| **Participant Name:** | **Date:** |
|---|---|
| **Title of Study:** Feasibility of a Combined Neuromodulation and Yoga Intervention for Veterans with Mild Traumatic Brain Injury and Chronic Pain | |
| **Principal Investigator:** Amy Herrold, PhD | |

**SUMMARY**

The research is being conducted *to develop* a non-invasive treatment combining intermittent theta burst stimulation (iTBS), and an evidence-based yoga program, developed specifically for mild traumatic brain injury (mTBI) called LoveYourBrain Yoga, for Veterans with co-occurring Mild Traumatic Brain Injury (mTBI) and chronic musculoskeletal pain. Musculoskeletal pain is pain in the muscles, bones, ligaments, tendons and/or nerves. Once we develop the treatment, we will look at whether the treatment is feasible and acceptable for Veterans with these conditions. You are being asked to participate in this research study because you are a Veteran and may have symptoms of mild traumatic brain injury and you may also have experienced some poor rehabilitation outcomes including impairments in cognition, physical health, and psychological health.

If you agree to participate in the study, and you meet study criteria, you will be asked to complete the following research procedures: Informed consent, HIPAA Authorization, a urine sample for drug screening, a Saliva test strip for breath alcohol concentration screening, structured clinical interviews and questionnaires, 6 iTBS+LoveYourBrain Yoga sessions and an MRI, conducted by the PI, Dr. Herrold, or a trained research team member.
Your participation will last for 6-8 in-person research Visits.

**During your participation** in this study, treatment with real iTBS+LoveYourBrain Yoga may improve mTBI symptoms or symptoms associated with existing chronic musculoskeletal pain. This may also improve your quality of life. However, neither of these benefits is guaranteed. <u>You may not personally benefit</u> from taking part in the research, but the knowledge obtained may help the health professionals caring for you better understand the disease/condition and how to treat it.

The most common risks of participation are***:***

- Skin irritation from the use of electrodes
- You may experience unpleasant emotions, thoughts or memories during assessments
- Some people experience mild discomfort during the MRI because of tight spaces and keeping still
- The seizure risk for people with mild TBI and chronic musculoskeletal pain is unknown, and this is why we are investigating safety in this study.
- Mild temporary headache and/or hearing loss is possible after each iTBS treatment session
- Injury due to physical requirements associated with this protocol (ex. muscle soreness due to increased activity, headache or fainting)

**We will stop iTBS treatments if you go into shock or have a seizure.**

Please note that there are other factors to consider before agreeing to participate, such as additional procedures, use of your personal information, costs, and other possible risks not included here. If you

are interested in participating, a member of the study team will review the full information with you. You are free to not participate or stop participating at any time during or after the consenting process.

## INTRODUCTION

You are being invited to participate in a research study that is being carried out at the Edward Hines Jr. VA Hospital. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. The sponsor of the study is Veterans Affairs Research and Development Rehabilitation Research and Development Service (VA ORD RR&D). If you have any questions about your rights as a human research participant at any time before, during, or after participation, please contact the Institutional Review Board (IRB) at (708) 202-2811 for assistance. If you have questions about this study, you may contact the Principal Investigator, *Amy Herrold, PhD at (708) 202-5867 or (202) 413-1554 for assistance.*

Read the information below closely and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

## BACKGROUND AND PURPOSE

### Why is this research being done?

The purpose of this project is to develop a new treatment for Veterans with mTBI and chronic musculoskeletal pain, that combines iTBS brain stimulation with a yoga program that was created especially for people with mTBI, called LoveYourBrain yoga, and to decide how feasible and acceptable the new treatment is. We also plan to gather up all the data we collect in this small study and use it to develop a larger study in the future. The larger study will look at the effectiveness of the iTBS+Yoga program on Veterans' quality of life, function and pain levels.

The iTBS+LoveYourBrain Yoga treatments will be provided in small group settings once a week for 6 weeks.

### *Who will conduct the study and who is sponsoring it?*

*This VA ORD RR&D sponsored study will be conducted by trained research staff at Hines VA Hospital.*

### *Why am I being asked to participate in this study?*

You are being asked to participate in this research study because you are a Veteran and may have symptoms of mTBI and chronic musculoskeletal pain, and you have been fully vaccinated against COVID-19.

