

***Appendix B:* *Consent Form***

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The Enhancement of Motor Training of the Non-dominant Upper Extremity via rTMS and tDCS

1. **Introduction**

You are being asked to volunteer for a research study because you are a healthy, right- handed adult. Please read the following paragraphs carefully. If you have any questions or concerns regarding participation in this study, you are encouraged to raise these concerns with the investigators. The research is sponsored by the Department of Exercise Science at the University of South Carolina. The investigator in charge of this study is Raymond J. Butts. Raymond Butts is presently a graduate student conducting this study to fulfill a PhD degree requirement.

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***Purpose of Study***The purpose of this study is to determine how two forms of brain stimulation, transcranial magnetic stimulation (TMS) and transcranial direct current stimulation (tDCS) may help to enhance motor training of the left upper extremity. We will use TMS and tDCS to pass a weak electrical current into the area of your brain responsible for active movement. This current will increase nerve activity or the likelihood of nerve activity under the location we are stimulating. In the current study, we are interested in the most appropriate time to use TMS and tDCS in combination with motor training of left upper extremity in order to optimize the benefits of the training. TMS and tDCS will be presented either prior to training, during training, or prior to and during training. Training will consist of 4, 9-minute sessions made up of exercises that will simulate typical activities of daily living. Improvements made during training will be recorded immediately following, 24 hours after, and 7 days after completion of the four days of training. The data obtained through your participation may help to find better ways of helping patients that have suffered a stroke regain function.

***Eligibility to Participate***Approximately 58 healthy adults will participate in the current study. You must meet the following criteria: 1) be right handed 2) be a native speaker of English and 3) be able to provide informed written or verbal consent and 4) be between the ages of 18 and 30. Only participants who clearly understand the research and are able to indicate consent to participate can be enrolled in this study. You must pass a TMS and tDCS Safety Screening along with a general Neurological Symptoms Screening in order to participate in this experiment.

**Description of Study Procedures**If you agree to be in this study, the following will happen:

1. If you qualify and agree to participate, you will take part in 8 separate sessions according to the following schedule. (See chart below for a sample schedule)

**Session 1:**

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You are presently completing session 1, whereby all necessary paperwork will be filled out to participate in this study. If you are reading this form, then you have already completed all screening forms associated with this study, and you have been cleared to participate in the investigation. The final step to complete session 1 is to read and sign this informed consent form. Upon completion, you will receive a schedule, to include dates and times of sessions 2-8.

**Session 2:**

Seven days prior to beginning motor training, participants will meet on the second floor of the Discovery I building with Raymond Butts. Ray will provide instruction on all exercises that will be included in motor training. Participants will be asked to practice the exercises X10 times each during this session. In addition, TMS will be used to map a specific region of the brain that is responsible for moving the thumb. This region will provide the target for TMS and tDCS during motor training with the left upper extremity.

**Session 3:**

The third session will take place on a Monday and within 7 days of Session 2. During Session 3, participants will use their left hand to complete 3 assessment tests involving the same tasks practiced during Session 2. Afterward, participants will receive either TMS, tDCS, or both in accordance with their assigned group and complete their 9-minute training session.

**Session 4-5:**

During Sessions 4-6, participants will receive the same stimulation as during Session 3, and they will complete the 9-minute training program.

**Session 6:**

The last day of stimulation / motor training will occur during session 6. Immediately following training, participants will complete the same assessments as during Session 3.

**Session 7:**

Participants will return 24 hours after completion of motor training to complete the same 3 assessments.

**Session 8:**

Participants will return 7 days after completion of motor training to complete the same 3 assessments.

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Version Valid Until:

Participation in this study will take approximately 3 weeks in total. The following is an example schedule:

3) **Statement of Health Risks**

**tDCS:**

Transcranial direct current stimulation involves the application of weak electric currents (generated by a single 9-volt battery) to change the firing rates of neurons under the scalp. The actual current entering your brain during tDCS is very small. tDCS has been used safely in hundreds of experimental studies. tDCS is safe to use when performed at parameters established by previous investigations. The tDCS parameters used in the present study have been verified with parameters previously established as being safe. This study will stimulate the brain at .02857 mA/cm2, a current density approximately 1000 times lower than the previously established safety threshold. Please be aware that the application of tDCS may cause you some temporary discomfort. You may notice some mild tingling where the electrode is placed on your scalp. It is also possible that you may feel some fatigue after treatment or some itching under the site where the electrode was placed on your scalp. There is a small chance you will experience a headache, nausea, or insomnia (1%). It is not absolutely known that these are the only risks associated with tDCS. Thus, it may be possible that there are unknown risks associated with the application of tDCS.

The effects of tDCS are temporary, and it is not known to cause any permanent effects, either beneficial or harmful. Please report any adverse effects you may experience during tDCS stimulation to the experimenter so that they can monitor these symptoms.

**TMS:**

Like tDCS, stimulation with TMS may also result in a minor headache or discomfort at the site of stimulation. An addition risk of TMS is seizures, which are thought to be caused by

group of nerves that become hyper-synchronized. According to the 2008 Safety of TMS consensus group, the risk of seizures with repetitive TMS is VERY low. Out of 3000 studies published within the last 10 years, only 17 have resulted in seizures, 12 of which occurred following parameters that exceeded clinical safety guidelines. The current study is accordance with these guidelines. Of the 4 studies that met the clinical safety guidelines, all participants suffered from additional neurological impairments. All TMS seizures have occurred under close observation. All seizures have stopped spontaneously with no long-term adverse effects. Importantly, no one has ever developed a recurring seizure disorder (epilepsy) after a TMS induced seizure.

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4) **Participant Injury**

In the unlikely event that you are injured as a result of your participation in this study, the research staff will assist you in obtaining appropriate medical treatment. However, you will be responsible for any costs associated with medical treatment.

5a) **Benefits of Participation**There is no prediction that participants will directly benefit from participation in this experiment. Although greater motor function with the left upper extremity may result from TMS / tDCS stimulation and training, the effects may be short-term.

5b) **Participant Compensation**

Participants will be compensated for their participation at the rate of $100 for the entire experiment. In the event that you should wish to discontinue your participation, which you may do at any time, you will be paid for the time you have already invested in the experiment (rounded up to the nearest half-hour).

6) **Data Confidentiality and Participant Identification**

Your name will not be used in any publication that may result from this study. The USC Office of Research Compliance may request access to this form to ensure procedures designed to protect research participants are being properly followed. Your data may also be shared with other researchers around the world or with a publicly available data archive. In such cases, every reasonable effort will be made to remove identifiers from the data that would indicate any connection to you (e.g. the removal of your name, address, etc.). Any information that is obtained in connection with this study and that could identify you will remain confidential and will not be released or disclosed without your further consent, except as specifically required by law.

7**) Expiration Date on the Viability of the Collected Data**

Data concerning your age, gender, handedness, task performance, etc. will be collected. All data gathered from this study will be maintained by the principle investigator for three-years or as required by journal, federal or state regulation.

**8) Voluntary Withdrawal**

Participation in this study is voluntary. You are free to withdraw your consent and discontinue participation in the study at any time throughout the study without negative consequences to your relationship with the University of South Carolina.

**9) Involuntary Withdrawal**You may be removed from the study if you do not adhere to the study guidelines outlined above (e.g. failure to show up for assigned appointments) In the case of involuntary removal from the study you will be paid for all work completed to that point in the study (rounded up to the nearest half-hour).

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**10) Investigator Contact Information**

This research is being conducted by faculty and researchers of the University of South Carolina. For further information about this study, you may contact:

Roger Newman-Norlund

Department of Exercise Science

Phone Number (Cell): (910) 713-8672

Phone Number (Office): (803) 777-7167

Email: rnorlund@mailbox.sc.edu

Raymond Butts

Department of Exercise Science

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Email Address: buttsraymond@yahoo.com

If you have any questions regarding your rights as a research participant, you may contact:

Thomas Coggins, Office of Research Compliance, University of South Carolina, Columbia, SC 29208, Phone: (803) 777-7095.

**11) Participant Signatures**I have read this informed consent form and have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. I agree to participate in this study. I have received (or will receive) a copy of this form for my own records.

Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_

Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_\_\_