FCBG NMOD Facility Use Policy & Agreement

Table of Contents

A. General Description

A.1. Mission

The NMOD facility of the Fondation Campus Biotech Geneva (FCBG) is a research facility dedicated to high-risk and high-yield studies in neuroscience with strong technological, methodological, and/or analytical components.

A.2. **Management**

The NMOD Facility at the Fondation Campus Biotech Geneva (FCBG) is part of the Human Neuroscience Platform (HNP). The facility is managed by the Facility Manager and staff and is governed in coordination with the Faculty Advisors and the Platform Advisory Committee (PAC) including faculty of the EPFL and University of Geneva. Faculty Advisors as well as the PAC are appointed by the FCBG steering committee. The staff members as well as the faculty advisor are listed in Appendix C.1.

A.3. **Study Eligibility**

The platform will support research projects in human neuroscience according to its mission as defined above. Animal studies are not permitted at the HNP MRI facility.

All human studies must have a current, valid, Ethics Committee Approval. It is the responsibility of the Principal Investigator (PI) to ensure that a valid Ethics Committee Approval is in place, and that all aspects of the human study are performed consistently with that approval.

In case of limited resources, priority is given to projects proposed by principal investigators (PIs) based at Campus Biotech (from UNIGE, EPFL and HUG).

A.4. **Getting an approval to conduct a study**

To obtain access to the Facility, the researchers must follow the procedure outlined below and regulated in detail in the following sections:

- The applicant fills out the application form on the HNP website https://hnp.fcbg.ch indicating the required resources and time, as well users (researchers) involved.
- The project PI signs the application form and submits it to the relevant manager(s).
- The Faculty Advisors evaluate the project on the basis of its scientific relevance and available resources.
- When approved by the Faculty Advisors, the project receives a project code.
- Users contact neuromodulation@fcbg.ch to request training on the requested resources.
- Once fully trained, users can book the required resources in our online booking system using the project code.

The Faculty Advisors may at their discretion require additional information, assurance or documents before approving a project. They may also make such requirements of an already ongoing project and suspend it until they are satisfied.

Please note that

- We do not intend to scrutinize your research plans, but we do need some control over what happens in our Facility.
- We are well equipped, but our resources are not unlimited. If we exceed our capacity, we may have to introduce additional rules.

B. NMOD Facility Use Policy

B.1. Training

The access to the scanner room can be granted only after approval by the NMOD safety officer. FCBG reserves the right to refuse or revoke the access to the NMOD facility at any time.

Our training & access management defines four levels of users:

- **Visitor** – This is a person who has not taken any safety training. Access to the NMOD restricted area can be granted only after being screened for safety. A visitor needs to be **escorted at all times** inside the restricted area; a visitor is not allowed to enter the room without supervision of an Assistant or Operator; a visitor cannot assist in setting up the TMS/tES or the participants, or to operate the stimulators.
- **Assistant** – To role of an assistant is to assist a certified operator in planning and conducting experiments at the neuromodulation facility. It is an opportunity to gain first insight into neuromodulation techniques. An assistant is not allowed to perform neuromodulation techniques, without supervision. For achieving an assistant status it is necessary to participate in one non-invasive brain stimulation introduction and safety seminar.
- **Operator In Training** – This is an Assistant who is **in training to become operator**. The Operator in Training can assist to set up the room and the participant, assist in case of emergency, and operate the stimulator under the supervision of a Certified Operator.
- **Certified Operator** – This is a person who **passed all training levels and has learnt how to operate the TMS/tES stimulators**. The Certified Operator is allowed to scan independently and is the responsible person for all the operations in the scanner for the given experiment.

Training requirements to obtain an ASSISTANT include:

- Attend the NMOD introduction and safety lecture (given by the NMOD Safety Officer or by a delegate of the NMOD Safety Officer). The safety lecture will develop the following four topics:
    - Safety rules and lab regulation
    - How to interact with the study participants
    - How to set-up, use, and arrange properly the lab equipment
    - How to react in case of an emergency

The accreditation as Assistant must be renewed every two years by attending the NMOD safety lecture. People not renewing their accreditation will have their access to the NMOD temporarily blocked until completion of the Assistant accreditation.

