Kela's Research Ethics Committee and the ethical review of research dealing with human sciences

General

Kela's research organisation is committed to compliance with The ethical principles of research with human participants and ethical review in the human sciences (TENK 2019), as issued by the Finnish National Board on Research Integrity TENK, appointed by the Ministry of Education and Culture. These instructions complement the said guideline[1] for the part of any research involving Kela.

The task of Kela's Research Ethics Committee is to conduct, upon request, an ethical review of research projects involving human participants and to issue relevant statements. The Research Ethics Committee will not conduct a review of research projects that fall within the scope of the Medical Research Act (488/1999, *Laki lääketieteellisestä tutkimuksesta*)[2]. The Committee holds no legal position, and its tasks do not include the granting of official approvals to carry out research projects.

Researchers are required to carefully read the ethical principles for research involving human participants, as issued by the Finnish National Board on Research Integrity TENK, to independently assess the need for an ethical review of their intended research and, if necessary, to request a statement from the Research Ethics Committee. If the research project includes several sub-projects, the researcher shall request an ethical review separately for each sub-project. According to the TENK guideline (TENK 2019, p. 61), research in human sciences always requires an ethical review prior to the initiation of the research if the research contains any of the settings described below (items 1–6):

1. Participation in the research deviates from the principle of informed consent (ethical review is, however, not required if the research is based on public or published data, registry or documentary data and archived data);
2. The research involves intervening in the physical integrity of research participants;
3. The research involves children under the age of 15 without obtaining a separate consent from a parent or guardian or without providing a parent or guardian with information that would enable them to prevent the child's participation in the research;
4. The research exposes research participants to exceptionally strong stimuli;
5. The research involves a risk of causing mental harm beyond the risks encountered in normal daily life, either to research participants or their family members or others closest to them;

[1] The TENK guideline is available at: tenk.fi/en > Ethical review

[2] According to Section 2(1) of the Medical Research Act (488/1999, *Laki lääketieteellisestä tutkimuksesta*), for the purposes of the Act, *"**medical research** means research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of health, the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of diseases in general"* (amendment 794/2010). As part of the preliminary work for Act 794/2010, the Government Proposal (HE 65/2010 vp) describes this provision as follows: "*In the Medical Research Act, 'intervention in the integrity' refers to the intervention in the physical or mental integrity of a subject, i.e. interventional examinations. Examples of intervention in the physical integrity include sampling of blood, biopsies or corresponding samples, examinations involving physical strain, or studies where foods are used with the purpose of affecting health or the risk or symptoms of a disease. Examples of intervention in the mental integrity include studies that may cause harm to the subject's mental well-being. The Medical Research Act would be applicable if research could cause mental harm to the subject that is beyond harm encountered in normal daily life and which the subject is not able to assess when considering whether or not to participate in the study. The Medical Research Act would not be applicable to registry studies based on documents alone. Research that utilises only registry data or is based on statistics does not meet the criteria of an intervention study. Survey and interview studies, service development and observational studies carried out within healthcare, as well as quality and process projects would fall outside the scope of the Medical Research Act, when they do not involve intervention in the integrity of individual persons. The Medical Research Act would, however, continue to be applicable to such clinical pharmaceutical research where, in order to clarify the effects of a drug, it is necessary to carry out extraordinary examinations and follow-up measures, including questionnaires and interviews with the subjects."* (HE 65/2010 vp, pp. 17–18).

6. Conducting the research could involve a threat to the safety of participants or researchers or their family members or others closest to them;
7. Moreover, it is possible to request an ethical review statement if it is required by, for example, a funding body, collaborative partner, object of study or publisher of the research.

