UNIVERSITY OF TURKU

Instructions
4 September 2025

NON-MEDICAL RESEARCH INVOLVING HUMAN PARTICIPANTS

Guide to requesting an ethical review

The Ethics Committee for Human Sciences at the University of Turku reviews the ethical principles of non-medical research conducted on human participants and provides ethical review statements on these projects. The ethical review of medical research is a legal requirement (488/1999) and studies governed by the law are subject to the assessment of the Ethics Committee of the Wellbeing Services County of Southwest Finland.

The statements of the Ethics Committee for Human Sciences at the University of Turku are free of charge for researchers and doctoral researchers of the University of Turku and the Wellbeing Services County of Southwest Finland. The Ethics Committee for Human Sciences at the University of Turku also provides statements to other parties for a fee.

The ethical principles for research involving human participants are set out in the guideline of the Finnish National Board on Research Integrity (TENK): The ethical principles of research with human participants and ethical review in the human sciences in Finland. Finnish National Board on Research Integrity TENK guidelines 2019. Researchers should refer to the guideline when assessing whether their research requires ethical review.

The ethical review is carried out before research data is collected and an ethical review statement cannot be issued afterwards.

The researcher must request an ethical review statement from the Ethics Committee for Human Sciences if their research contains any of the following: (TENK 2019,4.2):

a) participation in the research deviates from the principle of informed consent,
b) the research involves intervening in the physical integrity of research participants,
c) the focus of the research is on minors under the age of 15, without separate consent from a parent or guardian or without informing a parent or guardian in a way that would enable them to prevent the child's participation in the research,
d) research that exposes participants to exceptionally strong stimuli,
e) research that involves a risk of causing mental harm that exceeds the limits of normal daily life to the research participants or their family members or others closest to them, or
f) conducting the research could involve a threat to the safety of participants or researchers or their family members or others closest to them.

The researcher can also request the ethical review if it is required by the funding body, partner, subject or publisher. It is the responsibility of the researcher to find out whether the potential publisher requires an ethical review.

Submitting the ethical review request

- The ethical review request is submitted electronically at https://asiointi.utu.fi/s/eettinenennakkoarviointi/lausuntopyynto. **You can log in to the system with your Suomi.fi e-Identification**.
- The statement request must be submitted at least two weeks before the meeting of the Ethics Committee at which the statement request is to be reviewed. The upcoming meetings of the Ethics Committee divisions: https://www.utu.fi/en/research/ethics/ethical-review-in-human-sciences-research#requests.

- All fields marked with an asterisk (*) are mandatory.

Support and further information
- requests for support and questions regarding the ethical review, please contact eettinen@utu.fi.
- questions regarding the electronic application system, please contact asiakirjapalvelut@utu.fi.

INSTRUCTIONS FOR FILLING IN THE REQUEST FORM

The system allows you to fill in the form in sections. Remember to save the request by clicking the Save draft button. You can find the saved draft in the Applications tab.

Please note that the ethical review will assess the research particularly from the perspective of whether the conduct of research or its results could potentially cause risks or harm to the participants, their families or the researcher themselves. These are weighed against the intended scientific value of the research.

Person submitting the ethical review request

Contact information of the person submitting the ethical review request
- The name and contact details of the person submitting the ethical review request are required for any communication related to the request.
- This includes the possible requests for supplementary information, information on the processing of the ethical review request, and the decision of the Ethics Committee.
- It is the responsibility of the contact person to ensure that documents related to the ethical review of the research plan are properly stored and distributed.
- The principal investigator may act as the contact person for the ethical review request.
- In the case of a thesis, the person submitting the ethical review request is a student or a doctoral researcher.

Principal investigator or thesis supervisor

Contact details of the principal investigator or the thesis supervisor
- Typically, the principal investigator possesses a doctorate, is an independent researcher, and supervises the other researchers on the project. They are responsible for ensuring that good scientific practice is applied in the research and that the research is conducted in a legal, safe and competent manner. They ensure that qualified staff conduct the research with adequate facilities and equipment, and that the research is otherwise conducted safely and to a high standard. They must ensure that the research is conducted in compliance with the EU General Data Protection Regulation (EU 2016/679), other data protection legislation, international obligations concerning the status of the data subject, and other regulations and guidelines concerning research.
- With theses, the contact details of the thesis supervisor should be entered here.

