

## TERMS OF OPERATION OF THE RESEARCH ETHICS COMMITTEE (CER) AT PARIS-SACLAY UNIVERSITY

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### PREAMBLE

The scope of the present document is to define the rules of operation for the Paris-Saclay University's Research Ethics Committee (CER-PS) Under the aegis of the **Paris-Saclay University's Council for Ethics and Integrity in Scientific Research (POLETHIS)**, the CER-PS has the remit of providing a consultative opinion on research protocols to any researchers, teaching researchers or to permanent engineers at Paris- Saclay University who apply for one.

In the remainder of this document, the terms President, Vice-President, Director, Managing Director and reporter may apply to the men and women who hold the corresponding posts.

### Clause 1 ASSIGNMENTS

#### 1.1 Protocol Assessments

CER-PS shall examine the ethical aspects of research projects involving human participants, excluding research intended to develop biological and medical knowledge (research handled by the Personal Protection Committee (CPP) under the Jardé law). It may also appraise research on data collected on medical files (retrospective data) which need an ethical opinion. In that case it shall make pronouncements on information provided in good faith by participants on the use of their data. CER-PS does not examine other kinds of retrospective applications, and in particular those where research on human beings has already started.

CER-PS consultative opinions shall be given following an appraisal of the research protocol involving an ethical analysis of goals, approach, and the terms for including participants, information and consent offered to participants, data collection and storage, compliance with confidentiality, support and respect of dignity, integrity and the rights of persons during the research. An opinion issued by the CER-P shall exclusively bear upon the ethics of research on human beings and not on compliance with laws and regulations in France. In particular, it shall not release researchers from ensuring their project complies with legislation on data protection and any other relevant legislation.

## 1.2 Awareness-Rising and Fostering Good Practices

CER-PS also has the remit of encouraging and promoting good research practices in the field of ethics within the Paris-Saclay University. It shall inform and advise Paris-Saclay University's scientists on the preparation of their protocols, and as appropriate, shall advise them in their proceedings with a Personal Protection Committee (CPP).

In particular, it shall organise one day each year for training and awareness raising.

### Clause 2 FIELDS OF OPERATION

CER-PS can be applied to for all research that comes within its remit, as defined in Clause 1 of the present document.

In particular this includes data collection in the context of:

- Studies that use personal data
- Studies that use cognitive testing, perception testing, aptitude testing, performance testing and usability testing
- Investigations, meeting, questionnaires, focus groups and behavioural observation
- Physiological, neuro--physiological, bio-mechanical and behavioural measurement
- Studies in the field of handicap training
- Human-Computer- Interaction studies (HCI)

Such studies can take place in the laboratory or on site (real or virtual)

In particular, this excludes any research performed on human beings to develop biological or medical knowledge as defined in Sections L-1121-1 and following of the French Public Health Code and which require the opinion of a Personal protection Committee (CPP). This also excludes experiments upon animals, which come under an animal experimentation ethics committee.

An opinion relating to a research project, issued by the CER-PS, shall in no way release any researcher from liability. An opinion issued in favour in essence indicates that a researcher has applied to the committee for an opinion and that the project has been considered as corresponding to internationally accept ethical principles.

## Clause 3 COMPOSITION

### 3.1 Composition of the CER-PS

The CER-PS is a multi-disciplinary body, made up of at least 20 members (researcher, engineers, doctors, paramedics, psychologists and lawyers...) chosen for their belonging to disciplines involved in research concerning human beings.

CER-PS members shall be appointed by the president of Paris-Saclay University following an opinion issued by the Academic Council of Paris-Saclay University (CAC), on a proposal made by the board of the CAR-PS, if necessary, after agreement from their employers. The list of members shall be updated annually in accordance with the same terms and published on the CER-PS website.

### 3.2 Members

CER-PS members must have enough experience and expertise to take enlightened decisions on the studies put before them. Training will be offered to them.

The CER-PS will include a balanced representation of various bodies and disciplines involved in the CER-PS work, and members from outside Paris-Saclay University.

### 3.3 Remit and Renewal

CER-PS members shall be appointed for a four-year term renewable once.

### 3.4 Board

CAR-PS shall be managed by a board made up of at least three persons: a President, a Vice-President and a Director. A fourth person may be added with the title of Managing Director. An administrative assistant shall support the board.

The President and Vice President shall be elected by the ER-PS members on an absolute majority of votes made for a renewable term of two years.

The board shall receive applications, appoint reviewers within the CER-PS and allocate the files put before them.

The board may appoint experts outside the committee to examine an application. They shall then take part in CER-P discussions, without the right to vote.

The board with the support of an assistant shall perform the administrative handling of application.

### 3.5 Member Commitments

CER-PS members shall declare any interests<sup>1</sup> involving applications prior to their examination. In the case of any interests, they may not be rapporteurs and cannot take part in voting.

