Title: TMS-fNIRS Personalized Dosing

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RESEARCH PARTICIPANT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

STUDY TITLE: Personalized Dosing of Non-invasive Brain Stimulation Using TMS-fNIRS Technology

STUDY #: STUDY00004007

PRINCIPAL INVESTIGATOR: F. Andrew Kozel, M.D., M.S.C.R.

SPONSOR: Department of Defense

NOTE: In this consent form, "you" always refers to the research participant.

ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. It is important that you carefully think about whether being in this study is right for you and your situation.

This consent form is meant to assist you in thinking about whether or not you want to be in this study. Please ask the principal investigator or the study staff to explain any information in this consent document that is not clear to you. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

This study is sponsored by the Department of Defense and will be carried out at Florida State University.

AN OVERVIEW OF THE STUDY AND KEY INFORMATION

The following is a short summary of this study to help you decide whether or not you would like to participate in this study. More detailed information will be provided later on in this form.

Why is this research study being done?

The overall goal of this project is to demonstrate the utility of transcranial magnetic stimulation - functional near-infrared spectroscopy (TMS-fNIRS) technology as a direct measure of frontal brain activity, replacing the indirect motor threshold procedure that may lead to improper dosing of TMS. Personalized TMS-fNIRS technology may guide future therapy for depression, post-traumatic stress disorder (PTSD), and/or traumatic brain injury (TBI).

TMS is a non-invasive medical device that safely stimulates the brain. The device is placed on the head and creates magnetic pulses that reach the brain surface. TMS is FDA cleared for treating depression, but not for PTSD. Depression and PTSD share some overlapping symptoms, and patients often suffer from both conditions. TMS is a promising potential therapy for PTSD, and the technology developed in this project will help advance research and clinical practice for PTSD, depression, and other brain-based disorders.

The dose (strength of the magnetic pulses) must be personalized for each person receiving TMS. Individuals have differences in anatomy (e.g., skull thickness) and brain function (e.g., brain activity levels) that require different doses. If the dose is too weak, TMS will not generate a therapeutic effect in the brain. If the dose is too strong, a patient may experience unnecessary pain and an increased risk for seizure. There are no simple methods to verify TMS dose for the frontal brain locations where depression and PTSD are treated. The current standard uses an indirect proxy measure based on stimulating the brain region that controls hand movement. As hand movement may be a flawed proxy for the frontal brain dysfunction involved in PTSD, we will develop a technology to directly measure the TMS effect. We are using fNIRS to measure brain activity. fNIRS technology has small light sources and optical sensors that are relatively small and inexpensive to translate for clinical practice. Thus, the brain measure technology (light spectrum) does not interact with the brain stimulation method (electromagnetic spectrum). This is important for safety and disruption of the measured signal.

In this project, we will characterize the feasibility and validity of this TMS-fNIRS technology for personalized dosing. We plan to conduct this research with volunteers suffering from PTSD, as this technology will guide future clinical research for this population. Many traumatic events result in both mental (PTSD) and physical (TBI) brain injury. Thus, we also plan to characterize this technology with volunteers suffering from TBI.

How many people will be part of this study?
We expect that about 60 people will be part of this research study.

If I decide to participate, how long will my participation last and what will I need to do?
We expect that you will be in this research study for 1 to 3 weeks. During that time, you will be asked:

- to attend 3 separate study visits, each lasting 1 to 3 hours.
- at Visits 1 - we will collect safety information, you will meet with a member of the study team for a clinical interview, and you will have your motor threshold (TMS dose) determined
- at Visit 2 - you will have an MRI
- at Visit 3 - you will have the TMS-fNIRS testing

More detailed information about the study procedures can be found under, "**What happens if I say yes, I want to participate in the research study?**"

What I choose not to participate in the study?
This study provides no treatment. If you decide not to enter this study, you can still receive the usual care that you would receive even if you were not in the study. You do not have to participate in this study to be treated for PTSD.

Is there any way being in this study could be bad for me?
There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the *"What risks and discomforts can I expect from being in the study?"* section.

