Participant Name: _____ Date:_____

Title of Study: **Remotely supervised tDCS for persistent post traumatic headache in Veterans (ReStore)**

Principal Investigator: X. Michelle Androulakis, M.D. VA Facility: WJB Dorn VAMC

Sponsor: VA RR&D Small Projects in Rehabilitation Research

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

You are being invited to take part in a research study for chronic post traumatic headache disorder. 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. Taking part in this study is completely voluntary.

We are doing this research study to find out if at home Transcranial Direct Current Stimulation (tDCS) can be a beneficial treatment method for post-traumatic headaches (PTH) in veterans. If you are to participate, you will receive a total of 20 tDCS treatment or sham (control) sessions over a time period of four weeks. The tDCS device will apply a very weak electrical current to stimulate your brain. All these sessions (except the first and last session if deemed necessary by the study team) will be done at your home via VA Telehealth program using your personal computer or tablet device. If you do not have access to a computer or tablet at home, you will be provided with a VA approved tablet with wireless connection during your participation in the study. These sessions will also be combined with a mindfulness meditation through a mindfulness coach app approved by the VA.

This study is being funded by the VA RR&D Small Projects in Rehabilitation Research.

The tDCS device that we are using in this study is called the Soterix Medical mini Clinical Trial (CT) device. This device is for investigational use only.

Currently, there are no known long-term negative effects of tDCS. However, a small number of populations may experience side effects such as: temporary tingling, itching, skin irritation, or slight pain around the area of stimulation. These symptoms are usually temporary and can be easily treated with over-the-counter pain medications if deemed necessary. There are no direct benefits to you for participating in this study. However, knowledge gained from this study could be used to develop new treatment options for your condition, which could ultimately benefit all Veterans with PTH in the future.

Your participation in this study is completely voluntary. If you choose not to participate, your standard of care will not be affected. You may talk to your doctor about other options to treat your condition.

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn more about the potential benefits of at home tDCS treatment for post-traumatic headaches (PTH) in war veterans. We are trying to see if tDCS can improve functional recovery and reduce the number of headaches in these patients. We will compare active treatment sessions of tDCS with sham (control sessions). tDCS treatment has been shown in previous studies to improve chronic pain.

HOW LONG WILL I BE IN THE STUDY?

A total of 24 veterans will be included in this pilot study. This research study is expected to take approximately 24 months. Your individual participation in the project will begin with a 4-week baseline period, followed by 4 weeks of tDCS or sham treatment, then followed by a 12 week follow up period.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you decide to participate, you will first receive a physical and neurological exam and be asked to fill out questionnaires. You will also be given a tolerability test of the tDCS treatment regardless of the treatment group you are randomized to. This is to ensure you can tolerate the tDCS treatment. The questionnaires will be used to collect data on your age, sex, race, marital status, education level, and characteristics of your headaches. You will also be asked to fill out information about your current medications, past medical history, and your family medical history.

If you qualify to be included in the study, you will receive 20 sessions of tDCS stimulation lasting 20 minutes each. You will be assigned to either the tDCS treatment group or sham (control group) randomly. You and the study team will not know what

treatment group you are in during the study. The study doctor may request to know what treatment you received in the event it becomes medically necessary. You will complete your first tDCS session with a mindfulness meditation session in clinic or via Telehealth. We will give you a tDCS study kit including a tDCS device, a mirror, headset, sponges, saline solution, and batteries for this study. We will also give you instructions on how to use the VA Telehealth service and the VA mindfulness coach app on your computer or tablet. A VA approved Telehealth tablet with the mindfulness coach app will be provided to you if you don't have access to equipment at home.

You will do the next 18 tDCS sessions at home along with mindfulness meditation sessions. These sessions will be monitored by a member of the study staff through the VA Telehealth platform. You will also complete a Daily Headache Diary to describe the symptoms from your headaches throughout the study.

The last tDCS session and mindfulness meditation will be done at the clinic or via Telehealth. After the last tDCS treatment, we will call you daily to discuss your current headache symptoms. This follow-up period will last for about 12 weeks.

Additionally, before the first in-clinic tDCS session, during treatment, and during the follow up phase, you will be asked to fill out a series of questionnaires to describe the symptoms associated with your headaches. Some surveys will be completed over the phone with a study staff member. These questionnaires include the Patient Health Questionnaire (PHQ-9) to assess symptoms of depression, Beck Anxiety Inventory (BAI) to asses symptoms of anxiety, the River mead post-concussive symptoms questionnaire, the Headache Impact Test (HIT-6), the PLC-5 questionnaire to assess symptoms of post-traumatic stress disorder (PTSD), the Positive and Negative Affect Schedule (PANAS-SF), and the insomnia severity inventory (ISI) to assess any sleep issues.

WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

As a participant you will be expected to follow the study protocol. You will need to come to the clinic or connect to VA telehealth for the baseline visit, all the tDCS sessions. Additionally, you will need to fill out a Daily Headache Diary to describe the symptoms related to your headaches throughout the study.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

There may be side effects from the tDCS including tingling, itching, warm sensation, slight pain, and skin irritation in the area of stimulation. These side effects are usually mild and disappear within half an hour after stimulation. If needed, these symptoms can be treated with over the counter pain medications. Please let us know if you have any side effects, including those not listed here.

