**INSTRUCTIONS FOR ETHICAL REVIEW REQUEST IN NON-MEDICAL RESEARCH WITH HUMAN PARTICIPANTS**

The Ethics Committee for Human Sciences at the University of Turku reviews the ethicality of non-statutory research with human participants and provides ethical review statements on these projects. The statements issued by the committee are free of charge for researchers and doctoral candidates of the University of Turku and the Hospital District of Southwest Finland. The Committee also provides statements subject to a charge to other parties. Studies that fall within the scope of the Medical Research Act (488/1999) are evaluated by the [Ethics Committee of the Hospital District](https://www.vsshp.fi/en/tutkijoille/eettinen-toimikunta/Pages/default.aspx).

The request for ethical review is submitted electronically at <https://eettinen.utu.fi/>. **Read the instructions for filling out the request for ethical review before filling out the form, and prepare all the necessary appendices in PDF format. The ethical review request form cannot be saved for later editing.**

The request for ethical review must be submitted not later than two weeks before the meeting in which you wish to have your research plan reviewed. The upcoming meetings of the committee divisions are listed on the University's website (<https://www.utu.fi/en/research/ethics/ethical-review-in-human-sciences-research>).

When assessing the need for an ethical review, researchers should primarily refer to the guidelines 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](https://www.tenk.fi/sites/tenk.fi/files/Ihmistieteiden_eettisen_ennakkoarvioinnin_ohje_2019.pdf).[Guideline of the Finnish National Board on Research Integrity (TENK) (2019)](https://www.tenk.fi/sites/tenk.fi/files/Ihmistieteiden_eettisen_ennakkoarvioinnin_ohje_2019.pdf).

A researcher must request an ethical review statement from the Ethics Committee for Human Sciences, if their research contains any of the following:

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 carer or without informing a parent or carer in a way that would enable them to prevent the child’s participation in the research,

d) the research exposes participants to exceptionally strong stimuli,

e) the research 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.

In addition to the above-mentioned cases specified by TENK, there may also be other research designs in which an ethical review is required.

An ethical review statement may also be requested when a funding body, collaborative partner, research object or publisher so requests. Ethical review is carried out before the collection of research data. An ethical review statement cannot be issued afterwards.

For support and further information on ethical review, please contact [eettinen@utu.fi](mailto:eettinen@utu.fi).

**INSTRUCTIONS FOR FILLING OUT THE REQUEST FORM:**

1. **Contact information of the person submitting the ethical review request**

The name and contact information of the contact person of the ethical review request is needed for communication related to the request. The contact person is sent a notification about the appropriateness or possible shortcomings in the ethical review request form, information related to its processing and the decision of the Ethics Committee. The contact person must make sure that the documents related to the ethical review of the research plan are stored and distributed in an appropriate manner. The person responsible for the study may act as the contact person of the request.

If the research is a thesis, the contact person is a student or a doctoral candidate.

1. **Contact information of the person responsible for the study or the supervisor of the thesis**

Typically the person responsible for the study has completed a doctoral degree, is an independent researcher and supervises the other researchers in the project. They are responsible for responsible conduct of research in the study and for making sure that the study is conducted in a lawful, safe and competent manner. They make sure that a competent staff as well as adequate equipment and devices are available for the study, and that research can be carried out safely and with high quality. They must make sure that the research is compliant with the EU General Data Protection Personal Data Regulation (EU 2016/679), other data protection regulations, international obligations related to the research participants’ position and other regulations and guidelines related to research.

If the study is a thesis, enter here the contact information of the supervisor of the thesis.

1. **Research information**

**Does the request concern a new study / a change to a study?**

Choose whether the request for an ethical review statement is for a new study or for a change made in a research plan of a study that has already received an ethical review statement. If a statement is requested for a change in a research plan of a study that has already received a statement, the number and date of issue of the previous statement are also included.