Basic information on the study

Title of the study
Write the title of the study in Finnish and English.

Research participants
- Indicate whether the research participants are adults, minors, children under 15 years of age and/or people with limited capacity.
- In case the participants cannot give informed consent, the procedure for recruiting participants must be described and justified in the request. The procedure must also be described in the documentation given to the participants.

Nature of the study

Indicate whether theses are or are not conducted in the research project, or what kind of thesis the request concerns.

Estimated start and end date of the study
Sufficient amount of time is reserved for conducting the study.

Additional information on the study

Organisations participating in the study
- Indicate the organisations and their departments/units and researchers involved in the study.
- In case of an international study, the countries involved in the research are also indicated.

Funder or commissioner of the study

Indicate the funder and possible commissioner of the study. The commissioner of a study is a person, company, institution or organisation responsible for initiating, managing and funding the study.

Compensations and rewards paid to participants
- Indicate the compensations and rewards paid to the participants.
- The participants of a study are not usually paid a separate compensation. If the researcher wants to thank the participants for their time and effort in a concrete way, the reward should be reasonable. Research participants can be compensated for reasonable travel and food costs (TENK 2019, 3.2).

If you plan to use AI in your research, describe how you plan to use artificial intelligence
If artificial intelligence (AI) is used in the research, describe it briefly. The application of AI should comply with the University of Turku's guidelines for AI use in research.

The University of Turku is committed to following the open science policies. This should be taken into account in research conducted at the University of Turku. Describe how you follow the guidelines.

Open science policies are taken into account in all research conducted at the University of Turku.

Information for the request

New or changed study

A new ethical review request is selected when the study has no previous statement.

Change to a research plan is selected if a statement is requested for reviewing changes to a research plan that has already received an ethical review statement earlier.

- The principal investigator will assess the need to request a new ethical review for the research.
- A new ethical review must be requested if there is a significant change in the research that affects the ethical principles of a previously assessed study. A new review must be requested if, for example, the research plan is modified in such a way that the change may undermine the rights of the participants or increase the risks, damage or harm to the communities or other subjects of the research.
- A new review must also be requested if a setting, sub-study or data is added to the research plan that is not mentioned in the original plan and it has an impact on the ethics of the study. Instead, changes in the members of the research group or a change in the research schedule are not typically factors affecting the ethics of the study that would require a new ethical review.
- The request for a new review must include all the documents of the prior ethical review.
- An appendix is added to the request, where any changes made to the study are tabulated and justified.
- The documents must indicate how they have been modified (for example, by marking deleted text with a strikethrough and added text in italics/colour font).
- The principal investigator's assessment on the necessity for the ethical review is also required for any changes made to the research plan.

More information on changes to the research plan

If a statement is sought to a change to a previously reviewed research plan, the requester must provide information on the changes to the research plan as well as the document ID and date of the previous review.

Division of the Ethics Committee

The researcher must select which division of the University's Ethics Committee for Human Sciences they are requesting the ethical review from.

- *The Health Care Division* issues ethical review statements on non-medical research related to health care, whose ethical review is not already regulated by the Medical Research Act (488/1999).
- *The Humanities and Social Sciences Division* issues ethical review statements on all non-statutory studies other than medical studies. These include humanities and social sciences as well as natural sciences and technology research concerning people.

Grounds for requesting an ethical review

- The reasons for requesting an ethical review (cf. TENK 2019, 4.2).
- In addition to these provisions, the request for statement may be based on a request for ethical review made by the research funder, partner, subject or publisher.

- The researcher may also request an ethical review on other grounds.

Additional information
Describe any other factors affecting the ethics of the research.

APPENDICES TO THE REQUEST OF REVIEW

All appendices marked with an asterisk (*) are mandatory.

Appendices to the request should be named as listed below and the date should be indicated in the name of the attachment (e.g. "Attachment 1 Summary of the research plan 01012025" or "Attachment 5 Information sheet for participants under 15 years of age 01012025"). This information should be included not only in the names of the appendices, but also in the documents themselves.

