

Directive on the missions and organisation of the EPFL Human Research Ethics Committee **LEX 1.3.4**

1st January 2017, status as at 15 September 2024

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 for research. It upholds the three fundamental ethical principles governing research involving human beings, namely:
 - i. the respect for persons (autonomy);
 - ii. beneficence;
 - iii. justice, in order 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 missions, organisation and workings of the EPFL Human Research Ethics Committee, HREC; (hereafter referred to as 'the Committee').

Article 2. Mission of the EPFL Human Research Ethics Committee

1. All research projects conducted by EPFL that involve human beings and/or personal data and which do not fall within the scope of competence of the Cantonal Ethics Committee are submitted to the Committee for review and approval prior to submission of an application for their funding or before their commencement.
2. The Committee is competent to approve or refuse, from a point of view of ethical acceptability, projects conducted by EPFL researchers that involve human beings and/or personal data. It evaluates the respect of ethical and data protection standards in research projects and ensures their application.
3. Research projects within the ambit of:
 - the Federal Act on Research involving Human Beings (Human Research Act, HRA, SR 810.30);
 - the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA, SR 812.21);
 - the Federal Act on Research involving Embryonic Stem Cells (Stem Cell Research Act, StRA, SR 810.31);
 - the Federal Act on the Transplantation of Organs, Tissues and Cells (Transplantation Act, SR 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.

4. The HREC Committee is not competent if the Cantonal Ethics Committee is designated as the competent authority.
5. Under no circumstances does a decision in which the Committee rules on its jurisdiction, or an ethical evaluation of the said Committee, signify that the research project in question shall not be subject to the approval of another body, particularly with regards to the scientific or ethical aspects of the project, or if further authorisations are required in accordance with applicable internal or external regulations.
6. The Committee implements actions for raising awareness within EPFL in order to raise ethical awareness among researchers.

Article 3. Involvement of the Committee

1. The Committee is contacted by the researcher responsible for the research project. If a project is being conducted by a student, the Committee is contacted simultaneously by the student concerned and the person supervising the research project.
2. The Committee provides an on-line standard form to be completed for the request of a decision.
3. The person making the request to the Committee sends it 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 in order for additional information and revisions to be added and made in the manner necessary to ensure that the request can be properly understood.

Article 4. Composition of the Committee

1. The Committee is composed of a minimum of seven members with varying profiles chosen on the basis of their interest in ethical questions, their competencies with regard to legislation and the regulations governing research involving human beings, their probity and their availability.
2. The members of the Committee reflect the opinions of the public and expert opinions.

In particular, they possess knowledge in the fields of ethics, data protection, law, medicine, life sciences, engineering science and technology, computer and communication sciences, architecture, civil and environmental engineering, and social and human sciences.

3. The members of the Committee, regardless of whether they are affiliated to EPFL or a third-party body, act within the Committee as independent individuals and not as a representative of the institution (EPFL or a third-party body) to which they are affiliated.

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 a member of the Committee is unable to adjudicate for a research project, the President of the Committee shall, where necessary, designate another member of the Committee for the examination of the research project in question.

Article 6. Organisation

1. The Presidency of the Committee is fulfilled by the Associate Vice President for Research.
2. The function of Vice President of the Committee is fulfilled by one of the members of the Committee designated as such by the President of the Committee.
- 2bis All members of the Committee, including the persons fulfilling the role of President and Vice President shall have an equal voting right.
3. The Committee may have recourse to internal and/or external experts (for example, in the area of data protection, or risk management). These experts do not have the right to vote.
4. The Research Office liaises between the researchers submitting requests and the Committee members. It notably receives requests and sends back the Committee's decisions.
5. The Committee is responsible for its own organisation.

Article 7. Duration of mandate of the members

1. The duration of the mandate of the President of the Committee corresponds to the duration of the mandate of the Associate Vice President for Research.
2. The Committee members are nominated for a period of three years and, unless they resign, their mandate is automatically renewed twice for the same duration; accordingly, the maximum mandate duration is therefore nine years.
3. The EPFL Direction may, at any time, revoke the mandate of a Committee member.
4. Resigning members shall announce their withdrawal from the Committee at least three months in advance.

Article 8. Obligation of secrecy

1. Committee members, internal and external experts selected by the Committee, as well as all other individuals involved in the procedures and activities of the Committee are bound by 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 reasonably be perceived to be in a position of apparent conflict of interest,must recuse themselves.

