provide you information about scheduling, appointments notes or to send you information about your participation in the study. Email communications pose a risk, as they are often not secure and may be seen by others as a result. If you wish for us to use a different means to communicate with you during the course of this trial please discuss this with the research team and alternative methods can be arranged. Do you agree to being contacted via email?

☐ Yes ☐ No (Preferred method of contact:_____)

If the task for *Visit 5: Task MRI Scan* is available, would you like to complete this visit? *Please note if the task is not available, we will not conduct this study procedure and you will not receive the compensation for this visit, even if you answer yes to this question.*

☐ 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.

An 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

IRB Approval From: 6/15/2023 To: 6/5/2024