It is up to the researcher to ensure that the attachments do not contain conflicting information. For example, discontinuation and withdrawal from the research, number of participants, research schedule, and data management and processing of personal data must be described in the same way in all the documents included in the request. If the committee asks the researcher to supplement the appendices, the researcher is responsible for the consistency of the appendices even after the supplements have been made.

1. **Signature of the thesis supervisor**

   The thesis supervisor confirms by signing the form Signature of the thesis supervisor that they are the supervisor of the research for which the ethical review is requested, that they have read the request and all its appendices, and that they are requesting the ethical review of the Ethics Committee together with the student/doctoral researcher. The form can also be signed electronically.

2. **Summary of the research plan**

   The maximum length of the summary is one page.

3. **Research plan**

   The research plan included in the request may be the research plan already prepared for the research project/thesis.

   If the research plan attached to the application has already been drafted earlier or if an ethical review is requested for a sub-study part of a larger research project plan, this should be clearly stated in the introduction to the research plan. The research plan should highlight the parts of the plan for which the review is requested.

   The maximum length of the research plan for the request for an ethical review is 10 pages and should include the following:

   - the background and purpose of the research and the justification for conducting the research
   - research methods, including
     - research design and data collection methods
     - informing and recruiting participants

  - a description of the analysis, processing and archiving of the data
- the progress and schedule of the research.

4. Principal investigator's assessment of the ethical nature of the research

The starting point for the principal investigator's assessment of the ethical nature of the research are the guidelines of the Finnish National Board on Research Integrity (TENK): The Finnish Code of Conduct for Research Integrity and Procedures for Handling Alleged Violations of Research Integrity in Finland and The ethical principles of research with human participants and ethical review in the human sciences in Finland. If necessary, the more specific ethical guidelines of the discipline in question can also be applied.

With theses, the thesis supervisor and the author of the thesis must sign the principal investigator's assessment of the ethical nature of the research.

The principal investigator's assessment of the ethical nature of the research should reflect the research ethics at all stages of the study, particularly from the point of view of avoiding risks and harm. The research should take into account TENK's ethical principles of research with human participants, discipline-specific guidelines, and data protection and security considerations. The choices made in the research must be justified.

In the assessment, you should consider e.g.:

- what ethical issues and considerations are involved, such as informing and recruiting subjects, the used research methods and data collection practices, analysis and interpretation of data, the life cycle of data storage, opening data, and publishing results.
- whether the research group needs to agree on issues such as ownership and management of data, supervisory relationships, authorship of publications, and copyright. It is a good idea to discuss contractual issues and need for agreements within the research group well in advance before starting the practical stage of the research. In case of conflict, only a written agreement is unambiguous.

In addition, the assessment of the ethical nature of the research must consider and assess the harms and risks included in the research from an ethical point of view in a versatile and comprehensive manner:

- What are the potential physical, psychological, social and financial risks to the participant? Are there any environmental risks associated with the research?
- What is the probability that the risks are realised? What methods are used to manage the risks? Are the methods sufficient?
- How is the risk handled if it is realised?
- What is the relation between the harms caused to the research participants and the benefits of the study?

If the researcher deviates from the principle of informed consent, the justification for the solution is presented in the principal investigator's assessment of the ethical nature of the research.

5. Information sheet delivered to research participants

These may include several documents, such as information sheets for a participant, a member of the control group, a close relative or a friend. Separate information sheets are prepared for minors/children of different age and their guardians. The information sheet must be clear and easy to grasp, and use language that the recipient can understand. Information sheets for children take into account their age and developmental level.

