NIBS Procedures at the Faculty of Psychology and Neuroscience at Maastricht University

---

In this document, the following is discussed:

Aim of this document

This document describes the procedure for administration of NIBS in an experimental context, at the Faculty of Psychology and Neuroscience (FPN), Maastricht University. It has been assessed and approved by the Ethics Review Committee of Psychology and Neuroscience (ERCPN) and consists of professional standards for safe and meaningful NIBS experimentation. It is based on published and generally recognized guidelines and adapted to the local situation. The procedures and NIBS protocols described in this document provide safety and best practice constraints to which all administration of NIBS at FPN must adhere.

Glossary of functional roles

CU = Certified User, allowed to operate NIBS application
NIBS advisor, allowed to approve NIBS projects
NIBS assessor, allowed to award CU status

Starting a NIBS study: project approval

In order to be allowed to start a NIBS study, the following steps must be taken:

1) The project must obtain **ethical approval from ERCPN**. An applicable ERCPN code must be available before proceeding to the following steps.

2) The project must be presented at a **project proposal meeting (PPM)** organized by the NIBS advisors.

NIBS advisors advise, provide feedback on, and must ultimately approve the planned NIBS project presented during the NIBS PPM. NIBS advisors will

1. provide feedback on the experimental design
2. provide feedback on ethical concerns related to the proposed research
3. check safety of the NIBS parameters.

A project proposal should take maximally 30 minutes and includes a slideshow that contains minimally the following information:

1. background
2. research question
3. experimental design, main stimuli and tasks
4. NIBS approach and parameters
5. planned analyses and hypotheses.

To plan a PPM meeting, contact the PPM coordinator Teresa Schuhmann (t.schuhmann@maastrichtuniversity.nl)

3) The researcher must complete a **NIBS PPM approval form** after the PPM presentation and send this to the PPM coordinator. A final form must be signed by two NIBS advisors not *directly* involved in the preparation of the project proposal, in absence of communicated objections by other NIBS advisors.

In sum, a NIBS project may only be conducted after ERCPN approval has been obtained AND at least two NIBS advisors have advised positively and signed the PPM form of the project.

NB1 For each and every measurement involving NIBS, a NIBS Certified User, with certification for the NIBS method that is used, must be present during stimulation.

NB2 For NIBS measurements that include (f)MRI in any form or stage, the project must adhere to (f)MRI procedures as well, which are handled by the (f)MRI project proposal committee and generally requires a project proposal in an (f)MRI project proposal meeting. Project approval by NIBS advisors does not imply approval for (f)MRI, independently of whether (f)MRI is sequential or simultaneous with NIBS. See section on multimodal measurements below.

TMS and/or TCS Certified User: certification types and procedures

At FPN, in- or outside the NIBS labs, any NIBS (transcranial magnetic stimulation (TMS) and transcranial current stimulation (TCS)) administration must be supervised or executed by a certified user (CU). No NIBS can occur without a CU present, this is to ensure participant safety and comfort. No montage application for TCS can occur without a CU present. There are different types of CU status.

1. TMS CU: certified for all TMS protocols and multimodal TMS. Not TCS.
2. TCS CU: certified for all TCS protocols and multimodal TCS. Not TMS.
3. NIBS CU = TMS CU & TCS CU: certified for all TMS and TCS protocols and multimodal NIBS.
4. Internship TCS CU: certified for TCS. These CU's will not be allowed to check the initial main screening form of the participants.

FPN students are only eligible for 'internship TCS CU' status. UM or outside staff is eligible for the other NIBS CU statuses. Below, the requirements and CU training procedures are detailed.

NB: TMS, TCS, and NIBS CUs can operate and supervise operation of NIBS equipment. Internship TCS CUs can only operate NIBS equipment themselves.

TMS CU, TCS CU, NIBS CU
The CU training demanded and offered by FPN is a practical training. Theoretical knowledge of NIBS must be obtained by eligible staff/students independently, prior to the CU training and is the responsibility of the aspirant CU.

