

Regulations for the Ethics Review Board in Eurac Research

Article 1. Scope and Purpose of the Ethics Review Board

1. The Ethics Review Board in Eurac Research is an independent body that has been convened upon recommendation by the Head Office, the Research Support Office, and the Legal Office, and the Statistics Office.
2. The purpose of the Ethics Review Board is to review projects and research protocols involving human participants (including secondary use of personal data) and/or social science research methods presented to the Ethics Review Board for review by collaborators of Eurac Research. The ethics review devotes special attention to the protection of participating members of vulnerable groups. The Ethics Review Board also participates in delivering awareness-raising and training activities on research ethics in Eurac Research and offers opportunities to receive training on research ethics.
3. The Ethics Review Board can also be asked to review projects or research protocols that do not involve human participants (including secondary use of personal data) and/or social science research methods in cases when ethics review is necessary for the purposes of a funding proposal, grant agreement obligations, or scientific publication.
4. Review of projects or research protocols must occur before data processing, including collection, or the application of the research protocols under review takes place. Retrospective ethics review i.e. request to approve research that has been commenced or completed, is not permitted.
5. The actions of the Ethic Review Board are not a substitute for the legal, ethical and moral responsibility of principle investigators.
6. In all its activity, the Ethics Review Board references national, European, and international codes of research ethics and legal norms. The Ethics Review Board also refers to relevant disciplinary codes and guidelines for research ethics.
7. The Ethics Review Board does not review such research projects or research protocols that, according to law, must be reviewed by the *Comitato etico per la sperimentazione clinica* of the Südtiroler Sanitätsbetrieb and the *Comitato etico provinciale* of the Province of Bozen/Bolzano. The Ethics Review Board also does not review research projects or research protocols that fall within the purview of the ethics committee of the terraXcube or the data access committee of the Cooperative Health Research in South Tyrol (CHRIS) study.

Article 2. Composition of the Ethics Review Board

1. The Ethics Review Board will consist of 5 permanent members nominated by the Head Office of Eurac Research and appointed by the Board of Directors. The Head Office includes the President, the Director and the Vice-Director of Eurac Research.
2. The permanent members of the Ethics Review Board will be appointed with the aim to ensure knowledge of the research areas and methods that the Ethics Review Board reviews. The balance between benefits and risks is central to ethics review. Since researchers tend to over-estimate benefits of research projects or protocols involving human participants and under-estimate the risks of such research protocols to research participants, one of the five permanent members of the Ethics Review Board shall be a layperson, i.e. a member of public. The Board

will have knowledge of the following areas and this knowledge may also be achieved thanks to the interdisciplinary competences of permanent members:

- a. Research ethics and integrity
 - b. Qualitative social science methods
 - c. Quantitative social science methods
 - d. Participative research design approaches and citizen science approaches
 - e. Emerging, disruptive technologies in social sciences
 - f. Understanding of the risks and benefits of social science research from a lay perspective
3. The majority of the permanent members of the Ethics Review Board must be independent from, i.e. not affiliated to, Eurac Research.
 4. The permanent members of the Ethics Review Board are appointed for a 5-year term. Their tenure may be extended once for another 5-year term. The names, qualifications, and the CV of the permanent members of the Ethics Review Board are made public on the website of the Ethics Review Board, which is part of the website of Eurac Research.
 5. A representative of the Privacy Team, part of Legal Office in Eurac Research, consults the Ethics Review Board on matters of personal data processing and delivers her opinion by participating in relevant Ethics Review Board meetings upon invitation. She does not act as a member of the Ethics Review Board, permanent or external. She neither participates in the consensus decision making nor signs the resulting Review Reports.
 6. In addition, the Ethics Review Board may appoint additional ad hoc external members with specific disciplinary or methodological expertise to support the review of particular projects or research protocols. The ad hoc external members act as consultants to the Ethics Review Board and deliver their opinion either in written format to the Ethics Review Board or by participating in the relevant Ethics Review Board meeting. Ad hoc external members neither participate in consensus decision making nor sign the resulting Review Reports.
 7. Ethics Review Board permanent members as well as external members:
 - a. Must consider applications submitted to the Ethics Review Board in a timely manner and express their opinion only after familiarizing themselves with the full application presented to the Ethics Review Board. Members of the Ethics Review Board are not allowed to delegate their review duties to a third party.
 - b. Must preserve the confidentiality of all information they learn in the process of their ethics review duties. Ethics Review Board permanent members and external members sign a non-disclosure agreement with Eurac Research.
 - c. Must advise the Chair of the Ethics Review Board and the Ethics Review Board Administrator of any conflicts of interest with relation to any application for review. Permanent members must abstain from consensus decision making in case of conflict of interest.
 8. The permanent members of the Ethics Review Board elect a Chair and a Vice Chair. The Chair of the Ethics Review Board is responsible for:
 - a. Convening the meetings and presiding over the meetings of the Ethics Review Board.
 - b. Ensuring due process and transparency of the proceedings of the Ethics Review Board.
 - c. Coordinating the preparation of an annual activity report to the Head Office.