Training requirements to obtain an OPERATOR IN TRAINING include:

- Being a certified Assistant
- Participating in a practical training supervised by the NMOD staff. During this practical training, the candidate will learn how to operate the stimulators, and how to react to technical failures.

Specific Transcranial Magnetic Stimulation (TMS) Training:

- The observation of 5 TMS experiments under the supervision of a certified operator. This includes the observation of 2 repetitive TMS experiments or participation to a substitute rTMS seminar. The training schedule for usage of TMS includes technical and medical safety instructions, as well as instructions of how to stimulate the primary motor cortex and evoke motor evoked potentials from hand muscles, and an instruction of how to record surface electromyography and use the equipment. Neuronavigation (Brainsight) training may be included if the study plans to use Neuronavigation system.
- Participating in a basic safety training.

Specific Transcranial Electrical Stimulation (tES) Training:

- Two practical experience sessions to obtain instructions on safety concerns, operation of the devices, and of how to perform standard montages.
- Neuronavigation (Brainsight) training may be included if the study plans to use it.

The member of the NMOD staff training the candidate will inform the NMOD Safety Officer when s/he considers that the Operator in Training has reached the required level of skill and experience. The MRI Safety Officer will then issue the accreditation to Certified Operator.

B.2. **Responsibilities**

The employer of the PI bears the general responsibility for the study.

It is the responsibility of the PI that any experiment conducted at the Facility, for which an ethical approval is required, has obtained it and is performed in accordance with it.

The participants are under the responsibility of the researchers and should be never left unattended.

B.3. **Equipment**

The equipment available at the NMOD facility is listed in Appendix C.2

Caring for equipment

It is understood that equipment in constant use might wear out or occasionally experience a break down. You will not be held responsible, but we cannot fix items unless we know they are broken.

Please, report all broken equipment and equipment failures immediately to the NMOD facility staff via email (neuromodulation@fcbg.ch).

Setup and cleanup

Any researcher using the NMOD facility is required to set it up and clean it up properly. If the area is untidy when you arrive, or if equipment has not been returned to its proper position or default state, inform the platform staff by email.

One operator must always be present during the experiment.

It is responsibility of the investigator to obtain and archive the signed informed consent.

The safety checklist must be completed, signed and dated by both the Operator and the study subject. The safety checklist must be filed by each lab according to their ethics protocol.

It is the responsibility of the investigators to ensure on-time arrival of research subjects, their suitability for study, and the availability of any non-standard materials (hardware, coils, software, ancillary equipment) required for the study.

Each investigator is responsible to finish his/her study on time. Time for setup, cleanup and data storage must not infringe on the time of the following investigator. Unforeseen events such as failure of the equipment, late arrival of volunteers, etc. do occur and may shift or prolong the examination with a resulting infringement of the right of the subsequent investigator to start on time. While this should be a very rare exception and flexibility of all involved parties is expected, an overtime that exceeds 15 minutes is not tolerated.

Food and Drink

No food or drinks are allowed in the facility room. The ONLY exception is that research subjects may have a drink of water prior to or immediately following an experiment.

Do not throw food wrappers of any kind in the wastebaskets in the facility.

Use of non-standard equipment

Research involving hardware modifications or installation of non-standard equipment requires the prior approval of the FCBG NMOD Safety officer.

B.4. **User Fees**

The use of the NMOD is charged by the reserved time, in steps of 15 minutes. The fees for the use of the NMOD are detailed in https://hnp.fcbg.ch/guidelines-and-fees/. The fees for NMOD operator training are detail in Annex C3.

Pilot studies

To pilot new experiments, researchers have up to 4 participants (healthy and adults) free of charge. Filling the protocol application form is nonetheless required for pilot studies.

Cancellations

Reservations can be cancelled without fee up to 24 hours prior to the start of the allotted time slot by deleting the reservation on the booking system. After this deadline, the reserved time will be charged at rate of 50% unless it is not used by another study. In addition, researchers are required to advertise the cancellation on the NMOD users mailing list. This does not free the researchers to delete the reservation in the calendar.

Billing

invoices are sent to researchers every three months at the beginning of March, June, September, and December. Charges are based on the number of hours reserved on the calendar system of the NMOD

facility, at steps of 15 minutes. In case of pending payment for prior invoices, the FCBG may revoke the access to the NMOD facility.