The current study addresses specific research interest areas to the VA including chronic diseases, neurological dysfunction, brain injury and rehabilitation outcomes. Current military conflicts in Iraq and Afghanistan have led to over 300,000 reported cases of mild traumatic brain injury (mTBI). Among Veterans, mTBI commonly co-occurs with chronic pain, psychiatric conditions including substance use disorders (SUD) and post-traumatic stress disorder (PTSD). In particular, mTBI negatively affects rehabilitation outcomes in Veterans.

**Why an alternate treatment approach is being used in this study:**

This project will directly benefit Veterans and VA Services by developing a new treatment for Veterans with mTBI and chronic musculoskeletal pain that can be used instead of the opioid-based treatment options currently available. Right now, TMS is offered at 30 VA hospitals nationwide for treatment-resistant depression, and yoga is one of the holistic health programs offered at VAs across the country as well. Our hope is to show that a program that combines both of these treatments could be a reasonable and effective alternative VA facilities nation-wide can offer.

**FDA Investigational Device Exemption:**

Dr. Herrold has an FDA Investigational Device Exemption (IDE) approval (#G200195) for this study. This means that the FDA has reviewed and approved this study protocol because iTBS is not yet clinically approved by the FDA for the specific use evaluated in this project. The reason for this study is to determine if it can be used to help Veterans with these chronic problems.

**DURATION OF THE RESEARCH**

This research study will take one year. However, you are only consenting to participate in 11 in-person visits, taking 15 hours total over the course of approximately 6 weeks. The first individual screening visit will take approximately 2 hours, the individual MRI will take approximately 30 minutes, the individual baseline assessment and motor threshold visit will take approximately 1 hour, each of the 6 weekly iTBS+yoga sessions will take approximately 1.5 hours, the endpoint assessment will take approximately 1 hour and the qualitative interviews will take approximately 1 hour. The details of these visits are described below.

**STUDY PROCEDURES**

Our goal is for 20 veterans to complete this study.

All study visits will occur at Edward Hines Jr., VA Hospital (Hines VAH).

If you are eligible to participate in this research study and you chose to continue, you will then complete research procedures over the course of 6 in-person research Visits, each described below. The research procedures including informed consent, HIPAA Authorization, urine sample for drug screening, Saliva test strip for breath alcohol concentration screen, neurobehavioral interviews and questionnaires, a structured interview, 6 iTBS+Yoga sessions and an MRI will be conducted by the PI, Dr. Herrold, or a trained research team member.

**Drug and Alcohol Screening:** Abstinence from alcohol and illicit substances will be requested for each visit and will be confirmed with a Saliva test strip and urine drug screen. No results from the urine drug screen will be entered into your medical record. These results will be for research purposes only. If you test positive for alcohol, drugs, or cannabis intoxication, you will be asked to re-schedule research procedures, and safe transportation home will be arranged (e.g., taxi) or you will be escorted to the ER or mental health intake as appropriate.

To reduce potential exposures to SARS-COV-19, you will be asked to complete some study assessments, using a secure, VA approved virtual meeting system. Research staff will explain how the system works and get you set up at a video conferencing station before providing you with study forms and assessments to complete.

**Visit 1 (Individual Screening Visit)**: In an effort to reduce potential exposure, a study team member will contact you by phone prior to this study visit to complete a COVID-19 pre-screening to help determine whether any symptoms have occurred or whether you have been exposed to SARS-COV-19. The study team member will also review requirements for accessing the Hines VA facility. On the day of your study Visit 1, authorized research staff will meet you at a designated entrance, closest in proximity to a private room, where the study visit is to take place and escort you to the room. All established COVID-19 safety precautions will be followed, as identified by Edward Hines Jr. VA Hospital administration.

For visit 1, you will complete a structured interview about mild TBI. The interview will include an evaluation of mTBI symptoms using the Neurobehavioral Symptom Inventory (NSI). The California Verbal Learning Test-II (CVLT-II) will be used to assess verbal memory and to evaluate your effort. We will use the Brief Pain Inventory (Short Form) to identify and confirm inclusion criteria related to your reports of musculoskeletal pain. We will also use the Minnesota Multiphasic Personality Inventory-2-RF to verity reported symptoms. Finally,the Hines VA MRI Safety form will be completed to check for any issues that might prevent you from safely getting an MRI.

