FCBG Clinical and Sleep Research Platform Guidelines

Table of Contents

A. General Description

A.1. Mission

The Clinical and Sleep Research Platform at Campus Biotech is an ensemble of laboratories dedicated to state-of-the-art investigations in human neuroscience.

Patients in need of a calm and private environment are welcomed in the Clinical and Sleep Research Platform when they come to Campus Biotech to take part in research trials. For this purpose, the platform is equipped to monitor clinically ambulatory patients. Rooms are dedicated to perform neuropsychological interviews and a battery of neurogical, -psychological tests frequently used is available for children and adults. Finally, a nurse/TSM technician is present on site for medical assistance if needed.

A second major axis of the platform is enabling **research on sleep**. We spend the third part of our life to sleep and sleep plays a fundamental role in brain functioning, like memory consolidation or emotions regulation. The platform contains two rooms each fitted with a comfortable bed. Its proximity to the other platforms, particularly MRI, is a considerable benefit and makes it possible to construct multidisciplinary research protocols where brain function can be measured using MRI before, during and after a night's sleep.

The platform also offers a **Biomarkers service**, that can :

- ADVISE researchers & DESIGN experimental protocols in genetics and biomarkers,

- MANAGE dataflow and financial aspects: get quotes and establish links between existing local services

- PREPARE and ANALYSE collected samples at Campus Biotech

- INTERPRET and DISCUSS the obtained results with researchers together with multimodal integration of other measures (fMRI, EEG, NIRS, TMS).

A.2. Management

The Clinical and Sleep research Head(s) of Platform is/are in charge of operations. Scientific supervision is done in coordination with the Platform Advisory Committee (PAC) including faculty of the EPFL, University of Geneva and Geneva University Hospitals (HUG) . Faculty members of the PAC are appointed by the FCBG Academic Council. 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.

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 platform, the researchers must follow the procedure outlined below and regulated in detail in the following sections:

- Read and acknowledge the platform guidelines in the present document
- Fill the online application form located at https://platforms.fcbg.ch indicating the required resources and time, as well users (researchers) involved.
- The Clinical and Sleep Research PAC evaluates the project on the basis of its scientific relevance and available resources.
- If needed, the Head of Platform establishes a quote for the entire study, which must be validated by the PI.
- When approved by the PAC, the project receives a project code.
- Users contact clinical@fcbg.ch or biomarker@fcbg.ch to request training on the requested resources (booking of EEG or medical assistants for blood sampling for example).
- Once fully trained, users can book the required resources in our online booking system https://campusbiotech.calpendo.com using the project code.

The PAC 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 the platform.
- We are well equipped, but our resources are not unlimited. If we exceed our capacity, we may have to introduce additional rules.

B. Use Policy

B.1. Training

The use of platform resources can require prior training. The training includes how to use the EEG systems, the organization of the IT equipment and the cleaning of the material, and sheets and towels of the rooms. If you still have any doubt about the use of the material, do not hesitate to contact the Head(s) of Platform. The duration of the training will depend on the complexity of the relevant equipment and the experience of the user.

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 on the platform, for which an ethical approval is required, has obtained it and is performed in accordance with it.

The PI and Users conducting the research project bear responsibility for the safety and well-being of their participants. Participants should not be left unattended. After the training, experimenters can use the lab alone, without the presence of a member of the staff (the staff is still accessible for any question by mail or phone).

A medical doctor related to the study must be present at the Campus Biotech if it is a clinical study involving patients.

<u>Note for Biomarker users:</u>

The PI is responsible for the storage of samples. The FCBG can provide temporary storage at -20°C and -80°C on Campus Biotech grounds, but is not liable in case of storage equipment failure. Researchers looking for long term storage should consider their own storage facilities. Please contact facility@fcbg.ch or the Head(s) of Platform to know more about these options.

B.3. Equipment

The equipment available is listed in Appendix C2.

Caring for equipment

Users are responsible for the condition of the platform resources they use. It is understood that equipment in constant use will occasionally break. You will not be liable for any normal wear-and-tear on unlucky accidents, which were not caused by your negligence.

Users should immediately report all broken equipment, malfunctioning software, or other damage to the Staff on site or by email. We cannot fix things unless we know they are broken.

Users are required to clean the equipment and put all the resources back in order. Any encountered disarray or dirty equipment left by previous Users should be reported to the Staff on site or by email.

Outages

Necessary repairs and other unforeseeable outages supersede any user bookings.
The platform can make no guarantee as to the availability of the equipment or staff, and cannot be held liable for any outages. We will try to inform you in advance of any outages that impact your booking. However, unexpected equipment failures or other unforeseeable circumstances can always occur.

Use of non-standard hardware or software

Usage of hardware other than platform equipment, or software other than platform software, such as custom stimulus presentation programs or real-time processing (BCI) applications, requires approval from the staff.

B.4. User Fees

For clinical and sleep studies, the use of the platform is charged by the reserved time, in steps of 15 minutes during the day. For sleep studies, the fee is computed for the full night, starting from 7pm to 9 am the next day. For biomarker studies, quotes are established for each study.

The fees for the use of the Clinical and Sleep research platform equipment are detailed in https://clinical-sleep.fcbg.ch/fees/ .

The fees for operator training are detailed in Annex C3.