The Vice Chair substitutes the Chair of the Ethics Review Board in the Chair's absence.

9. A permanent member of the Ethics Review Board can lose their place on the Board when they remain absent, unexcused, from 3 consecutive meetings of the Ethics Review Board. Three consecutive unexcused absences result in a recommendation to exclude the permanent member from the Ethics Review Board made by the Chair of the Ethics Review Board to the Head Office; the decision to exclude a member from the Ethics Review Board lays with the Head Office. A member of the Ethics Review Board can also be excused from the Board if duties or obligations incompatible with membership in the Ethics Review Board emerge; such motivations need to be communicated to the Chair of the Ethics Review Board, who recommends the exclusion to the decision of the Head Office.

Article 3. Submitting an Application to the Ethics Review Board

1. An Application to the Ethics Review Board must be submitted using the application forms available on the website of the Ethics Review Board. Before filling in and submitting an Application for review, researchers must complete the self-guided ethics check tool available on the same website. The self-guided ethics check tool supports researchers in determining whether an Application to the Ethics Review Board is necessary for their research project or research protocol.
2. The Application must be submitted by the Principal Investigator of the project or research protocol. In case of large-scale projects with multiple partners, the application to review the research activities and protocols of Eurac Research affiliated researchers must be submitted by the Principal Investigator of the Eurac Research part of the project. In case of projects related to Masters-thesis or PhD-thesis, the Application must be signed both by the student/Principal Investigator and their Eurac Research supervisor/tutor.
3. The Principal Investigator must submit the Application to the Ethics Review Board at least 15 business days before a scheduled regular meeting of the Ethics Review Board. A calendar with planned meetings is published on the website of the Ethics Review Board by the beginning of each calendar year.

Article 4. Procedures of the Ethics Review

1. The Ethics Review Board adopts a schedule of regular meetings to review submitted Applications. The aim is to ensure a timely but considered ethics review:
 - a. The Chair of the Ethics Review Board convenes at least 10 meetings of the Board in a calendar year. A calendar with planned Ethics Review Board meetings is published on the website of the Ethics Review Board by the beginning of each calendar year.
 - b. The meetings can take place both in person or online at the discretion of the Chair of the Ethics Review Board.
 - c. The Chair of the Ethics Review Board convenes a meeting and announces its agenda 10 business days in advance of the meeting, by which time all Applications to be reviewed during the meeting are made available to the Ethics Review Board members.