Risks and Discomforts

- Transcranial Magnetic Stimulation (TMS): The most common side effect of TMS is temporary physical discomfort or headache at the site of stimulation.
- Transcranial Magnetic Stimulation (TMS): There is a rare risk of seizure from TMS.
- Transcranial Magnetic Stimulation (TMS): The magnetic fields used in TMS may harm people who have metal in their head.
- Magnetic Resonance Imaging (MRI): During the MRI, some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel "closed in" and become anxious while in the scanner.
- Magnetic Resonance Imaging (MRI): The magnetic field used in MRI scanning may harm people who have metal in their bodies (pacemakers, neurostimulators, certain clips, or staples from surgery). It may cause problems with devices, such as pacemakers. If you have metal in your body or a pacemaker, you should not have an MRI.
- Functional Near Infrared Spectroscopy (fNIRS): There may be mild, temporary discomfort from the device placed on the scalp.
- Questionnaires and Assessments: You may be asked questions about topics which may make you feel uncomfortable, for example discussing past traumatic events or your medical history.
- General Health and Wellness: This is not a treatment study. There is a risk your symptoms may worsen during the study.
- Privacy: Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.
- Unknown Risks: The devices as used in this study are investigational. There may be some risks that the researchers do not know about yet, so we will let you know of any new findings.

Will being in this study help me in any way?

- This is not a treatment study, and you are unlikely to receive any direct medical benefits from your participation. The information from this research study may lead to a better treatment in the future for people with PTSD.

DETAILED INFORMATION:

Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you do not understand, be sure to ask the study staff.

What will happen if I say yes to participating in this study?

At your first study visit (Visit 1), after your written consent is obtained, your medical history and demographic information will be collected through a series of questionnaires. You will then meet for an interview with a member of the study staff who will ask you questions in order to make sure that it is safe for you to participate in the study. Urine samples will be collected for urine drug tests. Women of childbearing potential will also have a urine pregnancy test done.

After the screening, study staff will confirm that it is safe for you to undergo TMS-fNIRS. If it is, the fNIRS cap will be placed on your head and your motor threshold will be determined, meaning we will determine the least amount of energy necessary to activate the nerves in your brain that move your fingers. At the end of the visit, you will be scheduled for your MRI.

At Visit 2, you will visit the FSU Imaging Center to have Magnetic Resonance Imaging (MRI) of your brain done. An MRI, is a noninvasive medical imaging test that can produce detailed images of almost every internal structure in the human body, including the organs, bones, muscles and blood vessels. For the MRI, part or all of the body will be passed into a long, narrow tube scanner, which is open at both ends. For the MRI, you will be asked to hold still for both structural and functional brain scans. Depending on time, you may be asked to move your fingers and/or do a memory task while being scanned. The total time in the scanner will be approximately one hour and the visit will be about two hours.

At Visit 3, you will have two sessions of TMS stimulation with the additional fNIRS tool. Because this is not a treatment study, we refer to these as *protocols*.

Visit 3-Session 1:
You will receive four TMS-fNIRS protocols with stimulation over the front of your brain.

- Each of the four protocols will be eight minutes long, including one minute before and one minute after each protocol in which you simply hold still with eyes open.
- During the protocol you will need to be sitting quietly with your eyes open.

Randomization during Session 1
There is a one in five chance you will receive a sham (or fake) TMS stimulation during the TMS-fNIRS protocols. Neither you nor the research team administering TMS will know which study stimulation you are receiving.
This information is available to the study doctor if needed in an emergency. This is called blinding, and it is done so that a fair evaluation of results may be made.

Visit 3-Session 2:
After the twenty-minute break you will start *Session 2* and receive an additional four TMS-fNIRS protocols over the portion of the brain that moves your fingers.

- All of these TMS stimulations will be active (or real).
- Each of the four protocols will be eight minutes long, including one minute before and one minute after each stimulation in which you simply hold still with eyes open.
- During the protocol. you will need to be sitting quietly with your eyes open.

The total time for Visit 3 should be approximately two hours.

