

Procedure from submission to the final ethics statement by the Ethics Committee¹

Version 2.0 from 25 February 2021

Procedures

- 1. Submission** of the research proposal to the office of the Ethics Committee
 - Submission only in digital form via the [website](#) of the Ethics Committee
(at least 2 weeks before the date of the meeting, see GeO §5 para. 3) [GeO = *Geschäftsordnung* = Rules of Procedure]
- 2. Formal review** of the proposal by the office, within two working days after submission.
 - Does the research fall within the remit of the Ethics Committee (see GeO §1 para. 3)
 - Is the proposal complete? If necessary, request additional documents
- 3. The Chair assigns the proposal** to a primary and a secondary reviewer for assessment
(assigned within two working days).
- 4. Preparations for the next committee meeting**
 - The invitation to the meeting is sent out with the agenda, which includes the list of submitted proposals to be discussed and the names of the reviewers.
(at least 1 week before the date of the meeting, see GeO §7 para. 3)
 - All proposals are stored on BOKUdrive, where they are accessible for all committee members.
 - The main and the secondary reviewer jointly prepare a written draft of the decision.
 - The draft decision is sent to the office before the meeting.
 - If required, reviewers communicate with the office (request additional written information, or invitation for oral explanations by the researcher during the committee meeting). The office forwards the request to the researcher.
- 5. Meeting of the Ethics Committee**
 - Reviewers briefly present the research proposal, explain the ethical aspects, assess the strengths and weaknesses of the proposal regarding these ethical aspects, and present their proposed decision and statement.
 - If applicable: oral explanations by the researcher.
 - Discussion of the proposal and deliberation by the entire Ethics Committee.
 - Decision regarding the core points of the statement as well as the decision (which may have been changed through the discussion) by the entire Ethics Committee.

¹ This document is continuously revised and updated. Please make sure that you download the latest version from the website of the Ethics Committee.

6. Written decision

- If applicable: reviewers and Chair assist the office in the wording of the comments to the statement as well as of the decision.
- The office issues the decision as well as the relevant parts of the statement to the researcher within 2 weeks of the meeting (GeO §10 para. 7).

Possible decisions by the Ethics Committee regarding a proposal

- **The research does not fall within the remit of the Ethics Committee:**

As defined in the Rules of Procedure (GeO):

- The research project is subject to legal approval (e.g. if it includes experimenting on animals), see GeO §10 para. 1.
- The research project is not within the topics listed in GeO §1 para. 3. For example clinical or medical research, or research with human cells/tissues, requires an ethical approval from a suitable Ethics Committee.
- For research consortia, the project coordinator is responsible for the ethical approval of the overall project. For a clearly defined work package, a proposal may be submitted to the BOKU Ethics Committee if the work package is led by a BOKU researcher.

- **The research is granted ethical approval:** the proposal, as submitted, meets all ethical principles, as stated in GeO §10 para. 2. The statement thus confirms that:

- Adequate measures are taken to protect the rights, safety, and well-being of the study participants and of the researchers.
- If animals are used, research is in compliance with the animal welfare law.
- In the case of interventions in the ecosystem, the welfare of the animals that may be significantly affected is adequately ensured.

- **Amendments are required:** there are only minor weaknesses in the research proposal, with some aspects requiring clarification, as listed in the comments to the statement. These must be addressed by the researcher before the research is approved, but the revised proposal does not have to be discussed by the Ethics Committee. After comprehensively addressing the issues listed in the comments to the statement, the proposal is resubmitted to the office, the amendments are checked by one of the referees and by the chair (4-eyes principle). If the amendments are satisfactory, an ethical approval is issued. At the next meeting of the Ethics Committee, the Chair reports whether the required amendments have been implemented and whether an ethics approval was issued. If the revised proposal is not submitted within 12 months after the decision has been communicated, and if no extension of this resubmission period has been requested, the researcher is informed and the submission is closed.

- **Statement regarding a project concept:** The research project is at an early stage, the proposal is still sketchy, i.e. not detailed enough to comprehensively assess the ethical aspects. This concerns, for example:

- Proposal for a doctoral research, submitted immediately after the start of the doctoral studies (see GeO §5 para. 5). As soon as a detailed research proposal (for the complete research project or parts thereof) is available, it must be submitted to the Ethics Committee in accordance with GeO §5 para. 6.
- Research project to be submitted to the European Commission: a statement by the Ethics Committee is required at the time of submission, but a detailed research plan which allows an in-depth review of the ethical aspects is not yet available.
- **Decision to adjourn:**
 - *Request for additional information:* The information included in the submitted project proposal does not allow to comprehensively assess the ethical aspects. The researcher is invited to resubmit a more detailed proposal.
 - *Invitation to amend the research:* There are substantial criticisms regarding ethical aspects in the submitted research proposal. The weaknesses are detailed and justified by the Ethics Committee (GeO §10 para. 4) and forwarded to the researcher. The researcher is invited to address to each point and to submit a revised research proposal.
 - *Commissioning of expert opinions:* The research project contains challenging ethical issues that require assessment by external experts. The researcher may recommend several experts. The Ethics Committee selects at least two experts and requests an assessment.
- **Rejection of the research proposal for non-compliance:** The proposed research raises serious ethical concerns. These cannot be eliminated even after an invitation to amend and the submission of a revised proposal; or the proposal concerns research activities that have already been implemented (in the case of an ethics approval being required for a publication). The researcher may withdraw the application (GeO §10 para. 6). If the proposal is not withdrawn within two weeks of being informed of the decision by the Ethics Committee, a statement of non-compliance with ethical standards will be issued.

For further information

Website of the Ethics Committee: <https://short.boku.ac.at/ethics>
Office of the Ethics Committee: ethikkommission@boku.ac.at

