Title of Study:
Passive electrical neurofeedback treatment of mTBI: MEG and Behavioral Outcomes

Principal Investigator: Mingxiong Huang, Ph.D.	**VAMC:** VA San Diego Healthcare System
Subject Name:	**Date:**

1) Purpose of this research study

Dr. Mingxiong Huang and Co-Investigators are conducting a research study to find out more about mild traumatic brain injury (mTBI), how post traumatic stress disorder (PTSD) can effect mTBI, and the effectiveness of a brain neurofeedback treatment (called IASIS Micro Current Neurofeedback) intervention using magnetoencephalography (MEG), a neuroimaging tool that reads brain waves.

You have been asked to participate because you have been diagnosed with mTBI, have combined TBI and PTSD, or you are a healthy control without TBI. If you have mTBI, you will either be placed in the mTBI-IASIS group or mTBI-Sham group. You will not know which group you are placed in until the end of the treatment sessions. At that time, if you are in the mTBI-Sham group, you will have the opportunity to complete the IASIS treatments at no cost to you.

Nexalin is another passive transcranial electrical stimulation (TES) technique. For a subset of participants who may have remaining symptoms at the end of all IASIS treatment sessions, Nexalin treatment will be offered. MEG slow-wave changes will be recorded before and after additional Nexalin treatment, at no cost to you. If you decide to participate in the additional treatment, you will either be placed in the mTBI-Nexalin group or mTBI-Nexalin-sham group. You will not know which group you are placed in until the end of the treatment sessions. At that time, if you are in the mTBI-Nexalin-sham group, you will have the opportunity to complete the Nexalin treatments at no cost to you.

There will be approximately 175 participants at this VA site.

2) How long the study will take

Your participation will take approximately up to 30 minutes - to 3.5 hours each time you come to the VA Hospital, Aspire Center, or UCSD Radiology Imaging Laboratory (RIL), depending on the type of visit. You will be expected to come to the VA hospital, Aspire Center, or UCSD RIL between 2-3 visits for the initial MEG, MRI, Neuropsych Testing, Mental Health Interview, and questionnaires, 10-20 visits for TES treatments, and 2-3 visits for follow-up MEG, Neuropsych Testing, Mental Health Interview, and questionnaires over an 8-12 week period:

- After consenting, **Visit 1** includes the neuropsychological testing and mental health assessment (MHA) for all participants. *(Total time up to 3 hours)*

- **Visit 2** includes the baseline MEG and baseline MRI for all participants. *(Total time up to 2 hours)*
- **Visit 3** includes a re-test resting state MEG for a subset of healthy controls (last visit for healthy controls) while the mTBI-IASIS and mTBI-Sham groups undergo a pre-session MEG, IASIS session 1, and a post-session MEG. *(Total time between 30 minutes for healthy controls and 2 hours for mTBI-IASIS and mTBI-sham groups)*
- **Visits 4-8** include IASIS sessions 2-6. *(Total time for each visit is less than 1 hour)*
- **Visit 9** includes a mid-point neuropsychological session, pre-session MEG, IASIS session 7, and a post-session MEG. *(Total time up to 3 hours)*
- **Visits 10-13** include IASIS sessions 8-11. *(Total time for each visit is less than 1 hour)*
- **Visit 14** includes a pre-session MEG, IASIS session 12, and a post-session MEG. *(Total time is up to 2 hours)*
- **Visit 15** includes the 1 week follow-up MEG, neuropsychological testing, and mental health assessment. *(Total time up to 3.5 hours)*
- **Visit 16** is only for the mTBI-IASIS subset group who will complete a 1 month follow-up MEG. *(Total time is about 30 minutes)*

Specifically:

- The pre-IASIS visits:
  - MEG will last up to 1 hour
  - MRI will last up to 1 hour
  - Neuropsychological testing will last up to 2 hours
  - MHA will last up to 1 hour