Use of Investigational Devices:
The TMS stimulation is done using a device called the MagVenture TMS with the Cool-B70 A/P. The additional fNIRS tool is called the NIRx fNIRS Scout. Both the TMS and fNIRS devices are being used in this study as *investigational devices*, meaning the devices have not been approved by the U. S. Food and Drug Administration (FDA) for this particular use.

What risks and discomforts could I experience from being in the study?

Possible Risks Associated with MagVenture TMS with the Cool-B70 A/P coil

- There is a risk of headache or other physical discomfort. We can make some adjustments during your stimulation if you are experiencing discomfort.
- TMS may impact hearing, especially at high power settings. Earplugs can mitigate this risk.
- The magnetic field produced by TMS can interact with metal near the site of stimulation or impact the functioning of other medical devices. Careful participant screening and monitoring can mitigate risks.
- There is a rare risk (less than 1%) of seizure from TMS. Careful participant screening can mitigate risks.

Possible Risks Associated with MRI Imaging:
The magnetism of the machine attracts certain metals; therefore, people with these metals within their bodies (such as pacemakers, infusion pumps, aneurysm clips, metal prostheses, joints, rods, or plates) will be excluded from the study. You will be expected to notify the investigator conducting the study of any metal in your body.

While there are no known permanent negative effects from exposure to a strong magnetic field of an MRI machine, there may be some temporary ones. These temporary effects may include:

- The MRI scanning procedure requires that you be confined in a small partially enclosed space. Some individuals find this to be uncomfortable and may exhibit symptoms of claustrophobia including nervousness, sweating or other minor discomfort.
- Dizziness
- Nausea
- Metallic taste in your mouth.
- The MRI produces very loud pulsating sounds. You will be required to wear earplugs or a headset to protect your hearing.
- Some types of MRI scan can cause temporary peripheral nerve stimulation which causes mild discomfort but is not harmful.
- Some types of MRI scan can cause heating of your body.

If you experience any discomfort that you cannot tolerate, you will be given an alarm bell to notify researchers that you would like to discontinue the study.

Possible Risks Associated with NIRx fNIRS imaging:
fNIRS is non-invasive but involves wearing a fabric cap with small detectors on it that may press on your skin. The cap may become uncomfortable for some people, especially after doing many sessions. We will check in with you during the sessions to make sure that you are still comfortable enough to continue or if you would like to take a break.

Non-Physical Risks

- Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

- This study will ask you questions about personal topics that might be embarrassing to talk about and that could affect your relationships if this information were to become known outside of the study.

- You will also be asked about illegal activities, which could have legal and financial consequences if this information were to become known outside of the study.

Risks for pregnant women and fetuses
If you are or may become pregnant, TMS might involve risks to the embryo or fetus that are currently unforeseeable. Because of the limited data on the risk to fetuses from TMS treatment and the risk of seizure causing complications during pregnancy, **if you are pregnant or become pregnant you cannot participate in this study.** We will conduct a pregnancy test at Visit 1, and we may retest during the study if indicated.

Unknown or Unforeseeable Risks
In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. The study investigators will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

This is not a treatment study and there is a risk that you may experience a worsening of symptoms. Participation involves three visits over a short period of time. You will be monitored closely the study investigators and may discontinue enrollment at any time.

What are the costs related to participating?
Routinely, FSU, its agents, or its employees do not compensate for or provide free care for human subjects in the event that any injury results from participation in a research project. If you become ill or injured as a direct result of participating in this study, contact your regular medical provider. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be billed. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. Florida State University has no program to pay for medical care for research-related injury.

Will I be paid to participate in the study?
You will be paid by gift card for each study visit, and if you complete all scheduled study visits, you will have received a total of $100. If you withdraw before the end of the study, you will be paid per the amount below per completed study visit.

- Visit 1 $20
- Visit 2 $30
- Visit 3 $50

Total payments from this and other studies within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. FSU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

Statement About Future Clinical Development
There is a possibility that this research may lead to development of products that will be commercialized. If this happens, there is no plan to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value.

What happens if I say "yes", but change my mind later?
You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at FSU. Tell the study staff if you are thinking about stopping or decide to stop.

