

Statutes of the EPFL Animal Research Ethics Committee

Preamble

Article 1. Aim

1. Within the context of its core missions, EPFL is committed to respecting ethical principles concerning experimentation using animals, whether conducted in Switzerland or abroad, and promotes responsible and ethical animal research in which full consideration is given to the welfare of animals.
2. The aim of the present regulations is to outline the organisation and workings of the EPFL Animal Research Ethics Committee (hereinafter: the Committee).

Title I: Missions of the EPFL Animal Research Ethics Committee

Article 2. Missions of the EPFL Animal Research Ethics Committee

1. The Animal Research Ethics Committee (AREC; in French: Le Comité d'éthique de l'expérimentation animale de l'EPFL, AREC) has the authority to approve or refuse a research project involving animals and conducted abroad on grounds of ethical compliance.
2. The term "research project involving animals" refers to all projects led by an EPFL researcher or a third party in the context of a collaboration with EPFL. The term "collaboration" is understood to mean that an agreement exists by the terms of which EPFL researchers are granted a status of author or co-author of possible publications based on this collaboration.
3. Research projects using animals conducted in Switzerland are authorised and monitored by the competent cantonal and federal authorities and by the cantonal commission on animal experimentation for the canton concerned. The AREC committee is not involved in the approval and monitoring of these projects.
4. Research projects using animals conducted abroad are subject to ethical approval by the AREC committee in the cases defined by the present regulations. In order to assess ethical compliance, the Committee bases its reflections on:
 - the principles laid out by the Rectors' Conference of the Swiss Universities (CRUS) regarding animal research;
 - the Ethical Principles and Guidelines for Experiments on Animals established jointly by the Swiss Academy of Medical Sciences (SAMS) and the Swiss Academy of Sciences (SCNAT).

Titre II: Composition and procedure for appointment

Article 3. Committee composition

1. The Committee is composed of at least seven members of varying profiles, selected for their interest in ethical questions relating to animal experimentation, their competence regarding legislation and the rules governing ethical conformity, their integrity and their availability. It is made up of individuals who reflect both public and expert opinion, and includes at least:
 - the EPFL Resource Manager (DEA, in French: Directeur de l'Expérimentation Animale);
 - the EPFL Animal Welfare Officer (AWO, in French: Délégué à la Protection des Animaux);
 - the EPFL representative within the cantonal commission on animal experimentation for the Canton of Vaud;
 - individuals from EPFL or another institute with knowledge notably in the field of law, ethics, life sciences, human or veterinary medicine, engineering sciences, and human and social sciences.
2. Members who are employees of EPFL or another institute act in their personal capacity within the Committee, not as representatives of their institute.

Article 4. Appointment of members

1. Committee members are appointed by the EPFL Direction upon proposal by the EPFL Resource Manager (DEA), who acts as President of the Committee. The EPFL Direction confirms the appointment in writing.
2. If a member is unable to rule on a research project, if necessary, the President of the Committee will appoint a temporary replacement for the assessment of the research project in question.

Article 5. Mandate period

1. Members of the Committee are appointed for a 3-year period. Except in the event of resignation or in the cases listed below, their mandate may be automatically renewed twice for the same period.
2. The EPFL DEA occupies the role of President of the Committee for as long as he/she remains in the former role.
3. The EPFL AWO is a member of the Committee for as long as he/she remains in the former role.
4. The EPFL representative within the cantonal commission on animal experimentation for the Canton of Vaud is a member of the Committee for as long as he/she remains in the former role.
5. Members announce their resignation with a prior notice period of three months.

6. The EPFL Direction may revoke the mandate of members at any time, without justification.

Article 6. Professional secrecy

1. Members of the Committee, external experts selected by the Committee and all individuals participating in the procedure are strictly bound by professional secrecy.

Article 7. Recusal

1. All members of the Committee:
 - who are personally involved or whose employee is personally involved in a research project to be assessed,
 - whose financial interests are concerned by the research project to be assessed,
 - who are involved or whose employee is involved in a rival research project,
 - who find themselves subject to any other conflict of interest,
 - or who could be perceived as being subject to a conflict of interestare required to recuse themselves.
2. Where a member should recuse himself/herself, if necessary, the President of the Committee will appoint a replacement for the assessment of the research project in question.

Titre III: Workings

Article 8. Referral to the Committee

1. The EPFL Principal Investigator for the research project initiates referral to the Committee. If the Principal Investigator is a student, referral to the Committee is made jointly by the Principal Investigator and his/her supervisor.
2. The Principal Investigator submits to the Committee all research projects with animals where experiments are conducted abroad, whether these experiments are conducted by himself/herself or by a third party in the context of a collaboration.
3. The Committee provides an application form for requesting a decision.
4. The applicant submits the completed application to the Center of PhenoGenomics (CPG) by email to the following address: arec@epfl.ch. The case is referred to the Committee upon reception of the completed form by the CPG.
5. Incomplete applications will be returned to the applicant.

Article 9. Organisation

1. Committee decisions are made by simple majority vote. If there is no majority, the President

- of the Committee will make the final ruling.
2. The President of the Committee is the EPFL DEA. He/she has the right to vote.
 3. The Committee may call on external experts. However, these experts do not have the right to vote.
 4. The Center of PhenoGenomics, via the EPFL AWO, acts as an intermediary between the applicants and the members of the Committee. It notably receives applications and transfers Committee decisions to the applicant.
 5. The Committee is responsible for its own organisation.