- IASIS Micro Current Neurofeedback (up to 12 sessions)
  - Brain signal treatment session and questionnaire will last up to 45 minutes per session

- The post-IASIS visits:
  - MEG will last up to 30 minutes
  - Neuropsychological Testing will last up to 2 hours
  - MHA will last up to 1 hour

The total commitment for the mTBI-IASIS and mTBI-Sham groups is 24.5 hours across 12 weeks. If you are asked to be in an additional subset group that completes a 1 month follow-up MEG, you will be asked to come in for additional 30 minutes. Since the IASIS device is portable, most IASIS and sham-IASIS sessions can be completed at the VASDHS, UCSD RIL, or the Aspire Center. However, the IASIS sessions attached to a pre- or post-MEG will be required to be completed at the UCSD RIL.

Title of Study:
Passive electrical neurofeedback treatment of mTBI: MEG and Behavioral Outcomes

Principal Investigator: Mingxiong Huang, Ph.D.	**VAMC:** VA San Diego Healthcare System

If, at the end of the study sessions, you find that you are in the mTBI-Sham group and wish to complete 12 sessions of the IASIS Micro Current Neurofeedback treatment across 6 more weeks, you will be scheduled for the treatment at no cost to you. However, you will not be paid for the treatment.

The total time commitment for the healthy control group (no TBI) is 5 hours across 3 weeks. If you are asked to be in an additional subset group that completes a re-test MEG, you will be asked to come in for an additional 30 minutes.

If you are in the mTBI-IASIS group, have participated in the 6-week IASIS treatment, and feel that you have remaining post concussive symptoms in a follow-up phone interview 1 month post-IASIS treatment, you will be offered Nexalin TES treatment and be placed in either a mTBI-Nexalin group or a mTBI-Nexalin-sham group.

If you opt-in for the Nexalin treatment, your participation will range from between 1 - 1.5 hours each time you come to the VA Hospital, Aspire Center, or UCSD Radiology Imaging Laboratory (RIL), depending on the type of visit. You will be expected to come to the VA hospital, Aspire Center, or UCSD RIL up to 10-20 visits over a 4-10 week period:

- **Nexalin-Visit 1** includes a pre-Nexalin MEG session and questionnaires. *(Total time up to 1.5 hours)*
- **Nexalin-Visits 2-11** include 10-20 sessions of Nexalin or Nexalin-sham treatments 2-3 times a week for about 4-10 weeks. *(Total time for each visit about 1 hour)*
- **Nexalin-Visit 12** includes a post-Nexalin MEG session and questionnaires. *(Total time up to 1.5 hours).*

Specifically:

- The pre-Nexalin visit:
  - MEG will last up to 1 hour
  - Questionnaires will last up to 30 minutes

- Nexalin visits (10-20 sessions)
  - Brain signal treatment session and questionnaire will last up to an hour per session.

- The post-Nexalin visits:
  - MEG will last up to 1 hour
  - Questionnaires will last up to 30 minutes

Title of Study:
Passive electrical neurofeedback treatment of mTBI: MEG and Behavioral Outcomes

Principal Investigator: Mingxiong Huang, Ph.D.	**VAMC:** VA San Diego Healthcare System

The total commitment for the mTBI-Nexalin and mTBI-Nexalin-sham groups is up to 26 hours across 12 weeks.
The study will last about 4 years.

3) What will happen to you in this study
If you agree to be in the study, the following will happen to you:

MEG Exam: you will be seated in a comfortable chair. Your head will be placed in a special, helmet-like "head-holder" to help you keep your head still. Four electrodes will be placed at various locations on your head (two on your forehead and one behind each ear) to assist in measuring your head position, and two may be placed on your face, above and below your eyes, to record eye-blinks, and on your arms to measure when you move your muscles, and a last pair on your chest to record heartbeat. A conductive paste will be used to attach the electrodes to help them stay in place. The paste can be easily washed off with warm water.