All females will be asked to complete a pregnancy test. If a pregnancy test is positive, then participation in the study will stop.

You will also meet with a study team physician to review your pain medications, pain management strategies and to determine whether or not it is safe for you to participate in gentle physical movements.

We will also screen the electronic medical record for medical history criteria.

A study team member will contact you by phone after you have completed Visit 1 to complete a follow- up COVID-19 screening to help determine whether any symptoms have occurred after making face-to- face contact.

**Visit 2 (Individual MRI):** A high-resolution, structural MRI scan will be collected to help us find the best location for iTBS treatments. The MRI will take place at Hines VAH and this visit will last approximately 30 minutes.

***MRI Scan***

- You will also undergo a **magnetic resonance imaging scan (MRI)** to look at the brain. An MRI is a type of scan that uses magnetic fields and radio waves to take a picture of the brain. The MRI will last about 8 minutes.

In order to make sure the MRI procedure will be safe; you will be asked to fill out a screening form before starting the study. It is important that you tell the researchers in this study if you have any history of:

- Metal fragments in your eyes or face.
- Implantation of any electronic devices such as (but not limited to) cardiac pacemakers, cardiac defibrillators, cochlea implants or nerve stimulators.
- Surgery on the blood vessels of your brain or the valves of the heart
- Claustrophobia (fear of enclosed places)
- Body piercing or tattoos

You will be asked to change into a hospital gown or surgical scrubs and remove any metal, such as earrings.

An MRI technician will give you instructions outside the MRI scanner about the scanning. Next, you will be asked to lie still on the MRI patient table and your head will be placed in a specially designed head holder. Your head will be cushioned by a firm foam pillow. The table will then slide into the enclosed space of the MRI scanner.

The information from the MRI scanner is only useful if you are able to complete the whole imaging session and hold your head very still the whole time. Therefore, you will be encouraged to hold as still as possible, and to let the investigators know if you are uncomfortable in any way as soon as possible after the imaging session begins.

The front of the head-holder will be open, which lets you look through a special mirror and see pictures presented to you on a projection screen near your feet. Sounds may also be presented to you using

specially designed headphones. You will be asked to hold your head as still as possible and to respond to the pictures or sounds by pushing a button or thinking quietly to yourself.

The MRI scanner makes loud banging noises while taking a measurement, so either ear plugs, or specially designed headphones will be used to reduce the noise. The researchers will be in communication with you through an intercom system to tell you how the study is going. The earplugs or headphones should not get in the way of communicating with the researchers. You can speak to the technician by talking out loud. If at any time or for any reason, you wish to stop the exam, you may do so by squeezing a rubber ball. This will signal the MRI technician to stop the scanner.

The MRI pictures in this study will be reviewed by a neuroradiologist. If an abnormality is detected during the processing of the scan you will be contacted immediately. You will be asked to provide us with the name and address of the doctor you want us to contact. You will be encouraged to follow up with your provider to discuss the information we provided.

**Visit 3 (Individual Baseline & Motor Threshold):** Individual baseline assessments will be completed during this study visit. These will include self-report questionnaires about TBI-related quality of life, function and pain. You will also be instructed to keep diaries of your pain medication use and other pain management strategies. You will also complete weekly diaries detailing the time you spend at home or in the community engaging in meditation or yoga practices.

*Individual Motor Threshold (MT)*: This test involves magnetic stimulation of the brain while recording muscle activity from the arm, wrist, hand, finger, leg and/or foot. The structural brain image collected during the MRI procedure described above will be used to help locate the correct site of stimulation.

Electrical activity from the arm, wrist, hand, finger, leg and/or foot muscles will be recorded using surface electrodes placed on the arm, wrist, hand, finger, leg and/or foot. These electrodes will be placed using a gel or sticky paste.

A researcher will hold a figure-of-eight (8) shaped magnetic coil on the top of your head at different points along the scalp and provide a pulse of magnetic stimulation to confirm magnet placement. The test will take about **1 hour**.

