If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. plate

tDCS and Cognition in Adults With Multiple Sclerosis or Encephalitis

NCT02538094

Date: 10/17/2016

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Transcranial Direct Current Stimulation and Cognition in Adults with Multiple Sclerosis or Encephalitis**

Application No.: **IRB00033581**

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1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- 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 at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to determine whether transcranial direct current stimulation (tDCS) can improve certain mental abilities, such as working memory. In this research, a device is used to deliver very weak electrical current to the surface of the scalp while participants perform cognitive tasks. Our aim is to find out whether tDCS will improve task performance.

For this study, we will be using one of the following, similar devices: the Iomed Phoresor II Auto, the Chattanooga Ionto, or the NeuroConn DC-Stimulator Plus. Traditionally, such devices have been approved by the Food and Drug Administration for the delivery of salts and other drugs into the body. However, NO drugs or salt will be administered in this study. Instead, the Iomed Phoresor II, Chattanooga Ionto, or the NeuroConn DC-Stimulator Plus will be used only to deliver a weak electrical current while participants engage in cognitive tasks.

Subjects in this study will be asked to participate in several study conditions. The exact conditions and their order will be randomized. That is, they will vary by chance (like the flip of a coin). Under some conditions, they might receive active stimulation (tDCS) and under other conditions, they might receive placebo (or sham) stimulation. Placebo stimulation is similar to active tDCS but lasts only a few seconds.

You must be age 18 or older and be able to understand and comply with the task demands in order to join this study.

You must also belong to one of two groups to join this study:

1. Adults with multiple sclerosis
2. Adults with a history of encephalitis

How many people will be in this study?

About 50 participants will be enrolled in the study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

- Come to our testing office in Fell's Point or at Johns Hopkins Hospital, where the tDCS equipment is located for 11 to 21 study visits. Your involvement in the study would last about 10 to 13 weeks. As shown in the example study calendar below, of those 10 to 13 weeks, you would come in for study visits during only selected weeks and would not come in for study visits during the other weeks (i.e. a "washout period" between sessions).

Study Calendar					
Example 1	**Week 1**	**Weeks 2-5**	**Week 6**	**Weeks 7-10**	**Week 11**
	Come in for study visits 5 days per week	No study visits (washout period)	Come in for study visits 5 days per week	No study visits (washout period)	Come in for 1 study visit
Example 2	**Weeks 1 & 2**	**Weeks 3 - 6**	**Weeks 7 & 8**	**Weeks 9-12**	**Week 13**
	Come in for study visits 5 days per week	No study visits (washout period)	Come in for study visits 5 days per week	No study visits (washout period)	Come in for 1 study visit

- Grant permission for the researchers to view medical records associated with your multiple sclerosis or encephalitis (if you have one of these conditions), or general health.
- Complete a questionnaire and provide a health history in order to verify that you are eligible to participate and able to safely undergo the experimental procedures.

- Complete several computerized, written, and/or aural tasks (i.e., saying words out loud) that assess different cognitive functions such as attention, memory, language, or processing speed.
- Wear electrodes that will be placed on your scalp with a large rubberized band. These electrodes will administer very weak electrical current (tDCS) for 30 minutes.
- Participate in several study conditions. The exact conditions and their order will be randomized. That is, they will vary by chance (like the flip of a coin). Under some conditions, you might receive active stimulation (tDCS) and under other conditions, you might receive placebo (or sham) stimulation. Placebo stimulation is similar to active tDCS but lasts only a few seconds or less. However, all groups will wear the electrodes for the same length of time to prevent you from knowing whether you are receiving active tDCS or sham stimulation. The study doctor and research staff will know which group you are in.
- Permission to audio tape test sessions for later scoring and observation. These tapes will not be viewed by anyone not affiliated with the study without your consent.
- Have one or more structural Magnetic Resonance Imaging (MRI) scans of your brain (if you have not recently had a brain MRI scan as part of your regular clinical care). Additionally, you will be asked to have one or more functional Magnetic Resonance Imaging (fMRI) scans as a part of the study.

