

Statutes of the EPFL Human Research Ethics Committee

LEX 1.3.4

1st January 2017, status as at 14 September 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 the promotion of high ethical standards in research and to upholding the three fundamental principles of research ethics: i) the respect for persons (autonomy); ii) beneficence; and iii) justice, to ensure both the protection of those participating in research projects, 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 by EPFL researchers involving human beings and/or personal data. In doing so, the Committee evaluates the respect of ethical and data protection standards in research projects and ensures their application.
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, 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 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 Commission 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.
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 on-line 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 via the [on-line submission platform](#). 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 and shall include
2. individuals displaying knowledge notably in the fields of ethics, data protection, law, medicine, engineering science and technology, computer and communication sciences, data science, social and human sciences.
3. EPFL staff members 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 confirms 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 Associate Vice President for Research. He/She has the right to vote.
2. The Vice President of the Committee is nominated among the committee members by the Associate Vice President for Research. He/She has the right to vote.

3. The Committee may have recourse to internal/external experts (for example, in the area of data protection, risk management). These experts do not have the right to vote.
4. 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.
5. The Committee is responsible for its own organisation.

Article 7. Duration of mandate

1. The Associate Vice President for Research remains the President of the Committee as long as he/she holds this former position.
2. The Vice-President and the Committee members are nominated for a period of three years and, unless they voluntarily resign, their mandate is automatically renewable twice for the same duration.
3. The EPFL Direction may revoke the mandate of a Committee member at any time.
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 and/or personal data which are not subject to the Federal Act on Research Involving Human Beings (HRA) and which involve a high risk for the participants.
2. The Committee acts with a minimum composition of seven members. Its composition must guarantee a competent and interdisciplinary evaluation of the request and includes in any case an ethics and data protection review.

10.1.2 Simplified Procedure

1. The simplified procedure is applicable to all low risk projects involving human beings and/or personal data, to modifications of authorized research projects if they raise minor ethical, scientific or legal issues and sub-projects covered by an already approved general protocol.
2. The Committee acts with a minimum composition of three members. Its composition must guarantee a competent and interdisciplinary evaluation of the request and includes a data protection and ethics review.
3. The application may be made subject to the standard procedure upon the request of a member and/or the (Vice) President or if there is no unanimous consent.

10.1.3 Presidential Decision

1. The Presidential Decision procedure is applicable to projects that involve further use of data obtained with informed consent and/or those that do not entail any major/specific ethical, scientific or legal issues.
2. The project will be reviewed by the President and, where applicable, the data protection reviewer. The President may delegate the review to the Vice-President.
3. The submission may be made subject to another review procedure upon the request of the data protection reviewer and/or the (Vice) President.

10.2 Ethical evaluation of a research project

1. The Committee gives its ruling on the basis of an application 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 (five) 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 is considered to be approved if it receives the unconditional approval of three of the Committee members evaluating the request. If there is no unanimous consent, the research project will become subject to approval in accordance with the standard procedure.
5. A research project subject to the Presidential Decision procedure is considered to be approved if it receives the unconditional approval of the President or the Vice-President and, where applicable, the data protection reviewer.
6. If the research project is approved with conditions, it may be re-examined twice. The decision taken at the third examination is considered final.
7. 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.

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 with 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 completing the evaluation form in the on-line platform, 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 (five) of the members (for a standard procedure), three members (for a simplified procedure), or the President or the Vice-President and, where applicable, the data protection reviewer (for a Presidential decision) 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 Vice-President may convene a Committee meeting when justified by the circumstances.
5. 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.
6. The President or the Vice-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

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 status entered into force on on 1st January 2017 and were revised on 14 September 2021 (version 1.4).

On behalf of the EPFL Direction:

President
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