Subject's Name: **Date:**

Principal Investigator: **Jeffrey J. Borckardt, Ph.D.**

Study Title: **The Effects of Cognitive Behavioral Therapy and Transcranial Direct Current Stimulation (tDCS) on Chronic Lower Back Pain**

CONSENT TO BE IN A RESEARCH STUDY
"The Effects of Cognitive Behavioral Therapy and Transcranial Direct Current Stimulation (tDCS) on Chronic Lower Back Pain"

A. PURPOSE AND BACKGROUND

You are being asked to volunteer for a research study. This research is sponsored by the National Institutes of Health (NIH) and the Medical University of South Carolina (MUSC). The purpose of this study is to determine whether a new medical technology, called Transcranial Direct Current Stimulation (tDCS), can help reduce chronic lower back pain, improve sleep, and reduce the need for pain medication when applied in combination with cognitive behavioral therapy ("talk therapy"). tDCS is a minimally-invasive technique (i.e., it does not involve any surgical procedures, additional medication or sedation, or needles) that uses a very small amount of electricity to temporarily stimulate specific brain areas in awake people. The electrical current passes through the skin, scalp, hair and skull and can temporarily increase or decrease activity in areas of the brain that are thought to be involved with pain reduction. Some preliminary studies suggest that tDCS may be effective in reducing chronic lower back pain and altering pain perception in both healthy adults and in patients with various types of pain conditions. However, tDCS is not approved by the FDA as a treatment for pain conditions.

You are being asked to participate in this study because you are between the ages of 18-70 and may meet criteria for these conditions. The investigator in charge of this study is Jeffrey Borckardt, Ph.D. This study will involve approximately 150 volunteers and will be conducted in Charleston, SC. Part of the study will occur at the Ralph H. Johnson VAMC (Baseline assessment and follow-up visits) and part will occur at MUSC (weekly therapy sessions, neuroimaging, pain testing).

Subject's Name: **Date:**

Principal Investigator: **Jeffrey J. Borckardt, Ph.D.**

Study Title: **The Effects of Cognitive Behavioral Therapy and Transcranial Direct Current Stimulation (tDCS) on Chronic Lower Back Pain**

B. PROCEDURES

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

If you agree to be in this study you be asked to sign an informed consent the following will happen:

1. You will complete several self-report screening measures designed to assess your pain history, level of depression, and anxiety. Additionally, you will be given a physical exam and interviewed by one of the research team members about your medical history including history of seizures, implanted medical devices, skin conditions, and history of brain injuries. You have the option of taking your own blood pressure if you or someone you know has a blood pressure cuff, getting your blood pressure measurement from a medical provider or an automated machine (for example, those that can be found in pharmacies and grocery stores), or the study staff may view a recent blood pressure reading in your EPIC or CPRS record. You will also be asked questions about your use of prescription opiates and other substances, and be asked to take a urine drug screen test and breathalyzer test.
2. You will be permitted to continue your current pain treatments (including medications), but will be asked not to change the treatment regimen during your enrollment in the study.
3. If you are a woman who is able to become pregnant, the study team will perform a urine pregnancy test. If the pregnancy test is positive you will not be eligible to participate in the study.
4. You will be randomized to one of two groups; neither the researcher nor you will make the choice of which group you are assigned. The two groups are A and B. If you are randomized to Group A, you will meet with a clinician for 11 sessions of cognitive behavioral therapy (CBT) for pain and you will receive real tDCS. If you are randomized to

Group B, you will meet with a clinician for 11 sessions of CBT for pain and you will receive sham tDCS (this is not real stimulation). CBT sessions will be conducted either in person or via telehealth in a MUSC office. This will be done over the computer using MUSC approved teleconferencing applications. Telehealth allows your therapist to communicate with you while in separate rooms.