A new statement must be requested if the research plan is changed in such a way that the change may affect the safety of the research participants or it changes the interpretation of the scientific documents used to support the research or if the change is otherwise significant. Above mentioned significant changes include changes that may, for example, affect the following:

* the physical and psychological integrity of the research participants
* possible damages caused by the research
* distress caused by the research and risks of the research
* the scientific value and significance of the research
* Implementation of the research (e.g. new sub study in the research or new research material)

In the review statement request related to a change in the study, the changes made in the study and grounds for the changes must be presented to the Ethics Committee. The Ethics Committee requires that all the appendices of the request form are included. The appendices must indicate how they have been changed (e.g. deleted text can be crossed over and added text can be highlighted with italics). The person responsible for the study is required to provide an assessment of the ethical nature of the research also in relation to changes in the research plan.

**Reviewing division**

Choosing from which division of the Ethics Committee for Human Sciences at the University of Turku the ethical review is requested. The Health Care Division assesses all health care related research where ethical review is not regulated separately in the Medical Research Act (488/1999). The Humanities and Social Sciences Division assesses all other non-statutory research except health care related studies. Besides humanities and social sciences, these include e.g. research with human participants in the natural sciences and technology.

**Research participants**

Indicate whether the research participants include adults, minors, children under the age of 15, and/or persons with disabilities. If the study includes participants who are unable to give their informed voluntary consent, the method for recruiting the participants must be described and justified in the appendices delivered to the research participants.

**Grounds for requesting an ethical review statement**

Indicate the grounds for requesting an ethical review statement. The first page of these instructions includes a list of the research designs which must always undergo an ethical review according to the guidelines of the Finnish National Board on Research Integrity (TENK). In addition to these cases, there may be other research designs in which an ethical review is required. In addition, grounds for requesting an ethical review statement may also include the request by a funding body, collaborative partner, research object or publisher.

**Title of the study**

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

**Estimated start date and end date of the study**

**Organisations participating in the study**

Indicating the organisations that participate in the study as well as their units/departments and researchers. If the study is an international joint study, the form should also state the participating countries. A separate appendix can be used if needed.

**Funder or commissioning party of the study**

Commissioning party and, if the funder of the study is different from the commissioning party, also the funder of the study should be marked. The commissioning party (sponsor) of the study can be a person, a company, an institution or an organisation, which is responsible for initiating, leading or funding the study. In so-called researcher-led research, the researcher themself is the commissioning party of the study. Even in these cases the funder must be mentioned (e.g. a scholarship granted by the Academy of Finland, a foundation or a company or a grant agreement).

**Compensations and rewards paid to the research participants**

Indicating the possible costs and compensations for research participants.

**Additional information**

Describing other factors possibly affecting the ethicality of the study.

**APPENDICES TO THE ETHICAL REVIEW REQUEST**

**All appendices are mandatory. Prepare all the appendices in PDF format before filling out the ethical review request form. The ethical review request form cannot be saved for later editing.**

1. **Signature of the thesis supervisor**

The supervisor of the thesis assures with a signed form that they are the supervisor of the study for which the ethical review is requested. They also assure that they have studied the request form and its attachments and that they are requesting for an ethical review from the Ethics Committee together with the student or doctoral candidate they are supervising.

1. **Summary of the research plan**

The recommended maximum length of the summary is 1-3 pages. It should include the following:

* purpose and objective of the study and justification for conducting it
* research design and data collection methods
* recruitment of research participants and most important criteria for the exclusion and inclusion of research participants
* estimated number of research participants and justifications for whether the data is large enough relative to the research question
* research method, research progress and description of research procedures
* concrete impacts of the research to the research participants (e.g. number of interviews and meetings related to the research, length of the participation in the research)
* processing, storage, archiving and access to the research data
* processing of personal data and data protection arrangements

1. **Research plan**

Mark the document with a date and preferably a version number.

1. **Assessment of the ethical nature of the research by the person responsible for the study**

[Responsible conduct of research and procedures for handling allegations of misconduct in Finland](https://www.tenk.fi/sites/tenk.fi/files/Ihmistieteiden_eettisen_ennakkoarvioinnin_ohje_2019.pdf) and [The ethical principles of research with human participants and ethical review in the human sciences in Finland](https://www.tenk.fi/sites/tenk.fi/files/HTK_ohje_2012.pdf) by the Finnish National Board on Research Integrity serve as the starting point for the ethical assessment by the person responsible for the study. When necessary, detailed ethical guidelines of the particular research field should also be applied.

