You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 60 people who are being studied, at Emory and elsewhere.

Why is this study being done?

This study is being done to answer the question: Can Transcranial Magnetic Stimulation (TMS) treatment be used to help people with Post-traumatic Stress Disorder (PTSD). You are being asked to be in this research study because you have many of the symptoms of PTSD and have indicated that you are willing to participate in research.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you are eligible and choose to join the study, you will participate for 3 months (16 study visits). The researchers will ask you to do the following: Interviews about your symptoms, Magnetic Resonance Imaging (MRI) scans, TMS treatment, and physiology tests. ALL of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. This study is not intended to benefit you directly.

What are the risks or discomforts you should know about before deciding?

The study will take time. The procedure that is being tested may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- Discomfort and feeling upset while talking about difficult events and feelings
- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

There is more information in the "Costs" section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Effect of Transcranial Magnetic Stimulation (TMS) on PTSD Neuroimaging and Psychophysiological Biomarkers

IRB #: STUDY00000338

Principal Investigator: [redacted], PhD

Study-Supporter: *National Institute of Mental Health*

Introduction
You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:
- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

What is the purpose of this study?
The purpose of this study is to see if regular Transcranial Magnetic Stimulation (TMS) treatment over a two-week period is a good treatment for the symptoms of Post-Traumatic Stress Disorder (PTSD).

What will you be asked to do?
Your first study visit will be a pre-intervention assessment. This visit will start with confirmation of inclusion and exclusion criteria, pregnancy test in childbearing age women, and gathering of verbal and written informed consent. Following the pre-intervention assessment, participants will be randomly assigned (like flipping a coin) to either the active TMS or sham control TMS (like a placebo, these participants will not receive the actual treatment, but a pretend version).

During the second visit you will have TMS motor threshold testing. This will be used to help the study team figure out the best levels for your treatment. During the first week you will also complete an interview and some measurement of your skin sweatiness during the interview, Emory Multimodal Learning Test (EMLT), Magnetic Resonance Imaging (MRI), and startle test (all explained more below).

During weeks 2 and 3 you will come to the Emory Brain Health Center every weekday (Monday through Friday) for your treatment session (90 minutes to 2 hours). The study can provide transportation for you to these sessions.

During week 4 you will again complete the startle test, EMLT, Interview and MRI. After you complete these assessments, you will be given the option to participate in Open Label TMS, which is the same as the study protocol but we will know you are receiving active TMS and not sham TMS.

Three months after your treatment you will return for one follow-up visit where there will be an interview and some measurement of your skin sweatiness during the interview.

You will be given the opportunity to participate in an optional portion of the study where we record your brain waves (using EEG) at 7 various time-points during the study. This portion is completely optional and if you choose not to participate it will not affect your involvement in the study in any way.

Description of the Interview: During the interview sessions, we will ask you questions related to your current life, your life history, and your family history. We will also ask about any trauma you have experienced. We will ask you questions about symptoms related to trauma such as depression, anxiety, and substance use. At times if you find the questions upsetting to you, **you are free not to answer. You may also take a break from the interview or stop the interview at any time.** During one set of questions we will ask you to wear two small plastic clips on your fingers, attached to an iPad. These clips will measure how much sweat is on your fingers and will cause you no discomfort. This interview will take anywhere from 2 hours to 4 hours in week 1, 4, and at the 3-Month Follow-up visit. During weeks 2&3, the interview will take approximately 30-45 minutes.

Description of the acoustic startle measurement procedure: People with PTSD may have an increased reaction to sudden noises or lights. We will play sudden tones, lights or pictures, and blasts of air. We will measure your reaction by recording your eye blink. We will do this by washing your cheek below your eye and behind your ear. A sticky tape will be used to attach three small electrodes (tiny metal discs with wires attached to them) to your face: two below your eye and one behind your ear. You will listen to some clicks and tones for about 30 minutes, either straight through or in two 15-minute sections with a short break in the middle. The sounds will be presented through earphones. We expect that some of the sounds will startle you a little, and you will blink your eyes. The electrodes allow us to measure your eye blinks. The startling sounds will be about as loud as a train. They will last a fraction of a second. Between clicks or tones you will hear a background noise that will not be so loud. While you listen, we will ask you to sit quietly with your eyes open. There will also be 2 interactive tests using a computer where we ask you to identify pictures on the screen. The total time for this startle test session will be about 60-90 minutes.