5. You will be given an actigraphy monitor to wear on the non-dominant wrist. This device will monitor your sleep pattern. Data from this device will be recorded by the study staff after the 2-week baseline period, post treatment, and at 1-, 3-, and 6-months post-treatment follow-up visits. If you decide to discontinue treatment or upon completion of the study, you are required to return the actigraphy monitor to the study staff.
6. If you have a cell phone, it will be registered into a diary system that will ask you daily about your pain, mood, and cravings. If you do not have a cell phone we will provide one to you for use during the study. If you decide to discontinue treatment or upon completion of the study, you are required to return the phone to the study staff. This is considered the baseline period and will last 2 weeks. During this time you will have a MRI (magnetic resonance image) which will take place at 30 Bee Street in the Center for BioMedical Imaging and Quantitative Sensory Testing (QST) which will take place in the Brain Stimulation Laboratory in the Institute of Psychiatry at MUSC. QST evaluates your response to pain by using a blunt tip needle that will be pressed into your finger while recording your response to the pressure (you feel the pressure, you feel pain and you ask to stop). The study team will also record your response to heat and cold using a thermode (small pad applied to the inside of your forearm).
7. During the treatment phase, you will receive 11, 1-hour therapy sessions of CBT for pain. Therapy sessions can be conducted in person or via telehealth in a MUSC office. If you are completing the treatment phase via telehealth, you will be placed in a private MUSC office with a computer. During each of these CBT therapy sessions, you will undergo

approximately 30 minutes of either real or sham tDCS. You will also be asked to fill out questionnaires about your mood, pain, and drug/alcohol as well as opiate medication use at each session.

8. When conducting a tDCS session, the investigators may pre-treat your skin with a small amount of mild pain-reducing cream. They will then place 2 water-soaked sponges over the area of your scalp corresponding to your group. The sponges will be held in place by a Velcro headband. After stimulation, the investigators may apply a vitamin-E/Aloe cream to the skin to reduce problems associated with skin-drying.
9. You may experience 30 minutes of mild, constant stimulation through the sponges. Some people experience a mild tingling or itching under the sponges during the stimulation. Some people feel tired, some feel nothing at all.
10. Within 3 week following completion of the CBT treatment, you will have another MRI and quantitative sensory testing (QST) procedure.
11. You will then return at 1-, 3-, and 6-months post-treatment for follow-up visits that will consist of questionnaires. These follow-up visits can also be conducted via telehealth (urine sample will not be collected).

C. DURATION

Your participation in the study will involve 17 appointments (baseline visit, 11 therapy sessions, 2 MRI/QST sessions, 3 follow-up appointments). The baseline assessment may last up to three hours. The therapy sessions are 1 hour each. The follow up sessions will last approximately one to two hours. The MRI procedure will last approximately one hour each and the QST will last approximately 45 minutes each.

Project staff will contact you to schedule appointments and provide reminders for those appointments. We will ask for your phone number, email and mailing address to contact you.

Any contact associated with the study will simply remind you of the time and date of an appointment and will not include information indicating that this study is related to psychiatric, pain, or opiate medication research.

D. RISKS/DISCOMFORTS

Potential Risks of tDCS:

tDCS has been found to be safe in humans with mild side-effects such as tingling sensations under the sponge electrodes (experienced by 70% of tDCS patients), moderate fatigue (35%), and light itching sensations under the sponges (30%). After tDCS, the incidence of side-effects is lower, but include headache (12%), nausea (3%) and insomnia (<1%). There is no evidence to date suggesting that tDCS causes seizures. This technique is currently being used as a method to reduce seizure frequency in epileptic patients. However, there is at least a theoretical possibility that tDCS could induce a seizure in some patients, thus if you have epilepsy or are taking medications known to lower seizure threshold, you will not be eligible for participation in this study.