During the tests, you may be asked to: 1) sit still for about 30 minutes; 2) perform various memory tasks. You may also be asked to make various movements with your hands or fingers by lifting a finger or pressing a button. The MEG system will merely monitor your ongoing brain activities. The entire MEG session will be about 1 hour.

MRI Exam: you will lie down on a bed and be placed in a tunnel that is open on both ends. Your will lie in the tunnel for about 1 hour, during which time you will be asked to keep your head still. While your head and shoulders are in the MR machine, you will periodically hear sounds similar to a jack hammer in the background. These sounds can be loud at times, but you will be provided with earplugs to place in your ears. The MRI will give your doctors and the research team pictures of your brain. You may feel tired during this procedure. You will be given several breaks. You may stop the research at any time. You will be asked to fill out a routine MRI screening form that is administered to all individuals having an MRI scan.

Paper and Pencil Tests: You will be asked to take a series of tests that measure your reaction time, memory, and reasoning skills on a computer. You will also complete paper and pencil tests of speed, fluency, and mental flexibility. This may last up to 2 hours.

MHA Session: Mental health symptoms that can accompany TBI, such as PTSD, depression and anxiety will be evaluated. Interview (about 1 - 2 hours): A trained interviewer, in a private area, will ask you questions about symptoms and problems that you may have experienced stemming from exposure to a serious stressful or traumatic event. These questions may be upsetting. Memories of trauma can be unpleasant or distressing. The risks of answering the interview questions are minimal, but if severe discomfort occurs, members of the research team will be available to talk about your discomfort. Questionnaires (about .5 to 1 hours): A variety of

questionnaires will be used to evaluate your background, stressful events that you may have experienced, your mental health, mood and health habits and current quality of life and ability to function.

IASIS Micro Current Neurofeedback: For the intervention portion of the study, you will be required to attend 12 of IASIS Micro Current Neurofeedback. Each intervention session will last approximately 30 minutes and will be conducted at the UCSD RIL. Prior to each session, you will be given a questionnaire to fill out rating your current TBI symptoms. This will take 15 minutes or less. During the intervention session, 3 sensors with conductive paste will be placed on the head with one behind each ear and one behind the neck. Several other electrodes will be pre-placed and positioned on different locations on the scalp following the pattern of a standard 10-20 EEG cap. At each of these locations a weak electrical signal (~1.5 milliVolts -less than an AA battery) will be generated that will not be felt and will require no input from you. You will sit still for about 30 minutes as the IASIS Micro Current Neurofeedback generates the weak signal through the sensors.

If you are placed in the Sham-IASIS group, electrodes will be placed in the same locations: one behind each ear, one behind the neck, and several others pre-placed and positioned on different locations on the scalp following the pattern of a standard 10-20 EEG cap. However, for this group, the IASIS program will not deliver any electrical signal because the electrodes will not be plugged into the IASIS device, which is kept away from the subject's view.

Nexalin TES Treatment (for only a subset of participants): For participants who have participated in the 6-week IASIS treatment and are found to have lasting symptoms, the Nexalin TES treatment will be offered. Each Nexalin visit lasts a little over an hour and will be conducted at the UCSD RIL. Prior to each session, you will be given a questionnaire to fill out rating your current TBI symptoms. This will take 15 minutes or less. During the Nexalin TES treatment, 3 conductive pads will be placed on your head (one on the forehead and one behind each ear). Then, you will be asked to sit as the device administers the current through the pads using a square waveform. You will sit still for about 60 minutes as the Nexalin TES device generates the weak signal through the sensors.

If you are placed in the mTBI-Nexalin-sham group, the conductive pads will be placed in the same locations and will exactly mimic the active treatment: one on the forehead and one behind each ear. However, for this group, the Nexalin program will not deliver any electrical signal.

