Statutes of the EPFL Human Research Ethics Committee

Article 1. Mission of the EPFL Human Research Ethics Committee

1. The EPFL Human Research Ethics Committee (HREC) is competent to approve or refuse, from an ethical point of view, the conducting of non-invasive research projects involving human beings. The Committee becomes involved when approval from EPFL is required for a project on an institutional level.

2. Research projects relating to:
   - the Federal Act on Medicinal Products and Medical Devices (Act on Therapeutic Products, LPTh, RS 812.21)
   - the Federal Act on Research involving Embryonic Stem Cells (StRA, RS 810.31)
   - the Federal Act on the Transplantation of Organs, Tissues and Cells (Act on Transplantation, RS 810.21)
   - the Federal Act on Human Research (LRH), upon its entry into force on 1 January 2014
   - the Cantonal Law on Public Health (LSP-VD, RSV 800.01; Cantonal Law on Biomedical research, RRB, RSV 800.21.1)

   do not fall within the competence of the Committee.

3. The competence of the Committee ends when the Cantonal Human Research Ethics Committee (VD) becomes the competent authority.

4. In all other cases, the President of the EPFL Research Commission decides on the competence of the Committee on a discretionary basis, after consulting with the Committee and in accordance with legal and institutional regulations.

5. Under no circumstances does a decision in which the Committee questions its competence, or an ethical review of the said Committee signify that it is not necessary for the research project in question to receive approval from another institution, in particular with regards to the scientific aspects of the project, or where other authorisations are required concerning legal or institutional regulations.

Article 2. Involvement of the Committee

Status as at 1 January 2017
1. The Committee is contacted by the principal researcher from the research project. If the principal researcher is a student, the Committee is contacted jointly by the principal researcher and his/her supervisor.

2. The Committee provides a standard form for the request of a decision.

3. The person making the request submits the completed request form to the Research Office by post or email (research@epfl.ch). The Committee is considered to be involved upon reception of the completed request form from the Research Office.

4. Incomplete request forms will be returned to the person who has made the request.

Article 3. Composition of the Committee

1. The Committee is composed of a minimum of seven members of varying profiles chosen for their interest in ethical questions, their probity and their availability. The Committee is made up of individuals who reflect public and expert opinions. It includes at least:
   - the President of the EPFL Research Commission,
   - two members who are currently active neither in the medical sector (except for medical ethics), the legal sector or the domain of hard sciences,
   - a member of the EPFL Research Commission,
   - a professional from the health sector (doctor, nurse, psychologist…),
   - a lawyer.

2. Each individual on the Committee may satisfy one or more of the above requirements.

3. EPFL staff member or staff members of another institution act as independent individuals within the Committee, and not as representatives of their institution.

Article 4. Appointment of members

1. The members of the Committee are appointed by the EPFL Direction following proposals from the President of the EPFL Research Committee or from the EPFL Research delegate. The EPFL Direction confirm the nomination in writing.

2. If a member is unable to adjudicate for a research project, the President of the EPFL Research Committee will nominate a temporary replacement for the examination of the research project in question.

Article 5. Organisation

1. The President of the Committee is the President of the EPFL Research Commission. He/She has the right to vote.

2. The Committee may have recourse to external experts. These experts do not have the right to vote.

3. The Research Office acts as intermediary between those submitting a request and the Committee members. It notably receives requests and communicates the Committee’s decisions to those having submitted a request.

4. The Committee is responsible for its own organisation.

Article 6. Duration of mandate

Status as at 1 January 2017
1. The Committee members are nominated for a period of 3 years and, unless they voluntarily resign, their mandate is automatically renewable twice for the same duration.

2. The EPFL Direction may revoke the mandate of a Committee member at any time.

3. The President of the EPFL Research Commission remains the President of the Committee as long as he/she holds this first position.

Article 7. Obligation of secrecy

1. Committee members, external experts selected by the Committee and all other individuals involved in Committee procedures are sworn to strict official secrecy.

Article 8. Recusal

1. All Committee members:
   - who are personally involved or have a relative who is involved in the research project under examination,
   - whose financial interests may be concerned by the research project under examination,
   - who are personally involved or have a relative who is involved in a competing project,
   - who find themselves in any other position of apparent conflict of interest,
   - or who could be perceived to be in a position of apparent conflict of interest, must recuse themselves.

2. When a Committee member is recused, the President of the EPFL Research Commission will nominate a replacement member for the examination of the project in question.

Article 9. Decisions

9.1 Ethical evaluation of a research project

1. The Committee gives its ruling on the basis of a request form completed by the person submitting the request.

2. Each Committee member decides to approve, approve with conditions or refuse the research project.

3. A research project is considered to be approved if it receives the unconditional approval of at least five Committee members. A research project is considered definitively refused if it is refused by at least five Committee members. In any other case, the project is considered to be approved with conditions.

4. If the research project is approved with conditions, it may be re-examined twice. The decision taken at the third examination is considered final.

5. If a Committee member approves with conditions or refuses a research project, their decision must be accompanied by comments in order to enable the person submitting the request to adapt the research protocol. Several members may submit their comments jointly.

9.2 Decision on competence

Status as at 1 January 2017
1. In the case where the Committee is clearly competent, the President of the EPFL Research Commission shall transmit the request to the Committee.

2. If the Committee is not clearly competent, the President of the EPFL Research Commission will not transmit the request to the Committee and, in collaboration with the Research Office, he/she will decide to which authority the project should be submitted.

3. If in doubt regarding the competence of the Committee, the President of the EPFL Research Commission, in collaboration with the Research Office, shall decide on the competence of the Committee within a delay of 2 weeks in accordance with Article 1, para. 4.

**9.3 Methods**

1. The members may take a decision:
   - by means of circulation of a written proposal, or
   - during a meeting of members.

2. Where a decision is taken by means of circulation of a written proposal, if a member does not transmit his/her vote within the required timeframe, the research project will be considered as approved by this member. Notwithstanding the above, at least five members must explicitly vote in order for the decision to be considered valid.

3. For a decision to be taken within a meeting, the quorum is five members.

4. Two or more members may convene a Committee meeting. The President of the EPFL Research Committee or the Research Delegate may convene a Committee meeting when justified by the circumstances.

5. The Vice-President for Research and the Research Delegate are invited to participate in each Committee meeting.

6. The Committee has the right to communicate with the person submitting the request regarding their request. The Committee may notably invite the person submitting the request to attend the meeting so as to discuss matters with him/her.

7. The President of the EPFL Research Commission signs the final decision.

**9.4 Deadlines**

1. The Committee will submit an initial decision within 4 weeks from the reception of the completed request form. For each subsequent re-examination, the deadline for submission is 2 weeks.

2. If one or more members must be nominated for the examination of the research project, the initial deadline is extended by 2 weeks.

3. The decisions of the Committee are transmitted to the person(s) having submitted the request as soon as possible.

**9.5 Language**

1. The examination process takes place in English and projects must thus be submitted in English to allow for thorough understanding from the Committee.

Status as at 1 January 2017
2. However, documents (information sheet, consent form, other documents) intended for the participants of research projects must also be produced in the participants’ own language.

**Article 10. Entry into force**

The present statutes enter into force upon their approval from the EPFL Direction.

Date: .............................................. 2017

On behalf of the EPFL Direction:

Martin Vetterli
President

Susan Killias
General Counsel