Universität für Bodenkultur Wien
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Ethics Committee

Checklists for proposals submitted to the Ethics Committee[1]

Version 1.2 from 15 September 2022

Introduction

The checklists for research projects involving humans or animals are meant to help researchers when they prepare their proposal for submission to the Ethics Committee in accordance with GeschO §6 of the Ethics Committee. *(GeschO = Geschäftsordnung = Rules of Procedure)*

To assess whether it can grant an ethics approval, the Ethics Committee requires a research proposal to be submitted before the start of data collection, which includes a detailed description of the aspects relevant for the ethical assessment (GeschO §6 para. 2). Based on the submitted documents, the Ethics Committee must be able to assess whether all necessary measures are taken to safeguard the rights, safety, and welfare of the human participants and of the researchers during the implementation of the research project (GeschO §10 para. 2). Similarly for research projects involving animals, it must be able to assess whether the animals involved in the research will be treated humanely, will be cared for properly, and unnecessary suffering avoided.

The proposal submitted to the Ethics Committee includes a brief description of the overall research project as well as a detailed description of the ethical aspects and how they will be taken into account. Reference shall be made to all circumstances relevant to ethical aspects referred to in GeschO § 10 para. 2. The submitted proposal should be as succinct as possible and as comprehensive as necessary. It is therefore appropriate to submit only those documents that are relevant for the assessment of ethical aspects (see GeschO § 6 and checklists on the following pages). The submitted proposal should document an ethics-sensitive research attitude. They should reflect the researcher's ethical awareness and his*her careful consideration of all ethical issues in close connection with the research project, rather than merely resorting to vague generalities.

The questions listed in these checklists are meant to invite a reflection on the various aspects that might warrant ethical consideration. The questions are only indicative: not all questions are relevant to all research projects; on the other hand, projects may also involve ethical aspects that extend beyond the questions listed. Further information can be found on the Ethics Committee's website. Especially for projects submitted to Horizon Europe, please refer to the detailed information provided by the European Commission.

There is no standard form to fill out, however it is helpful if your proposal follows the structure of the checklist. A clearly structured proposal, with all required information and clearly worded, will reduce the need by the Ethics Committee to ask for further information or further documents, and thus ensure a rapid review process. The proposal may be submitted in German or English.

For consortia projects, the overall project management is responsible for the ethics review 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 researcher from BOKU.

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

Checklist for research with human subjects

1. General information about the research proposal submitted to the Ethics Committee

- Name, e-mail, title, position (e.g. project leader, PhD student), and Institute of the person submitting the proposal to the Ethics Committee.
- Title of the research project
- If it is a project within doctoral studies: Name of the supervisor
- Funding agency to which the research project is (was) submitted for funding
- Reason for the proposal (see GeschO §5 para. 2): what is the Ethics Committee vote needed for?
- Should the statement of the Ethics Committee be issued in German or in English? If in English, please make sure you provide an English project title
- Period of (planned) data collection

2. Research plan

Brief description of the research project or embedding of the work package in the overall research project. Please explain:

- the current state of knowledge and the objective of the research project
- the research question and the hypotheses that will be tested

3. Documentation of the general ethical aspects of the research project

- What is the objective of the research project? What is the expected knowledge gain / benefits to society / to a group?
- Will research findings be made available to study participants or relevant organisations? If yes, what format will this take (e.g. debrief, leaflets, publication in trade journals, website)?
- What are the possible effects on the groups or companies to which the participants belong? Can the project negatively affect the reputation of a specific group of people or businesses (e.g. reproduce stereotypes)?
- Do the expected benefits (e.g. knowledge gain) outweigh the foreseeable risks associated with the research project?
- Study design: How has the sample size been determined? Which groups will be compared?
- Are there conflicts of interest on the part of the researchers involved?
- What measures are taken to ensure that project staff are sufficiently trained and qualified (ethical competence)?
- What do researchers do, if they become aware of criminal acts by study participants, which they may have to disclose to authorities?
- How will ethical aspects be reviewed in the course of the project? What procedures are in place to deal with unforeseen events that impact ethical aspects (e.g. change in research design)?
- Should students participate in a research project: how is the principle of voluntary participation taken into account? (e.g. when collecting data as part of a course, is there an alternative form to complete the course requirements?)

4. Documentation of the ethical aspects related to the participants

- What criteria are used to select participants?
- How will participants be recruited?
- What benefits will participants gain from participating in the research project? Will there be any remuneration for participation?
- Will personal or sensitive issues be addressed? If so, what measures are taken to minimize the risks of causing distress?
- What risks or potential harms (in psychological, physical, social, legal, or economic terms) might the participants face as a result of the research project (during data collection or through the analysis, publication, use, and archiving of the results)? What measures are taken to minimize these risks?

- Could material harm (up to and including criminal penalties) result from the information collected? What measures are planned to minimize harm for participants?
- Is participation planned for people from vulnerable groups (e.g., children, refugees, the elderly, those in need of care, or who are cognitively impaired)? What steps are taken to protect them from exploitation or stigmatisation?
- Is intentional deception of participants planned? If yes, how do you justify it? Will participants be informed about this after data collection or analysis? If yes, how?

➔ Please attach documents such as questionnaires, interview guide.

5. Documentation of the ethical aspects concerning participant information and declaration of consent

- Have you prepared a Plain Language Statement (PLS) that explains the nature of the research, the aim of the data collection, their rights (e.g. voluntariness, possibility to withdraw at any time), and possible risks?
- How will you ensure informed consent for participation in the project?
- How does the principle of free and voluntary participation implemented?

➔ Please include the information sheet that will be given to participants.

➔ Please attach the Informed Consent Form for participation in the project.

