Investigation of Functional Networks in the Human Brain Using Brain Imaging and Neuromodulation

Informed Consent

Are you participating in any other research studies? _____ Yes _____No

INTRODUCTION TO RESEARCH STUDIES

A research study is designed to answer specific questions, sometimes about a drug's or device's safety and effectiveness. Being in a research study is different from being a patient. When you are a patient, you and your doctor have a great deal of freedom in making decisions about your health care. When you are a research participant, the Protocol Director and the research staff will follow the rules of the research study (protocol) as closely as possible, without compromising your health.

The purpose of this research study is to better understand the relationship between the type of brain stimulation used and how it changes brain activity. The goal is to use this understanding to develop a new, personalized brain stimulation for treating mental health disorders. This research study is expected to involve between 1 and 7 sessions depending on the specific research goals. Each session will take approximately 3-6 hours. After a clinical assessment of your symptoms, medical history, medications, and a brain imaging MRI session, you will undergo a series of brain stimulation sessions where we will record the brain changes associated with brain stimulation that measures brain waves. Consent for this study is being sought for research only and participation is voluntary. Common risks include some discomfort with the procedures. Brain stimulation has a very rare risk of seizures. Your mood may change during the study, but as this study only applies small doses of brain stimulation we do not expect this to be common.

PURPOSE OF RESEARCH

You are invited to participate in a research study of brain imaging with magnetic resonance imaging (MRI) and electroencephalography (EEG) aimed at understanding brain changes in response to focal, non-invasive brain stimulation with repetitive transcranial magnetic stimulation (rTMS). EEG measures the electrical current from the brain, displaying brain activation patterns with great temporal resolution. TMS is a procedure that uses magnetic fields to stimulate nerve cells in the brain. Although TMS is an FDA approved procedure for patients with depression who have failed one antidepressant treatment, because you will be receiving small doses of TMS, you may or may not benefit from TMS provided by our study. This study will enroll healthy control participants in addition to participants with major depressive disorder.

After an initial interview that reviews medical and psychiatric history, you may be asked to undergo an MRI scan. In later sessions, you will receive TMS with varying patterns of

stimulation. We will record EEG to measure how your brain responds to these different TMS patterns. Each of these procedures are described in detail below.

The knowledge gained from our study will help us learn more about the relationship between TMS patterns and changes in brain networks involved in mood and emotion. This work will help us develop a new type of personalized TMS.

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled. If you decide to terminate your participation in this study, you should notify the protocol director, Corey Keller, MD PhD at 650-498-9111.

This study is being done together by researchers at Stanford University and will include approximately 400 participants.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take up to a maximum of 7 days. Each session will take approximately 3-6 hours.

PROCEDURES

If you choose to participate, Dr. Keller, and his research study staff will ask you to participate in the following procedures:

1) ☐ **Psychodiagnostic Interviews, Medical History, and Neurocognitive Assessments**:

This baseline screening phase involves an assessment of anxiety or mood symptoms, medical history, and neurocognitive testing. This session lasts no longer than 2-4 hours. The assessment will be done by a trained clinical researcher and may involve interviews, completing questionnaires on a computer and doing computer and/or pen and paper evaluations.

We may suggest medication adjustment before enrolling you in our study. Several types of medications used for the treatment of psychiatric disorders could, as a side effect, increase your likelihood of having a seizure. While most medications will not increase the likelihood of a seizure enough to cause concern for including you in this study, our goal is to minimize these risks whenever possible. Therefore the experimenters will discuss with you all prescription drugs or other drugs that you may be taking. If any adjustment of your medication is indicated to include you in this study, we will discuss the options with you and your doctor if you give us permission before you are enrolled in this study. For this study,

we also require that you be on a stable medication regimen before enrolling in the study. Please let the researchers know if there are any medication changes in the two weeks leading up to the first study visit. You may be asked to complete a second screening visit after medication adjustments.

It is important for your safety that you discuss any and all drugs that you are taking.

Risks: Answering questions on some of the questionnaires and interviews used in this study may provoke mild feelings of frustration, fatigue, sadness or anxiety. You have the right to refuse to answer any question that makes you feel uncomfortable on any of the questionnaires or interviews. Information you provide will remain anonymous and will be used only for the purposes of the research study. However, it is possible that, based on information gained from this study, the researchers may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities.

We will keep your study data as confidential as possible, with the exception of certain information that we must report for legal or ethical reasons, such as suspected child abuse or neglect, suspected elder abuse or neglect, or intent to harm yourself or others.