The income from NMOD fees will be used for covering the operational costs of the facility, buying consumables, upgrading the equipment, based on the needs evaluated by the PAC.

B.5. **Facility safety**

Guidelines

The operator is responsible for the safety of the study subject. Individuals who meet exclusion criteria must not be scanned. Particular care should be paid to people with pace-makers, they should not approach the TMS equipment.

In case of Emergency

Users must follow the general Safety Directive of FCBG that can be found on the Extranet (https://extranet.campusbiotech.ch/).

Follow the safety indications reported to the User Guide of each piece of equipment; the safety indications reported on the equipment lists or on the machines are only informative and they do not cover all security alerts related to the equipment.

If a subject requires medical assistance, please follow these instructions:

- Step 1: move coils away from subject (if the situation permits it) and secure the access to the subject
- Step 2: While subject is being removed the second investigator calls the security lodge (058.944.03.33 from a mobile phone; 155 from a landline) or the emergency medical service (144)
- Step 3: Contact the technical staff

B.6. **Booking system**

The facility equipment can be booked via the Campus Biotech Calpendo system.

Researchers can book the equipment only after that they have attended to the NMOD security training and that the Faculty Advisors have approved the study.

Never use Facility resources for experiments other than that associated to the project code used for the booking.

Never use the Facility if you have not scheduled the time in the system.

Remember to save enough of your time slot for tidy up the equipment used.

B.7. **Data access**

Investigators must log on the NMOD facility computers using the Isilon account created for their lab. Different investigators on different projects initiated by the same lab share the same account. Please contact the NMOD facility manager (neuromodulation@fcbg.ch) if you have not received or are not aware of the credentials associated to your lab.

Once connected to your lab session, a folder specific to the lab is automatically mapped as a network drive. Use this folder to safely import and export data from the facility computers. The same folder is accessible from UniGE and EPFL networks to retrieve. No external devices (e.g. USB drives) shall be plugged in the NMOD Facility computers.

Important: This folder is only for **temporary** transfer of data to/from the NMOD facility. Data should not be stored *ad vitam eternam* on this server. A specific size will be allowed to the PI folder at the beginning of the collaboration. It is the responsibility of the investigators to back-up their data in his own institution's servers once the transfer is done and clean the folder. The FCBG is not responsible for the loss of data that would not have been backed up by the study investigator.

B.8. **Data management**

Data collection and documentation

Personal data are acquired only for safety reasons through the NMOD safety screening form and the form is archived by each lab according to the ethics protocol following official guidelines from swiss authorities. These data include the relevant medical history of the participant (see NMOD safety screening form), height, weight, sex, and date of birth.

Subject's identity is anonymized by a subject code. It is responsibility of the researchers to keep the link between the code and the participant's identity. The name of the subject is never stored within the data.

NMOD data (ie muscular responses) are stored on the network storage system (so-called Isilon), whose access is restricted to the members of the research group and the FCBG staff (protected by a password). Data on the Isilon system are backed up daily for the first 30 days (after which the back-up is less frequent). The Isilon system is accessible from the FCBG, EPFL, and UniGe networks. It is responsibility of the researcher to copy the images from Isilon to their data system.

Other data may be acquired (e.g. log of the stimulation, responses of the participants, eye-tracking and physiological data). These data are written on the Isilon system or, when this solution is not technically possible, locally on the PCs of the NMOD facility used for the recordings and eventually transferred to the Isilon. During an experiment, these PCs are managed by the researchers, who are responsible of the correct data anonymization, collection and management. As for the NMOD data, these data are backed-up daily for the first 30 days after which the back-up becomes less frequent. Users can access to the data through a computer connected to the FCBG, EPFL, and UniGe networks, and transfer the copy to their computer/servers.

Copyright and Intellectual Property Rights

The data and the results of the research are property of the PI. The FCBG does not claim any property right on the data or the results.

Policies for data sharing and reuse

From the FCBG perspective the PI is the owner of the data and hence can share are reuse the data. If a late download of the data is necessary for sharing purposes, the FCBG will remit the data only to the PI staff upon written request of the PI.

