

# Statutes of the EPFL Human Research Ethics Committee

LEX 1.3.4

1<sup>st</sup> January 2017, status as at 25<sup>th</sup> January 2021

*The Direction of the Ecole polytechnique fédérale de Lausanne,*

based on the Ordinance on the organisation of the Ecole polytechnique fédérale de Lausanne (LEX 1.1.1);

based on the Directive on Consultation Procedures within EPFL (LEX 1.1.2);

*hereby adopts the following:*

## **Article 1. Subject**

1. Within the context of its core missions, EPFL is committed to defending three fundamental principles of research ethics: i) the respect of individuals; ii) charity; and iii) justice and human rights with regards to research, in such a way as to ensure both the protection of those participating in research projects or surveys, as well as the quality of the research being carried out.
2. The present rules and regulations are intended to outline the organisation and workings of the EPFL Human Research Ethics Committee (HREC; hereafter: the Committee).

## **Article 2. Mission of the EPFL Human Research Ethics Committee**

1. The Committee is competent to approve or refuse, from a point of view of ethical acceptability, the conducting of research projects involving human beings. The Committee becomes involved when approval from EPFL on an institutional level is required for a project; the Committee also reserves the right to examine and provide remarks on all other EPFL research projects. Furthermore, the Committee reserves the right to give both its opinion regarding the ethical acceptability of a project and remarks regarding a project's ethical aspects in a broader sense.
2. Research projects within the ambit of:
  - the Federal Act on Research involving Human Beings (Human Research Act, HRA, (RS 810.30);
  - the Federal Act on Medicinal Products and Medical Devices (Act on Therapeutic Products, LPT<sub>h</sub>, 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 Cantonal Law on Public Health (LSP-VD, RSV 800.01) and the 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 becomes the competent authority.
4. In all other cases, the EPFL Research Office decides on the competence of the Committee on a discretionary basis, after consulting with the Committee and in accordance with legal and institutional regulations.

#### **LEX 1.3.4, status as at 25.01.2021**

5. Under no circumstances does a decision in which the Committee rules on its jurisdiction, or a decision regarding an ethical evaluation of the said Committee, signify that the research project in question shall not be subject to the approval of another institution, particularly with regards to the scientific or ethical aspects of the project, or if further authorisations are required in accordance with legal or institutional regulations.
6. The Committee implements actions for raising awareness within EPFL in order to draw the attention of researchers to the theme of ethics.

#### **Article 3. Involvement of the Committee**

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 to be completed for the request of a decision.
3. The person making the request submits the completed request form to the Research Office by email ([research@epfl.ch](mailto:research@epfl.ch)). The Committee is considered to be involved upon reception of the completed request form by the Research Office.
4. Incomplete request forms will be returned to the person who has made the request.

#### **Article 4. Composition of the Committee**

1. The Committee is composed of a minimum of seven members with varying profiles chosen for their interest in ethical questions, their competence with regards to legislation and the regulations governing ethical acceptability, their probity and their availability. The Committee is made up of individuals who reflect the opinions of the public and expert opinions. It includes at least:
  - the President of the EPFL Research Commission,
  - individuals displaying knowledge notably in the fields of law, ethics, medicine, engineering science and technology, computer sciences, communication systems, data science, social and human sciences, and/or data protection.
2. EPFL staff member or staff members of another institution act as independent individuals within the Committee, and not as representatives of their institution.

#### **Article 5. Appointment of members**

1. The members of the Committee are appointed by the EPFL Direction following proposals from the President of the Committee. The EPFL Direction confirm the nomination in writing.
2. If necessary, if a member is unable to adjudicate for a research project, the President of the Committee shall nominate a temporary replacement for the examination of the research project in question.

#### **Article 6. Organisation**

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

## **LEX 1.3.4, status as at 25.01.2021**

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 7. Duration of mandate**

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 former position.
4. Members shall announce their resignation three months in advance.

### **Article 8. 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 9. 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. If necessary, when a Committee member is recused, the President of the Committee shall nominate a replacement member for the examination of the research project in question.