CER-PS work shall be confidential. Documents and information that are disclosed to CER-PS members and the secretariat in the context of the examination of submitted applications, and the related discussions, may not be disclosed outside of the CER-PS. These rules of confidentiality also apply to outside experts invited by the CER-PS.

## Clause 4 PROCEDURES

### 4.1 Applications

Permanent scientists should submit ethical review applications to the CER-PS board from Paris-Saclay University and, by way of exception, by staff from other laboratories. The CER-PS board alone shall be entitled to assess the acceptability of the latter applications, in a context set by the President of Paris-Saclay University.

If a research project is prepared by a student or by a Doctorate postgraduate student, only the research director may submit an application to the CER-PS.

The CER-PS shall meet monthly.

After an application is submitted, a file number shall be allocated to the application, in the form of date and order received (e.g. 2012--1). ..."

The application should be submitted in accordance with the procedure outlined on the website<sup>2</sup>

A receipt shall be sent that states the date of the application assessment.

### 4.2 Terms of File Assessment

Ethical assessments shall be based on the following aspects in particular: research goals, methods, restrictions, compensation, inclusion of persons, terms relating to freedom of choice and informed consent of research participants and confidentiality and data protection.

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<sup>1</sup> Interests include, for example, involvement in a research project whose scope is connected with an application being processed or in a competing project, as adviser for a public or private organisation, whose interests could be affected by the research being processed, or family or links of friendship with the person responsible of any projects submitted.

<sup>2</sup> <https://www.universite-paris-saclay.fr/recherche/polethis-ethique-et-integrite/comite-dethique-de-la-recherche>

The following points shall govern the examination of files:

- Two weeks prior to a monthly plenary meeting, the board shall appoint two rapporteurs per file.
- An agenda shall be sent out by the board to members (protocols to be assessed, and re-assessed) and sundry matters.
- The rapporteurs shall have two weeks in which to prepare their report. A guide shall be made available to them to prepare their report, stating the headings that the CER-PS intends to have covered. Files shall be examined in simple anonymity (rapporteur knows the identity of the project bearers, who doesn't not know the identity of the rapporteurs).
- The person(s) responsible for the project may be invited to take part in discussions; under no circumstances can they take part in voting. As appropriate, they may be represented by colleagues involved in the project who hold a doctorate. Students involved in a project may support the person in charge or his/her representative.
- If neither of the two rapporteurs is present at the meeting, the projects shall be reviewed at the following meeting.
- Within two weeks after the plenary meeting, each project leader shall receive an ethical opinion about the project and the list of CER members in attendance at the meeting.
- The CER-PS may issue five classes of opinion at the end of discussions and of any voting:
  1. In Favour
  2. In Favour with Reservations (minor amendments approved by the Board and the rapporteurs)
  3. Major Amendments, involving a fresh opinion from the CER-PS
  4. CPP Re-qualification, with advice about filing the dossier
  5. Unfavourable
- When a project leader receives an Opinion number 2 or 3, he/she must re-apply with the full file, highlighting the changes made and answering the CER-PS opinion. In order to do so it must go through the website platform. Protocols with a class 3 opinion shall be reviewed in a plenary session.
- In the case of a vote, it shall be performed by a show of hands showing a majority of members in attendance.
  - Quorum: for the discussions and any vote to be valid, at least one third of the CER-PS members must be present.
  - In the case of equal votes, the President shall have a casting vote.
- The opinion shall be drafted by the rapporteurs and sent by the Board to the project's leader within 15 days following the meeting.

### 4.3 Re-examination Following an Unfavourable Opinion

In the case of an “Unfavourable” opinion, the project leader shall have an option to re-file the project once only, considering the CER observations, except if the study requires filing towards a CPP.

### 4.4 Amendments to a Project that has Received a Favourable Opinion

A project that has received a favourable opinion and is being re-implemented with minor changes to the protocol or/and information sheet (additions of subjects, new measurement, new stimuli, extension, etc.) can be amended to extend the favourable opinion to the new implementation

The project leader shall file a letter in which the amendments made to the project and the initial documents amended are explained on the CER-PS platform. The amendment shall be handled by the President and by the board, and the rapporteurs of the initial project.

### 4.5 Activity Report

The Paris-Saclay University Academic Council shall examine an account of the CER-PS work presented by its President.

The Paris-Saclay University Academic Council shall examine each year any proposals to amend the running of the CER-PS put forward by its Board.

## Clause 5 ARCHIVES AND PRECEDENTS

A confidential register of the opinions, of the reports on the files and of the workings of the CER-PS shall be created and may be consulted by the CER-PS board members in office.

## Clause 6 RESOURCES

The work performed by the CER.PS members in the context of the committee shall be taken into account and acknowledged by the Paris-Saclay University establishments under which they come, in accordance with terms to be defined within each establishment (terms and times of service, and training entitlement).

In particular, for its operations, CER-PS shall have available:

- A website hosted by the Paris-Saclay University, a secure digital storage area, administrative assistance for preparing and monitoring meetings, communicating opinions to project leaders and archiving them.
- With a dedicated budget.