

**Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT**

TITLE OF RESEARCH: Direct measurement of motor cortical responses to transcranial direct current stimulation.

Principal Investigator: Dr. Nathan Rowland, M.D., Ph.D.

NCT04759898

SUMMARY

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to participate. The purpose of this study is to better understand how stimulation of the brain can help patients with movement disorders. The type of brain stimulation used in this study is called **transcranial direct current stimulation or tDCS**. It is placed on top of the scalp and stimulates the brain through the skull.

This is how the study works: You will be undergoing deep brain stimulation (DBS) surgery to treat your movement disorder. DBS surgery involves drilling a hole in the skull and implanting a DBS electrode deep within the brain. Before we implant the DBS electrode as part of your clinical care, we will first place the tDCS electrodes on top of your scalp and then insert another electrode, called a subdural electrocorticography (ECoG) electrode, right beneath the skull but on top of your brain. The ECoG electrode will not go into your brain but will sit right on the surface. The tDCS and ECoG electrodes are placed purely for research purposes. The tDCS electrodes will be for stimulating only and the ECoG electrode will be for recording only. If you choose to be awake during the surgery, you may be asked to look through a pair of virtual reality goggles and point to the dots shown to you in the goggles. We will give you instructions on how to do this, and you will be able to practice this while you wait in the pre-operative area. We will test your reaching and pointing movements, then turn on the tDCS stimulation at various times to see how those movements are affected while recording signals in the motor region of your brain. If you choose to be asleep during the surgery, we will record signals in the motor region of your brain while turning the tDCS stimulation on and off. Since you will be asleep, you will not use the virtual reality goggles. Once the stimulation and recording are over, we will remove the tDCS and ECoG electrodes and all other research-related equipment and continue the rest of the DBS surgery. Duration of participation in this study will be for 20 minutes during your DBS procedure, a followup call approximately one week after the procedure and a medical chart review that will occur at 30 days following the procedure to ensure that you have not been harmed in any way by your participation in this study.

It is important for you to know that you may experience additional risks or discomforts if you participate in this study, including skin irritation from the tDCS electrodes and/or injury to nearby structures such as blood vessels during insertion of the ECoG electrode. There is also a

IRB Number: «ID»
Date Approved «ApprovalDate»



risk of a loss of confidentiality of your personal information as a result of participation in this study. This research will not benefit you personally but may benefit others with your same condition in the future.

Since the tDCS stimulation is not intended as a treatment for your symptoms, the alternative to study participation is not to participate.

If you are interested in learning more about this study, please continue reading below.

A. PURPOSE OF THE RESEARCH

Transcranial direct current stimulation (tDCS) has not been approved by the FDA and is considered investigational for the purpose of this study. It has been used on a few patients with movement disorders whose symptoms improved. However, not all movement disorder patients are helped by this type of stimulation. We want to better understand how the stimulation is affecting the brain and how we can improve it in the future to help even more patients with your disease. The ECoG electrode is a sterile device that is FDA approved to take readings on the brain.

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you have decided to undergo DBS treatment. The study is sponsored by MUSC. The investigator in charge of this study at MUSC is Nathan C. Rowland, MD, PhD. The study is being done at one site. Approximately 25 people will take part in this study at MUSC.

B. PROCEDURES

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

- 1) After the DBS surgery has started, we will insert the ECoG electrode onto the surface of the brain and place the tDCS electrodes onto your scalp.
- 2) If you are awake and are undergoing frameless DBS, we will also fit virtual reality goggles onto your face. You will participate in a reaching and pointing task that takes 3 minutes to complete. We may ask you to repeat this. We will turn on the tDCS machine at various points during the task. We will videotape you while you do this. If you are either awake and undergoing framed DBS or you are asleep, you will not perform this task or be videotaped, however we will still turn on the tDCS machine to see how your brain is affected. This part of the research will take no more than 20 minutes.
- 3) In all patients, we will take photographs of the electrodes and any other aspect of the research setup in order to correlate with the brain signals we record. Some of these photos may include your face.
- 4) In addition to the fluoroscopy images that will occur as part of clinical care for the

placement of the DBS electrode, there may be additional fluoroscopy images that occur to evaluate the placement of the research electrodes.