**Visits 4-9 (iTBS+Yoga Treatment Sessions):** iTBS+Yoga sessions will occur once a week for 6 weeks. These sessions will occur at Hines VAH and take approximately 1.5 hours. Each session will start with individual iTBS (3 min.). Then, small group yoga sessions will occur. The smallest number of research staff will be present for your visits in order to comply with social distancing requirements whenever possible.

Because of potential pain (see POSSIBLE RISKS OR DISCOMFORTS below), we recommend that you bring an over the counter pain reliever of your choice to take prior to each iTBS session. We will ask you when you took the medication and the amount.

**Pre-iTBS Assessments:**

- You will be asked to complete a Saliva alcohol test to help the research team determine the amount of alcohol that may be in your bloodstream. During this alcohol screening, you will be asked to blow into a tube attached to a special hand-held machine. No results will be entered intoyour electronic medical record.

- You will be asked to provide a urine sample to allow the research team to determine if certain drugs are in your body. This includes pain medications like morphine and Vicodin; benzodiazepines such as Valium, Librium, Xanax and Ativan, that are usually used to treatanxiety or alcohol withdrawal; and substances like cocaine, marijuana/cannabis, heroin, amphetamine or speed and barbiturates.

- It is important to know that any Saliva alcohol test or urine drug screening results are used to determine if you are eligible to continue in this research study and will **NOT** be entered into your medical record or reported to legal authorities.

**Intermittent Theta Burst Stimulation (iTBS) Treatment Sessions:** Once all the tests listed above are complete, the experimental treatment will begin. Intermittent Theta Burst Stimulation (iTBS) stimulates the brain using magnetic pulses. The magnetic pulses create electrical currents in the brain. The electrical currents may affect brain activity and function. The long-term effects of iTBS are not known.

During the iTBS treatments, ear buds will be placed in your ears because the magnetic stimulator makes a loud clicking noise. Tape may be placed over the ear buds to make sure the ear buds stay in place. During the iTBS treatments, the researcher will hold a figure-of-eight shaped magnetic coil on your head. It takes approximately 3 minutes to provide iTBS during each treatment.

Each session will take about 15 minutes to allow for set-up and take-down. Appropriate surfaces will be sanitized before and after you receive iTBS treatments. The weekly schedule for iTBS will be one session of iTBS every week (on the same weekday and for safety. A total of 6 iTBS sessions will be provided over six weeks.

**Love Your Brain Yoga Sessions:** After your iTBS sessions, you will complete a small group (approximately 3-6 people) yoga session. Each yoga session includes 10 minutes of breathing exercises, 45 minutes of gentle yoga/stretching, 15 minutes of guided meditation, and 20 minutes of facilitated discussion with psychoeducation.

**Safety Measures:** You will participate in safety monitoring using the Data Safety Monitoring Scale (DSMS). This scale helps us to monitor physical changes you might experience from the beginning of the study to the end. These might include things like temperature, blood pressure, ringing in the ears, sleep, dizziness, seizure, syncope (fainting), headache, and substance use. We will use this form before every treatment session to help us keep track.

**Visit 10 (Endpoint Assessments):** Individual endpoint assessments will be completed during this study visit. These will include repeating self-report questionnaires about TBI-related quality of life (TBI-QOL),

function (Mayo Portland Adaptability Index) and pain (Brief Pain Inventory and Pain Interference Scale). Additionally, we will ask you to complete satisfaction ratings of the iTBS+Yoga sessions and to turn in your pain management and yoga/meditation diaries.

**Visit 11 (Qualitative Interviews):** You will be asked to take part in semi-structured interviews that will be audio-recorded. We will ask for opinions about your treatment experiences with iTBS+Yoga. We would like to know what you think about the treatment and how participating in this study may have affected your pain levels, and- quality of life. We also want to know what we did right and how we can improve.

## POSSIBLE RISKS OR DISCOMFORTS

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

**iTBS/TMS:** The biggest concern with utilizing iTBS is seizure. Other known side effects of iTBS include headache, dizziness, ringing in the ears, nausea, neck pain or scalp burns. Your electronic medical record will be reviewed for any notes or procedures about metal implants. If any implants or prosthetics are found, then we will need your help to find the manufacturer of the implant to make sure it is safe to expose the implant to a strong magnet. All manufacturer recommendations will be followed to ensure your safety. All investigators and research team members who will be providing the experimental treatment will undergo training on the use of the iTBS/TMS device.