2) ☐ **Magnetic Resonance Imaging (MRI) scan of the head**

MRI machines use a strong magnet and radiofrequency magnetic fields to make images of the body interior. The scanning procedure is very much like an X-ray or CT scan. You will be asked to lie on a long narrow couch for up to an hour while the machine gathers data. During this time you will not be exposed to x-rays, but rather a strong magnetic field and radiofrequency magnetic fields, which you will not feel. Your head and shoulders lie in a plastic rounded tray, which makes it more comfortable and easier to lie still. You will hear repetitive tapping noises that arise from the Magnetic Resonance scanner. We will provide earplugs that you will be required to wear. The space within the large magnet in which you lie is somewhat confined, although we have taken many steps to relieve the "claustrophobic" feeling. You will have a hand-held control box to manually respond to stimuli.

As MRI may involve risks to the subject (or the embryo, fetus, or nursing infant if the subject is or may become pregnant), which are currently unforeseeable, if you are pregnant, or currently trying to become pregnant, you may not participate in this study.

Risks:

Magnetic fields do not cause harmful effects at the levels used in the MRI machine. However, the MR scanner uses a very strong magnet that will attract some metals and affect some electronic devices. If you have a cardiac pacemaker or any other biomedical device in or on your body, it is very important that you tell the operator/investigator immediately. As

metallic objects may experience a strong attraction to the magnet, it is also very important that you notify the operator of any metal objects (especially surgical clips), devices, or implants that are in or on your body before entering the magnet room. All such objects must be removed (if possible) before entering the magnet room. In some cases, having those devices means you should not have an MRI scan performed. In addition, watches, credit cards, hearing aids, and acupuncture should also be removed as these could be damaged. You will be provided a way to secure these items. If you have any history of head or eye injury involving metal fragments, if you have ever worked in a metal shop, or if you could be pregnant, you should notify the operator/investigator. You should also notify the operator/investigator if you have any tattoos on your body, including eyeliner and other permanent makeup. Tattoos could become warm and irritated during the scan and remain so for several days. If you would prefer not to participate in the MR scan due to the presence of tattoos on your body, please inform a research team member.

There is a possibility that you will experience a localized twitching sensation due to the magnetic field changes during the scan. This is expected and should not be painful. Please notify the researchers scanning you if you should experience this sensation.

Dizziness or nausea may occur if you move your head rapidly within the magnet.

The MRI scanner makes loud, periodic sounds that can cause hearing damage. With earplugs or ear protection properly worn, there is no known risk of permanent hearing damage. Rarely, your hearing may be less sensitive for several days after an MRI scan, but if this happens your hearing should return to normal within a few days. MRI sounds could cause ringing in the ears or aggravate any underlying ear conditions like tinnitus (undiagnosed or diagnosed). If you feel any discomfort during the procedure, please notify the operator immediately. You can tell the operator to stop the exam at any time.

IF YOU FEEL DISCOMFORT AT ANY TIME, NOTIFY THE OPERATOR AND YOU CAN DISCONTINUE THE EXAM AT ANY TIME.

Incidental Findings:

The investigators for this project are not trained to perform radiological diagnosis, and the scans performed in this study are not optimized to find abnormalities. The investigators and Stanford are not responsible for failure to find existing abnormalities in your MRI scans. However, on occasion the investigator may notice a finding on a MRI scan that seems abnormal. When this occurs, a radiologist will be consulted as to whether the finding merits further investigation, in which case the principal investigator of the research study being conducted will contact you and inform you of the finding. The decision as to whether to proceed with further examination on treatment lies solely with you and your physician. The investigators, the consulting radiologist, and Stanford are not responsible for any examination or treatment that you undertake based upon these findings. Because the images collected in this study do not comprise a proper clinical MRI series, these images will not be made available for diagnostic purposes.

3) ☐ **Behavioral testing:**

You may be shown images of things, such as simple letters, words, numbers or pictures that will be projected onto a screen in front of you. You may be asked simple questions relating to these letters, words, or pictures. Your responses to these questions will be recorded. This component of the study may happen alone or simultaneously with components 3-5, described below.

Risks: Some pictures or words that you see may provoke mild emotional responses such as fear, disgust, or sadness, though we do not anticipate that this will cause discomfort.