  Magnetic Resonance Imaging (MRI) scans create images of the body using a magnet and radio waves. While the procedure is much like a CT scan, there is no radiation involved in an MRI exam. The MRI exam(s) in this study will take about 90 minutes.

  To be sure that it is safe for you to have an MRI exam, you will be asked to complete standard MRI screening questionnaires.

  Since the MRI machine uses a strong magnet that will attract other metals, you may not take part in this study if you have a pacemaker, an implanted defibrillator, or certain other implanted electronic or metallic devices, shrapnel, or other metal.

  If you have a history of metal in your head or eyes, you cannot take part in this study.

  Although the MRI machine is open at both ends, you may still feel confined (claustrophobic). If this bothers you, please tell the MRI staff. The MRI machine periodically makes loud banging noises.

  We will provide earplugs or headphones for you to wear during the MRI exam.

  During the exam, you will be able to hear the MRI staff. They will be able to see and hear you.

How long will you be in the study?

You will be in this study for about 10 to 12 weeks. You will be asked to participate for 5 to 10 days of experimental sessions, and then return about 1 month later for another 5 to 10 days of participation. One month after that, you will be asked to return for a single day of participation. Most days the study will involve 45 to 60 minutes of participation, whereas the initial and final study visits of each 5-10 day study wave will include additional time spent completing the consent documentation (first day only) as well as three hours spent completing cognitive measures and neuroimaging.

Future Contact:

We would like your permission to contact you about other studies that you may be eligible for in the future.

Please check box and sign to indicate your choice below:

YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

4. What are the risks or discomforts of the study?

tDCS

You may perceive a tingling sensation under the electrodes during tDCS. Following tDCS, most people experience no adverse effects. When people do report adverse effects, they typically include fatigue, itching at the electrode sites, headache, or nausea. There are no known serious or long-term risks associated with tDCS.

Behavioral Tasks

You may get tired or bored when we are asking you questions or you are completing tasks and questionnaires. You do not have to answer any question you do not want to answer, although refusing to provide some details of your health history could prevent you from joining the study. You may experience mild fatigue and/or frustration associated with the behavioral tasks.

MRI

While no significant risks have been found from the use of MRI scans, you may be bothered by the MRI machine noise and by feelings of being closed in (claustrophobia).

Incidental Finding

The MRI you may have as part of this research study will be reviewed by a qualified person just as it would be if you were having the MRI as part of your routine medical care. There is a possibility that while reviewing your MRI we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding." We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail or by phone. In the case of a potential serious emergency, someone may go to your home. A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

5. Are there risks related to pregnancy?

If you are pregnant, trying to become pregnant, or nursing a baby, possible risks of being exposed to the stimulation are unknown.

If you are asked to undergo a brain MRI scan, there are no known risks from MRI imaging without contrast during pregnancy. There may be risks that are currently unknown**.**

This research may hurt an embryo or fetus in ways we do not currently know.

6. Are there benefits to being in the study?

There is no direct benefit to you from being in this study.

If you take part in this study, you may help others in the future. The information that we learn from this study may help us understand more about how electrical currents may improve behavior.

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

No.

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).

- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

9. Will you be paid if you join this study?

You will be reimbursed for parking fees as a result of participating in this study. You will be paid at a rate of $15 for each hour (or fraction of an hour) of participation in the study procedures. Payment occurs at the end of the experimental session or, should you choose not to complete the session, payment would occur at that time. If you participate in a study design that involves returning for testing across a number of days, you will receive a bonus payment of $50 if you complete the final session. If you don't, you will still be paid $15 for each hour you do complete.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total

payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical 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 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 (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be redisclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

14. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you? The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Tracy Vannorsdall at 410-955-3268. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Arun Venkatesan at 410-955-6626 during regular office hours.

d. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

15. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time
Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.