**Additional Known Risks of iTBS/TMS**:

- Possible electrocution during iTBS due to insufficient insulation of the coil. The coils will be inspected before and after each iTBS session to ensure that the coil does not have any damage.
- Over-heating of the coil which may lead to scalp burns or damage to underlying tissue. The iTBS device has a sensor that alerts the researcher when the coil is beginning to overheat so the coil can be replaced.
- Physical discomfort, facial numbness, headache or dental pain. Mechanical vibrations that occur within the coil while an iTBS pulse is being generated, for example, may result in discomfort or headache
- Device failure due to overheating, electrical short-circuiting or mechanical breakdown from the force on the device. All precautions will be taken to prevent device breakdown that may affect your welfare. The iTBS device will be inspected routinely, and safety guidelines from the manufacturer will be followed.
- Contamination transferred from one person to another following treatment. The device will be disinfected after every use to prevent the spread of germs between participants.
- Mania, depression, anxiety, and suicidality, although rare and usually associated with depression or bipolar depression. If new conditions emerge or existing conditions worsen, then you will be withdrawn, and clinicians on the study team will evaluate you to make recommendations for treatment.

Before receiving treatment, you will meet with a study team physician to review your pain medications, pain management strategies and to determine whether or not it is safe for you to participate in gentle physical movements. You may be advised to take a pain reliever of your choice (i.e. Acetaminophen /Tylenol) prior to iTBS sessions if you anticipate any discomfort.

There may be other unknown and/or unanticipated side effects that could occur. The study team will monitor for any side effects.

If, in the opinion of the PI, you are no longer appropriate for the study, you may be discontinued without regard to your wishes to remain, in order to ensure your safety. This would apply if you do not comply with the requirements for participation, if it becomes medically unsafe for you to continue, if the study is stopped by a sponsor, or if the Department of Health and Human Services withdraws approval.

**LoveYourBrain Yoga Program:** As with any exercise program, there is a risk of pain or muscle soreness due to increased physical activity. There is also a low risk of falling due to the physical activity and balance challenges involved in the yoga group. To minimize the risk of unnecessary increases in pain or muscle soreness or falls, you will work with trained researchers and clinicians certified in the LoveYourBrain Yoga program. You will have an opportunity to rest and you will be monitored for verbal or visual signs of fatigue or discomfort.

Because psychological symptoms might surface or get worse during the discussion portion of the LoveYourBrain Yoga program, you will be monitored for changes in psychological symptoms and will be offered resources and follow-up care if needed (i.e. psychological support/follow-up, support groups, etc.).

**Structural MRI:** There are no known risks associated with MRI, although some people have experienced discomfort in trying to remain still. The MRI scanner makes loud banging noises while taking a measurement, so earplugs will be used to reduce the noise. The researchers will be in communication with you through an intercom system to ask how you are doing. The earplugs should not get in the way of communicating with the researchers. You can speak to the technician just by talking out loud. If at any time or for any reason, you wish to stop the exam, you may do so by squeezing a rubber ball we provide. Some people have been noted to be anxious or claustrophobic during the scan.

**Psychological:** During the study visits, you will complete self-report measures and structured interviews related to mTBI, quality of life, pain, and functioning. You may experience distress in speaking about these sensitive topics. You will be asked to notify study staff if these questions or questionnaires make you feel uncomfortable. If needed, research staff will make sure you have timely access to mental health resources or information on organizations to contact for support. If you express extreme distress while completing these assessments, research staff will stop the interview.

**Loss of confidentiality:** Loss of confidentiality is a potential risk. You will complete questionnaires that discuss mental health symptoms, disability, mTBI symptoms. All of your responses will be documented.

To protect you from a breach of confidentiality, you will be assigned a unique identification number by the study personnel. This number will be placed on all hard forms, and kept in a locked file cabinet in a locked office at Hines VA. Any specimens you provide will also be marked with this identification number and the collection date to guard against privacy risk. The consent and HIPAA documents you sign will contain protected information (i.e., Name, social security number, etc.). To keep them safe, these documents will be stored in a different area from the rest of the study forms, but still in a locked file cabinet inside a locked office at Hines VA. All electronic data will be entered in an electronic database on the Hines VA secure server.