Information sheets usually contain the following information:

- The name and contact information of the principal investigator
- the research organisation(s) and the research funder
- invitation to participate in research
- the purpose, aim and significance of the study
- an explanation of why the recipient has been selected for the study, possible exclusion criteria, estimated number of participants
- the rights of participants: voluntary participation, the right to ask for further information about the study, and the right to discontinue or withdraw from the study at any time without having to give any particular reason and without any negative consequences
- how the data collection/research will be conducted (what does it require in concrete terms to participate in the study, how much time will the participation take, etc.)
- possible benefits and risks of taking part in the research
- compensations for participation
- processing of personal data in the study
- the purpose of the research data, safeguarding confidentiality (pseudonymisation, if applicable)
- retention, archiving, further use, and possible opening of research data
- identification of the registers used in the study, if the information from the participants is combined with register data from the authorities
- contact person for further enquiries

A template with instructions for drafting an information sheet can be found on the University's website under the section *Appendices to the ethical review request*.

If persons who are not able to give informed consent participate in the study, the procedure for recruiting participants must also be described and justified in the documents provided to the participants (information sheets and consent forms).

6. Informed consent

Obtaining informed consent for research from the research participants is a key ethical principle that ensures voluntary participation in research.

Several consent forms can be needed, for example, for the research participant, guardian, close relative or a friend. The informed consent form must be written in clear and plain language separately for each group and so that the recipient is taken into consideration. The language used in the consent form must be understandable to the research participant.

In addition to the information sheet to the participants, a signed consent form is required if the analysed research data contains identifiers and sensitive information.

Responding to a survey can also be considered as giving consent. If responding to a survey is considered as giving consent, it is recommended to include the consent form to the survey and mention that by responding to the survey the participant gives consent for the research. Documenting and proving consent that has only been given orally is difficult subsequently.

The researcher has the duty to store the original consent forms. The researchers can give the research participant a copy of their signed consent form upon request.

The consent form should cover the following matters:

- the study for which consent is requested, the location of the research, and who is conducting the research
- the research participant has read and understood the research information sheet they have received. The participant has received a sufficient amount of information about the research, data collection, data storage and further use of the data, and understood this information
- the participant has been adequately informed about the processing of personal data
- the participant has understood that participation in the study is voluntary
- the participant has had time to consider participating in the study. They have been adequately informed about their rights and the risks and benefits of the research
- the participant has the right to discontinue or withdraw from the study at any time without having to give any particular reason and without any negative consequences
- how the research data that has been collected before participant's withdrawal from the research is used
- the participant has had the opportunity to ask additional questions and has received answers to their questions
- the research participant's dated signature and name in block letters.

If the data collected in the study are combined with data from other sources (e.g. data collected through a questionnaire combined with register data), the explicit consent of the research participant must be obtained (e.g. each register is mentioned by name and the research participant indicates their consent by ticking a box).

A template with instructions for drafting an informed consent form can be found on the University's website under the section *Appendices to the ethical review request*.

7. Other materials to be provided to the participants (questionnaire, interview framework, observation plan, etc.)

8. Recruitment advertisements for research participants (advertisements in newspapers/bulletin boards/social media, emails, etc.)

9. Description of the recruitment of research participants

The description must contain two parts:

- *A description of the selection of participants*, i.e. how participants will be recruited (e.g. advertisements in newspapers and on bulletin boards, on social media, emails, random sample from a certain register). At the same time, the researcher must describe the procedure for handling calls/visits/interviews of persons who are in contact through an advertisement.
- *Description of the methods for obtaining informed consent*. The researcher must provide a description of the methods for obtaining informed consent from each participant before the start of the study. Informed consent is a process in which the research participant voluntarily confirms their willingness to participate in a specific study, after having received sufficient information, both in writing and verbally, on all matters related to the research that are relevant to their decision to participate. Participants must be given the opportunity to discuss their participation in the study with people close to them and enough time to decide whether to participate. The procedure must be described separately, if persons who are unable to give informed consent are asked to participate in the research.

10. Data management plan

A data management plan (DMP) is made for all studies. It describes the technical and data management solutions for the acquisition and storage of research data: the research data used and produced in the study, and how they are managed during and after the research.

Good data management ensures the integrity, quality, ethical and legal compliance of the data as well as the implementation of the FAIR principles (findability, accessibility, interoperability and reusability). The data management plan outlines the ownership of the data used and produced in the study, access rights, storage solutions (including long-term storage), security and data protection solutions, possible opening of the data, and the costs and resource needs of data management. Once the research project has started, the data management plan should be revised and updated when necessary.

