INSTRUCTIONS FOR THE ETHICAL REVIEW REQUEST FORM FOR HUMAN SCIENCES RESEARCH

Request for an ethical review statement must be submitted by e-mail to the secretary of the committee two weeks before the meeting in which you wish to have your research plan reviewed. The request form and the required documents must be merged into a single PDF document. The upcoming meetings of the committee divisions are listed on the website of the committee (<https://www.utu.fi/en/research/ethics/ethical-review-in-human-sciences-research>).

**Secretary of the Ethics Committee for Human Sciences**

Development Specialist Kirsi Klemelä

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The Ethics Committee for Human Sciences issues ethical review statements on the ethics of non-medical research conducted on human subjects. The statements issued by the committee are free of charge for the researchers and doctoral students of the University of Turku and the Hospital District of Southwest Finland. Statements to other parties are subject to a charge. Studies that fall within the scope of the Medical Research Act (488/1999) are evaluated by the ethics committee of the hospital district.

When assessing the need for an ethical review, researchers should 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).

The researcher must request an ethical review statement from a human sciences ethics committee, 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) 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.

In addition to the above-mentioned cases specified by TENK, there may also be other cases 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 data is collected. An ethical review statement cannot be issued afterwards.

**Instructions for filling out the form:**

**1) Markings of the Ethics Committee**

To be filled in by the secretary of the Committee. The comment request becomes pending when the documents have arrived to the secretary, who records and registers their arrival. Studies are identified primarily by their ID code or alternatively by their title if no ID code has been given. The Committee may use expert help. The Committee and its experts work confidentially.

**2) Ethical review requested for**

Mark whether the comment is requested for a new study or for a change made in a study. A new comment 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. Such relevant and significant changes 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
* implementing the research (e.g. scope, timetable)

Amendment applications must contain the date of the previous review of the Ethics Committee or previous statements. The Ethics Committee must be given detailed clarifications on and justifications for the changes in the research.

The assessment of the ethical nature of the research by the person responsible for the research is also required for changes in the research plan. The change notification must include the researcher’s own assessment of the significance of the changes relative to the risks and benefits of the research. In addition, all amended and corrected documents as well as the summary of the original research plan must be delivered as attachments to the comment request form. The documents must indicate how they have been changed (e.g. a deleted text can be marked with a strikethrough and an added text with italics). The version number and date of the attachments must also be updated.

**3) Grounds for requesting ethical review**

Indicate the grounds for requesting a statement. The Finnish National Board on Research Integrity (TENK) has specified six cases in which a research must always undergo an ethical review. These cases are presented on the first page of these instructions. In addition to these cases, there may be other cases in which ethical review is required. The grounds for requesting ethical review should refer to a case specified by TENK or to some other aspect in the research design requiring an ethical review.

An ethical review statement may also be requested when a funding body, collaborative partner, research object or publisher so demands. This demand can be used as the grounds for requesting an ethical review statement.

**4) Identification code of the study, date of the research plan, and possible version number**

Here, the identification code of the study should be marked. The code can be made up by the researcher him-/herself or it can be given by the commissioning party. The code can consist of, for example, the initials of the official title of the study. Using the ID code enables identifying and processing the matter without bringing up classified or confidential information (e.g. commissioning party, product to be researched). If an ID code has not been written, the Ethics Committee identifies the study based on its title which hence becomes public. Also the date of the research plan should be indicated and preferably a version number, which is changed if the research plan is amended (e.g. version-1, version-2 and so forth). It is strongly recommended that each document and attachment delivered to the Ethics Committee has a version number and a date. This also facilitates the researcher’s own document management.

**5) Title of the study (also in Finnish or Swedish)**

Write the official title of the study in the original language and in Finnish or in Swedish. The Ethics Committee also has to be notified whether the title of the study contains confidential information. If this is the case, the Ethics Committee is obliged to use only the ID code of the study when handling the research plan. The Finnish title of the study should be as short as possible, preferably a maximum of one sentence without sub clauses.

**6) Commissioning party / Funder or sponsor of the study (if applicable)**

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 him-/herself 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).

**7) Contact person of the ethical review request and his/her contact information**

The name and contact information of the contact person of the request or the commissioning party 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.

**8) Person responsible for the study and his/her contact information**

The name and contact information of the person responsible for the study, including his/her education and occupation/organisation. The person responsible for the study is chosen by the research team from among itself. Usually the person responsible for the study is the principal researcher of the study (e.g. a doctoral thesis employee) who also assumes responsibility for the good scientific practice in research and for making sure that the study is conducted in a lawful, safe and competent manner. S/he must make sure that a competent staff and adequate equipment and devices are in use for the research and that the study can be carried out safely and with high quality. She/he 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. The request must contain an assessment of the ethical nature of the research (see the attachments; attachment 2).

**9) Summary of the research plan**

The summary of the research plan (in Finnish or Swedish) must be clear and understandable also to persons unfamiliar with the discipline in question. The summary has a recommended length of max. one page and it should briefly clarify the following issues:

- purpose of the research and justification for conducting it

- research design, sources of information and data collection and evaluation methods to be used

- most important research procedures and plans related to the monitoring of the research participants

- 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

- processing of personal data and data protection arrangements

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

The estimated timetable of the study.

**11) Research centres, their units/departments and researchers. Other collaborating units/departments and their researchers. Countries participating in an international joint study.**

Research centres and their units / departments and researchers participating in the study. At the same time, the researchers’ education and occupation should be mentioned. If the study is an international joint study, the form should also state the participating countries. A separate attachment can be used if needed (attachment 9).