Some mild skin irritation can occur after tDCS treatment. If tDCS is delivered at 20 minutes per day, every day for 4 or more days in a row, mild skin burns have been reported. However, these problems have only been seen when the electrode sponges are soaked in certain types of liquid, none of which will be used in this study. Further, these problems have only been seen when the skin is not treated with moisturizer creams after stimulation. The investigators will apply a vitamin-E/Aloe cream to your skin after each stimulation session. Lastly, these rare instances of burns reported in the research literature have all been reported to heal without scarring within 1 to 3 weeks following the end of tDCS treatment. Because we are using liquids that have not been associated with skin irritation, and because we will be applying a moisturizing cream after each treatment, we believe that the risk of mild burns is very minimal. Further, if the investigators detect any evidence that you are developing a skin irritation in response to the treatment, the treatment will be discontinued.

tDCS is thought to be safe, with no potential for brain damage, despite extensive use in humans and other animals. There have been no reports of long-term changes in cognitive function (memory, attention, etc) in tDCS studies. However, tDCS is an experimental procedure and may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

Potential for allergic reaction:
Some people report allergic contact dermatitis as a result of exposure to creams such as Benzocaine and Vitamin-E lotion. Dermatitis is described as inflammation of the skin and may present as an itchy rash. The rash may be treated with corticosteroid creams (such as hydrocortisone), antihistamines, or wet compresses. If contact dermatitis develops, the investigator will immediately remove any cream from your skin and apply a wet compress.

Potential Risks of Actigraphy Device:
Some mild skin irritation or allergic contact dermatitis can occur from wearing the actigraphy device. Dermatitis is described as inflammation of the skin and may present as an itchy rash. The rash may be treated with corticosteroid creams (such as hydrocortisone), antihistamines, or wet compresses. Further, if the investigators detect any evidence that you are developing a skin irritation in response to the device, its use will be discontinued. If you feel that the irritation was a result of the covered area not being allowed to breathe, once healed, you may given the option to resume wearing the device, but not required to.

Risks regarding Confidentiality:
All study records will be placed in a locked, secure, limited access location. Your participation in the study and the information you provide will be treated as confidential. In order to protect your confidentiality, the information we collect will contain your code number and not your

name. Codes linking numbers and names will be kept in a locked secure location and will not be accessible to anyone outside the research team. Participants seen at the VA or referred from the VA will have an electronic medical record. This is documentation of a scheduled visit. No specific information about the type of visit including diagnosis, medication or research information obtained during the visit will be entered into this record. You should know that if you threaten to harm yourself or others, or give information about child or elder abuse, this information will be reported to appropriate clinical staff and other persons outside the research program as necessary to protect you and others.

Even without your consent, suspected or known abuse or neglect of a child, disabled or elder abuse, or threatened violence to self or others may be reported to appropriate authorities.

Your urine will be screened for the use of abused or illegal drugs. These results will not be part of your medical record but will be kept in research records maintained by the investigator. Every effort will be made to protect the confidential nature of this information. However, there may be circumstances under which the investigator may release this information. If you are pregnant or become pregnant and test positive for illegal drugs, we may notify the SC Department of Social Services (DSS) and you will be at risk of going to jail or losing custody of your children.

If you are active duty military, there may be repercussions associated with participating in this study.

Randomization Risk:
As there is a 50/50 chance of you receiving either the real or sham stimulation, there is the risk of being assigned to the sham group which may not receive a benefit.

E. BENEFITS
You may (or may not) experience a reduction in pain as a result of participating in this trial. It is hoped that the information gained from the study will help in the treatment of future patients

with chronic pain conditions.

F. COSTS

If you choose to use your own phone then the data usage and rates of your plan will apply. Apart from the cost of your phone plan, there are no other costs to you for your participation. You will not be required to pay for medical care or services received as a participant in a VA research project except as follows: Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

G. Payment

In return for your time and effort, you will be paid up to $1061 for participation in this study. You will either receive cash at the time of your visit or payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet. If preferred, a check will be mailed to the address provided by you. It can take up to 60 days to receive compensation via mail. Each visit, you will be compensated:

- Baseline visit=$40
- Each therapy session=$20 (total of 11 sessions=$220)
- MRI visit=$50 (2 MRI visits=$100)
- QST visit=$25 (QST visits=$50)
- Each follow up visit=$75 (3 follow up visits=$225)
- Each E-diary entry=$1 ($14 for 2 week baseline phase, $77 for 11 week treatment, $180 for 6 month follow-up=$236)