MRI data will be de-identified and uploaded to a VA secure server.

Any loss of confidentiality will be immediately reported according to Hine VA Information Security guidelines

Because *this is a new use for the iTBS device, we do not know all of its negative effects; and it cannot be guaranteed that you will be able to continue receiving this treatment after this study is over.*

**Reproductive and Sexual Activity Information:**
All women who are enrolled in the study will be asked to take a urine pregnancy test prior to initiating study procedures (Visit 1). If the test is positive, you will be withdrawn from the study. If the test is negative, you will continue with study participation. You will be asked before every treatment session if there is a chance you may be pregnant. If you become pregnant, the research procedure, iTBS, might involve risks to the embryo or fetus which are currently unforeseeable. *If, while participating in the study, you suspect you have become pregnant, please contact the study PI or coordinator immediately.*

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care. Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible.

**POTENTIAL BENEFITS:**
You may not personally benefit from participation in the study. However, the Veteran population as a whole will potentially benefit from findings acquired in the research study. It is expected that by receiving iTBS and the LoveYourBrain Yoga program, you may benefit by experiencing an improvement in quality of life and/or chronic musculoskeletal pain.

**CONFIDENTIALITY and DATA ACCESS:**
Information about you will be combined with information from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

The information collected for this study will be kept confidential.

There are times when we might have to show your records to other people. Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as the Food and Drug Administration, (FDA), the Government Accounting Agency (GAO) or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), as well as members of the Research Administration staff of Edward Hines Jr. VA. The Department of Veterans Affairs (VA) requires some information to be recorded in the VA electronic medical record for all veteran research participants. Because this study involves the use of a regulated test article (iTBS), the FDA may choose to inspect research records, including your individual medical records. By signing this document, you consent to such inspection.

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

This informed consent form does not give the study doctor permission to access, record, and use your private health information. You will be given a separate HIPAA form which provides more information about how your private health information will be used in this study, who will have access to your records, and how you can revoke (take back) your permission in the future. You will not be able to participate in this study if you do not sign the separate HIPAA authorization form.

**COSTS TO PARTICIPANTS AND PAYMENT**

**Costs to Participants***:*

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

**Payment Offered for Participation:**

You are eligible to receive up to $190 for participation in the study ($50 for baseline and endpoint visits, $50 for the MRI scan, and $15 for each of the 6 treatment intervention sessions). This compensation is intended to facilitate participation without adding undue influence. If you withdraw or the PI withdrawsyou from the study, you will receive a prorated amount based on how much of the study you completed. All payments will be made by direct deposit via Electronic Funds Transfer (EFT). The EFT process will use your social security number. Veterans who are unable to utilize this option (i.e., do not have a bank

account or the ability to get a Direct Express Debit card) may not be able to receive compensation. You will have an opportunity to discuss these options before you consent to participate in the study.

***Your social security number (SSN) will be used during this process, and to confirm your identity.***

**MEDICAL TREATMENT AND COMPENSATION FOR INJURY**

According to federal regulations (Title 38 CFR17.85), the VA will provide necessary medical treatment to you as a research participant if you are injured by participation in this research project approved by the Research & Development Committee and conducted under the supervision of one or more VA employees. Except in limited circumstances, this care will be provided at this VA facility.

This does not apply to treatment for injuries that result from non-compliance by you with study procedures.

The Department of Veterans Affairs does not normally provide any other form of compensation for injury.
You have not released this institution from liability for negligence.
Participation in this research may involve risks that are currently unforeseeable.
You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.
In case (If) there are any medical problems, complaints, concerns, or if you have questions about the research, you can call:
DURING THE DAY: Dr. Amy Herrold at 708-202-5867 and 202-413-1554.

