

Donders Centre for Cognition (DCC)

Regulations and guidelines for brain stimulation research at the DCC (Version 1.4).

1. Research ideas that involve brain stimulation have to be presented first during the Brain Stimulation meeting at the DCC. During these meetings practical as well as ethical issues of the research idea will be discussed. Note, all brain stimulation research at the DCC has to be approved by the CCMO (centrale commissie mensgebonden onderzoek). The discussion at the brain stimulation meeting will help to provide a decent protocol to the CCMO. Different rules apply for pilot studies, which are described in the ***pilot-study*** document.
2. Everybody who desires to use brain stimulation needs to be familiar with the side effects and safety issues of the techniques as summarized by:
 - a. For TMS experiments: “Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research” by Rizzo et al. 2009.
 - b. For tCS experiments: “Regulatory considerations for the clinical and research use of transcranial direct current stimulation (tDCS): Review and recommendations from an expert panel” by Fregni et al. 2014.
3. Everybody who desires to use brain stimulation needs to be trained by an expert brain stimulation researcher in order to use all equipment properly (***brain stimulation training***). Also, all ECU’s and SECU’s need to be in possession of a safety training certificate. This is important:
 - To provide safety for the participant and the researcher.
 - To prevent damage to the equipment.
 - To ensure properly executed research.

A researcher that has been trained will become a certified user (CU):

* Regular certified user (RCU) – Can perform brain stimulation experiments (i.e. is familiar with the equipment hardware and software and knows how to use it) and is aware of safety concerns. At least 15 hours of labwork.

** Expert certified user (ECU) – Has experience performing brain stimulation experiments (as demonstrated by publications, internships,

courses, etc.) and has received a safety training certificate. Also, an ECU is familiar with all equipment and is able to train researchers that desire to perform brain stimulation.

*** Senior expert certified user (SECU) – Expert in brain stimulation (as demonstrated by, for example, publications, internships, courses, etc.). Has responsibility over all brain stimulation labs and equipment. Only one researcher can be SECU to avoid diffusion of responsibility (Dennis Schutter; Status: 07-07-2015)

To perform brain stimulation experiments the researcher must have at least the status of RCU. Significantly shorter trainings can be provided for researchers that have had experience with brain stimulation in other institutes.

4. All brain stimulation research needs to be done under the oversight of a brain stimulation group (Dennis Schutter, Rogier Mars; Status: 16-04-2015).
5. A “buddy-system” applies for doing research with brain stimulation. A buddy needs be familiar with the brain stimulation safety guidelines. The following rules apply:
 - a. RCU’s are only allowed to test during business hours (9.00-17.00). For tCS and TMS research a buddy needs to be present in the lab or in direct vicinity of the lab until the end of the experiment
 - b. ECU’s and the SECU are allowed to perform TMS and tCS both during and after business hours (also during weekends). During business hours, no buddy needs to be present. Outside business hours buddy needs to be present in the lab or in adjacent room. See “DCC buddy rules” document for more details.
6. During and after brain stimulation the primary researcher is not allowed to leave the lab environment as long as the participant is present.
7. Any incident concerning the health of the participants needs to be reported to the SECU and documented in detail (***incident-logbook***):
 - a. The type of incident (fainting, headache, seizure, etc.)
 - i. Severity of incident.
 - ii. Duration of incident.
 - iii. Prior history of similar incidents in this person.
 - b. The situation/timing the incident occurred in (before, during or after stimulation).
 - i. The type of stimulation that has been used (e.g. 1 Hz rTMS, cTBS, 10 Hz tACS, etc.).

- ii. The exact time point the incident happened (e.g. 2 minutes after the start of stimulation, 10 minutes after the end of stimulation, etc.).
 - iii. Provide if possible other details (participant reported being nervous, room temperature was high, light intensity was strong, participant looked pale, etc.).
 - c. The action that has been taken to help the participant. Be as specific as possible. Also, report if external assistance was acquired. In this case also specify who assisted (buddy, general practitioner, emergency help (55555 or 112)).
---NB. Participants can get Paracetamol only if specifically asked for. Any other medication cannot be provided by the researcher.---
 - d. Report how long the care of the participant lasted and how the participant left the experiment (i.e. the participant was able to leave without assistance; a friend or family member was contacted to pick up the participant; the participant left in an emergency vehicle).
8. A ***presence logbook*** needs to be signed when experiments are performed in the TMS lab.
 9. In the case of equipment failure or damage to (part of) the equipment abort the experiment and inform the SECU.
 10. After completing all experiments of a study fill out the ***Study Overview*** document.
 11. A yearly report (December) will be made that will give an overview of all experiments (number of TMS/tCS studies, number of participants, etc) incidents concerning brain stimulation experiments at the DCC.