4) ☐ **Transcranial Magnetic Stimulation (TMS):**

TMS involves a procedure where parts of your brain will be non-invasively (ie indirectly) stimulated by magnetic pulses. These magnetic pulses induce very brief activity in brain areas underlying the TMS coil. You will hear a clicking noise as a few magnetic pulses are produced. To begin, you will sit in a chair and will be asked to 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 head. Stimulation intensity will be calibrated according to the amount of energy needed in the coil to induce activity specifically in your brain. To do so, the researchers will increase the intensity of the stimulation until it causes your thumb to move (when the coil is placed over the part of the brain controlling movement on the other side of the body). Electrodes will be placed on the hand and forearm to record muscle activity. This calibration is done to ensure that sufficient power is used for each individual without excessive stimulation.

TMS may be performed by giving single magnetic pulses to the brain or by giving repetitive pulses (rTMS). During rTMS, you will receive repetitive pulses either continuously when at low frequency (≤1Hz or one time per second) or during brief periods lasting several seconds when at >1Hz. Stimulation periods will be separated by a rest period, consistent with published TMS safety guidelines. rTMS may also be delivered where the stimulation frequency changes within a session. The parameters may be selected by a computer algorithm, but you will only receive stimulation within the published safety guidelines. At no point will TMS exceed 60 times per second. rTMS does not involve any anesthesia or sedation, therefore you will remain awake and alert during the stimulation. During some parts of the experiment, you may receive either real or sham TMS. This may also involve weak electrical stimulation of the scalp, delivered through two noninvasive electrodes temporarily taped on your skin. For your session, the TMS coil may be held in place manually or with a robotic arm.

Risks: While any procedure has possible risks and discomforts, TMS is considered to be a low-risk procedure. The only common side effect of TMS (approx 25% of patients) is a mild headache. 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. The exception is if

you have a cardiac pacemaker, or a certain type of metallic clip in your body (i.e., an aneurysm clip in your brain). The TMS device could cause discomfort or pain to the head. TMS can be felt as a dull tapping sensation on the head or a hard flick when administered at higher intensities. rTMS can produce a more sharp and uncomfortable sensation. TMS may also cause temporary muscle twitching in hands or the face, in response to the pulses, that can be uncomfortable. It is also possible that you may experience some neck stiffness or neck pain. This is believed to be due to the fact that participants tend to maintain a particular posture of the head and neck during the experiment. If you experience neck stiffness, discomfort, or pain at any point during the experiment, please let us know immediately. Patients who have a history of vasovagal response may experience a fainting episode at the time of TMS. A very small number of patients receiving rTMS have had seizures. All of the reported seizures resolved promptly on their own and none had lasting effects or adverse impact on the patients. There is little evidence of risk of seizures using rTMS the way it will be used in this study. However, there are certain medical factors that could increase the risk of seizure. If any of these apply to you or if you have any questions, please inform the study personnel immediately. In patients with epilepsy, activation of the brain with rTMS could also activate a seizure. Patients with stroke can also develop seizures with rTMS due to the brain scar. Therefore, magnetic stimulation of the brain with rTMS could conceivably activate a seizure in a stroke survivor with such a scar. Those with a history of epilepsy or stroke will be excluded for rTMS studies. However, single-pulse TMS studies have not been found to carry these added seizure risks. For a normal healthy person, producing a seizure from TMS in this experiment is very unlikely. In the unlikely event that a seizure does occur, safety procedures will be followed and you will be closely monitored.

There are no known long-term adverse effects reported with the use of this device. Rarely, device malfunction could result in a scalp burn. There may be unforeseen risks in the long-term that are currently unknown. 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 or noise cancelling headphones. Audio may be played through earbuds or headphones to mask the sound of the TMS device. Although uncommon, some subjects have experienced nausea during the experiment. If this occurs you can discontinue the experiment. Objects such as watches and credit cards should also be removed as these could be damaged If you are or could be pregnant, the effects of TMS on a fetus are unknown and, therefore, we will not perform the examination at this time. Please take note that some subjects experience a minor headache, migraine or local pain or swelling as a result of the TMS procedure; you may discontinue the experiment at anytime. You may also experience temporary and local bruising, swelling, or pain from the swim cap and/or muscle activation by TMS.

You may be asked to have an electroencephalogram (EEG) or psychophysiological measurement done at the same time as TMS, which does not involve any additional risks when done together with TMS. Please see separate sections on the procedures and risk involved with EEG or psychophysiological assessment.