Can I be removed from the study without my permission?
Your participation in this study may be stopped at any time by the study doctor without your consent. The reasons might include:

- the study doctor thinks it necessary for your health or safety
- you are found to not be eligible for the study
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

If you withdraw from the study, data that has already been collected about you will remain part of the study database and may not be removed.

What happens to my information that is collected and how it be protected?
FSU has established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases according to FSU's policies (i.e., for a minimum of 5-6 years). It is only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside FSU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- US Army Medical Research & Development Command Institutional Review Board
- US Army Human Research Protections Office and other DOD offices charged with oversight of human research
- The FSU IRB and other institutional representatives of FSU.
- Officials of the Department of Health and Human Services (HHS) and/or the Federal Food and Drug Administration (FDA).

The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

Designated Healthcare Provider(s):
Please list below any healthcare providers that you give the authority to release or be provided with your healthcare information as relevant to this study.

	Name	Telephone # or Email	Provider Type
1.			
2.			

EMERGENCY/SECONDARY CONTACT INFORMATION:
You may but are not required to share up to four names of Emergency/Secondary Contacts below. By sharing this information, you are giving permission for the research study staff to contact these individuals in case of an emergency or for a follow-up status check.

Emergency and/or Secondary Contact(s)

	Name	Telephone # or Email	Relationship
1.			
2.			

If you are having thoughts of harming yourself or experiencing a mental health crisis we urge you to immediately seek social support and medical assistance. If these strategies fail, please contact an emergency mental health resource or go to the emergency room. Below are a list of resources available to you.

- Dial 9-8-8 to reach the National Suicide and Crisis Lifeline.
  When people call, text, or chat 988, they will be connected to trained counselors that are part of the existing Lifeline network. These trained counselors will listen, understand how their problems are affecting them, provide support, and connect them to resources if necessary.
  Hours: Available 24 hours. Languages: English, Spanish

- Dial 9-1-1 and specifically tell the operator this: "*I am requesting the aid of a Crisis Intervention Team (CIT) officer*." The operator will then send specially trained law enforcement officers, if available; who are trained in dealing with individuals undergoing a mental illness crises. You can request that officers arrive without lights or sirens.

- Dial 2-1-1 for 211 Big Bend - Just as you would call 9-1-1 for other emergencies, you can call 211 for human service information and assistance. They are available 24 hours a day to listen and provide emotional support, crisis counseling, suicide prevention, and information & referrals. You do not have to be in crisis to call, there is no eligibility criteria, and their services are free. They help you navigate through the maze of community services in a nonjudgmental manner.

- Tallahassee Police Department and Leon County Sheriff's Office Central Dispatch – The new 24 hour non-emergency number is 850-606-5800. Ask for a CIT trained officer or deputy.

Please let us know if having thoughts of harming yourself or experiencing a mental health crisis. We can provide additional resources that may be helpful to you and will not tell anyone the information you share with us unless you are at imminent risk of hurting yourself or others.. If you are at imminent risk, the law requires that we take appropriate action, and we must let people in authority know.

Clinical Trials.gov
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 Website will include a summary of the results. You can search this Web site at any time.

Return of Individual Data:
In general, we will not give you any individual data from the study. All participant requests for individual data must be made in in writing, and a summary of the study and relevant details will be provided to the you and/or your healthcare provider.

Certificate of Confidentiality:
To help protect your privacy, the investigators of this study have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH), which is part of the U.S. Department of Health and Human Services (HHS), an U.S. government agency. With this Certificate, we, the investigators, cannot be forced (e.g., by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Be aware that disclosure of you and/or your child's identity may be found necessary, however, upon request of the HHS for the purpose of audit or evaluation.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about your child, yourself, or your involvement in this research. Note, however, that if an insurer or employer learns about you and/or your child's participation and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Future Use of De-Identified Data
In the future, identifiers will be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study team or another researcher without asking you for additional consent.

How will my health information be used and shared during this study?
As part of this research study, we will ask you about your medical history. This type of information is considered *"Protected Health Information"* (PHI) that is protected by federal laws related to HIPAA.