4) Which procedure(s) or treatment(s) are done for research only

The MEG, MRI, MHA, and paper and pencil neuropsychological testing are being done for research purposes only. These sessions are not sufficient for a clinical diagnosis of any brain

disorder. If any abnormal findings occur, however, you and your primary medical doctor will be notified by Dr. Mingxiong Huang.

The IASIS Micro Current Neurofeedback sessions are being done for treatment purposes.

5) RISKS reasonably to be expected

Participation in this study may involve some added discomforts. These include the following:

1. MRI is a non-invasive procedure with no known risks. An MRI machine acts like a large magnet, so it could move iron-containing objects in the room during your examination. Precautions have been taken to prevent any such event from happening and injuring you.
2. If you have any metal clips or plates in your body or a pacemaker, you should tell the investigator about it. MRI may not be appropriate under some of these conditions: a cardiac pacemaker; metal fragments in eyes, skin, body; heart valve replacement, brain clips, venous umbrella; being a sheet-metal worker or welder; aneurysm surgery, intercranial bypass, renal, aortic clips; prosthetic devices such as middle ear, eye, joint or penile implants, joint replacements; hearing aid, neurostimulator, insulin pump; I.U.D.; being pregnant or trying to become pregnant; shunts/stents, metal mesh/coil implants; metal plate/pin/screws/wires, or any other metal implants; permanent eyeliner, eyebrows.
3. The MRI testing may produce fatigue and discomfort due to sitting motionless for up to 1 hour. You will be given frequent breaks. Your head and neck will be padded and legs supported to make you as comfortable as possible during the MRI exam.
4. MRI may also cause claustrophobia due to the confined space in the center of the machine or anxiety from the loud banging noise made by the machine. If you become claustrophobic, testing will be immediately stopped and you will be removed from the scanner. You will be provided with headphones to decrease the scanner noise so that it does not cause any hearing loss.
5. The MEG exams may produce discomfort due to sitting motionless and keeping head still during a 1 hour period. You will be given breaks. Your neck and waist will be padded and legs supported (or not based upon your request) to make you as comfortable as possible during the MEG exam.
6. No unfavorable effects from the MEG or MRI are known. Since the MRI effect upon early development of the fetus is unknown, participants who are pregnant will not be studied. We will reply on the participant to let us know if they are pregnant or not. Participants who are unsure will not be studied.
7. Because this is an investigation study it may involve risks that are currently unforeseeable. If any new risks become known in the future, you will be informed of them.

Title of Study:
Passive electrical neurofeedback treatment of mTBI: MEG and Behavioral Outcomes

Principal Investigator: Mingxiong Huang, Ph.D.	**VAMC:** VA San Diego Healthcare System

There is a risk of possible loss of your confidentiality. We will try to protect your confidentiality to the best of our ability as outlined in the 'What about your confidentiality?' section below.

8. The MEG/MRI scan is not being done for clinical diagnosis, and is not sufficient for a clinical diagnosis of any brain disorder. If any abnormal findings occur, however, you and your primary medical doctor will be notified by Dr. Mingxiong Huang. This may result in additional costs to you in further medical tests and treatment.
9. Risks from participating in the intervention, IASIS Micro Current Neurofeedback, are low. Risks include temporary side effects of feeling tired, wired (slightly anxious), nauseous, having a mild headache or feeling lightheaded and if greater than low side effects are experienced during the session, the session will stop.
10. Potential Risks from Nexalin: TES devices are classified as a Class III device. These types of devices have been used for many years and occasional adverse effects have been reported, including: headache, nausea, minor burns, increased agitation, minor rash from specific electrodes, and electrical discharge when electrodes are removed. Specifically, headaches and nausea have only been noted when current levels are higher than those used in the present study.
11. The questionnaires and the interview may bring up unpleasant memories or distress or discomfort. The photographic images may also bring up unpleasant memories or negative emotions. Typically these experiences are short-lived. You may skip any question that makes you uncomfortable. If any of your responses indicate an immediate danger to the safety of yourself or others, you will be asked to meet with a research staff member who is a licensed mental health clinician. Confidentiality will be kept unless, by law, we will have to release confidentiality.
12. Testing may also cause potential worsening of PTSD or post-concussive symptoms, but once again, these experiences are typically short-lived.
13. Your personal information and responses on the study will not be filed with your names. All measures will be used to protect the privacy of your data and identity.
14. Every effort will be made to protect the confidentiality of your records. However, there is still a potential risk for loss of your confidentiality; an authorized VA San Diego Research auditor will review your consent form for appropriate documentation of your informed consent.

