BOKU UNIVERSITY

Applications to the Ethics Committee

Checklist for research with humans

Version 3.1 from 21 November 2024[1]

Introduction

The checklist for research projects involving humans is meant to guide researchers as they prepare their application for submission to the Ethics Committee in accordance with §6 of the Rules of Procedures of the Ethics Committee. 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 (Rules of Procedures §10 para. 2). Thus, reference must be made to all circumstances relevant to ethical aspects referred to in §10 para. 2.

The application should document an ethics-sensitive research attitude. The answers to the questions should reflect the researcher's ethical awareness and their careful consideration of all ethical issues in close connection with the research project, rather than merely resorting to vague generalities.

The submitted application should be as succinct as possible and as comprehensive as necessary. All questions of the checklist must be answered (if a question is not relevant, please answer 'not applicable' and briefly state why it is not applicable). Your application must include the numbering of the questions and their wording, as written in the checklist. Please provide clear and succinct answers to each question and avoid repeating the same information in your answer to different questions. Should you be unsure about the topic of a question, please consult the commented checklist available on the website of the Ethics Committee.

There is no standard form to fill out. However, a clearly worded, well-structured application, with all required information will reduce the need by the Ethics Committee to ask for further information or further documents, and thus ensure a rapid review process.

The application may be submitted in German or English.

Applications must be submitted in good time, so that the final ethics statement can be issued before the start of data collection. Take into account, that the Ethics Committee might request additional information after discussing your application in a meeting, and that this will need to be provided before the final ethics statement can be issued.

Documents on ethics in research projects 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.

For consortia projects, the overall project management is responsible for the ethics review of the overall project. For a clearly defined work package, an application 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 application submitted to the Ethics Committee

- Name, e-mail, title, position (e.g. project leader, PhD student, supervisor (for research in the framework of MSc theses), and Institute of the person submitting the application to the Ethics Committee.
- Title of the application (you may add the title of the project in which the research described in this application is embedded)
- For research in the framework of a doctoral study:
    - Name of the supervisor
    - Has the supervisor reviewed and approved the application?
- For research outside of a doctoral study:
    - Name of project leader
    - Has the project leader reviewed and approved the application?
- Funding agency to which the research project was (will be) submitted for funding
- Reason for the application: what is the statement of the Ethics Committee needed for? (e.g. requirement of journals where the results will be published, request of a funding body, see Rules of Procedures §5 para. 2)
- Should the statement of the Ethics Committee be issued in German or in English? If in English, please make sure you provide an English title for the research described in the application
- Planned period of data collection (please note that contacting potential participants and data collection can only begin after the Ethics Committee has issued the final statement)

2. Research plan

Brief description of the research project or embedding of the work package in the overall research project (max. 1 page). Please briefly present:

- 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 (for all ethical aspects that are directly related to participants, see section 4)

3.1. What is the expected societal impact of the research? How will it benefit society at large or a specific group?

3.2. Will research findings be made available to stakeholders, policy makers or relevant organisations? If yes, what format will this take? (e.g. summary report for users, leaflets, publication in trade journals, documents offered on the project website)

3.3. What possible risks (for which groups?) are associated with the project? How will they be mitigated? Do the expected benefits (e.g. knowledge gain, practical value for users) outweigh the foreseeable risks associated with the project?

3.4. Are there conflicts of interest on the part of the researchers involved? If yes: which?

3.5. How will ethical aspects be reviewed during the project? What procedures are in place to deal with unforeseen events that have an ethical dimension?

3.6. If students participate in a research project: how is the principle of voluntary participation implemented? (e.g. if data is collected data as part of a course held at BOKU, is there an alternative form to complete the course requirements?)

3.7. Will the project contribute to Open Data? (i.e. will anonymised, processed or unprocessed raw data be made available to other researchers) If yes: which data? When? In which repository? If not, please briefly state why not.

4. Documentation of the ethical aspects specific to the participants

4.1. What criteria are used to select participants? Who will be included/excluded? How do you consider diversity, equity and inclusion? How big is the sample size and how was it determined?