What type of health information will be used or shared with others during this research?
The following types of information may be used for the conduct of this research:

- Medical and treatment history
- Laboratory test results
- Medical imaging reports
- Imaging films/scans/pictures (including MRI full face images)
- Information about drug or alcohol abuse
- Information about mental health history

Who will use or share protected health information about me?
We are required by law to protect your identifiable health information. By consenting to this

study, you authorize the use and/or sharing of your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- US Army Medical Research & Development Command Institutional Review Board
- US Army Human Research Protections Office and other DOD offices charged with oversight of human research
- The FSU IRB and other institutional representatives of FSU.
- Officials of the Department of Health and Human Services (HHS) and/or the Federal Food and Drug Administration (FDA).
- Principal Investigator and Research Staff
- Study Sponsor
- Others as Required by Law

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?
This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights
You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at:

F. Andrew Kozel, M.D., M.S.C.R.
2000 Levy Avenue, Suite 337.
Tallahassee, FL 32310.

What else should I know?

Consent to MRI Incidental Findings Review and Report:
As stated before, during Visit 2, you will visit the FSU Imaging Center to have Magnetic resonance imaging (MRI) of your brain done.

The MRI scan is being done to answer research questions, not to examine your brain for medical reasons. This MRI scan is not a substitute for a clinical scan (the type a doctor would order). The research scan might not show problems that may be picked up by a clinical MRI scan. However, **all research MRI scans will be read by a neuroradiologist (a doctor with experience reading MRI scans) unless you have been scanned at FSU in the previous six months.**

Incidental findings are potential health problems that are discovered during the course of conducting research. At Florida State University Magnetic Resonance Imaging Facility, we have all neurological research MRI scans evaluated for incidental findings, **UNLESS YOU DO NOT CONSENT TO THIS EVALUATION.**

If you consent to having your scans reviewed for incidental findings, your data will be transferred using secure encrypted methods to password-protected servers. As with all such data transfer, this ensures integrity, authenticity and confidentiality of the data in transit.

To permit the generation of your incidental findings report, your name and date of birth will be supplied to the provider of neuroradiological review services. This will also be transferred via secure encrypted methods which ensures integrity, authenticity and confidentiality of the data in transit.

The provider of neuroradiological review services may maintain your data indefinitely and may use de-identified and aggregate incidental findings data with existing and future data for statistical analysis.

When your scan is read, we will mail a copy of the report to you or contact you (with your permission) by phone to help answer questions. Due to the very high sensitivity of MRI in detecting abnormalities, there is a risk of false-positive findings, identifying something on imaging studies that may or may not be important. This may result in anxiety and additional testing, possibly including a recommendation for clinical scans at your cost. The radiology report or other study data will not be put into your medical record unless you provide it to your physician. If the radiology report becomes part of your personal medical record, it may or may not have an effect on getting health insurance or life insurance in the future.

Please check the appropriate box regarding your decision to have your scan reviewed for incidental findings.

Name of Participant:_____ Date:_____

☐ **I DO** consent to have my MRI scan reviewed for incidental findings.

☐ **I DO NOT** consent to have my MRI scan reviewed for incidental findings.

Additional HIPAA Authorization for Use for Evaluation and Reporting of Incidental Findings:

I, _____ authorize the MRI facility at Florida State University, at the College of Medicine (the Facility) to collect, use and disclose_____(’s) protected health information (PHI) to the entities listed below at the request of the individual for the purposes of research.

- The Mind Research Network for MRI radiology review purposes
- The FSU MRI Facility Associate Director
- The FSU MRI Facility Scientific Director;
- The FSU MRIF and FSU MRI Facility Technologist and Program Director;
- The Principal Investigator and research study staff

Limited Information:
This information will be limited to the generated image data of _____ from the MRI scan and the contact information for release to the referring researcher or their staff for use in an IRB approved research project.

Effective Period: This authorization for release of PHI is in full effect until the conclusion of research.

Extent of Authorization:
By signing below, I authorize the release of any PHI provided by me and/or generated by the Facility.