- d. The time taken by the Ethics Review Board to complete a review of an Application will depend on the number of Applications considered in any session, but should not exceed six weeks for any Application.
 2. The Ethics Review Board adopts the following working order based on consensus decision making:
 - a. Ethics review is based on consensus. All permanent members who are present at the Ethics Review Board meeting and discuss an Application also sign the resulting Review Report. Consensus is recorded in the minutes of Ethics Review Board meetings and the resulting Review Reports, which are signed by all participating permanent members. It is the responsibility of the Chair of the Ethics Review Board to facilitate consensus.
 - b. Ethics Review Board can review Applications and reach a consensus when half of the permanent members plus 1 permanent member are present; this means when at least 4 permanent members are present. The lay member of the Ethics Review Board must always be present for consensus decision making.
 - c. Any absences of permanent members from the convened meetings of the Ethics Review Board must be communicated to the Chair of the Ethics Review Board at least 48 hours before the meeting. If an absence is communicated in time, the absentee permanent member may also send written notes and opinions on the Applications to be reviewed during the meeting and such notes and opinions will be acknowledged by the Ethics Review Board. However, since absent members cannot participate in the consensus decision making process, they do not sign the resulting Review Reports.
 3. Ethics review results in one of the following recommendations:
 - a. Approved: the project or research protocol can proceed as presented in the Application to the Ethics Review Board
 - b. Approved with conditions: the project or research protocol can proceed after changes recommended in the Review Report are made or any compulsory requirements are met
 - c. Not approved: the project or research protocol shall not proceed for the reasons clearly specified in the Review Report
 - d. No decision: the project or research protocol requires further clarification or further review
 4. All Review Reports include a clear motivation for the specific review result.
 5. Approved projects must be carried out in accordance with the original Application and the Review Report. If changes are made to the project or the research protocol, then the Ethics Review Board must be informed immediately using the dedicated form available on the website of the Ethics Review Board.
 6. Projects or research protocols approved with conditions must submit a record of modifications to the project or research protocol to the Ethics Review Board, using the dedicated form available on the website of the Ethics Review Board, before they shall proceed.
 7. Not approved projects can re-submit their Application for review by the Ethics Review Board. The resubmitted Application must clearly respond to comments made by the Ethics Review Board in the initial Review Report. The resubmitted Application will be considered, usually by the original team of reviewers, and recommendations will be made.

Article 5. The Ethics Review Board Administrator

1. The Head Office selects and appoints an Administrator who supports the work of the Ethics Review Board. The Ethics Review Board Administrator has a work contract with Eurac Research.
2. The Ethics Review Board Administrator has the technical and administrative knowledge and skills to support the work of the Ethics Review Board.
3. The Ethics Review Board Administrator is responsible for:
 - a. Developing and updating, when necessary, the guidelines and application materials made available by the Ethics Review Board to researchers in Eurac Research.
 - b. Corresponding with researchers and guiding researchers through the ethics review process
 - c. Receiving from researchers Applications for review and protocolling the Applications received;
 - d. Organizing the meetings of the Ethics Review Board that have been convened by the Chair of the Ethics Review Board;
 - e. Distributing among the members of the Ethics Review Board the Applications to be reviewed during convened meetings in timely manner, and at least 10 business days before the meeting;
 - f. Participating in the meetings of the Ethics Review Board and keeping records of these meetings (i.e. minutes);
 - g. Preparing the Review Reports and facilitating their digital signing by the permanent members of the Ethics Review Board
 - h. Delivering signed Review Reports to researchers
 - i. Maintaining the archive of the Ethics Review Board. The archive must contain the following:
 - i. Regulations of the Ethics Review Board
 - ii. Applications made to the Ethics Review board and any supporting documents, including copies of consent forms
 - iii. Minutes of the Ethics Review Board meetings
 - iv. Review Reports as well as any post-review exchanges between researchers and the Ethics Review Board
 - v. CVs of Ethics Review Board members and expressions of conflict of interest by Ethics Review Board members
 - vi. Any other relevant documents as necessary
 - j. Supporting the Chair of the Ethics Review Board in annual reporting to the Head Office
 - k. Organizing awareness-raising and training events around research ethics in Eurac Research, also involving the members of the Ethics Review Board.
 - l. Liaising with institutes and centers, Legal Office, Statistics Office, Research Support Office and other relevant stakeholders to ensure visibility of the Ethics Review Board and its insertion in research and support workflows in Eurac Research.

Article 6. Financial Aspects

1. Permanent members of the Ethics Review Board receive a honorarium of 50 euro per meeting for their time and effort. If a permanent member is an employee of Eurac Research, they will receive an annual bonus commensurate with the honoraria received by other permanent Ethics Review Board members.
2. The Ethics Review Board has an annual operating budget made available by the Head Office to cover the costs of the activities of the Ethics Review Board and the Ethics Review Board Administrator.

These regulations have been approved by the Board of Directors of Eurac Research on 10.11.2023 and will go into effect from 01.01.2024. The regulations will be reviewed after 1 year of application, during which time their effectiveness and fit-for-purpose will be evaluated.