Title: Rapid Treatment of PTSD With Accelerated Non-Invasive Brain Stimulation
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RESEARCH PARTICIPANT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

STUDY TITLE: Rapid Treatment of PTSD with Accelerated Non-Invasive Brain Stimulation

STUDY #: STUDY00005179

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 goals of this project are to test the clinical effectiveness of an accelerated Transcranial Magnetic Stimulation (accel-TMS) protocol that may improve Posttraumatic Stress Disorder (PTSD) symptoms with one week of concentrated treatment and to learn more about the effectiveness of various accel-TMS treatment parameters for PTSD with an additional week of concentrated treatment.

This study will also involve participants completing virtual reality (VR) mindfulness meditation sessions. We have looked at the effects of participants completing VR mindfulness meditation prior to accelerated TMS in previous studies and are looking to continue to evaluate it as a tool to improve symptoms of PTSD.

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.

You are being asked to participate in this study because you suffer from Posttraumatic Stress Disorder (PTSD).

How many people will be part of this study?
We expect that about 132 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 up to 8 months. During that time, there will be four parts to the study, the VR phase, the Acute TMS phase, the Extended TMS phase, and the final part of the study where we follow-up with how you are doing after treatment.

In the VR Phase, participants will complete up to 10 separate once-a day visits over two weeks where you will do mindfulness meditation using virtual reality equipment and complete brief questionnaires. These visits will last up to two hours.

In the Acute Phase, you will be randomized to receive either active (real) or a sham (fake) TMS stimulation for 5 continuous days, 5 sessions per day. The visits will last about 4-5 hours each. Approximately one week after treatment, you will fill out rating scales and be asked about your symptoms. This visit will take about 1-2 hours. We refer to the TMS treatment you receive this week as the Acute Phase, as we are focusing on looking at how the accelerated treatment effects people.

In the Extended Phase, you will receive active TMS for 5 continuous days, 5 sessions per day. The visits will last about 4-5 hours each. Approximately one week after treatment, you will fill out rating scales and be asked about your symptoms. This visit will take about 1-2 hours. We refer to the TMS treatment you receive this week as the Extended Phase, as we are focusing on how receiving additional TMS treatments will impact people.

You will then meet with study staff for follow-up visits 1-month, 3-months, and 6-months after your prior one-week follow-up visit. This visit will take about 1-2 hours. Your last study visit will be the 6-month follow-up. These visits will last up to two hours and can be done remotely.

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?
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.
- There is a risk of motion sickness with VR headsets (or temporary feelings of nausea, dizziness, disorientation).
- Because the VR headset blocks your vision when you are using it, there is a risk you may injure yourself because you can't see.
- There is a risk of contagious conditions from shared use of equipment.
- 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: 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?

- You may or may not receive 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?

Your first study visit (Visit 1) is the beginning of the **VR Phase.**
At this visit, 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.

You will also complete your first two sessions using the VR headset during this visit.
First, you will try on the VR device to make sure it fits. Then you will be given instructions on how to use the headset and once you feel comfortable, you will complete your first session. There will be an approximate 50-minute break and then you will complete your second session.

At Visits 2-10,
Visits 2 -10 will take place over two weeks following Visit 1. At each visit you will be asked about any changes in your in psychiatric or medical conditions, including changes in medication and substance use. You will then complete two VR sessions with an approximately 50-minute break between them. Additionally, at Visit 5 you will complete questionnaires and at Visit 10 you will complete questionnaires and meet with a member of the study staff for a clinical interview about how you are feeling.
If during these visits you wish to stop having VR sessions, please let the study staff know and we will move you onto TMS. At that point, we can also refer you to other wellness alternatives if desired.

Moving to the Acute Phase:
As mentioned earlier, before you start the Acute Phase, you will be randomized to either an active (real) or a sham (fake) TMS stimulation during the first week of TMS treatment.
There is a two-in-three chance of receiving active TMS. Neither you nor the research team administering TMS will know which study stimulation you are receiving. This information is available to the Principal Investigator if needed in an emergency. This is called *blinding*, and it is done so that a fair evaluation of results may be made.

Visit 11
At Visit 11, you will complete any remaining questionnaires and urine samples will be collected for routine lab tests, including drug screening and pregnancy testing. This test along with other procedures are done to see if it is safe for you to be in study. After that you will receive single pulses from the TMS machine (called a "motor threshold"), so we can determine the best setting for your treatments.

During Visits 11-15:
You will come in for treatment continuously for 5 days. For these visits you will need to plan on being at the lab for longer because you will be receiving multiple TMS treatments at each visit. Each time you come in for a visit, you will have a total of five sessions. Each session will last 10 minutes and there will be at least a 50-minute breaks between each. We will note any side-effects you may experience, and other information will be recorded. At Visit 15, in addition to treatment, you will fill out rating scales and meet with the clinician to go over how you are feeling.

At Visit 16: (one week after your last Acute TMS treatment) At this visit you will fill out rating scales and meet with the clinician to go over how you are feeling. This visit can be done remotely, if needed.

Moving onto the Extended Phase:
As mentioned earlier, you will receive active TMS stimulation during the Extended Phase.

Visit 17
At Visit 17, you will receive single pulses from the TMS machine (called a "motor threshold"),

so we can determine the best setting for your treatments like what was done during Visit 11.

At Visit 17-21:
You will come in for treatment continuously for 5 days. For these visits you will need to plan on being at the lab for longer because you will be receiving multiple TMS treatments at each visit. Each time you come in for a visit, you will have a total of five sessions. Each session will last 10 minutes and there will be at least a 50-minute breaks between each. We will note any side-effects you may experience, and other information will be recorded. At Visit 21, in addition to treatment, you will fill out rating scales and meet with the clinician to go over how you are feeling.

