FCBG MRI Facility Use Policy & Agreement 3T scanner

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A. General Description

A.1. **Mission**

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

A.2. Management

The MRI 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, University of Geneva, and of the Geneva University Hospital (HUG). 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 **Error! Reference source not found.**.

A.3. Study Eligibility

The platform will support research projects according to its mission as defined above. Living 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) affiliated to any of the Campus Biotech funding institutions (i.e., UNIGE, EPFL, and HUG).

A.4. Getting an approval to conduct a study

To obtain access to the 3T scanner of the Facility, the researchers must follow the procedure outlined below and regulated in detail in the following sections:

- The PI sends a signed application form via email to mri@fcbg.ch, indicating the required resources and time, as well users (researchers) involved.
- The Facility Advisory Committee evaluate the project on the basis of its scientific relevance and available resources.
- When approved by the Facility Advisory Committee, the project receives a project code.
- Users contact mri@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 Facility Advisory Committee may at its discretion require additional information, assurance, or documents before approving a project. It may also make such requirements for 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. MRI Facility Use Policy

B.1. Training

The access to the scanner room can be granted only after having passed the safety training and having been approved by the MRI safety officer. FCBG reserves the right to refuse or revoke the access to the MRI facility at any time.

Our training & access management defines four levels of users:

- **Certified Scanner Operator** – This is a person who **passed all training levels and has learnt how to operate the scanner**. The Certified Scanner Operator is allowed to scan independently and is the responsible person for all the operations in the scanner for the given experiment.
- **Operator in Training** – This is an Assistant who is **in training to operate the scanner**. The Operator in Training can assist to set up the magnet room and the participant, assist in case of emergency, and operate the scanner under the supervision of a Certified Scanner Operator
- **Assistant** – This is a person who **passed the safety training**. The Assistant is available to set up the magnet room and the participant in the magnet, to assist in case of emergency, but can not operate the scanner
- **Visitor** – This is a person who has not taken any safety training. Access to the MRI restricted area can be granted only after being screened for safety. A visitor must be **escorted at all times** inside the restricted area; a visitor is not allowed to enter the magnet room without supervision of an Assistant or Operator; a visitor cannot assist in setting up the magnet area or the participants, or to operate the scanner.

Training requirements to obtain an ASSISTANT include:

- Fill in the MRI Safety Questionnaire that will be archived by the MRI Safety Officer.
- Watch the scanner manufacturer's safety video
- Attend the MRI safety lecture (given by the MRI Safety Officer or by a delegate of the MRI Safety Officer). The MRI safety lecture will develop the following four topics:
    - Safety rules and facility 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 MRI safety lecture. People not renewing their accreditation will have their access to the MRI temporarily blocked until completion of the Assistant accreditation.

Training requirements to obtain an OPERATOR IN TRAINING include:

- Being a certified Assistant
- Participating in a 4-hour session during which all the theoretical topics will be presented in detail to the trainee.
- Participating in a series of practical sessions, always conducted under the supervision of the FCBG MRI Technologists. During this series the trainee learns to act in a manner that it is safe for all the people in the area (i.e., participants, researchers, additional people) as well as for

the equipment, to be able to run the scanner smoothly, to be able to manage unexpected circumstances (e.g., dealing with implants in the participants, incidental findings, interruption and restart of the protocol), to know and to follow the FCBG procedures.

The duration of the training cannot be estimated in advance but includes a minimum of 10 scanning sessions (reduced to a minimum of 3 sessions for trainees that are/were MRI operators in other MRI facilities). Once the FCBG MRI Technologist supervising the training considers that the trainee has reached the necessary level of skill, experience, and reliability, the MRI Safety Officer will be informed, and the exam session scheduled.

During the exam session, the MRI Safety Officer will oversee one (or more) scanning session and ask questions on the above-mentioned topics to test the candidate's knowledge. At the end of the session, the MRI Safety officer will either issue the accreditation (exam passed) or suggest further practice (exam failed).

The accreditation will be effective only after the payment of the training fees.

The MRI operator MUST have an appropriate liability insurance covering during all the time of the MRI usage.

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 MRI facility is listed in Appendix C.3

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 MRI facility staff via email (mri@fcbg.ch).

Setup and cleanup

Any researcher using the MRI platform 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.

Two trained people (one Operator plus at least one Assistant or Operator in Training) must always be present during scanning. During technologist supported hours, the MR technologist may be the second person. During off hours, each group must have two investigators in the scanner bay.