4.2. How will participants be recruited?

4.3. What benefits will participants gain from participating in the project? Will there be any remuneration for participation?

4.4. Will participants be informed of the research results? If yes: how and when?

4.5. Will personal or sensitive issues be addressed? If so, what measures are taken to minimize the risk of causing distress?

4.6. 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?

4.7. 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?

4.8. Is the participation of people from vulnerable groups planned? (e.g., children, refugees, the elderly, those in need of care, or who are cognitively impaired) If yes: what steps are taken to protect them from exploitation or stigmatisation?

➔ Please attach documents such as questionnaires, interview guide[2]

5. Documentation of informed, free and voluntary participation

5.1. How will you implement the principles of informed consent before and of free and voluntary participation during data collection?

5.2 Have you prepared a Plain Language Statement (PLS) that explains the nature of the research? Have you prepared a consent form? (see commented version of the checklist for a list of information that should be provided in the participant information sheet and the consent form).

➔ Please attach the information sheet that will be given to participants[2]

➔ Please attach the Informed Consent Form to be signed by the participants[2]

6. Documentation of aspects related to anonymity of participants[3]

6.1. Do you collect data anonymously? If yes, please briefly describe how you ensure anonymity

6.2. Should data not be collected anonymously: will the research data be anonymised/pseudo-nymised? If yes: how and when?

6.3. Should data not be collected anonymously, and you have informed participants that their anonymity will be protected, which measures will you implement to ensure this anonymity? (e.g. how do you ensure the anonymity of known experts? Can colleagues or acquaintances guess who has made statements you might quote? Can anonymity be ensured if participants are invited to workshops?)

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[2] An ethics statement can only be issued if all relevant documents have been submitted (e.g. (preliminary) questionnaire or interview guide, information for participants, declaration of informed consent)

[3] For a guideline on how to distinguish between anonymous/anonymised research data (which may include demographic data) and personal data as defined in the GDPR, see the information sheet on the website of the Ethics Committee

➔ Please include the text in which the participants are informed how anonymity will be handled (may be part of the Information Sheet for Participants)

7. Documentation regarding the processing of personal data: implementation of the GDPR[3]

7.1. Which personal will be processed? Please be specific, e.g. names, street address, personal email, GPS-coordinates. For what purpose is this personal data collected and processed?

7.2 How will personal data be protected against unauthorized access? This includes digital data (e.g. lists of participants) and data in paper form (e.g. printed lists of workshop participants, surveys that carry the name of the participant)

7.3. When will the personal data be erased? Please indicate a specific date (month, year) and the name of the person responsible to erase the data

7.4. Are the participants informed of the implementation of the GDPR and of their rights in easy-to-read, plain language (PLS) (see information to be provided according to Art. 13 GDPR) [4]

➔ Please include the text in which the participants are informed how their personal data is protected in accordance with the GDPR (may be part of the Information Sheet for Participants)

8. Ethical aspects in case of interventions in an ecosystem[5]

8.1. What are the expected impacts on animals covered by the Animal Protection Act?

8.2. Which measures are being taken to minimise suffering of vertebrates?

8.3. What are the expected impacts on the ecosystem?

9. For research projects that (partially) take place in the Global South[5]

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).

9.1. Does the research project meet the needs of the country where the data will be collected?

9.2. Will local researchers be involved in the research project? Will the results be provided to local researchers? If yes: in what form and when?

9.3. 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)?

9.4. 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? If yes: which?

9.5. Have you followed the provisions of the BOKU Emergency Plan for Travel Abroad (website)?

9.6. 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).

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[4] See the right to be informed according to Art. 13 GDPR, includes among other the contact of the project leader and the data protection officer, Purposes of the processing of personal data, and date when the data will be erased.

[5] If your research does not affect the environment or does not take place in the Global South, just list Question 7 and/or Question 8 and write 'not applicable' and briefly explain why not. There is no need to list the sub-questions.

For further information

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