2. If a Committee member is recused, the President of the Committee shall, where necessary, nominate a replacement person for the examination of the research project in question.

Article 10. Decisions

10.1 Procedures and deadlines

10.1.1 Standard Procedure

1. A 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 high risks for the participants.
2. When called upon to act in the context of a standard procedure, the Committee must have a minimum composition of seven members. It must guarantee a competent and interdisciplinary evaluation of the request, which must, in all cases, include an ethics and data protection review.

10.1.2 Simplified Procedure

1. A simplified procedure is applicable to all low risk projects involving human beings and/or personal data; to amendments of research projects that have already been authorized by the Committee, if those amendments raise minor ethical, scientific or legal issues; as well as to sub-projects covered by an already approved general protocol.
2. When called upon to act in the context of a simplified procedure, the Committee must have a minimum composition of three members. It must guarantee a competent and interdisciplinary evaluation of the request, which must include a data protection and ethics review.
3. A request shall be made subject to a standard procedure upon request of a member of the Committee, its President or Vice president, or if the project does not receive the unanimous agreement of the members of the Committee assigned to review the project.

10.1.3 Presidential Decision Procedure

1. A 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. In such cases, the project is reviewed by the President of the Committee and, where applicable, the member of the Committee responsible for data protection. The President may delegate the review of the project to the Vice-president.
3. The project may be made subject to another review procedure upon the request of the Committee member responsible for data protection and/or the President of the Committee 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 researcher responsible for the project.
2. Each Committee member assigned to review a research project may approve it (with or without comments), approve it with conditions, or refuse it.

3. A research project subject to a standard procedure is considered:
 - approved if it receives the unconditional approval of at least two thirds of the Committee members assigned to review it.
 - definitively refused if it is refused by at least two thirds of the Committee members assigned to review it.

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 unanimous approval of the Committee members evaluating the request. If there is no unanimous approval, the research project will then be made subject to a standard procedure.
5. A research project subject to a presidential decision procedure is considered to be approved if it receives the approval of the President of the Committee or the Vice-president and, where applicable, the member of the Committee responsible for data protection.
6. If a 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 a statement of reasons in order to enable the researcher responsible for the project to understand the decision and, where necessary, to adapt the research protocol for a further re-examination by the Committee. Several members may issue a joint statement of reasons.
8. If the Committee refuses a project, the researcher responsible for the project shall have the right, subject to a strict time limit of six weeks following notification of the decision, to request a reconsideration if one of the following three situations applies:
 - a. circumstances or information exist that are of relevance to the examination of the project but of which the Committee was initially unaware;
 - b. procedural irregularities were committed while the Committee was examining the project;
 - c. there is evidence of prejudice or an inadequate examination.

Any request for reconsideration must be substantiated and accompanied by relevant supporting evidence.

10.3 Decision on competence to give a ruling

1. The Research Office shall transmit to the Committee requests that clearly fall within the Committee's scope of competence to give a ruling.
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 to give a ruling, the Research Office, in collaboration with the applicant, shall submit to the competent Cantonal Ethics Committee a request for "clarification of responsibility" and then rule on the question of competence of the Committee in accordance with Article 2, para. 4.

10.4 Methods of decision-making

1. The members may communicate their decisions:
 - by completing the evaluation form provided for that purpose and made available on the Research Office on-line platform, or
 - during a meeting held either in person or by videoconference;
 - by circular.
2. Where a decision is taken by means of circulation or via the online platform, 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 of the members for a standard procedure, all members for a simplified procedure, or the President of the Committee or the Vice-president and, where applicable, the member of the Committee responsible for data protection 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 researcher responsible for the project regarding their request. The Committee may notably invite that person to attend a Committee meeting for an oral discussion.
6. The President or the Vice-president of the Committee signs the final decision.

10.5 Deadlines

1. The Committee shall issue its decisions within 6 weeks of receipt of the duly completed request form.
2. If one or more experts must be appointed 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 researchers responsible for the projects 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 by the members of the Committee.

Article 11. Entry into force

The present directive entered into force on 1st January 2017 and was revised on 14 September 2021 (version 1.4) as well as on 15 September 2024 (version 1.5).

On behalf of the EPFL Direction:

President
Martin Vetterli

Director of Legal Affairs
Françoise Chardonnes