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 participant. The safety checklist must be filed in the MRI facility archives.

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, pulse sequences, 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 MRI area. 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 MRI area.

Use of non-standard equipment

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

B.4. **User Fees**

The use of the 3T MRI is charged by the reserved time, in steps of 15 minutes. The fees for the use of the MRI and for attending the operator training are detailed in Appendix C.4

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 MRI 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 MRI scanner. In case of pending payment for prior invoices, the FCBG may revoke the access to the MRI facility.

The income from MRI fees will be used for covering the operational costs of the facility, buying consumables, upgrading the equipment of the MRI facility, 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.

Anyone entering the scanner room must first be "metal-free" (empty the pockets; remove jewelry, watches, wallets, beepers, hair clips; leave pens, clipboards etc. outside the magnet room).

Hearing protection (in the form of earplugs and headphones) must be used when scanning any subject.

Double check that the wires of the equipment in use in the scanning room do not form loops that can cause serious electrical burns.

Don't use paper clips or other small metal objects (staples, etc.) in the console room. They tend to land on the floor and find their way into the magnet room and into the magnet.

Incidental findings

The investigators shall inform the participants of the following:

- that the imaging data to be acquired is not appropriate for clinical purposes
- that incidental findings are a rare but a known risk for imaging studies in healthy subjects
- prior to the study, participants shall declare whether they want to be informed in case an incidental finding occurs and to whom this information should be communicated (e.g., own physician; see below)

This information needs to be explicitly included in the informed consent form and indicated verbally before the scanning session from experimenter to participant.

The PIs are asked to obtain agreement of a physician trained in medical imaging to be the referent medical imaging specialist on their study in case of suspicion of incidental findings. This should occur prior to the submission of the study protocol to the Ethics Committee.

In case of suspicion of incidental findings, the MRI staff will send the images to the Radiology Department of the HUG together with the name of the referent medical imaging specialist. The Radiologist will communicate the results of his/her evaluation as well as his/her recommendations to the medical referent of the study which in turn will communicate them to the study subject (if needed).

The researcher should never discuss the potential abnormality with the study subject before the medical specialist has been consulted and a medical professional has explained the situation to the study subject. The researcher may or may not decide to terminate the study. In either case, care should be taken not to alarm the study subject.

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: remove subject from magnet (if the situation permits it) and secure the access to the magnet
- Step 2: While subject is being removed the second investigator calls the security lodge (058.944.03.33) 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 MRI 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 MRI 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 MRI facility manager (mri@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 the data. No external devices (e.g. USB drives) shall be plugged in the MRI Facility computers.

Important: This folder is only for **temporary** transfer of data to/from the MRI 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 MRI safety screening form and the form is archived for 10 years by the MRI facility staff. These data include the relevant medical history of the participant (see MRI safety screening form), height, weight, sex, and date of birth. This information is stored in a key-locked cabinet within the restricted area of the MRI (only authorized

people can have access to this area), and the key of the cabinet is stored within a code-protected locker located inside the MRI facility premises. The code is known only by the MRI facility staff and by the security personnel. In case the MRI is operated by a person that does not belong to the FCBG, the MRI safety screening form relative to the scan is temporarily stored in a drop-box that can be opened only by the MRI facility staff, that is responsible for archiving the forms stored in the drop-box within the shortest possible delay.

MRI data include in their header information on participant's 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.

MRI data are stored on the FCBG PACS server for 10 years. The access to the server is limited to computers connected to the FCBG internal network and is protected by password. Only the MRI operators can have access to the PACS database. The MRI images are downloaded from the PACS server to a directory of 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 in parallel to the imaging data (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 MRI 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 MRI images, 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**

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

Acknowledgements

For acknowledgements in articles, publications, projects, presentations, the following text must be added (choose the text most adapted to the situation and space):

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

Or

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

Or

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

Or

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C. Appendix

C.1. **Facility Advisory Committee**

- Prof. Olaf Blanke
- Prof. Patrik Vuilleumier
- Prof. Dimitri van de Ville
- Prof. François Lazeyras
- Prof. Maria Isabel Vargas
- Dr. Roberto Martuzzi

C.2. MRI facility Staff

MRI safety officer:

- Dr. Roberto Martuzzi

MRI staff:

- Dr. Roberto Martuzzi
- Ms. Loan Mattera
- Ms. Nathalie Philippe

C.3. Equipment List

MRI Siemens Prisma 3T equipped with a 20 and a 64-channel head and neck coil

MRI compatible goggles capable of stereoscopic vision, with a resolution of 1920x1080 refresh rate 60Hz and integrated eye-tracking cameras (https://nordicneurolab.com/visual-system-hd/).