If an ethical review is requested for a thesis, the ethical assessment by the person responsible for the research is signed by both the student / doctoral candidate and the supervisor of the thesis.

In the ethical assessment, the person responsible for the study should discuss the ethicality of all the phases of the research, especially from the perspective of avoiding risk and harm:

* What ethical questions and views are related to e.g. informing and recruitment of participants, research methods and data collection practices, analysis and interpretation of data, storing and archiving data as well as publication of the results?
* Is it necessary to agree on e.g. the ownership and administration of the data, supervising relations, authors of publication and copyrights? Agreement matters and the need for agreements should be discussed in the research group well before beginning the practical measures of the research. In the case of a dispute, only a written agreement is unambiguous.

In addition, the ethical assessment should consider and assess the risks of the research from an ethical point of view versatilely and comprehensively.

* What physical, psychological, social and financial risks the research might cause to the research participant? Are there any environmental risks related to the research?
* What are the odds for the risks to be realised? What measures are used to control the risks? Are the measures adequate?
* How to act when a risk is realised?
* What is the relation between the harms caused to the research participants and the benefits of the study?

If the research deviates from the principle of informed consent, the justification for the solution is presented in the assessment of the ethical nature of the research by the person responsible for the study.

1. **Documents delivered to research participants**

The documents delivered to the research participants must be prepared separately for each research group. The information sheets, consent forms and other material delivered to research participants must be in clear and plain language.

1. **Information sheet intended to be given to research participants**

The information sheet must include the date and preferably the version number. Several information sheets might be needed, for example for the research participants, control subjects, relatives or family members of the participants. Under-aged children/children of different ages and their guardians must receive their own information sheets and other materials. The information sheet must be written in a language understandable to the research participant. Pay special attention to the clarity and readability of the information sheet.

The information sheet given to the participants must include the following:

* person responsible for the research and his/her contact information
* research organisation(s) and funding of the research
* invitation to participate in research
* purpose, objectives and significance of the study
* explanation as to why the research subject would be suitable for the study and the possible selection and exclusion criteria. Describe also the number of research subjects/those invited to participate in the study
* rights of the research participants: voluntariness of participation, right to ask additional information about the study and right to discontinue participation in the study
* methods of collecting data / implementing the study (what the participation concretely requires from the participant, how much time will the participation take, etc.)
* possible benefits and risks of taking part in the research
* incentives for participation
* purpose of use of the research material, safeguarding of confidentiality (possible pseudonymisation) and archiving of the material for further research purposes
* storage, archiving, further use and opening of research data
* processing of personal data (personal data means any kind of data that may be used to identify a person directly or indirectly)
* If the research involves combining register data with data collected from the participants themselves, the participants must be informed about the use of register data

Please find a template for information sheet on the [university’s website](https://www.utu.fi/en/research/ethics/ethical-review-in-human-sciences-research) (Appendices to the ethical review request)

1. **Informed consent**

Requesting an informed consent form the research participants is a central ethical principle with which the voluntariness of the participation is ensured.

Mark the date and preferably also the version number on the document. Several informed consent forms may be needed, for example for the research participants, control subjects, relatives or family members of the participants. The informed consent form must be written in clear and plain language separately for each group and for children so that their level of development is taken into consideration. The language used in the consent form must be understandable to the research participant.

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

Also, e.g. responding to surveys can be viewed as providing an informed consent. If e.g. a survey response is regarded as an informed consent, it is still advisable to attach the informed consent form to the survey and mention that responding to the survey equals a signature. Documenting and proving a verbal consent afterwards is difficult.

The researcher is obligated to store the original consent forms. The researcher can give a copy of the signed consent form to the research participant upon request.