Description of the MRI: The MRI will take about 1 hour and during about 15 minutes of the MRI, you will be asked to complete a short computer task that involves making ratings about pictures of facial expressions. The scanner is a donut-shaped magnet, and you will lie on a comfortable padded table that moves into the scanner. You may feel mild discomfort because the scanner is noisy, you will be unable to move your head for some period of time, or you may feel tired of lying still for a long time. You can ask to change your position or move around in the scanner if you become uncomfortable. We also will be monitoring your bodily responses with sensors on the sole of your left foot and lower ribs and collar bone. These sensors will tell us about your heart rate and sweat response while in the scanner. You will not feel any unusual sensations associated with the scanning procedure. You may be asked to play a game in which you look at pictures of people's faces and answer questions about them. For each response, you will press a button on a button box you will hold in your hands. You may also see pictures appear on the screen in front of you and answer questions about them. While you are performing these tasks, we will be taking pictures of your brain at work. The scanner makes loud noises, so you will be asked to wear earplugs during the scan.

Description of transcranial magnetic stimulation (TMS): People with PTSD may have parts of their brain that do not work quite the same as other people. TMS is a treatment that places a small magnetic coil on the outside of your head. This coil is controlled by a computer program and sends pulses through the brain to activate these brain areas. The coil is placed on the right front part of the brain, which is called the prefrontal cortex. TMS is a non-invasive treatment, that means, it does not involve surgery and does not put anything else in your body. It also does not require anesthesia or sedation. For this study, we will ask you to come 11 times for a TMS treatment. The first time, we will help you get used to the treatment and we will figure out the right strength of the pulses for you. If you are willing to continue the study after this first treatment, you will be placed in one of two groups. One group will get the real TMS treatments, and the other group will get sham or "pretend" treatments. You will not know in which group you are, and the research staff will also not know. This is important to test the effects of the treatment. After this first treatment, you will be asked to come for treatments the next week. You will be asked to come every day (Monday to Friday) around the same time for two weeks to receive the treatments. Each day, you will have a treatment of 30 minutes, we will then take a 10-minute break and then you will have a second treatment of 30 minutes. During the treatment, you will sit in a comfortable chair, like when you are at the dentist, and you can relax, use your phone, watch a movie or read. The only thing that is really important is that you hold your head in the same position for these 30 minutes. After the post-treatment assessments are over, you can come back for 2 more weeks to receive the real treatment if you are interested.

Emory Multimodal Learning Test (EMLT) –You will watch a series of videos showing a normal life activity (e.g., eating a meal at a restaurant, a volleyball match), during which a professional actor stops, introduces themselves to the viewer, and tells some kind of brief story. You are required to learn the face, name, location, story, and incidental detail as best you can. This attempts to capture how real-world memories are formed. This is tested over a delay of 30 minutes. Participants will be given the option to complete longer term follow-ups of recall only, which can be completed from your home. This is done with input from your Emory assessor, which can be provided over zoom. Eye tracking can be utilized with this measure and it can be given with a virtual reality headset.

Who owns your study data and samples?

If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. If you leave the study, the data and samples that were already collected may still be used for this study. You will be given the option to destroy all of your study information when you notify the study team of your desire to withdraw from the study.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

Psychological tests and interviews sometimes can bring up painful emotions. These emotions may include sadness, worry, or increased anxiety. If you have trauma-related stress symptoms, you may have an increase in nightmares or flashbacks related to these traumatic experiences. You can decide to stop answering any questions at any time. You may also stop participating in the study at any time. This will not in any way affect your future medical care. During the computer task and startle procedure, scrubbing your skin with cleanser or application of skin tape may cause mild skin irritation. If the sensors cause you discomfort, you can stop the test session at any time. Withdrawal from the study will not affect your future medical care.