6. Documentation of the ethical aspects related to anonymity and data protection

Please briefly explain how you implement the provisions of the GDPR. In particular:

- How will personal data be protected? This includes digital data, but also e.g. signed consent forms which carry the names of the participants.
- Will personal data be erased? If yes, when?
- Will the data be anonymized/pseudonymized? If yes, how?
- Will the participants be informed of their rights[2] (see Art. 13 GDPR)? It this in easy-to-read, plain language (PLS)?

➔ Please include the data protection information sheet.

7. Ethical aspects of interventions in the ecosystem

- What are the expected impacts on animals covered by the Animal Protection Act?
- Which measures are being taken to minimise suffering of vertebrates?
- What are the expected impact on the ecosystem?

8. For research projects that (partially) take place in third countries, esp. non-EU countries

For research projects conducted in the Global South, please explain in particular, how you implement the provisions of the 'Global code of conduct for research in resource-poor settings' as well as 'free, prior, informed consent' (see FPIC Website of FAO).

- Does the research project meet the needs of the country where the data will be collected?
- Will local researchers be involved in the research project?
- How do you take into account local customs and social norms (e.g. how has it influenced the study design, access to the field, selection of participants)?
- How do you ensure informed consent if participants are illiterate or come from educationally poor backgrounds or belong to vulnerable groups? Is a written consent culturally appropriate? If not, how will you ensure oral consent? Do you also have to receive consent from a local authority or ??
- Have you followed the provisions of the BOKU Emergency Plan for Travel Abroad (website)?

[2] See the right to be informed according to Art. 13 GDPR, which includes: contact of the project leader and the data protection officer, Purposes of the processing of personal data, period for which the data will be stored, right to erasure of personal data, right to restrict processing, right to withdraw consent, right to lodge a complaint with a supervisory authority.

- If your research (partly) takes place in a non-EU country, have you taken into account the relevant provisions of the European Commission (e.g. material transfer agreement, export authorization, benefit sharing).

Note: for research projects with humans, an ethical approval for the research project can only be issued once all documents are available (i.e. incl. questionnaire, information sheet, consent form, etc.). If these have not yet been elaborated, a statement on the project concept will be issued.

For further information

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

Checklist for research involving animals

1. General information on the proposal to the Ethics Committee

- Name, e-mail, title, position (e.g. project leader, PhD student), and Institute of the person submitting the proposal to the Ethics Committee.
- Title of the research project
- If it is a project within doctoral studies: Name of the supervisor
- Funding agency to which the research project is submitted for funding
- Reason for the proposal (see GeschO §5 para. 2): what is the Ethics Committee vote needed for?
- Give reasons as to why this research is not classified as an experiment on animals which requires legal approval.
- Should the statement of the Ethics Committee be issued in German or in English? If in English, please make sure you provide an English project title
- Period of (planned) data collection

2. Research plan

Brief description of the research project or embedding of the work package in the research project. Please explain for both research under laboratory and field conditions (e.g., on farms, in ecosystems):

- the current state of knowledge and the objective of the research project
- the research question and the hypotheses that will be tested
- Key words

Describe and justify the methods, following the ARRIVE-Guidelines 2.0. It may include the following aspects:

- Test planning: Study design, e.g., description of treatments and controls, including groups to be compared, including control groups.
- Measurement parameters: Which are collected and how?
- Intervention on the animal: What is to be done, when and how often, where and why? (including capture, isolation, restraining, marking, tagging, transporting, etc.)
- Experimental animals: Number, species, sex, age, stage of development, breeding line if applicable
- Sample size: Explain how it was determined for the different groups
- Inclusion and exclusion criteria: Describe any criteria for inclusion and exclusion of animals or groups of animals
- Randomization: How are animals selected, how are they assigned to control or experimental groups?
- Blinding of observers: Is blinding possible or why not? Who knows about group assignment (with/without intervention) and when?
- Statistical methods: Which ones are used to test the assumptions?

3. General ethical aspects of the research project

- What are the expected benefits to society?
- Can the results of this study be applied to other species?
- Are there conflicts of interest on the part of the researchers involved?
- Should students participate in a research project: how is the principle of voluntary participation taken into account? (e.g. when collecting data as part of a course, is there an alternative form to complete the course requirements?)

4. Ethical aspects of housing, care, and supervision

- Responsible person(s)
- Who takes care of sick animals? Who euthanizes, if necessary?

- What data is collected on mortality (number of deaths and number of animals which had to be euthanized, reasons)?
- What measures are taken to ensure that project staff are sufficiently qualified (knowledge, experience)?
- Origin of the animals and what happens to the animals after the research project? Will they be re-used in other research projects?
- How are the animals housed and kept, including environmental enrichment?
- What measures are taken to ensure that animals can express their natural behaviours?
- Describe the measures taken to prevent pain, suffering, and anxiety.

5. Ethical aspects of the experimental procedures

- Who is the responsible/executing person
- What measures are taken to ensure that project staff are sufficiently qualified (knowledge, experience)?
- Describe steps to minimize pain, suffering, and anxiety associated with the interventions (see 3R).
- What treatments are applied in the framework of the experiment?
- How will expected or unexpected adverse events be reported?
- Are there discontinuation criteria (humane endpoints)? If yes: which? What signs are monitored and how often are they monitored?
- How does the intervention affect post-release behaviour/survival?

6. Ethical aspects of interventions in the ecosystem

- What other animal species are affected and how? Are they protected species?
- What are the expected effects on animals not in the focus of the research project that are covered by the Animal Protection Act?
- Which measures are being taken to minimize the suffering of vertebrates?
- Research with vertebrates in the wild: what are the expected impacts on the ecosystem?

For further information

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