- 5) We will then remove the tDCS and ECoG electrodes and all other research-related equipment. Once this is done, we will complete the DBS surgery.
- 6) A member of the research team will follow up with you within a week of your procedure by phone. The research staff will also review your medical record for up to 30 days after your procedure to collect information on your clinical outcomes and any additional treatments, tests or procedures you may have had.

C. DURATION

The amount of time of your involvement in this study consists of 1) the duration of your procedure on the day of surgery and 2) a followup phone call within a week of your procedure to check on any side effects you may be having. Thirty days after your procedure your medical record will be examined to collect information on your clinical outcomes and any additional treatments, tests or procedures you may have had.

D. RISKS AND DISCOMFORTS

Transcranial direct current stimulation (tDCS) – Many people who undergo tDCS experience either a tingling (70%) or itching (30.4%) sensation. If you experience a headache (11.8%), skin lesion (11.8%) or skin rash (1.5%), we will remove the electrodes and withdraw you from the study. Withdrawal from the study will not affect your clinical treatment.

ECoG – In a recent study of 200 ECoG insertions in patients undergoing DBS surgery, 1 person (0.5%) returned to the hospital with a brain bleed on the surface of the brain that did not produce lasting effects. No brain infections occurred in any patient in that study. To protect against these risks, we will review your medical history with you to determine if there are reasons you cannot have this electrode inserted. These reasons include prior brain surgery (with the exception of DBS), radiation, infection, tumor, vascular malformation or history of seizures. If one of these is present, you will not be able to participate in this study. If you are eligible to participate, as we are inserting the ECoG electrode, if we feel any resistance whatsoever, we will remove the electrode and you will be withdrawn from the study. Withdrawal from the study will not affect your clinical treatment.

Virtual reality (VR) goggles – Approximately 5% of people who wear virtual reality goggles experience symptoms related to eyestrain, visual discomfort, discomfort associated with the headset and/or difficulty focusing. If you experience any of these symptoms during the study, the goggles will be removed, we will continue the DBS procedure, and we will keep any data that we were able to record.

Behavioral task – If you are awake and undergoing frameless DBS surgery, you will participate in a task in which you reach and point to dots on a virtual screen in front of you. This will take 3 minutes. We may ask you to repeat this. If you participate in the task, your arm will not be outstretched for the entire 3 minutes, however if you experience muscle strain, pain, or any discomfort related to the task, we will stop the task and give you 1 minute to rest. If you are not able to complete the task, you will be withdrawn from the study. Withdrawal from the study will not affect your clinical treatment. If you are asleep, you will not perform this behavioral task.

Photography and videography – The videos and photos we record can include your full face, upper body, arms, legs and back of the head where we are operating. Photography and videography carry a risk of loss of privacy. We will store your photos and videos on a secure server. Only approved study personnel will have access to these files.

Fluoroscopy – The amount of radiation to which you will be exposed is relatively small (similar to a dental xray). Such doses of radiation may be potentially harmful, but the risks are so small that they are difficult to measure. The amount of radiation you will receive from participating in this research study is within the normal range you would receive if you did not participate in this study, because the standard of care DBS surgery involves many fluoroscopic xrays as a normal part of the procedure. Additionally, if the research electrode placement is captured during one of the xrays taken as a normal part of the procedure, you will not require extra fluoroscopic xrays as part of the research.

Loss of confidentiality - Once you are enrolled in this study, we will record private information about you, including your name, medical record number, date of birth, gender, and telephone number. Loss of privacy is a risk of this study. We will take precautions to reduce this risk by limiting who can see your private information (only research staff approved for this study) and keeping this information in a separate file from the rest of the data collected during your procedure. If a privacy breach is discovered you will be immediately notified and given the option to withdraw from the study and delete all private information that we have collected.

E. MEDICAL RECORDS

If you are an MUSC patient you have an MUSC medical record. If you have never been an MUSC patient, an MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC Epic medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law.

F. COSTS

There will be no cost to you as a result of participation in this study.

G. PAYMENT TO PARTICIPANTS

There will be no payment to you for participating in this study.

H. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

I. DISCLOSURE OF RESULTS

Due to the extensive amount of time needed for data processing, it will not be possible to disclose individual research results to subjects.

J. EMPLOYEE PARTICIPATION

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

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 sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, 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.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

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, I may contact **Nathan C Rowland, MD, PhD at 843-792-4165**. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

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 Person Obtaining Consent Date

Signature of Participant Date

IRB Number: «ID»
Date Approved «ApprovalDate»