The risks to pregnant women and their developing baby are not well known. Therefore, we will not include any pregnant women or women trying to get pregnant in our study. If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below. You must use this birth control during your participation in this study. Acceptable birth control methods for use in this study are:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring or implants.
- Barrier methods (such as condom or diaphragm) used with a spermicide (a foam, cream or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

If you miss a period, or think you might be pregnant during this study, you must tell the study staff immediately. If you become pregnant, you must stop your participation in the study.

There are no known long-term negative effects of tDCS stimulation. It is possible that the researchers will learn something new during the study about the risks associated with tDCS. If this happens, they will tell you about it. Then you can decide if you want to

continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may or may not be benefit to you by participating in this study. However, the information that we gain from this study can be used to better understand post-traumatic headaches. This information may also be used help develop better treatment methods for post-traumatic headaches in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

Joining this study is completely voluntary. If you decide not to enter this study, your standard of care will not be affected. You do not have to be in this study to be treated for your condition. You can discuss other treatment options with your regular doctor, such as medication for pain symptoms.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Every effort will be made to keep the information in the study confidential. In the case of screen failures, all documents containing the participant's health information will be destroyed. All data files and analyses will be performed on VA research computers using only code numbers to identify participants. Only summaries of group data will be reported in any publications or presentations, with no identification of individuals.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your "authorization", for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as drug, alcohol or mental health treatment.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the Institutional Review Board, Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to obtain treatment or benefit outside of the study.

If you revoke this authorization, Dr. X. Michelle Androulakis and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT IS THE COST TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments 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. You will be responsible for the costs of transportation when you visit the VA center for this study. However, you will be paid

$20 for every tDCS session that you complete. This includes completing the headache diary and questionnaires. Payments will be made via check at the end of each month.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

The VA will provide any necessary medical treatment should you be injured by participation in this study and you will be treated for the injury within this VA facility, with limited exception, at no cost to you. This also pertains to non-veteran participants enrolled in VA-approved research who sustain a research-related injury. Exceptions would be situations where this facility would not be capable of furnishing the care required, and in this case the Medical Center Director of this VA facility will provide reasonable reimbursement for emergency treatment in a non-VA facility. This requirement does not apply to treatment for injuries that result from non-compliance by a research participant with study procedures.

In case of injury, please contact the study's principal investigator:

Dr. X. Michelle Androulakis
803-776-4000 Extension 4077

DO I HAVE TO TAKE PART IN THE STUDY?

This study is completely voluntary. If you refuse to take part in the study, your standard of care will not be affected. You have the right to leave a study at any time without penalty. If you withdraw from the study, the data already collected on you can still be used but we will not collect any new data on you.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you need to contact the study team regarding any questions, complaints, and concerns about the research study or related matters, you may call the study investigator:

Dr. Xiao Michelle Androulakis
Xiao.Androulakis@va.gov
803-776-4000 Extension 4077

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

If we find out any new information that may change your mind about participating in this study, we will notify you immediately. You will not be given the results of this study unless they are published.

FUTURE USE OF DATA AND RE-CONTACT

Personal identifiers might be removed from the identifiable private information and after such removal, the information could be used for future research studies or shared with other investigators without additional informed consent from the participants. Data from this study will be saved and may be used for publication and future research. However, your name or any identifying information will not be used for these purposes without your permission.

Study data will be stored on VA research computers using only code numbers to identify participants. Only study staff members will be allowed to have access to this data.

We may contact you in the future regarding this study if we need to collect more information for research purposes.

Research Participant's Rights

I have read, and/or I have had read to me all the above. I have been able to ask questions and I have had them answered. I have been told of the risks or discomforts and possible benefits of the study. I understand that I do not have to take part in the study and that my refusal to take part in the study will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty of loss of VHA, DVAMC and/or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.

CONTACT PERSONS

In case there are medical problems or questions, I understand that I can contact:

Dr. Xiao Michelle Androulakis, MD
6439 Garners Ferry Rd.
Columbia, SC 20209
(803)776-4000 ext. 4077

If any medical problems occur in connection with this study, the DVAMC will provide emergency care.

If I have questions about the informed consent or my rights as a research participant, I can contact: the Dorn VAMC Institutional Review Board (IRB)

Participant Name: _____ Date:_____

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Principal Investigator: X. Michelle Androulakis, M.D. VA Facility: WJB Dorn VAMC

Sponsor: VA RR&D Small Projects in Rehabilitation Research

Dr. John Steedman, MD, PhD
WJB Dorn VAMC, Research Office (151),
6439 Garners Ferry Rd.,
Columbia SC, 29209,
803-776-4000, ext. 6005.

If I wish to speak with someone not directly involved in the research to discuss problems, concerns, questions, complaints, obtain information or offer input about my participation in the research I can contact:

Dr. Michael Ryan, Ph.D.
WJB Dorn VAMC, Research Office (151),
6439 Garners Ferry Rd.,
Columbia SC, 29209,
803-776-4000, ext. 56670

I REALIZE I HAVE NOT RELEASED THIS INSTITUTION FROM LIABILITY FOR NEGLIGENCE. IF I AM INJURED IN ANY WAY BY MY PARTICIPATION IN THIS STUDY, APPLICABLE FEDERAL LAWS MAY OR MAY NOT ALLOW ME TO RECEIVE COMPENSATION FOR THOSE INJURIES.

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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 and authorize the use and disclosure of your health information for 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. *(A* copy of this signed consent will also be put in your medical record.*)*

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining consent	_____ Signature of person obtaining consent	_____ Date