**12) Processing of personal data**

Short description of how personal data will be processed in the study. Identify the data controller, and the person preparing the data protection statement for scientific research, and the person or organisation in charge of matters relating to data protection.

**13) Research participants**

Indicate whether the study has been planned to be carried out with a special group of some kind (minors, children, persons with incapacity, pregnant or breastfeeding women, prisoners or research participants belonging to other special groups) or whether the research participants are healthy volunteers. Also, the number of research participants and their lower and upper age limit should be marked. If the study includes participants who are unable to give their informed voluntary consent, the proceedings for recording consent must be described and justified in attachment 4.

Under-aged children/children of different ages and their carers must receive their own notifications, consent forms and other material (attachments 3 and 4). The notification and the consent form must be made in plain language separately for each group and for children so that their level of development is taken into consideration.

**14) Information about the budget of the study, e.g. funder, compensations and rewards of the research participants**

For reviewing the ethical aspects of the study, the Ethics Committee needs a summary of the cost estimate / budget of the study. In this section or in a separate attachment (attachment 9), indicate estimates for the compensations to both researchers and research centres as individualised calculations. In addition, indicate possible costs and compensations for research participants.

**15) Insurance policies: has any insurances been taken out for the study**

Indicate the possible insurance policies taken out for the research participants.

**16) Date and signature (person responsible for the study)**

The request form is dated and signed by the person responsible for the study.

**17) Appendices to the application**

All appendices are mandatory.

1. **Research plan** (in English or Finnish)

Mark the document with a date and a version number (e.g. version-1, version-2).

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

[The ethical principles of research with human participants](https://www.tenk.fi/sites/tenk.fi/files/Ihmistieteiden_eettisen_ennakkoarvioinnin_ohje_2019.pdf) described by TENK serve as a starting point for the ethical assessment by the person responsible for the research. When necessary, detailed ethical guidelines of the particular research field should also be applied.

In the assessment the responsible person should discuss the data collection plan, intended research method, the information provided to the research participants and the plan for processing and storing the data from the perspective of avoiding risk and harm. The assessment should weigh the potential harms and risks to the participants in relation to the significance of the new information that the research aims to obtain.

If the research design does not require an ethical review, this should be mentioned in the assessment with justifications.

If the study deviates from the principle of informed consent, this decision must be justified in the assessment.

1. **Information sheet intended to be given to research participants** (documents also in Finnish or Swedish when necessary)

Always mark the date and preferably also the version number on the information sheet. Several information sheets may be needed depending on the research plan, for example for the research participants, for control subjects, or for relatives of the participants. Under-aged children/children of different ages and their guardians must receive their own notifications and other material. The information sheet must be written in plain, non-technical language separately for each group and for children so that their level of development is taken into consideration. The language used in the information sheet must be 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
* purpose, objectives and significance of the study
* possible benefits and risks of taking part in the research
* methods of collecting data / implementing the study (what the participation concretely requires from the participant, how much time will the participation take, etc.)
* rights of the research participants: voluntariness of participation, right to ask additional information about the study and right to discontinue participation in the study
* purpose of use of the research material, safeguarding of confidentiality (possible pseudonymisation) and archiving of the material for further research purposes
* 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

1. **Informed consent form and description of the procedure for selecting the participants and obtaining the consent** (documents also in Finnish and Swedish when necessary)

Always mark the date and preferably also the version number on the document. Several different informed consent forms may be needed depending on the research plan, for example for the research participants, control subjects, and for relatives of the participants. The informed consent form must be written in plain, non-technical 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.

The person responsible for the research is required to store the original consent forms. If requested, the researcher may provide a copy of the signed consent form to the research participant.

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, and the method of collecting information
* 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

Description of the procedure for) selecting the participants and b) obtaining the consent:

1. Clarification on the detailed proceedings related to choosing the research participants. Describe how research participants are recruited for the study (e.g. advertisements in newspapers and on noticeboards, random sample from a certain register). Indicate the procedure for carrying out the telephone calls/visits to persons who have announced their interest to participate.
2. Clarification on the proceedings for obtaining the informed consent. Describe 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 confirms his/her willingness to participate in a specific study after having received sufficient, both written and verbal, information on all matters related to the research which are significant in terms of the decision of participation. The research participant must be given enough time for making a decision about his/her participation and a chance to discuss his/her participation with people close to him/her. If the study involves participants who are unable to give their informed consent, the procedure must be described and justified.
3. **Other data to be given to research participants**

E.g. questionnaires, interview outlines, diaries.

1. **Data management plan**

A data management plan includes a description of the acquisition, storage (incl. long-term storage) and ownership of the data and possibly granting access to the data.

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 by the Finnish Social Science Data Archive (<https://www.fsd.uta.fi/aineistonhallinta/en/index.html>).

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

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

Instructions for preparing a data protection statement for scientific research can be found on the [university intranet](https://intranet.utu.fi/index/Data-Protection/Pages/default.aspx).

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.

1. **Data protection impact assessment (DPIA), or justification for why it is not needed**

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

Instructions for performing the DPIA can be found on the [university intranet](https://intranet.utu.fi/index/Data-Protection/Pages/DPIA.aspx). Please contact the Data Protection Officer of the university ([dpo@utu.fi](mailto:dpo@utu.fi)) if you need support in performing the impact assessment.

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

1. **Other possible attachments**