Article 10. Decisions

10.1 Procedures and deadlines

1. Depending on the nature of the project involving animals in the context of research conducted abroad (place of performance, species, degree of severity), a simplified, ordinary or amendment procedure may be carried out.

10.1.1 Simplified procedure

1. The simplified procedure is applicable to all research projects conducted in countries where ethical judgement and the conditions for animal research are equivalent to those of Switzerland, with the exception of degree of severity 3 projects or projects involving non-human primates or endangered species.
2. The Committee defines the list of countries for which the simplified procedure applies. This list may be revised at any time.
3. The Committee defines the list of endangered species by referring to Appendix 1 of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES: <https://www.cites.org>).
4. The EPFL AWO and the representative for EPFL within the cantonal commission on animal experimentation for the Canton of Vaud check that the project meets the established criteria for the simplified procedure.
 - a. If the project meets the criteria for the simplified procedure, it may be conducted subject to the obtention of all necessary authorisations in the country where the experimentation is to take place. Copies of authorisations must be provided to the CPG/EPFL.
 - b. If the project does not meet the criteria for the simplified procedure, it is subject to the ordinary procedure.

10.1.2 Ordinary procedure

1. The ordinary procedure is applicable to:
 - a. all research projects of degree of severity 3 conducted in any country other than Switzerland;
 - b. all projects involving non-human primates or endangered species conducted in any country other than Switzerland;
 - c. all research projects involving animals (as per the *Loi fédérale sur la Protection des*

- Animaux*) conducted in a third country which is not included on the list of countries drawn up by the Committee for which the simplified procedure is applicable.
2. Rulings must be given with a Committee composition of at least seven members. The composition of the Committee must ensure the competent and interdisciplinary assessment of the application.

10.1.3 Amendment procedure

1. The amendment procedure applies to research projects which have already received authorisation, but which look to be modified, provided that the intended modifications do not raise specific ethical, scientific or legal questions.
2. If the amendment concerns a project which fulfils the established criteria for the simplified procedure, ruling is given by the EPFL AWO and the representative for EPFL within the cantonal commission on animal experimentation for the Canton of Vaud.
3. If the amendment concerns a project assessed according to the ordinary procedure, the Committee gives a ruling with a composition of three members in which the EPFL AWO must necessarily be included. This composition must ensure the competent and interdisciplinary assessment of the application.
4. The file may be made subject to an ordinary procedure upon request from a member of the Committee or if there is no unanimity.

10.2 Ethical assessment of a research project

1. The Committee rules based on the application completed by the applicant.
2. Each member of the Committee decides whether to accept, conditionally accept or reject the research project.
3. A research project is approved under ordinary procedure if it receives unconditional acceptance from at least two thirds of the Committee members assessing the application. A research project is definitively refused under the ordinary procedure if is rejected by at least two thirds of Committee members. In other cases, the project is conditionally approved.
4. A research project is approved under the amendment procedure if it receives unconditional acceptance from all members of the Committee assessing the application. If there is no such unanimity, the application becomes subject to the ordinary procedure.
5. If the research project is conditionally approved, it may be re-assessed twice following clarification provided by the applicant. The decision taken upon the third assessment is final.
6. If a member of the Committee conditionally accepts or refuses a research project, he/she must provide comments to support this decision in order to allow the applicant to understand the decision and, where appropriate, adapt the research protocol. Several members may provide joint comments.

10.3 Decision on competency

1. The Center of PhenoGenomics, via the AWO, submits the application to the Committee where the Committee has clear competence.
2. If the Committee does not have clear competence, the Center of PhenoGenomics does not transfer the application to it, but assesses to which body the project should be submitted in

collaboration with AREC members.

10.4 Methods

1. Members may take a decision:
 - by circular, or
 - at a meeting of members, in person or by telecommunication.
2. In case of a decision taken by circular, if a member does not communicate his/her vote within the given deadline, the research project is considered to be refused by that member. Notwithstanding this, at least two thirds of members (ordinary procedure) or two members (amendment procedure) must explicitly vote in order for a decision of refusal to be considered valid.
3. A quorum of five members is required for decisions taken within a meeting (ordinary procedure).
4. Two or more members may convene a Committee meeting. The President of the Committee may convene a Committee meeting when circumstances render it justifiable.
5. The Committee has the right to communicate with the applicant regarding his/her application. The Committee may notably invite the applicant to a Committee meeting for discussion.
6. The President of the Committee signs the final decision.

10.5 Deadlines

1. The Committee provides a decision for the first assessment within 6 weeks from the date of submission of the completed application. For each subsequent re-assessment, the deadline is 2 weeks.
2. If one or more experts must be appointed for the assessment of a research project, the initial deadline is extended by 2 weeks.
3. The final decisions of the Committee are communicated to the applicants as soon as possible.

10.6 Language

1. The procedure takes place in English and projects must therefore be submitted in this language to ensure sound understanding within the Committee.

10.7 Title IV: Entry into force and revision

Article 11. Entry into force

The present statutes enter into force upon their approval by the EPFL Direction (29th January 2019).

Article 12. Revision

The present statutes may be subject to revision upon proposal by members of the Committee or the President of the Committee. The revised statutes will be subject to the approval of the EPFL Direction.

On behalf of the EPFL Direction:

Ecublens, January 29th, 2019

Martin Vetterli
President

Susan Killias
General Counsel