It is recommended that the data management plan is prepared with the DMP Tuuli data management planning tool.

The University of Turku is committed to the national open science policies https://www.utu.fi/en/research/open-science/policies. If the research data can be reused, it should be opened and shared in a high-quality data archive.

Instructions for preparing a data management plan and using the DMP Tuuli tool can be found in the University's Research Data Management Guide and the Data Management Guidelines of the Finnish Social Science Data Archive.

Turku University generally recommends retaining research data for five years (15 years in medicine).

If you need help in drafting a data management plan, please contact openutu@utu.fi to reach the data service specialists of the University of Turku.

11. Privacy notice for scientific research or justification for why it is not needed

When personal data are processed in the study, a privacy notice must be attached to the request for an ethical review. The privacy notice is used to inform data subjects about the processing of personal data. Data subjects must receive the privacy notice and information sheet before giving informed consent.

Human sciences research where no personal data are processed (e.g. a completely anonymous survey) is exceptional. In most cases, personal data will be processed at least in the context of obtaining informed consent, unless consent is collected anonymously.

Personal data includes information that allows a person to be identified directly as well as information that allows a person to be identified indirectly, for example, by combining a piece of data with another piece of data that allows identification (indirect personal data). For example, a person can be identified by their name, social security number, email address, telephone number, mobile phone location data or any other characteristic that identifies them.

Special categories of personal data mean personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, genetic data, biometric data processed for the purpose of identification, health data, and data concerning sexual behaviour and orientation.

Processing of personal data means almost any activity that is performed on personal data, such as collection of data, combining with other data, data storage or erasure.

A template with instructions for drafting of a privacy notice for scientific research can be found on the University's website.

Please contact the lawyer of the Ethics Committee (legal@utu.fi) if you need support in preparing a privacy notice.

More information on data protection in scientific research:
https://tietosuoja.fi/en/scientific-research-and-data-protection

12. Data protection impact assessment or justification for why it is not needed

The purpose of the data protection impact assessment (DPIA) is to identify, evaluate, and control risks involved in the processing of personal data. Before preparing an impact assessment, the researcher should always check with the University's Data Protection Officer (dpo@utu.fi) if an impact assessment is necessary for the research.

An impact assessment must be carried out if the planned processing of personal data is likely to result in a high risk to people's rights and freedoms. In scientific research, an impact assessment must be carried out especially when

- new technologies are used in processing personal data,
- processing criminal convictions or offences,
- processing special categories of personal data such as data concerning health, ethnic origin, political opinions, religious beliefs, or sexual orientation,
- profiling or making automated decisions,

- processing genetic data,
- the controller deviates from the data subject's right to obtain information. An impact assessment must be carried out when the controller collects personal data from a source other than the data subject and deviates from the data subject's right under the General Data Protection Regulation to obtain information, since
  - notification proves impossible (especially if the data are processed for archiving in the public interest or for scientific and historical purposes or for statistical purposes),
  - notification would require unreasonable effort (especially if the data are processed for archiving in the public interest or for scientific and historical purposes or for statistical purposes),
  - delivering the data required for obtaining information is likely to prevent or considerably hamper the achievement of the objectives.

The impact assessment is carried out with a separate impact assessment form. The impact assessment form with instructions can be found on the University's website.

According to the Data Protection Regulation, the Data Protection Officer should always be consulted when carrying out an impact assessment. The University's Data Protection Officer can be contacted at dpo@utu.fi. The final version of the impact assessment should be submitted to the Data Protection Officer. If the controller of the study deviates from the rights of the data subject and processes special categories of personal data, the impact assessment with the comments of the DPO must also be submitted to the Office of the Data Protection Ombudsman (tietosuoja@om.fi). Deviation from Articles 17 (right to erasure) and 20 (right to data portability) does not require the submission of the impact assessment to the Office of the Data Protection Ombudsman.

More information on the impact assessment: https://tietosuoja.fi/en/impact-assessments.

13. Other possible appendices

Other appendices that may have an impact on the ethical review.

14. List of changes

List the replies to the requests for supplementary information made by the Ethics Committee and the amendments made to the ethical review request in response to the Committee's requests.