B.9. **Authorship and Acknowledgments**

Communication:

All articles and publications that use any HNP resources (e.g. equipment, protocol assistance and expertise, analyses) must be communicated to the HNP upon final acceptance.

Authorship:

FCBG adheres to the basic rules of Scientific Integrity regarding authorship of scholar work, in accordance with the Swiss Academy of Science regulations available at https://www.samw.ch/en/Projects/Overview-of-projects/Scientific-integrity.html

In order to be considered as an author, a researcher must fulfil the following criteria:

- having made an essential contribution to the planning, carrying out, evaluation and verification of the research work;
- having participated in the writing of the manuscript;
- and having approved the final version of the manuscript.

Other people who have contributed to the study, but only partially fulfil the above criteria, must be acknowledged ("Acknowledgements"), but are not designated as authors.

When appropriate, the member(s) of the HNP team who is/are listed as co-author(s) shall have the following affiliation:

- Human Neuroscience Platform, Fondation Campus Biotech Geneva, Geneva, Switzerland

Acknowledgments:

When the HNP provides a simple platform contribution (e.g. simple data acquisition, assistance in setting up procedures for presentation and collection of behavioral data), a co-author from HNP is not required. However, we ask to add one of the following sentence(s) in the acknowledgments.

This study was supported by the Human Neuroscience Platform, Fondation Campus Biotech Geneva, Geneva, Switzerland.

Or

This study was supported by the Neuromodulation facility of the Human Neuroscience Platform, Fondation Campus Biotech Geneva, Geneva, Switzerland.

Or

The authors thank XX (Neuromodulation Facility, Human Neuroscience Platform, Fondation Campus Biotech Geneva) for his/her/their help with ...

Or

This work was supported by the Human Neuroscience Platform, Fondation Campus Biotech Geneva (FCBG), Geneva, Switzerland. The institutional members of the FCBG are the Swiss Federal Institute of Technology Lausanne (EPFL), the University of Geneva (UNIGE), and the Hôpitaux Universitaires de Genève (HUG).

C. Appendix

C.1. Staff

Faculty Advisors:

- Prof. Sophie Schwartz (UNIGE)
- Prof. Friedhelm Hummel (EPFL)

NMOD manager and safety officer:

- Dr. Olivier Reynaud

C.2. Equipment List

MagStim BiStim TMS for single/dual coil experiments: https://www.magstim.com/product/bistim/

MagStim Super Rapid+ TMS for repetitive TMS (rTMS) including 2 EMG channels: https://www.magstim.com/product/rapid-family/

10+ **MagStim TMS coils** of various diameters (40-70 mm), handle design (flat / branding iron), wiring design (Figure-of-eight, double cone) with possibility of cooling for rTMS: https://www.magstim.com/product-category/coils/

MagVenture MagPro XP TMS stimulator for concurrent TMS-fMRI, capable of 250 Hz stimulation frequency: https://neurolite.ch/en/products/magnetic-stimulation/magpro-xp

BrainSight MRI-guided neuronavigation system: https://www.rogue-research.com/tms/brainsight-tms/

Neuroconn DC-stimulator tES device (x2), compatible with standard / 4x1 electrode montages, and MRI: https://www.neurocaregroup.com/dc_stimulator_plus.html

Hasomed Rehamove^3 tES devices (x2) for peripheral nerve stimulation (FES): https://hasomed.de/en/products/rehamove/

Neuroelectrics StarStim8 EEG+tES 8-channel system: https://www.neuroelectrics.com/solutions/starstim/8/

Starstim tCS Home devices (x3) + laptop for home-based stimulation: https://www.neuroelectrics.com/solutions/starstimhome

Digitimer DS7A tES device: https://www.neurospec.com/Products/Details/1011/ds7a-ds7ah

Noraxon wireless EMG system.

C.3. **Training fares**

The list of partner institutions include UNIGE, EPFL, HUG, HEPIA, the CIBM Center for Biomedical Imaging and the National Center of Competence in Research NCCR Evolving Language.

The rates for training are as follows, not including taxes.

		PARTNER INSTITUTION	**OTHER ACADEMIC**
MANDATORY TRAINING FOR BEGINNERS	CHF/training	350	420