This study complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected by Federal laws or regulations, and may be subject to re-disclosure by the recipient.

We will protect your confidentiality by assigning your research findings a study number rather than your name or social security number. Printed documents, such as screening

forms will be kept in locked cabinets, separate from the research data, in locked offices. The key that links your study number to your name will be kept in a locked cabinet, separate from the research data and printed documents. Electronic computer documents will not contain your name, birth date, contact information, or any other sensitive information. They will only contain your study number. All computers that have your study data on them will be encrypted.

Unforeseeable RISKS
Because this is an investigational study there may be some unknown risks that are currently unforeseeable. You will be informed if the researchers learn of any change in the amount of risk to you.

6) BENEFITS reasonably to be expected.
There may or may not be a direct benefit to you from these procedures. The investigator, however, may learn more about IASIS Micro Current Neurofeedback and evaluate whether this can lessen symptoms associated with mTBI and mTBI/PTSD. The possible benefit from this intervention is that symptoms of TBI and mTBI/PTSD may lessen. This effect on TBI and mTBI/PTSD has not been evaluated utilizing this Intervention so there is a possibility of no direct benefits.

There will not be any direct benefit to you from having the MEG and MRI exams. However, the research project may have future benefits to others, i.e., it may provide useful information for diagnosing mTBI in other patients whose MRI and/or CT show no visible abnormality.

7) Voluntary nature of participation and right to withdraw without penalty.
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without jeopardy to the medical care you will receive at this institution or loss of benefits to which you are entitled.

8) Alternatives to the research procedure or treatment
The only alternative is to not participate in the study.

9) Procedure for the orderly termination of a volunteer's participation
If you decide that you no longer wish to participate in this study please contact or call Dr. Mingxiong Huang, 858-534-1254, Dr. Scott Matthews, 619-497-8454, Research Associate contact numbers: 858-822-2352 or 858-246-5225.

You should come in for a final visit if you decide to stop your participation in this study so that the investigators can ensure your health and well-being.

Your participation in this study may be stopped if the investigator decides that stopping is in your best interest. If you do not follow the study instructions, you may be asked to stop participation.

10) Information learned from the study will be shared with you
While you are a participant in this study you will be told if any important new information is found that may affect your wanting to continue.

If the results of this research might influence your medical care after you have completed your participation, the investigators will contact you to let you know these results.

11) Care provided if you are injured as a result of this study
The VA will provide necessary medical treatment should you be injured as a result of participating in this study and following study procedures. You will be treated for the injury by the VA at no cost to you or your insurance but no additional compensation is available.

12) Privacy and confidentiality
Participation in this study may involve a loss of privacy, but information about you will be handled as confidentially as possible. CPRS medical record study notes will be required after each IASIS session and after each Nexalin session. If you are not already a VA patient, a medical record including your name and Social Security number will be entered in the VA Computerized Patient Record System.

SSN will be collected only for entering study notes on CPRS after each treatment session.

Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as files behind the secure VASDHS computer firewall.

VA subjects' non-sensitive data will be analyzed at the UCSD RIL. This data will not have subject identifiers.

Since neuropsychological paper and pencil testing and MHA may occur at the UCSD RIL, all personnel allowed to transfer and store the research data will have valid Authorization to Transport (ATT) forms.