You may also be asked to undergo/receive repetitive Transcranial Magnetic Stimulation for up to seven days within a two-week period. Multiple sessions may also be held on a single day. There are no known added risks with undergoing rTMS for multiple days. Please see the previous paragraph for details regarding the procedures and risks involved in rTMS.

5) ☐ **Electroencephalogram (EEG) and Psychophysiological Assessment**

EEG is a test that measures and records the electrical activity of the brain. To collect this information we will ask you to wear a cap on your head that is like a swimming cap. The cap has special sensors attached to it and is connected by wires to a computer. The computer will then record your brain's electrical activity on the computer screen as wavy lines. We may also put the sensors on your face with a sticky paste to record facial movements and eye-blinking. Electrodes will be attached to your face to measure eye-blink noise, heart-rate, and facial muscles which are associated with frowning and smiling. Finger sensors for skin conductance recordings may be attached to your left index and middle fingers. Electrodes may be placed on hand and forearm to record muscle activity.Your gaze may be monitored by an eye-tracking system during some study procedures. The test causes no discomfort. The electrodes only record activity and do not produce any sensation.

These recordings may be performed during your TMS sessions (see TMS above). The participant's breathing rate may also be tracked using 1-2 elastic breathing belts. Electrodes may also be placed on your skin near your wrists, ankles and/or chest area to measure heart activity (ECG). The electrodes only record activity and do not produce sensation.

These recordings may be performed during your behavioral assessments (see Behavioral testing below).

Risks: The rare and minor physical risks associated with EEG are possible skin irritation from the use of electrodes, a mild electrolyte gel, and/or the gel application process. You may feel discomfort due to having electrolyte gel in the hair; however, it is water-soluble and easily rinsed out of the hair. You may also experience fatigue or discomfort from wearing the EEG cap for extended periods of time.

6) ☐ **Video and Audio Recordings**

Video and audio recording may be requested during your study visits (baseline, active study assessments, follow-ups). The purpose of video and audio recording these sessions is to simultaneously evaluate behavioral data for mood (e.g. smile, frown) and/or physiological data (e.g. pupil size) for our studies. The recordings will be digitally recorded on a HIPAA-secure platform and your name and other identifying information will not be used. All video and audio recordings will be labeled using ID numbers of the participants and will be stored on a secure server only accessible by authorized lab personnel.

We would like you to indicate what uses of these video and audio recordings you are willing to consent to by initialing below. You are free to initial any number of spaces from none to all of the spaces, and your response will in no way affect your credit for participating. We will only use the video and audio recordings in ways that you agree to. In any use of these video and audio recordings, your name will not be identified.

Risks: There are no risks associated with video and audio recording during your study visit(s), and we do not anticipate that this will cause discomfort.

You give consent for your video and audio recordings to be used for the following (please select 'Y' next to the options you give consent to or 'N' if you do not give consent):

Y / N **Video and audio recordings can be made during study visits.**
Y / N **De-identified data extracted from the recordings (e.g. whether your eyes were open or closed at a specific time, whether you were smiling or frowning) can be used for our research. This extracted data may be shared in scientific publications, databases, and conferences without sharing your images or audio recordings.**

Y / N **Identifiable recordings (e.g. pictures of your face) may be shared in scientific publications and conferences. This sharing will not include your name or other protected health information.**

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the investigators and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the investigators or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigators or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the investigators or research staff if you change your mind about staying in the study.

- If you are a person of child-bearing age, protect yourself against pregnancy by using adequate birth control methods throughout the duration of the study. You agree to tell the study clinician immediately if you think you could be pregnant.
- If you are coming in-person to research visits, you are required to be fully vaccinated—2 doses (1 for Johnson and Johnson), 2 weeks out and to provide proof of your vaccination (e.g., CDC COVID-19 Vaccination Card, e-Health record, etc.) to the researcher prior to study participation.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are **free to withdraw** your consent and stop your participation at any time without prejudice to you or effect on your medical care. If you decide to withdraw from the study, you will not lose any benefits to which you would otherwise be entitled.

If you want to stop being in the study you should tell the investigators or study staff. You can do this by phone by calling Dr. Keller at 650-498-9111,or a member of his staff. There are no anticipated consequences to withdrawal from the research study.

The investigators may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the investigators and/or study staff.
- The investigator decides that continuation could be harmful to you.
- The study is cancelled.
- Other administrative reason
- Unanticipated circumstances.
- If you are found ineligible after intake

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions. The specific risks associated with each procedure are described above in the Procedures section.