Cancellations

Reservation cancellations should be effected at least 24 hours in advance through the online scheduling system. Late cancellations or no-shows without a valid reason are subject to a fee charged to the PI. Of course in unforeseeable, urgent cases you may cancel your booking with less notice than 48 hours. In such cases let us know by email and we will not charge you.

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, at steps of 15 minutes or full night. In case of pending payment for prior invoices, the FCBG may revoke the access to the platform.

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

B.5. Safety

Guidelines

The operator is responsible for the safety of the study subject.

In case of Emergency

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: calls the security lodge (058.944.03.33 from a mobile phone; 155 from a landline) or the emergency medical service (144)
- Step 2: Contact the technical staff

B.6. Booking system

Platform resources (i.e. medical assistants for blood samples, room, EEG) should be booked in the online booking system (https://campusbiotech.calpendo.com/) using the relevant project code. The code will be accessible after the validation of the application form, the presentation of the project at the seminar and the completed training. The 3 rooms can be booked separately and the relaxed seating area/kitchen can also be completely booked if necessary.

Users can access and use platform resources only after prior online booking of the time slot.

- Never use the platform if you have not scheduled the time in the system.
- Don't exceed your time. If the next slot is free, book more if needed, but do not run on unaccounted for.
- Remember to save enough of your time slot for cleaning the equipment and putting it back in order for the next User.
- Never use platform resources for experiments other than the project whose code you used for the booking.

The platform resources are available to trained Users at all times, except for breaks and outages indicated in the online booking system.

- Remember that the condition of the platform resources is your responsibility particularly if you work outside of the staffed hours.
- If you are starting a new experiment or have doubts, best get in touch with the staff and book time when they can help you get going.

Users that have not been trained by the staff may not book resources and can only participate in experiments accompanied by trained users.

Resources can be booked up to three months in advance.

To ensure fair distribution of resource time between studies, reservations can be limited to a certain number of hours over a fixed interval.

B.7. Data access

Investigators must log on the platform 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 Head(s) of Platform 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 platform computers. The same folder is accessible from UniGE, EPFL or other institutions networks to retrieve the data. No external devices (e.g., USB drives) shall be plugged in the platform computers.

Important: This folder is only for **temporary** transfer of data to/from the platform. 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
User data are 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.
Data can be saved 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.
Specific data may be acquired in parallel to the imaging data (e.g., log of the stimulation, responses of the participants 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 platform 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 other files, the data on Isilon server 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

All articles and publications that use any FCBG resource (e.g., equipment, protocol assistance and expertise, analyses) must be communicated to the platform 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 FCBG team who is/are listed as co-author(s) shall have the following affiliation:

- Clinical and Sleep Research Platform Platform, Fondation Campus Biotech Geneva, Geneva, Switzerland

Acknowledgments:

When the FCBG provides a standard platform contribution (standard data acquisition, assistance in setting up procedures for presentation and collection of behavioral data, etc.), a co-author from FCBG is not required. However, we ask to include the following sentence(s) in the publication:

This study was supported by the Clinical and Sleep Research Platform, Fondation Campus Biotech Geneva, Geneva, Switzerland.

C. Appendix

C.1. Staff

Faculty Advisors:
- Prof. Sophie Schwartz (UNIGE)
- Prof. Friedhelm Hummel (EPFL)
- Prof. Indrit Bègue (HUG)

Heads of Platform:
- Dr. Virginie Sterpenich
- Dr. Kinga Igloi

Biomarker Technician:

- Blanca Marin Bosch

Medical Assistants:
- Loan Mattera
- Nathalie Philippe

C.2. Equipment List

Clinical part :
Neuro-psychological tests
- For children
  - ADOS
  - ADI-R
  - WISC-IV
  - WPPSI-IV
  - RAVEN
- For motor assessement
  - ARAT
  - 9-Hole-Peg test
  - Purdue pegboard test
  - Box and Blocks test
  - Dynanometer: Jamar hand evaluation

Resuscitation trolley: Monitoring
- Tensiometer
- ECG
- Respiration

- Blood pressure
- Skin conductance
- Video : 3 cameras

Hospital bed, wheel chair

Sleep part

3 confortables rooms

- Bed
- Video control
- Air extractor for odor presentation

Different EEG systems

- Vamp (16 electrodes)
- Avatar (portable, 8 electrodes)
- Compatible EGI (256 electrodes),
- Compatible Brain Amp (64 electrodes)

Additional equipment

- Kitchen
- A living room
- 2 bathrooms
- Adapted for peoples in wheel-chair
- Child corner

Biomarker Unit:

- A fridge and a freezer at –20°C (additional storage is possible on FCBG grounds at -80°C)
- An equipped biosafety cabinet
- A desktop computer
- An equipped bench with micropipettes, eppendorf tubes erlenmeyers etc.
- A large and small centrifuge
- A hot water basin (bain-marie)
- A vortex

C.3. Training fares

The use of the platform is charged by the reserved time (in steps of 15 minutes during the day or full night).

The list of partner institutions include UNIGE, EPFL, HUG, HEPIA.

When applicable, the rates for booking the equipment are as follows, not including taxes.

		Partner Institution	Other Academic
Mandatory Training per project for beginners (4h)	CHF/Training	280	336