At Visit 22: (one week after your last Extended TMS treatment) At this visit you will out rating scales and meet with the clinician to go over how you are feeling. This visit can be done remotely, if needed.

Moving onto the Follow-Up Phase

At Visit 23 (one month after Visit 22 or last TMS treatment assessment) At this visit you will out rating scales, and meet with the clinician to go over how you are feeling. This visit can be done remotely, if needed.

At Visit 24: (three months after Visit 22 or last TMS treatment assessment) At this visit you will out rating scales, and meet with the clinician to go over how you are feeling. This visit can be done remotely, if needed.

At Visit 25: (six months after Visit 22 or last TMS treatment assessment) This will be your last study visit. You will complete surveys and meet with the clinician to go over how you are feeling. This visit can be done remotely, if needed.

Below is a table guide for all the study visits. The weeks listed may be adjusted if there are delays.

TABLE 1. SUMMARY OF VISITS

VISIT	WEEK	PROCEDURES	ESTIMATED TIME
Visit 1	Week 1	Screening and Clinical Evaluation, VR Orientation and VR Sessions	3 hours
Visits 2-5	Week 1	VR Sessions and Surveys	1.5 hours
Visits 6-9	Week 2	VR Sessions and Surveys	1.5 hours
Visit 10	Week 2	Clinical Evaluations, Surveys, and Motor Threshold for TMS	3 hours
Visits 11-15	Week 3	5 active or sham TMS Sessions Per Day (10-minute sessions with 50-minute breaks between each session)	5 hours / day

Visit 16	Week 4	Follow Up Visit one week after your last Acute TMS Session. Complete clinical interview and surveys.	1.5 hours
Visits 17-21	Week 5	5 active TMS Sessions Per Day (10-minute sessions with 50-minute breaks between each session)	5 hours / day
Visit 22	Week 6	One week Follow-up Visit after your last Extension TMS Session. Complete clinical interview and surveys.	1.5 hours
Visit 23	One month Follow-up Visit	Complete clinical interview and surveys.	1.5 hours
Visit 24	Three-month Follow-up Visit	Complete clinical interview and surveys.	1.5 hours
Visit 25	Six-month Follow-up Visit	Complete clinical interview and surveys.	1.5 hours

Use of Investigational Devices:

The TMS stimulation is done using a device called the MagVenture MagPro® R30 Magnetic Stimulator connected to the following Treatment Coils: B70 Mapping, Cool B70 Treatment, Cool B70 AP, and Cool D-B80 AP. Which coils are used will depend on which arm of the study you are randomized. The TMS device and coils that 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

- 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 Virtual Reality

Possible Physical Risks

- There is a risk of motion sickness with VR headsets (or temporary feelings of nausea, dizziness, disorientation). The study is using high-quality equipment and software minimize the potential for motion sickness. Participants may close eyes or remove the headset to recover from any discomfort.

- Because the VR headset blocks your vision when you are using it, there is a risk you may injure yourself because you can't see. To minimize the risk of injury, you will only

use the headset in in a space free of hazards and/or if you are sitting down.

- There is a risk of contagious conditions from shared use of equipment. We will ensure that shared contact surfaces will be protected with barriers and/or cleaning.

- Mild to moderate head or eye discomfort from the headset. Any discomfort from wearing the headset may be mitigated by adjusting the fit, taking breaks or discontinued use.

- The materials used to make the VR equipment are common, but there is a risk you may also experience skin irritation. To minimize this risk, we ask that you not use the device on wet skin, after you have put on lotion or other chemicals, or over injured skin. You can also take periodic breaks and the headset may be discontinued or adjusted for concerns of skin irritation.

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 urine pregnancy test on women prior to TMS 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.

There is a risk that you may experience a worsening of symptoms. Participation involves multiple 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?

Florida State University, 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 and you will be responsible for any costs not paid for by insurance. Funds to compensate

for pain, expenses, lost wages and other damages caused by injury are not available. If you need medical care because of taking part in this research study, contact the investigator and you will be referred to a medical care provider. 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 receive compensation during all phases of the study, and if you complete all scheduled study visits, you will have received a total of $300. If you withdraw before the end of the study, you will be paid per the amount below per completed study visit.

Phase	Visit	Amount
VR Phase	Visit 1 (First VR Session)	$25
	Visit 10 (Last VR Session)	$25
Acute Phase	One week after your last Acute TMS Session	$50
Extension Phase	One week after your last Extension TMS Session	$50
Follow-Up Phase	One-month after your last Extension TMS Session	$50
	Three-months after your last Extension TMS Session	$50
	Six-months after your last Extension TMS Session	$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 is 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.

You should also understand that the Certificate of Confidentiality does not preclude disclosing information with the appropriate authorities if you are at imminent risk of hurting yourself or others.

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
- 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.

Deidentified Data Sharing with National Institute of Mental Health Data Archive

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

It is your choice whether or not to let us share your data. If you say “yes,” you can change your mind later. If you say “no,” you can still fully participate in this study.

If you say "yes" but decide any time after today that you do not want your data to be added to NDA, please email the study staff, and they will tell NDA to stop sharing your study data.

However, please know that once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind.

If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

Please initial next to your choice:
_____YES, add my data to the NIMH National Data Archive
_____NO, do NOT add my data to the NIMH National Data Archive

Other 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.

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>