I understand that I have the right to revoke this authorization, in writing, at any time. I understand that a revocation is not effective to the extent that any person or entity has already acted in reliance on my authorization.

I understand that PHI used or disclosed by this authorization may be subject to re-disclosure by the recipient and may no longer be protected by Federal law.

I understand that I do not have to sign this Authorization, but if I do not, I will not receive authorization to participate as a research subject.

_____
Adult Participant Name (Printed)

_____ _____
Adult Participant’s Signature Date

Whom should I contact if I have questions about the study?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

Principal Investigator: F. Andrew Kozel, M.D., M.S.C.R. at (850) 644-2824 or FSUN@med.fsu.edu

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact the FSU Office of Human Subjects Research at 850- 644-7900 or humansubjects@fsu.edu.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent:
I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block for Enrolling Adult Participants

_____	
Adult Participant Name (Printed)	
_____	_____
Adult Participant's Signature	Date
_____	
Name of Person Conducting Consent Discussion (Printed)	
_____	_____
Signature of Person Conducting Consent Discussion	Date
_____	_____
Principal Investigator Signature (if different from above)	Date

OPTIONAL FUTURE CONTACT ABOUT RESEARCH:
As part of this study, we would like to keep your contact information (name, phone, email, etc.) along with any additional information you give us in response to the questions below, in an IRB approved registry so that we may contact you based on your eligibility for future FSU research studies.

WHAT IS MY INFORMATION USED FOR?
By giving your consent, you are giving permission:

1. For us to collect your name, preferred method of contact, as well as some other optional information–and store this in the secured electronic database.
2. For us to contact you if you may be eligible to volunteer as a participant in a future research study conducted by our team here at FSU.
3. For us to share your information with other FSU researchers who are conducting similar research to ours, so they can contact you about other studies.

OTHER INFORMATION INCLUDING RISKS AND BENEFITS:
By giving permission to share your contact information there is no guarantee that you will be contacted about potential participation in a study. There is no compensation for completing the questions nor for agreeing to be contacted. There are no direct benefits to you from agreeing to share this information and be contacted.

We will do our best to protect your information, but there is always a small risk of loss of confidentiality. To further minimize the risks to confidentiality, we do NOT ask for any details about your prior research studies, health information, doctors, hospitals, or any diagnoses.

We consider your records confidential to the extent permitted by state and federal law, however your information may be reviewed for audit purposes by authorized FSU employees or other agents who will be bound by the same provisions of confidentiality. Sharing your information and allowing us to contact your is voluntary. If you have any questions or change your mind at any time, please contact the FSU Neuromodulation Research Team at fsun@med.fsu.edu.

PLEASE SELECT ONE OF THE OPTIONS BELOW
☐ YES, I have read and agree to the above statements.
☐ NO, I do NOT wish to share my information and/or be contacted about future research studies.

<table>
<tr><td colspan="9">Preferred Method of Contact:</td></tr>
<tr><td colspan="4">☐ Phone:</td><td colspan="5">☐ Email:</td></tr>
<tr><td colspan="9">☐ Mailing Address:</td></tr>
<tr><td colspan="9">Optional Questions (these will help us better select studies that you may be eligible for):</td></tr>
<tr><td>Age Bracket:</td><td>☐ 18-24</td><td>☐ 25-34</td><td>☐ 35-44</td><td>☐ 45-54</td><td>☐ 55-64</td><td>☐ 65-74</td><td>☐ 75-79</td><td>☐ 80+</td></tr>
<tr><td colspan="3">Veteran: ☐Yes ☐No</td><td colspan="6">Student: ☐Yes ☐No</td></tr>
<tr><td colspan="9">What type of studies would you be interested in?</td></tr>
<tr><td colspan="3">☐ General Psychology Studies
☐ General Mental Health and Wellness
☐ Treatment Studies</td><td colspan="3">☐ PTSD
☐ Pain
☐ Depression</td><td colspan="3">☐ Bipolar Disorder
☐ Other Studies
☐ Anxiety</td></tr>
</table>