Basic requirements:
1. Attendance of a dedicated NIBS (certification) (safety) course, or hands-on training by NIBS CUs and perusal of NIBS advisor prescribed literature on NIBS procedures and safety.
2. Knowledge of FPN/UM procedures for handling participants and using NIBS.
3. Hands-on training by existing NIBS CUs until it is ensured that the NIBS equipment can be used both safely and efficiently. CU status can only be awarded by 'NIBS assessors': a select group of senior NIBS users employed by FPN. 'NIBS assessor' status can only be awarded by the head of the Brain Stimulation and Cognition section.
4. Signature on a document stating that certified user has read and understood all items and will comply with regulations.

Internship TCS CU
Internship students, meaning students that have an active role in a section at Cognitive Neuroscience Department at FPN, contributing to a TCS project satisfying all ERCPN regulations, are eligible to obtain the *internship TCS CU* status.

The procedure to obtain internship CU status is the same as the procedure to obtain regular CU statuses described above. Students need to receive formal documentation and training by a current CU, and be assessed by a NIBS assessor.

Internship TCS CU status is linked and limited to a particular project, allowing focused training. One NIBS advisor is responsible for both the training and that project with all associated measurements. The responsible NIBS advisor is informed of planned measurements, and is responsible for the TCS safety screening. Internship TCS CUs can do the pre-experimental check form screening, but not approve the participant screening form. Whenever a measurement is performed by an internship TCS CU, a TCS CU or NIBS CU must be on standby and reachable via mobile phone.

Participant screening

FPN NIBS measurements can only proceed after participants have been screened for contraindications, and approved for participation by Certified Users. At FPN, we utilize conservative screening criteria. Participants must complete the **participant screening form** for NIBS. These screening forms for NIBS, including TMS and the various forms of TCS, are continually updated as required based on the latest insights and community best practices. For each new study, researchers should ensure that they use the latest version of all forms. These will always be available in the NIBS documentation folder. Assessment of the screening forms is part of the Certified User training. The screening forms cover all the relevant aspects of NIBS safety related to individual participant circumstances, and internationally agreed contraindications.

Aside from the participant screening form, participants complete a **pre-experimental check form** for NIBS. Participants can fill out a participant screening form once for their first NIBS participation. In future sessions, *if the filled out form is still the latest version*, they can be asked to check their responses to ensure they are still accurate. In this case, they report on the pre-experimental check form that their screening responses are unchanged. The pre-experimental check form includes several additional questions that are relevant for NIBS safety/comfort, related to things that change from session to session (e.g. alcohol consumption in the last 24 hours, whether the participant is well-rested on the day of measurement, etc.).

In sum, participants fill out

- participant screening form (only if form or responses changed)
- pre-experimental check form (every session with NIBS)
- (written informed consent form)

All these forms must be signed by the participant and a Certified User before NIBS can be applied.

NIBS experimental procedures

Participant treatment

1) Participant will receive the 'participant information'. Templates are available in the NIBS documentation folder, and differ between TMS and TCS. The participant information templates include information about the risks and tolerability of NIBS, as well as relevant contact information. For each study, researchers adapt the templates to suit their experiment.
Participants can receive this information digitally before the session, or during the session. But in either case, they must receive ample time to review this information in the lab, and be explicitly allowed all opportunity to ask questions.
If participants have not previously been familiarized with NIBS, the researcher should reserve time to explain the machinery and associated procedures. For instance for TMS, demonstrate the device, apply low-intensity pulses to the hand, and explain the different components. Never rush the NIBS session, rather reserve a longer time slot. This can be very effective in reducing nervousness and ensuring well informed and comfortable participants.
2) Participant will complete or review the NIBS participant screening form. They fill out the pre-experimental check form.
3) Participant may receive further information as appropriate and provides written informed consent (see ERCPN website).
4) The experimenter emphasizes that participants can quit the experiment at any time without explanation, and that in such case they will still receive compensation for their time.