AFTER HOURS: Please call 911 for medical emergencies. Emergency and ongoing medical treatment will be provided as needed. Veterans may also contact the crisis line at **1-800-273-8255** and Press 1 or chat online to receive confidential support 24 hours a day, 7 days a week, 365 days a year.
You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

**PARTICIPATION IS VOLUNTARY**

Participation is voluntary and you can withdraw from the study at any time.
You do not have to take part in this study and refusal to participate will involve no penalty, consequences or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty, consequences or loss of VA benefits. *If applicable, you may withdraw and still receive the same standard of care that you would otherwise have received. If you are a VA employee or student, refusal to take part in the study will in no way influence your employment, ratings, subsequent recommendations, or academic progress as applicable. The investigator may also continue to review the data already collected for the study but cannot collect further information, except from public records, such as survival data. Please be advised that specimens already used cannot be withdrawn.*

You will still be able to receive your ongoing treatments to assist with the management of your chronic musculoskeletal pain and we encourage you to work with your provider on pain management strategies. While we require you to adhere to a stable pain management strategy while in the study, other treatments for your chronic musculoskeletal pain that your provider may discuss with you could include physical therapy, occupational therapy, chiropractic care, acupuncture, injections (steroid, prolotherapy, trigger point injections) if these are appropriate.

**SIGNIFICANT NEW FINDINGS (Include if Applicable)**

Sometimes during the course of a research study, new information becomes available about the use of iTBS+Yoga that is being studied that might change your decision to stay in the study. If this happens, your study investigator will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your study investigator withdraw you from the study. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your study doctor could also decide it is in your best interests to withdraw you from the study. If so, he or she will explain the reasons and provide any additional information you may need.

**RIGHT OF INVESTIGATOR TO TERMINATE PARTICIPATION**

The investigator has the right to terminate your participation in the research study if:

- You are uncooperative or unwilling to complete study tests
- You are experiencing undue stress from the study procedures
- You have a substance abuse, mental health, or medical problem that interferes with completion of the study tasks
- You sustain and injury or experiences some discomfort which the Investigator determines to be a safety risk for you or others

**FUTURE USE OF DATA**

As part of efforts to evaluate the study data for the development of future clinical studies, data collected during your study participation may be made available upon request to researchers and scientists in accordance with federal guidelines and Hines local policy without additional consent from you. Identifiers will be removed from the identifiable private information and, after removal, the information could be used for future research studies or distributed to another investigator for future research studies.
Only authorized research personnel will have access to both identifiable and de-identified study data. Safety data and neurobehavioral data will be kept in your folder in a locked cabinet in a locked office.

**CLINICALLY RELEVANT RESEARCH RESULTS**
Clinically relevant research results, including aggregate and/or individual research results, will not be disclosed to you.

| Participant Name: | Date: |
|---|---|
| **Title of Study:** Feasibility of a Combined Neuromodulation and Yoga Intervention for Veterans with Mild Traumatic Brain Injury and Chronic Pain | |
| **Principal Investigator:** Amy Herrold, PhD | |

**RE-CONTACT FOR FUTURE RESEARCH**

You may be eligible to participate in future research. Future studies may use some of the same information that you provide today but may also involve additional assessments. In order to contact you for future research, your information will be placed in a TBI data repository. This TBI data repository is its own Edward Hines Jr., VA IRB-approved protocol (IRB#14-003). This data repository may be shared with other investigators in keeping with that IRB-approved protocol through a formalized process. Choosing or Refusing to include your data in the TBI data repository will not affect your ability to participate in this research study as long as you meet study inclusion criteria. Additional clarification regarding the future use of data is included in the HIPAA Authorization that will be provided for your signature.

☐ I agree to have my data placed in the TBI data repository for future use._____(Initials)

☐ I do not wish to have my data placed in the TBI data repository_____(Initials)

You may be eligible to participate in future research. Future studies may use some of the same information that you provide today but may also involve additional assessments. If you would be interested in hearing about future research opportunities, please indicate your interest below:

☐ I agree to be contacted for future research._____(Initials)

☐ *I do not wish to be contacted about future research._____(Initials)*

**ADDITIONAL CONTACT INFORMATION**

If at any time before, during or after your participation in this study you have questions or concerns, want to get additional information, lodge a complaint or offer your input with a person who is not part of the study team, you can contact the IRB Administrator at 708-202-2811.

**AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY**

Dr./Mr./Ms._____,_____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

_____ ___/___/_____

Signature of Participant Date Written by Participant

| **Participant Name:** | **Date:** |
|---|---|
| **Title of Study:** Feasibility of a Combined Neuromodulation and Yoga Intervention for Veterans with Mild Traumatic Brain Injury and Chronic Pain | |
| **Principal Investigator:** Amy Herrold, PhD | |

_____
Participant's SSN