During the fMRI scan, there is the possibility that you may feel frustrated about playing the game in the fMRI scans, or that the pictures of faces will make you nervous. There are no risks of physical injury. Magnetic resonance imaging uses magnetism and radio waves (not x-rays) to make pictures. It has been in use for more than 20 years and millions of people have had fMRI scans without injury. Therefore, fMRI is thought to be safe, although no one can guarantee that there are no long-term negative health effects to individuals undergoing scans or to fetuses in pregnant women undergoing scans. The only known risks are to individuals with cardiac pacemakers and certain types of metallic implants. If you have either of these, you cannot participate in this study because of effects the magnetic field could have on the pacemaker or metallic implant. Be sure to tell us if you know or think that you have a pacemaker or metallic implant such as an aneurysm clip. All the equipment and fMRI methods used in this study are standard and have been approved by the U.S. Food and Drug Administration.

You may become tired from lying in the scanner, or may become uncomfortable from lying in one position for a long period of time. If you become too hot or too cold you may ask us to adjust the room temperature or give you a blanket. Some individuals experience mild anxiety or claustrophobia (fear of small spaces) while lying in the scanner. If this happens, you may ask to leave the scanner at any time. The fMRI machine makes loud metallic popping sounds that you may find irritating while it is taking pictures. We provide earplugs to help lessen this loud noise, but you will still be able to hear some noise during the scan. You can ask to stop the fMRI scan any time you want.

Risks related to the TMS procedure are minimal. TMS is used a lot and has been widely approved. Recent studies have showed a less than 0.002% risk of generalized seizures with the use of TMS. When the study used the same levels we will use in this study the risk was reduced to 0%.

There is a risk that the EEG device will feel tight or uncomfortable, especially at first. The experimenters can adjust this for you if you let them know.

There is a risk that there will be a breach of confidentiality within the study and your data and/or your participation in the study will be available to others outside of the study team. We will follow all protocols available to us to maintain and protect this confidentiality at all times throughout the duration of the study.

If it is biologically possible for you to become pregnant: to protect against possible side effects of the study procedure, people who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a person of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant people will be taken out of the study.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?

This study is not designed to benefit you directly. Your PTSD may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about how a regular TMS treatment will change the way that your brain responds to stress. The study results may be used to help others in the future.

Will you be paid for your time and effort?

You will get $20 for each completed TMS study visit, to compensate you for your time and effort. You will get $30 for each completed interview or startle testing visit to compensate you for your time and effort. You will get $60 for each completed MRI scan visit to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed (you will be compensated at the end of each visit). You will get $490 total, if you complete all study visits. You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

If you participate in the optional EEG sub-study you will receive $5 for each EEG recording session for a total of $35. You will have received $525 total for all completed study visits.

What are your other options?

Participation in this study is completely optional and you can simply choose not to participate.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.
Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the National Institute of Mental Health, the Emory Institutional Review Board, the Emory Office of Research Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

We will use your data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

Returning Results to Participants/Incidental Findings

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Incidental Findings from Imaging Tests
You will be getting a scan for research purposes only. The research does not require health professionals to read the scan. The researchers are not qualified to interpret the images for healthcare purposes. Do not rely on the scan for clinical or diagnostic purposes. However, if the researchers have a question about something they see on the scan they will tell you, and ask you if you want the scan sent to a qualified health professional for review and any further medical treatment. You or your insurance company may have to pay for the review and any such treatment.

Medical Record
If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study.

We have no plans to place any records of tests or procedures from this study in your medical record. We will take reasonable steps to keep copies of this form out of Emory's medical records system. If we aren't successful in keeping these forms out, despite our efforts, we will take steps to remove them. If they cannot be removed, we will take steps to limit access to them.

The results of ALL study tests and procedures will be used only for research purposes and will *not* be placed in your medical record.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact [redacted] at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study. Emory will help you get immediate medical care. However, Emory does not have programs to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not be covered by HIPAA.

Purpose of this Authorization:

By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

Research-Related Treatment

This study involved research-related treatment that will not be electronically billed to any insurance company or government benefits program (e.g., Medicare, Medicaid). You may not receive the research-related treatment unless you sign this authorization. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:

- Contact Information
- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory may use and disclose your IIHI to get payment for conducting the study and to run normal business operations.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- The National Institute of Mental Health is the Supporter of the study. The Supporter may use and disclose your IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices.