- Bonus=$20 (If arrived on time for the baseline visit)
- Bonus=$50 (If all 11 therapy sessions are complete within 14 weeks of treatment initiation)
- Bonus=$10 (If all daily diaries are completed during the 2-week baseline phase)
- Bonus=$25 (If all daily diaries are completed during the treatment phase)
- Bonus=$50 (if all daily diaries are completed between the last therapy session and first month follow up)

You are invited to participate in the recruitment of other subjects for this study. If you choose to participate, we will provide you with cards that you may give to other people (e.g., friends, acquaintances) who you think would be eligible and interested in this study. You may choose to tell people to whom you give these cards to call the study office if they are interested in participating in the study. These individuals will not be identified unless they contact the study office themselves. If any of the cards you are given result in successful study recruitment, you will receive $20 for each referred individual who consents to participate in the study. Participation in the recruitment process is completely voluntary and if you elect not to participate, your participation in this study will not be affected in any way.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099. However, if the payment for participation will be made through Austin Financial Services Center, it may generate IRS Form 1099 automatically, regardless of amount.

H. ALTERNATIVES

tDCS is not approved by the FDA as a treatment for pain. This treatment study is being conducted

to determine the effectiveness of tDCS for pain. If you choose not to participate in this study, you could receive other treatments for your conditions. We will be happy to provide referrals for other treatment clinics and health care providers in the community if you would like. You have the option of not participating in this trial if you choose.

I. NEW INFORMATION

If there are significant new findings during the course of this study, you will be notified.

J. RELEASE OF MEDICAL RECORDS TO ANYONE OTHER THAN THE INVESTIGATORS

If for any reason you would like your medical records released to anyone other than the study investigators, you will be asked to sign a release of information form. You will also sign a Health Insurance Portability and Accountability Act (HIPAA) authorization to use or disclose your protected health information for research purposes.

K. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance nor will it be part of your academic record at this Institution.

L. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be part of your personnel record at this Institution.

Subject's Name: **Date:**

Principal Investigator: **Jeffrey J. Borckardt, Ph.D.**

Study Title: **The Effects of Cognitive Behavioral Therapy and Transcranial Direct Current Stimulation (tDCS) on Chronic Lower Back Pain**

M. PERMISSION TO RECORD SESSIONS:

We would like to record the therapy sessions to assure treatment quality and adherence to the treatment manual. Recording the sessions is not required for participation, but is very useful to us. This could pose a risk to confidentiality and although we will take every step possible to ensure that all recordings are stored securely and any risks minimized, there is a risk is that you could be identified, including information regarding alcohol and drug use, or other criminal behavior. To minimize any risk, all recordings will be kept in a locked file cabinet or on a secure and encrypted server and only the project staff and supervisors will have access to the recordings. They will be destroyed after the study has been completed. Would that be acceptable to you?

*I permit audio or visual recording of my therapy sessions. Yes___ No _____

N. Study Posting:

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

CONSENT

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All

records in South Carolina are subject to subpoena by a court of law.

The VA will provide necessary medical treatment to a research subject injured by participation in a research project. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by this VA Medical Center. Financial compensation is not available for such things a lost wages, disability or discomfort due to an injury.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, or if I have comments, concerns or complaints, I may contact Dr. Jeffrey Borckardt (843-792-3295). I may contact the VA Medical Center's Medical Director (843-789-7200) concerning medical treatment.

If I have questions, comments, concerns, or wish to voice a complaint, I may contact the VA Research Compliance Officer at (843-789-7399).

Subject's Name: **Date:**

Principal Investigator: **Jeffrey J. Borckardt, Ph.D.**

Study Title: **The Effects of Cognitive Behavioral Therapy and Transcranial Direct Current Stimulation (tDCS) on Chronic Lower Back Pain**

If I have any questions about my rights as a research subject in this study I may contact the Medical University of SC Institutional Review Board for Human Research at (843-792-4148).

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

_____

Signature of **Participant** Date

_____

Signature of **Person Obtaining consent** Date