VA sensitive data, such as your name, date of birth, contact information, SSN, etc., will be securely stored in Dr. Huang's office, Building 13, Room 407. Only those with valid ATT forms

will be allowed to transfer and store this data, which will be kept in a locked cabinet, separate from the de-identified research data.

Any presentations or publications from this information will not identify you.

The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you upon request. Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons outside the VA/VHA as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

We will keep confidential all research and medical records that identify you to the extent allowed by law. However, you should know that there are some circumstances in which we may have to show your information to other people. For example, the Federal Office of Human Research Protections, the General Accounting Office, the VASDHS R&D Committee, the VASDHS Institutional Review Board, the Food and Drug Administration, VA Merit, and federal compliance officers may look at or copy portions of records that identify you.

13) Payment

Costs to you or your insurance

There will be no costs to you or your insurance for any procedures or testing done only as part of this research study. If you receive a bill for services that you think could be related to your participation in this study, you should contact the Principal Investigator.

Medical care and services provided by the VA that are not part of this study (e.g., normal hospital and prescription expenses which are not part of the research study) may require co-payments if your VA-eligibility category requires co-payment for VA services.

Payment for participating

You will receive between $225 - $1050 total for participation in the IASIS sessions and additional compensation for transportation. This total amount varies depending on your study group and how many visits you complete.

Title of Study:
Passive electrical neurofeedback treatment of mTBI: MEG and Behavioral Outcomes

Principal Investigator: Mingxiong Huang, Ph.D.	**VAMC:** VA San Diego Healthcare System

You will receive up to $75 for every full hour of MEG, $75 for every MRI, $75 for every neuropsychological exam with MHA, $25 per IASIS session (amounting to $300 for 12 IASIS sessions). All participants will receive an additional $40 per round trip to the UCSD RIL/UCSD CfMRI to cover transportation costs of gas, bus fare, ride sharing, etc.

If, at the end of the study sessions, you find out you were in the mTBI-Sham group receiving Sham IASIS treatment, you may request to complete 12 sessions of IASIS Micro Current Neurofeedback, and you will be compensated for these treatment sessions.

If you participate in the Nexalin treatments, you will receive up to $500 for total participation. Specifically, you will receive $75 for every full hour of MEG and $25 per Nexalin session (amounting to $250-$500 for 10 up to 20 Nexalin sessions). All participants will receive an additional $40 per round trip to the UCSD RIL/UCSD CfMRI to cover transportation costs of gas, bus fare, ride sharing, etc. if they participate in the Nexalin sessions.

If, at the end of the Nexalin sessions, you find out you were receiving the mTBI-Nexalin-sham treatment, you may request to complete 10-20 sessions of Nexalin treatment, and you will be compensated for these treatment sessions.

You may also receive a picture of your brain MRI in the form of 1 sagittal slice, 1 axial slice, and 1 coronal slice of your T-1 scan. Please remember that this picture is not completed for clinical purposes. This picture will not contain any participant information nor personal information.

14) Additional Information
The VA San Diego Healthcare System provides oversight and resources for this study.

Incidental Findings: MRI scans will receive a routine examination by a study investigator. The MRI procedures used in this study are for research and no clinical report will be generated from this study. If there are any MRI findings that may be significant, the PI, Dr. Mingxiong Huang, or Co-I, neuroradiologist Dr. Roland Lee, will notify you via phone call. These findings may cause you additional tests or doctor visits. The decision whether to proceed with further examinations will lie with you as there are no opportunities for clinical follow-up studies as part of this research.

Future Use of Data: De-identified research data will be stored at the UCSD RIL and may be used for future research and data analysis. Only Dr. Huang, the Co-Investigators, and the study's research staff will have access to this non-sensitive data.