During any NIBS session a first-aider or so-called 'bedrijfshulpverlener' (BHV; someone trained in dealing with emergency situations) will at least be on call (**number: 1333 from internal phone, +31433875566 from mobile phone**), if not physically present. Outside working hours, NIBS can only be administered with one CU present (as always), and a second NIBS CU on standby for assistance. Of these, at least one must be trained as BHV.

Procedure for incidents

1. If an incident has taken place in a lab, e.g. someone has fainted, the user should report the incident to the lab coordinator (Teresa Schuhmann) within 24 hours.
2. The lab coordinator must then inform the prevention officer by completing the attached form and sending it to info-crisp@maastrichtuniversity.nl (please add Pascal Stevens, email address: pascal.stevens@maastrichtuniversity.nl and Huub Hamers, email address: h.hamers@maastrichtuniversity.nl in CC).

Stimulation parameters

For NIBS, the safety and tolerability of protocols depend on an interaction between many factors such as intensity, frequency, train duration, inter-train intervals, stimulation site, coil geometry, single-coil vs multi-coil approaches, etc. There are an infinite number of possible protocols and it is impossible to put categorical constraints on any isolated parameter without taking the others into account. That is why researchers are advised to base their protocols as much as possible on published protocol consensus guidelines where safety guidelines are provided for a range of basic protocols. But the FPN NIBS advisors will provide feedback on and take the final decision on the proposed protocol. This is why stimulation parameters must be presented, and explicitly included in the PPM approval form for registration. Researchers in FPN NIBS labs are not allowed to administer NIBS beyond the protocols explicitly approved by the NIBS advisors and registered on a NIBS PPM approval form.

NIBS coil placement and montage instructions

For TMS, coil placement is practiced extensively in the CU training. As a general rule, ensure that the coil 'hotspot' touches the skull and the coil is placed tangentially. The coil should be positioned snugly, but without uncomfortable pressure. Especially when using coil holders, check with participants whether they are comfortable also *after* the coil has been fixed.

For TCS, electrode patches are applied to the head of the participant. **NO scratching or scrubbing of the skin is allowed!** Moreover, prior to placement of the electrodes, the skin underneath and around the electrodes **must be checked for spots or micro-lesions** that could enable condensed current as opposed to diffuse current underneath the surface of the electrode. The cable connectors must be fully inside the electrodes (no metal showing), or the metal connectors must be insulated. Electrode impedance should be checked and ideally be below 5-10 kiloOhm (the higher the impedance, the more uncomfortable the stimulation can be). **Ensure that whenever you are checking the impedance or stimulating you do not unplug any of the cables attached to the participant.** If impedance is unacceptable, instead of scratching or scrubbing, the CU can apply more gel, or attempt to position the electrodes more firmly. But 'bridges' of conductive fluids, gel, or paste, between TCS electrodes and/or EEG electrodes should be avoided.

Additional safety information and procedures

Equipment

All equipment used for NIBS is checked for safety by FPN IE minimally once per year. Only Certified Users will operate equipment, or supervise the operation of equipment if the experimenter is an aspiring Certified User in training. At no time, brain stimulation can occur without a Certified User present in the lab. Additionally, for TCS, the preparation of NIBS (i.e. the application of the electrode montage) cannot proceed without a Certified User present in the lab to supervise.

TMS and TCS equipment, as well as other (e.g. EEG, EMG, response box) equipment used in the NIBS labs, must be cleaned after use. Dedicated guidelines exist for the handling and cleaning of EEG equipment and materials (see FPN EEG procedures). For TMS, the casing of TMS coils must be cleaned, without water, using cloths or paper towel, using disinfectant in moderation as deemed appropriate/necessary. For TCS, the electrodes ('rubber electrodes') must be washed, avoiding water in the contact points as much as possible. The electrode cables must be washed and dried and rubbed clean. Towels used must be hung to dry on the available racks, not on equipment or on chairs.