MRI-compatible screen: BOLD screen 23 LCD screen from Cambridge Research Systems resolution 1920x1080 @60Hz. For specs: http://www.crsltd.com/tools-for-functional-imaging/mr-safe-displays/boldscreen-23-lcd-for-fmri/

Eye-tracking: Eye-link 1000+, sampling frequency 1000Hz monocular (http://www.sr-research.com/eyelink1000plus.html)

Auditory system: MR Confon "Starter f mkII+" http://www.mr-confon.de/en/products.html

Response box: 1x4-button, 2x4-button boxes, and a joystick from Current Design. For specs: https://www.curdes.com/mainforp/responsedevices/buttonboxes/hhsc-1x4-cr.html, https://www.curdes.com/mainforp/responsedevices/buttonboxes/hhsc-2x4-c.html, and https://www.curdes.com/mainforp/responsedevices/variabledevices/hhsc-joy-5.html

Physiological signal recording devices: Biopac MP160 (http://www.biopac.com/product/mp150-data-acquisition-systems/). It can record GSR, ECG, photoplethysmography, temperature, air flow, respiration, and EMG. The system also has a stimulator module, allowing for one channel electrical stimulation.

MRI-compatible glasses with correction lenses ranging from -6 to +6 dioptre Rx/lenses in 0.5 dioptre increments (https://www.crsltd.com/mri-patient-comfort-communication-and-entertainment/mri-patient-comfort/mediglasses/mediglasses-for-fmri/).

MRI-compatible wheelchair and stretcher (size 1950 x 800 mm; height: 620 - 980 mm)

Mock scanner: Mock scanner manufactured by Psychology Software Tools (https://pstnet.com/products/mri-simulator/) equipped with the head motion tracking system MoTrak (https://pstnet.com/products/motrak/)

MRI-compatible EEG systems: in collaboration with the EEG facility there are two MR-compatible EEG systems.

One is a Brain Products system including one **64-channels BrainAmp MR plus** amplifier (http://www.brainproducts.com/productdetails.php?id=6) and a **BrainAmp ExG MR** amplifier (http://www.brainproducts.com/productdetails.php?id=8) for recording external channels (e.g. EMG signals).
The other is a high density **EGI Geodesic EEG System 400 MR with 256 EEG channels** (https://www.egi.com/research-division/research-division-research-products/research-division-research-products-mr-compatible).

Reservation and use of the MR compatible EEG systems are subjected to the EEG facility use policy

MRI-compatible TMS system (3T only): in collaboration with the Neuromodulation facility there is one MRI-compatible TMS system, which includes the MagVenture MagPro XP stimulator (https://neurolite.ch/en/products/magnetic-stimulation/magpro-xp), the MRi-B91 Air Cooled TMS coil (https://www.magventure.com/tms-research/products-overview/research-coils/coils/mri-b91-air-cooled), and two 7-channel MR coil arrays specifically designed for being used in combination with the TMS coil (https://www.magventure.com/tms-research/products-overview/research-accessories/accessories/7-channel-mr-coil-array).
Reservation and use of the MR-compatible TMS system are subjected to the Neuromodulation facility use policy.

MRI-compatible tES system: in collaboration with the Neuromodulation facility there is one MRIcompatible tES system. The stimulator is a neuroCare DC-STIMULATOR MR (https://www.neurocaregroup.com/dc_stimulator_mr.html).

Reservation and use of the MR compatible tES system are subjected to the Neuromodulation facility use policy

MR-compatible motion capture system from Qualysis (https://www.qualisys.com/hardware/5-6-7/)

C.4. Use and training fares

The use of the MRI is charged by the reserved time (in steps of 15 minutes). The fees for the use of the MRI facility are detailed in https://hnp.fcbg.ch/guidelines-and-fees/.

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.

Late cancellation will be charged at rate of 50% unless the reserved time is not used by another study.

Operator training: the users that want to become operators need to pass a specific training for the 3T scanner.

The costs of the **MRI operator training** are:

- **CHF 1500** Regular fare
- **CHF 500** Discount fare for Ph.D. Students
- **CHF 500** Short training (for people that are operators in other centers)

Costs will be credited after completion of the training and a certificate will be issued by the MRI Safety Officer.