Title of Study:
Passive electrical neurofeedback treatment of mTBI: MEG and Behavioral Outcomes

Principal Investigator: Mingxiong Huang, Ph.D.	**VAMC:** VA San Diego Healthcare System

Data from this study may be submitted to the VA Center of Excellence for Stress and Mental Health (CESAMH) Biorepository. The CESAMH Biorepository is a research project at the VA San Diego Healthcare System that allows researchers to collect and share information with each other using a data and biological sample bank. With the CESAMH Biorepository, researchers studying trauma, traumatic brain injury and posttraumatic stress disorder will be able to combine information collected from multiple research efforts into large collections for future research. CESAMH Biorepository researchers hope to use this data bank to learn new and important things about the biological mechanisms to trauma response. The ultimate aim of the CESAMH Biorepository is to better understand a person's response to trauma and in doing so, be able to create new avenues for treating trauma-related disorders. With your permission, the researchers of this study will provide your research information including demographics, physical and mental health information provided in questionnaires and interviews, and behavioral task data to the CESAMH Biorepository. Your research information within the Biorepository will be labeled with a study code so that no identifiable information will be kept with research data. The list that matches your name with the code number will be kept in a locked file in the Biorepository team's office. Any research records that identify you will be kept only as paper records in a secure VASDHS location, or as files behind the secure VASDHS computer firewall. After research data are provided to the CESAMH Biorepository other researchers will be able to submit an application to access information within the CESAMH VA San Diego Healthcare System Biorepository for specific research projects. Experts whose responsibility is to protect health and science information will review every request carefully to minimize any risks to privacy.

Please indicate below if you agree to have your research information, including responses given to various health, behavior, and quality of life measures, provided to the CESAMH Biorepository for use in future research:

Yes, I agree to have my research information given to the CESAMH Biorepository.
_____ (initial)

No, I do not agree to have my research information given to the CESAMH Biorepository.
_____ (initial)

The CESAMH Biorepository researchers are also interested in having you provide additional research information directly to the Biorepository, including biological samples and general health and well-being information. This process would require a separate enrollment into the CESAMH Biorepository and providing information for future research. In this case, the Biorepository will be given your contact information and they will contact you to determine if you

Title of Study:
Passive electrical neurofeedback treatment of mTBI: MEG and Behavioral Outcomes

Principal Investigator: Mingxiong Huang, Ph.D.	**VAMC:** VA San Diego Healthcare System

would like to participate in that study. Please indicate below if you also agree to be contacted by the CESAMH Biorepository to learn more about the project and how to participate:

Yes, I may be contacted by the CESAMH Biorepository. _____ (initial)

No, I do not wish to be contacted by the CESAMH Biorepository. _____ (initial)
Re-contact: Please check mark and initial the option if you wish to be contacted for future research:

☐ _____ Initials — I consent to being contacted for possible participation in future studies.

☐ _____ Initials — I decline the consent for contact for possible participation in future studies.

15) RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above. **You have been informed that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.**

In the event of illness or injury that you believe to be related to the study, or have questions about this research, you can call Dr. Huang during the day at 858-534-1254. If you have any questions or concerns about your rights as a research subject, the validity of a research study, or research personnel you can contact the Research Compliance Officer at 858-642-3817, VA Research Service at 858-642-3657, VA Regional Counsel at 858-642-1540, or the VASDHS Human Research Protection Program at 858-642-6320.

_____ has explained the study to you and answered all of your questions. 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 will receive a copy of this consent form and a copy of the Health Insurance Portability and Accountability Act (HIPAA) Authorization that you signed. You will also receive a copy of the California Experimental Subject's Bill of Rights.

Title of Study:
Passive electrical neurofeedback treatment of mTBI: MEG and Behavioral Outcomes

Principal Investigator: Mingxiong Huang, Ph.D.	**VAMC:** VA San Diego Healthcare System

By signing this form you indicate that you have been informed of your rights as a research subject, and that you voluntarily consent to participate in this study. You have been informed what the study is about and how and why it is being done.

Subject's Signature _____ Date _____

Signature of Researcher obtaining consent _____ Name (print) _____ Date _____