### **Article 10. Decisions**

#### **10.1 Procedures and deadlines**

##### ***10.1.1 Standard Procedure***

1. The standard procedure is applicable to all research projects concerning human beings which are not subject to the Federal Act on Research involving Human Beings (HRA).
2. The Committee acts with a minimum composition of seven members. Its composition must guarantee a competent and interdisciplinary evaluation of the request.

## **LEX 1.3.4, status as at 25.01.2021**

### ***10.1.2 Simplified Procedure***

1. The simplified procedure is applicable to all low risk projects involving human beings.
2. A research project is considered to be of low risk if the probability and extent of the disadvantages, harm and/or damages possible as a result of participation in the research are no greater than those inherent to standard aspects of the daily life of the participant to the project.
3. The Committee acts with a minimum composition of five members. Its composition must guarantee a competent and interdisciplinary evaluation of the request.
4. The request dossier may be made subject to standard procedure upon the request of a member or if there is not unanimous consent.

### ***10.1.3 Amendment procedure***

1. The amendment procedure is applicable to all research projects involving human beings which have already been granted authorisation, to which there is a desire to make significant modifications which do not raise specific issues of an ethical, scientific or legal nature.
2. In this case, the Committee acts with a minimum of three members. This composition must guarantee a competent and interdisciplinary evaluation of the request.
3. The request dossier may be made subject to standard procedure or simplified procedure upon the request of a member or if there is not unanimous consent.

## **10.2 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, to approve with conditions or to refuse the research project.
3. A research project subject to the standard procedure is considered to be approved if it receives the unconditional approval of at least two thirds of the Committee members evaluating the request. A research project subject to the standard procedure is considered definitively refused if it is refused by at least two thirds of the Committee members. In any other case, the project is considered to be approved with conditions.
4. A research project subject to a simplified procedure or an amendment procedure is considered to be approved if it receives the unconditional approval of all of the Committee members evaluating the request. If there is not unanimous consent, the research project will become subject to approval in accordance with the standard procedure.
5. If the research project is approved with conditions, it may be re-examined twice. The decision taken at the third examination is considered final.
6. 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 understand the decision and, where necessary, to adapt the research protocol. Several members may submit their comments jointly.

## **LEX 1.3.4, status as at 25.01.2021**

### **10.3 Decision on competence**

1. In the case where the Committee is clearly competent, the Research Office shall transmit the request to the Committee.
2. If the Committee is not clearly competent, the Research Office will not transmit the request to the Committee, but in collaboration its members, will decide to which authority the project should be submitted.
3. If in doubt regarding the competence of the Committee, the Research Office, in collaboration with the applicant, shall submit a request for clarification under the jurisdiction of the competent Cantonal Ethics Committee and shall decide on the competence of the Committee in accordance with Article 2, para. 4.

### **10.4 Methods**

1. The members may take a decision:
  - by means of circulation of a written proposal, or
  - during a meeting of members, either in person or by telecommunication.
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 refused by this member. Notwithstanding the above, at least two thirds (for a standard procedure), three members (for a simplified procedure) or two members (for an amendment procedure) must explicitly vote in order for the decision of refusal to be considered valid.
3. For a decision to be taken within a meeting (for a standard procedure), the quorum is five members.
4. Two or more members may convene a Committee meeting. The President of the Committee or the Head of the Research Office may convene a Committee meeting when justified by the circumstances.
5. The Associate Vice President for Research is invited to participate in the annual 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 a Committee meeting in order to discuss matters with him/her.
7. The President of the Committee signs the final decision.

### **10.5 Deadlines**

1. The Committee shall submit an initial decision within 6 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 experts 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.

### **10.6 Language**

#### **LEX 1.3.4, status as at 25.01.2021**

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

The present statutes entered into force on 1<sup>st</sup> January 2017 and were revised on 25<sup>th</sup> January 2021 (version 3.1).

On behalf of the EPFL Direction:

President  
Martin Vetterli

Director of Legal Affairs  
Françoise Chardonnens