Repeated stimulation or multi-coil stimulation

In the context of single planned experiments, TMS protocols can be applied repeatedly within a day or in successive days. However, TMS cannot be applied more than once within 24 hours for different studies. This is because the NIBS advisors can evaluate the risk of repeated NIBS of single studies, but cannot assess the risk involved when a single participant partakes in different studies within a short time span since those studies were evaluated by NIBS advisors in isolation. In principle, NIBS at FPN involving multiple coils, or combined protocols or successive protocols are not restricted categorically, but will be evaluated on a case by case basis by NIBS advisors.

After the experiment

For TMS, experimenters must ensure participant comfort also once the protocol/experiment has ended. Emphasize that participants are free to use the supplied contact information if they have questions or experience adverse effects also after the session. In experiments with repeated sessions, experimenters should explicitly ask about experiences after the most recent NIBS measurements.

For TCS, experimenters should check the skin underneath the TCS electrodes, once the electrodes have been removed. Even if participants do not report it, take note of the skin and its colour, to ensure no adverse effects occurred. As for TMS, inquire in future sessions about past experiences.

For NIBS in combination with EEG, or TCS, participants should be offered the opportunity to wash their hair. The procedure is different for different NIBS labs, and is part of the CU training.

Hearing protection

For TMS specifically, one adverse effect involves hearing damage. TMS pulses can be loud, especially if the coil is located close to either ear. Because this risk is dependent on the combination of coil position, TMS intensity, and TMS protocol parameters, it remains at the discretion of TMS CUs whether hearing protection is required/appropriate for the session. But as a rule of thumb, if possible in the context of the experiment, ear plugs should be provided to participants for at least the ear closest to the TMS coil.

Multimodality

NIBS may be combined with the following additional measurements:

- Behavioural and psychophysical measurements
- Eyetracking measurements
- EMG measurements
- EEG measurements
- fMRI measurements
- TMS and TCS simultaneously or successively
- With combinations of all these methodologies (e.g. TMS-fMRI-EEG, or TMS-TCS-EEG-EMG)

For NIBS-fMRI combinations (with or without other methods), NIBS advisors *and* the (f)MRI PPM must see and approve the project proposal.
For NIBS-EEG combinations, only NIBS advisors need to approve the project proposal, as long as the EEG measurements are performed in the NIBS labs of FPN. Studies involving the EEG labs of FPN require further approval of the EEG PPM.
While these methods are all approved for simultaneous or sequential combination, NIBS advisors will evaluate each proposed project on a case by case basis. This is because the safety and tolerability of each hypothetical combination depends on the specifics and parameters of the proposal.

Addresses

Coordinator Laboratories and Procedures and Safety NIBS,

- Teresa Schuhmann, t.schuhmann@maastrichtuniversity.nl

Operational Lab Manager

- Felix Duecker, felix.duecker@maastrichtuniversity.nl

Section head Brain Stimulation and Cognition

- Teresa Schuhmann, t.schuhmann@maastrichtuniversity.nl

Server location for useful NIBS lab information

- \\unimaas.nl\Research\FPN\EEG-Labinfo\

IE

- Head: Huub Hamers (3881919), h.hamers@maastrichtuniversity.nl, UNS40-3.777a
- Johan Gielissen (3884007), j.gielissen@maastrichtuniversity.nl, UNS40- 3.756k
- Erik Bongaerts (3882175), erik.bongaerts@maastrichtuniversity.nl, UNS40- 3.756k

Ethical approval

- Ethical approval is required for all studies conducted under the responsibility of FPN staff: See: https://www.maastrichtuniversity.nl/about-um/faculties/psychology-and-neuroscience/facilities/ethical-review-committee-psychology-and