

HNP\_025\_SOP\_ENG

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# FCBG CSRU Facility Use Policy & Agreement

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### A. General Description

#### A.1. Mission

The Clinical and Sleep Research Unit (CSRU) at Campus Biotech is an ensemble of laboratories dedicated to state-of-the-art investigations in human neuroscience. It is part of Campus Biotech's Human Neuroscience Platform. The aim of this facility is to offer rooms and electroencephalographic





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material for clinical studies with patients (including neurologic, psychiatric or motor disorders) and for sleep studies on healthy subjects.

#### A.2. Management

The CSRU 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.

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 PI fills out the online application form located at <a href="https://hnp.fcbg.ch">https://hnp.fcbg.ch</a> or sends a signed application form via email to <a href="mailto:clinical@fcbg.ch">clinical@fcbg.ch</a>, indicating the required resources and time, as well users (researchers) involved.
- 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 clinical@fcbg.ch to request training on the requested resources.
- Once fully trained, users can book the required resources in our <u>online booking system</u> 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.



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• We are well equipped, but our resources are not unlimited. If we exceed our capacity, we may have to introduce additional rules.

### **B. CSRU Facility Use Policy**

#### **B.1. Training**

The use of Facility resources required 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 <a href="mailto:clinical@fcbg.ch">clinical@fcbg.ch</a>. 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 at the Facility, 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 use the lab alone, without the presence of a member of the staff in the facility (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.

#### **B.3. Equipment**

The equipment available at the CSRU facility is listed in Appendix C2.

#### **Caring for equipment**

Users are responsible for the condition of the Facility 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.



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#### **Outages**

Necessary repairs and other unforeseeable outages supersede any User bookings.

The Facility 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 Facility equipment, or software other than Facility software, such as custom stimulus presentation programs or real-time processing (BCI) applications, requires approval from the Staff.

#### **B.4.** User Fees

The use of the CSRU 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. The fees for the use of the CSRU are detailed in <a href="https://hnp.fcbg.ch/guidelines-and-fees/">https://hnp.fcbg.ch/guidelines-and-fees/</a>. 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 of the CSRU facility, at steps of 15 minutes or full night. In case of pending payment for prior invoices, the FCBG may revoke the access to the CSRU facility.

The income from CSRU 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.

#### In case of Emergency

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





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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**

Facility resources should booked online be in the 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 Facility resources only after prior online booking of the time slot.

- Never use the Facility 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 Facility resources for experiments other than the project whose code you used for the booking.

The Facility 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 Facility 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.





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#### **B.7. Data access**

Investigators must log on the CSRU 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 facility manager (<u>clinical@fcbg.ch</u>) 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, EPFL or other institutions networks to retrieve the data. No external devices (e.g., USB drives) shall be plugged in the CSRU Facility computers.

<u>Important:</u> This folder is only for **temporary** transfer of data to/from the CSRU. 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**

**EEG 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.

EEG 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.

Other 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 CSRU 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 EEG 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.





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#### 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 HNP resource (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 <a href="https://www.samw.ch/en/Projects/Overview-of-projects/Scientific-integrity.html">https://www.samw.ch/en/Projects/Overview-of-projects/Scientific-integrity.html</a>

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

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

Or



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

Or

The authors thank XX (Clinical and Sleep Research Unit, Human Neuroscience Platform, Fondation Campus Biotech Geneva) for his/her/their help with ...





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### C. Appendix

#### C.1. Staff

#### Faculty Advisors:

- Prof. Sophie Schwartz
- Prof. Friedhelm Hummel

#### CSRU Manager:

• Dr. Virginie Sterpenich

#### Medical Assistants:

- Loan Mattera
- Nathalie Philippe

#### C.2. Equipment List

#### **Clinical part:**

#### **Neuropsychological 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

#### **Resusication trolley: Monitoring**

- Tensiometer
- ECG
- Respiration
- Blood pressure
- Skin conductance
- Video: 3 cameras

#### Hospital bed, wheel chair



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#### 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

#### **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 training fee rates are as follows, not including taxes.

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