Optional Study: EEG Recording:
Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study: You do not have to authorize the use and disclosure of your PHI for the optional study(ies). If you do not authorize the use and disclosure of your PHI for the optional study(ies), then you may not participate in the optional research study, but you can still be in the main research study.

Expiration of Your Authorization

Your IIHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at: Dr. [redacted], [redacted]

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Program Director [redacted].

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**

Optional Study Information

Your data and/or specimens will be protected the same way as the data and/or specimens for the main study. There are no additional risks or costs for joining the optional study than the ones already described for the main study (see sections above).

What is the purpose of this study?
The purpose of this study is to learn more about how TMS effects the brain.

What will I be asked to do?
If you choose to participate in this optional part of the study, we will use a recording device that sits on your scalp and records the activity of your brain at up to seven different time points. Recordings will happen during week 1 (on the day you perform the Startle Test) before treatment begins, and then during week 4 (on the day you perform the Startle Test) when treatment has ended. We will also record every OTHER treatment session during weeks 2 and 3 (up to 5 total). The recording will take about 5 minutes each time, where you will sit in a comfortable chair and relax. The sensors on the EEG must be able to touch your scalp, so we will ask you to remove any hair pieces, etc and to not wear extra gel on those days. You will be donating the study data by participating.

Will I benefit directly from the study?
This sub-study is not designed to benefit you directly. Your PTSD symptoms may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about the effects of TMS on the brain. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
You will get $5 for each completed study visit, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get up to $35 total, if you complete all study visits. You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, if joining the sub-study increases your annual compensation over the taxable amount.

What are my other options?
You can participate in the main study and not take part in this sub-study.

Withdrawal from the Sub-study
You have the right to leave this sub-study at any time without penalty. You may stay in the main study even if you leave this sub-study.

The researchers also have the right to stop your participation in this sub-study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Contact Information
See contact information for the main study, above.

HIPAA Authorization for Optional Sub-study

Authorization for This Use of PHI is Required to Participate in Optional Sub-Study, but Not in Main Study: You do not have to authorize the use and disclosure of your PHI for the optional study(ies). If you do not authorize the use and disclosure of your PHI for the optional study(ies), then you may not participate in the optional research study, but you can still be in the main research study.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the optional study(ies) described above. By signing this form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

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Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**

Optional Study Information

Your data and/or specimens will be protected the same way as the data and/or specimens for the main study. There are no additional risks or costs for joining the optional open label TMS study than the ones already described for the main study (see sections above).

What is the purpose of this study?
The purpose of this study is to learn more about how TMS effects the brain.

What will I be asked to do?
If you choose to participate in this optional part of the study, we will be repeating the TMS sessions as they were done during the main study, but we only use the actual TMS and we will not use SHAM TMS. This will include 10 visits. Each visit will include two 30-minute TMS sessions with a 10-minute break in between. We also complete self-report measures at the 5th and 10th visits.

Will I benefit directly from the study?
This sub-study is not designed to benefit you directly. Your PTSD symptoms may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about the effects of TMS on the brain. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
You will not be compensated for participation in the open label TMS sessions, and you will not be charged for any part of the open label TMS sessions. You are responsible for your own transportation to and from the open label TMS sessions.

What are my other options?
You can participate in the main study and not take part in the open label TMS.

Withdrawal from the Sub-study
You have the right to leave this sub-study at any time without penalty. You may stay in the main study even if you leave this sub-study.

The researchers also have the right to stop your participation in this sub-study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Contact Information
See contact information for the main study, above.

HIPAA Authorization for Optional Sub-study

Authorization for This Use of PHI is Required to Participate in Optional Sub-Study, but Not in Main Study: You do not have to authorize the use and disclosure of your PHI for the optional study(ies). If you do not authorize the use and disclosure of your PHI for the optional study(ies), then you may not participate in the optional research study, but you can still be in the main research study.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the optional study(ies) described above. By signing this form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**