The consent form should include the following information:

* study for which consent is requested
* whether the participant has been provided with sufficient information about the specific study and its purpose, the method of data collection, storage and further use of the data and processing of personal data and they has understood it
* voluntariness of the participation
* if the research involves combining sensitive data collected from registers or other sources with data collected from the participants themselves, the participants’ consent for this must be obtained
* participant’s right to discontinue participation at any point without suffering any negative effects
* how research data that has been gathered before participant’s withdrawal from the research is used
* participant’s signature, name in block letters, and the date

Please find a template for informed consent form on the [university’s website](https://www.utu.fi/en/research/ethics/ethical-review-in-human-sciences-research) (Appendices to the ethical review request)

If the research data is combined with data collected from other sources, the participants’ particular consent for this must be obtained.

1. **Besides the information sheet and informed consent, the Committee requires the following separate appendices**
2. **Clarification of the research participant recruitment**, meaning how research participants are recruited for the study (e.g. advertisements in newspapers and on noticeboards, random sample from a certain register). At procedure for carrying out the telephone calls/visits/interviews with persons who are in contact through on an advertisement.
3. **Clarification of the methods for obtaining the informed consent.** The researcher must disclose a description of the proceedings used for acquiring the informed consent from each research participant before commencing the research procedures. 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 which are significant in terms of the decision of participation. The research participant must be given an opportunity to discuss their participation with people close to them and enough time for making the decision about their participation. The procedure must be described separately, if persons who are unable to give their informed consent themselves are asked to participate in the research.
4. **Other data to be given to research participants**

Questionnaires, interview outlines etc.

1. **Data management plan**

A data management plan includes a description of the acquisition, storage (incl. long-term storage), ownership of the data and possible access to the data. The ethical review contains checking the data management plan of the research and ensuring that technical data protection measures have been planned for the research.

Instructions for preparing a data management plan can be found in the [Research Data Guide of the University of Turku](https://utuguides.fi/researchdata) and in the [Data Management Guidelines](https://www.fsd.tuni.fi/aineistonhallinta/en/index.html) by the Finnish Social Science Data Archive.

It is recommended that the data management plan is prepared with the [TUULI data management planning tool](https://www.dmptuuli.fi/).

1. **Data protection statement for scientific research or justification for why it is not needed**

When personal data is handled in a study, a data protection statement is included in the request for an ethical review. With the data protection statement, the research participants are informed of the processing of personal data.

Personal data include data on the basis of which the person can be identified directly or indirectly, e.g. by combining a piece information with another that enables identification. A person can be identified by reference to e.g. name, social security number, email address, phone number, mobile phone location data or some other factor specific to that person. Special personal data categories refer to the personal data that reveals race or ethnic origin, political opinions, religious or philosophical beliefs, membership in a trade union, genetic data, bibliometric information, health data, and data on sexual behaviour and orientation.

An instructed example template for preparing a data protection statement is available at [the University’s website](https://www.utu.fi/en/research/ethics/ethical-review-in-human-sciences-research).

Please contact the lawyer of the Ethics Committee ([legal@utu.fi](mailto:legal@utu.fi)) if you need support in preparing a data protection statement.

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

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

Prior to carrying out an impact assessment, please contact the Data Protection Officer of the University ([dpo@utu.fi](mailto:DPO@utu.fi)) to determine whether an impact assessment is needed.

Data protection impact assessments (DPIA) are designed to identify, evaluate and control risks involved in the processing of personal data.

An impact assessment must be conducted if the envisaged processing of personal data is likely to result in a high risk to people’s rights and freedoms. An impact assessment must be carried out in a scientific research especially when

* using new technologies in processing personal data,
* processing data relating to criminal convictions or offences or 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 notification is likely to prevent or considerably hamper the achievement of the objectives.

The impact assessment is carried out with a separate impact assessment form. Instructed impact assessment form is available at [the University’s website](https://www.utu.fi/en/research/ethics/ethical-review-in-human-sciences-research).

According to the Data Protection Regulation, you must always contact the Data Protection Officer when performing an impact assessment. You can contact the Data Protection Officer of the University at [dpo@utu.fi](mailto:dpo@utu.fi). The final version of the impact assessment must be delivered to the Data Protection Officer. In case the study deviates from the rights of the research participant and special personal data categories are processed, the impact assessment commented by the Data Protection Officer must also be delivered to the Data Protection Ombudsman [tietosuoja@om.fi](mailto:tietosuoja@om.fi).

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

1. **Other possible appendices**

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