PEOPLE OF CHILDBEARING POTENTIAL

If you are pregnant or currently trying to become pregnant, you are not eligible to participate in this study. If you are a person who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. You understand that if you are pregnant, or if you become pregnant, you or your child may be exposed to an unknown risk.

You must agree to protect yourself against becoming pregnant during the study. You must accept the risk that pregnancy could still result despite the responsible use of a reliable method

of birth control. In this case, you agree to notify the investigator as soon as possible of any possibility of pregnancy, so that appropriate safety measures can be taken. This may result in your being withdrawn from the study.

POTENTIAL BENEFITS

Potential Benefit to you: You may experience a change in your mood, but this is not expected as you will be receiving small doses of TMS. We cannot and do not guarantee or promise that you will receive any benefits from this study.

Potential Benefit to other people: In the future, other people may benefit from the results of this research. New information may lead to improved medical care. However, we will not know whether there are benefits to other people until all of the information obtained from this research has been collected and analyzed.

ALTERNATIVES

For participants with major depressive disorder, you do not have to participate in this research study to receive care for your medical problem. Alternative care may include receiving TMS outside of this study and/or consideration of other medications or therapies, including adjusting the dose of your current psychiatric medication. Please ask your study doctor as many questions as you wish. The doctor's answers to your questions could help you decide whether to participate in this research or receive the standard care that is currently available for your medical problem outside of this study.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director. You will be told of any important new information that is learned during the course of this research study, which might affect you or your willingness to continue participation in this study.

CONFIDENTIALITY

Your identity will be kept as confidential as possible as required by law. Your personal health information related to this study may be disclosed as authorized by you. Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number. Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. Information about the code will be kept in a secure location and access limited to research study personnel.

Certain scientific journals also require that data used in a published study be contributed in an anonymous, de-identified form to a scientific database. If this is required, all identifying personal information will be removed before it is added to the database. Brain images are stripped of all external identifying characteristics, such as facial features, before submission to an imaging database.

Patient information may be provided to Federal and regulatory agencies as required. The Food and Drug Administration, for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NIMH which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
The purpose of this study is to learn more about connectivity between brain regions and understand how different types of stimulation modify those connectivity patterns. Knowledge gained from this study may further our understanding of how the brain works, and how brain abnormalities lead to psychiatric disorders. Your health information will be kept in secure settings so that only Stanford researchers will have access to any identifying information. This allows us to be certain that your identifying information is linked to the data acquired from you in this study. If this research leads to scientific publications, any and all identifying information will be removed.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your

information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Corey Keller, 401 Quarry Rd, Stanford, CA 94305.

What Personal Information Will Be Obtained, Used or Disclosed?
Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to the following types of data collected:
Clinical, neurocognitive, behavioral, magnetic resonance imaging (MRI), electroencephalogram (EEG), psychophysiological (including heart rate, respiration, pupil size, eye tracking, skin conductance), transcranial magnetic stimulation, and combinations of the above.

PHI obtained will include name, email address, phone number, mailing address, and social security number. This information will be used for communications and reimbursements during the study.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- Corey Keller, M.D., Ph.D. (protocol director)
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Stanford Center for Cognitive and Neurobiological Imaging.
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- National Institute for Health
- National Institute of Mental Health
- De-identified data may be shared publicly and with any third party.

- De-identified data may also be shared with other collaborating institutions

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

Will my data be used for future research studies?
Identifiers might be removed from identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on 12/31/2031 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

FINANCIAL CONSIDERATIONS

Payment
Research subjects will be offered $50 per hour of MRI scan time; $15 per hour for psychodiagnostics interviews, neurocognitive assessments, EEG/psychophysiological assessments; and $25 per hour for TMS participation in the study.

Some of these payments are made in increments, which builds up as completion nears, and are based on how many visits have been completed.

If you are able to attend all appointments without having to reschedule any of your original scheduled appointments and you arrive on time (less than 5 minutes late) to your session(s), you will be able to receive an additional $50 dollars upon your completion of your participation. If for some reason, you are found ineligible after consent, you will be reimbursed only for the assessments completed.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs
There will be no costs to you for any of the treatment or testing done as part of this research study.

Sponsor
The National Institute of Mental Health is providing financial support for the study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

- Questions, Concerns, Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the principal investigator, Dr. Keller at (650) 498-9111 or kellerlab@stanford.edu. You should also contact him at any time if you feel you have been hurt by being a part of this study.

- Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? ____ Yes ____ No

Signing your name means you agree to be in this study and that you were given a copy of this consent form.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent