**USC Brain Stimulation Lab General Policies**

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1. General: TMS may only be performed upon completion of the Brain Stimulation Laboratory Core TMS Training and with the subsequent written approval of the Lab Director, Dr. Roger Newman-Norlund. This training includes confirmation of completion of required USC Human Subjects and HIPAA training modules, training in human subject research, familiarity with Brain Stimulation Laboratory policies, and familiarity with the safe operation of the TMS software and hardware. When available, primary investigators of TMS studies will also complete the official TMS safety and application course at MUSC prior to operating TMS equipment at USC. TMS may only be performed in the official USC Brain Stimulation Lab at the Discovery I site.

A USC-approved, IRB-approved, TMS-trained investigator may perform single pulse TMS studies, double-pulse TMS studies (such as those used to measure intra-cortical inhibition), theta-burst studies, low frequency (1 Hz or less) repetitive TMS, or repetitive TMS protocols which have not resulted in seizures or other side-effects in healthy subjects without supervision if done in accordance with these policies.

For single pulse TMS studies of subjects with a condition associated with reduced seizure threshold (such as structural brain abnormality or neurologic condition) and for any studies using TMS in the repetitive-TMS mode at a frequency > 1 Hz, additional guidelines must be followed. These studies can only be performed when a certified American Red Cross Adult CPR / First Aid trained investigator is present on the second floor of the Discovery I building. In the unlikely case that a seizure does occur (the primary safety concern), a proper response must be initiated. All investigators will be trained to recognition and respond to seizures (see item 9 below). Emergency personnel (Palmetto Richland) will be notified (by phone) immediately. In order to minimize the chances of inducing a seizure, all TMS protocols of any variety must be approved by Dr. Newman-Norlund **and** be in accordance with current recommended safety guidelines41 prior to beginning any study.

tDCS may be performed in accordance with IRB-approved studies provided that investigators complete the USC Brain Stimulation Lab tDCS training course. This course will ensure that investigators are familiar with all potential risks of tDCS. Participants will also be required to demonstrate proper set-up / break-down of the equipment along with safe application of the technology. Training will be provided by senior faculty (Dr. Newman-Norlund, Dr. Julius Fridriksson) who oversee the USC Brain Stimulation Lab.

2. Hardware: Prior to performing TMS/tDCS studies, the investigator must demonstrate familiarity with, and safe operation of, all hardware involved. (This includes buts is not limited to computers, trigger cables, sham blinding devices, the TMS front panel, amplifiers, TMS coils, and (if used) the frameless stereotaxic components.) These components are very expensive and the investigator assumes cost of replacement if devices are damaged due to improper or irresponsible use. Familiarity with replaceable components, such as EMG lead materials, is also important. Please notify Dr. Newman-Norlund if replaceable supplies need re-ordering.

3. Software: The investigator must demonstrate familiarity with all software to be employed including Scope for motor evoked potential recordings, programs needed to transfer TMS/tDCS data as needed and (if used) for frameless stereotaxic methods. No software is to be installed by users on TMS/tDCS lab computers—software is to be installed only by the Brain Stimulation Laboratory Core personnel, otherwise software conflicts will be inevitable. The investigator must contact the Dr. Newman-Norlund for a TMS room computer account/login/password.

4. Compliance with rules: The investigator must comply with all USC IRB and Brain Stimulation Laboratory rules, general and those specifically outlined herein. Approval must be obtained from USC IRB and from the director of the Brain Stimulation Laboratory for all studies performed. Paramount among these rules for the current context is that TMS/tDCS may only be performed in the Discovery I site (Suite 216). A TMS, tDCS and Neurologic Screening Form must be completed as below.

5. Earplugs: All subjects in the TMS room during any TMS studies must wear protective earplugs.

6. TMS/tDCS Screening: According to Dr. Mark George (MUSC), a full neurologic evaluation by a medical doctor has not been shown to be necessary prior to TMS, as it **DOES NOT** add to the overall safety of the participant. This finding was substantiated by a recent TMS Consensus Group. For all subjects, a TMS/tDCS Screening Form, akin to an MRI Screening Form, must be completed for all subjects, signed prior to any TMS/tDCS performance, and placed in the ‘signed form bin’ that sits on the TMS Room desk. Any ‘Yes’ response on the tDCS screening form (other than item1, which is a relative contraindication, and may therefore be approved on a case-by-case basis as an exception by Dr. Newman-Norlund) requires that the subject be explicitly approved by Dr. Newman-Norlund and a medical doctor before tDCS is performed. Because of the increased risk of TMS, a ‘Yes’ response to any of the items on the TMS Screening form (with the exception of items 10, 12, and 13) precludes performance of any variety of TMS unless explicit exception is granted by Dr. Newman-Norlund and a medical doctor. Participants answering ‘Yes’ to item 10 may still undergo TMS, provided medicines are not being used to treat depression and/or psychotic conditions. Questionable medications will be referred for approval by a medical doctor prior to participation in the study. In addition, a ‘Yes’ response to any question on the Neurologic Screening Form will preclude participation in any TMS study. Participants will be advised to seek a medical evaluation to determine the cause of their neurologic symptoms. When a participant is studied a second time, either a new screening form must be completed, or the prior form must be initialed/dated to indicate that all responses are still accurate.

The following drugs have been identified as having seizure threshold lowering capability. As per the findings of the most recent systematic review on TMS safety41, the drugs have been divided into two groups: relative hazards and strong relative hazards. The USC Brain Stimulation Lab will not expose participants to TMS or tDCS if they are taking the drugs and going through withdrawal of the drugs in either category. Only lab personnel cleared to perform TMS and tDCS on subjects per “1.” are authorized to screen participants for these drugs. A review of seizure threshold lowering drugs will be included as part USC Brain Stimulation Lab Certification, and screeners will maintain the following list of drugs during the screening process. The list of seizure threshold lowering drugs will also be made available to all participants during the screening process. Participants taking drugs for depression and/or psychotic conditions that are not on the list will be referred to a medical doctor before being allowed to participate in the study.

**Relative Hazards**

* Mianserin (Bolvidon, Norval, Tolvon)
* Fluoxetine (Prozac)
* Fluvoxamine (Luvox)
* Paroxetine (Aropax, Paxil)
* Sertraline (Zoloft)
* Citalopram (Celexa, Cipramil)
* Reboxetine (Edronax. Vestra)
* Venlafaxine (Effexor, Efexor)
* Duloxetine (Cymbalta, Yentreve)
* Bupropion (Aplenzin, Wellbutrin, Wellbutrin SR, Wellbutrin XL)
* Mirtazapine (Remeron, Avanza, Zispin, Reflex)
* Fluphenazine (Prolixin)
* Pimozide (Orap)
* Haloperidol (Haldol)
* Olanzapine (Zyprexa, Zalasta, Zolafren, Olzapin, Oferta, Zypadhera or in combination with fluoxetine Symbyax)
* Quetiapine (Seroquel)
* Aripiprazole (Abilify, Abilify Discmelt)
* Ziprasidone (Geodon)
* Risperidone (Risperdal)
* Chloroquine (Aralen)
* Mefloquine (Lariam)
* Imipenem (Primaxin)
* penicillin
* ampicillin (Omnipen, Polycillin, Principen)
* cephalosporins (Cephalosporium)
* metronidazole (Flagyl)
* isoniazid (Laniazid, Nydrazid)
* levofloxacin (Levaquin)
* cyclosporine (USAN, BAN)
* chlorambucil (Leukeran by GlaxoSmithKline)
* vincristine (Oncovin)
* methotrexate (Trexall, Rheumatrex)
* cytosine arabinoside (Cytarabine)
* BCNU (Carmustine)
* Lithium (Eskalith CR, Eskalith, Lithobid)
* Anticholinergics (ipratropium, Atrovent, ipratropium, albuterol, Combivent, DuoNeb)
* Antihistamines (Allegra, AllegraD, Astelin, Clarinex, Claritin)
* Sympathomimetics ([ephedrine](http://en.wikipedia.org/wiki/Ephedrine), [pseudoephedrine](http://en.wikipedia.org/wiki/Pseudoephedrine), [amphetamine](http://en.wikipedia.org/wiki/Amphetamine), [methamphetamine](http://en.wikipedia.org/wiki/Methamphetamine), [methylphenidate](http://en.wikipedia.org/wiki/Methylphenidate) (Ritalin), [lisdexamfetamine](http://en.wikipedia.org/wiki/Lisdexamfetamine) (Vyvanse), [cocaine](http://en.wikipedia.org/wiki/Cocaine) (found in [*Erythroxylum coca*](http://en.wikipedia.org/wiki/Erythroxylum_coca), Coca), [cathinone](http://en.wikipedia.org/wiki/Cathinone), [cathine](http://en.wikipedia.org/wiki/Cathine), [benzylpiperazine](http://en.wikipedia.org/wiki/Benzylpiperazine) (BZP), [methylenedioxypyrovalerone](http://en.wikipedia.org/wiki/Methylenedioxypyrovalerone) (MDPV), [4-methylaminorex](http://en.wikipedia.org/wiki/4-methylaminorex), [pemoline](http://en.wikipedia.org/wiki/Pemoline) (Cylert), [phenmetrazine](http://en.wikipedia.org/wiki/Phenmetrazine) (Preludin), [propylhexedrine](http://en.wikipedia.org/wiki/Propylhexedrine) (Benzedrex)

**Strong Relative Hazards**

(Participants are considered a strong relative risk of seizures if they are going through withdrawl from one of the following drugs)

* alcohol
* barbiturates (Examples include amobarbital, butalbital, cyclobarbital, pentobarbital, allobarbital, methylphenobarbital, phenobarbital, secobarbital , vinylbital)
* benzodiazepines (Examples include *Xanax,Valium,Klonopin,Ativan,Restoril,Halcion)*
* meprobamate (Equanil, Mepriam)
* chloral hydrate ([Somnote](http://www.drugs.com/cdi/somnote.html), [Aquachloral Supprettes](http://www.drugs.com/cdi/aquachloral-supprettes-suppositories.html))

7. Emergency phone numbers to both the Thompson Student Health Center and Palmetto Richland Hospital will be clearly posted in the USC Brain Stimulation Lab, in the case of emergency. In addition, the name and cell phone number and office number of the CPR/First Aid trained responder that is “on call” will be posted prior to all TMS studies. Investigators must also be familiar with the Lab Policy for seizures, which is: (a) Call 911 for emergency assistance in most cases. (b) Alert the CPR/First Aid trained responder that is “on call” (c) Follow procedures set out by the American Red Cross for caring for patients that are having a seizure. The following “Seizure Symptoms” and “Seizure First Aid Steps” will also be posted in the USC Brain Stimulation Laboratory:

**Symptoms of a Seizure (American Red Cross):**

* A sudden rise in body temperature
* A change in the level of consciousness
* Rhythmic jerking of the head and/or limbs
* Unintentional urinating or defecating
* Confusion
* Drowsiness
* Crying out
* Becoming rigid
* Holding the breath
* Upward rolling of the eyes

**First Aid for a Seizure (American Red Cross)**

* Do not try to hold or restrain the victim.
* Protect the victim from injury and maintain an open airway.
* Remove nearby objects that could cause injury.
* After the seizure, position him or her on one side so that fluid can drain from the mouth.
* Check for life-threatening conditions.
* Stay with the victim until he or she is fully conscious and aware of his or her surroundings.

8. Reserving the TMS/tDCS room: The TMS room is shared by many investigators. Dr. Newman-Norlund is in charge of the calendar to the TMS room. Please contact him with the desired times.