Documents to be included in the statement request

The request for an ethical review statement shall be prepared as a single PDF file that includes numbered documents as follows:

1. Cover letter
2. Research plan and summary
3. Data management plan
4. Assessment of the ethical nature of the research by the person responsible for the research
5. Information leaflet to be given to research participants
6. Possible consent form
7. Data protection statement for scientific research (if data containing identifiers is gathered on participants)
8. Other material to be given to research participants (for example, questionnaire, interview outline)

1. Cover letter

- Grounds for the request for an ethical review statement (see items 1–7 on page 2)
- Assessment by the principal researcher as to why the research does not fall within the scope of the Medical Research Act 488/1999 (together with motivations if a borderline case)
- Information about any earlier ethical reviews
- Contact information for the person responsible for the research as well as the date (signature is not obligatory)
- List of appendices/table of contents

2. Research plan

- Including a summary (in Finnish or Swedish if the research plan is in English)
- Sample research plan outline that can be utilised as applicable:

  Name of the research (Title), Authors of the research plan, and date

  I. Background information and motivation for the research questions
  - Earlier research results on the topic
  - Possible theoretical framework
  - The unknown – grounds for your own study
  - Information about whether the research is part of a larger project

  II. Aims of the research
  - Key research problem
  - Specific research questions
  - Possible hypotheses

  III. Material and methods
  - Description of research material
  - Data acquisition and composition
  - Data analyses, research methods
  - Data lifecycle: destruction/archiving/further access

IV. Ethical and legal perspectives regarding the research
- Ethical and legal issues related to the topic, methods and material
- Issues concerning Responsible Conduct of Research
- Research permits and application processes

V. Research timetable and funding
- Implementation plan including an estimated timetable and the duration of the different phases
- Possible funding plan

VI. Description of the research team
- Organisation(s) involved in the research
- Key merits of researchers in terms of the project
- Division of work (incl. principal researcher/Principal Investigator)
- Possible research collaboration
- Disclosure of interests for the researchers (financial and other)

VII. Significance of the research
- Novelty value of the research
- Significance in terms of society, health etc.

VIII. Publication plan

IX. References

X. Appendices

3. Data management plan

- the instruction below is based on the Data Management Guidelines of the Finnish Social Science Data Archive

1. **The data:** What kind of data are collected/generated and in what way?
2. **Rights:** Who owns the copyright, intellectual property rights and management rights to data? Who has the right to grant access to data? What procedures are used to inform research participants?
3. **Confidentiality and data security:** How is the confidentiality of data and data security ensured? What kind of rights do different user groups have to access and process data files?
4. **File formats and software:** What software programmes are used to store and process data? What file formats and storage media are used?
5. **Documentation of data processing and content:** How is the (technical) quality of data ensured? How are the data processing methods documented? How are the metadata describing data collection methods and data content stored?
6. **Lifecycle:** What happens to data after the research has been completed?

4. Assessment by the principal researcher about potential ethical issues associated with the research

- The principal researcher describes the research data collection plan, the intended research methods, the documents prepared for informing research participants and obtaining their consent, and the data processing and storage plan, and assesses these from the perspective of avoiding or minimising risk and harm.
- If necessary, the ethical guidelines for the relevant discipline are also applicable.

5. Information leaflet to be given to research participants

- Basic information concerning the research
  - The name/title, purpose and significance of the research (briefly)
  - Research organisation and funding body

        - Members of the research team/possible collaborative partners
        - Source of contact information for research participants
    - Rights of research participants
        - Right to participate voluntarily
        - Right to withdraw their consent to participation/discontinue their participation at any time and without giving any particular reason or suffering any negative consequences
        - Right to receive information about the use of research data that has already been gathered if an individual decides to withdraw consent/discontinue participation, and about how to give notice of withdrawal/discontinuation
        - Right to request additional information concerning the research and the processing of personal data, together with the contact details of the person providing more information
    - Implementation and methods of the research
        - Procedures that the research participants will be required to undergo
        - How much time the participation in research will require of research participants
        - Information about whether the individual will be asked any questions of a sensitive nature (for example, about traumatic experiences, difficult life situations, severe diseases)
        - Potential benefits and harms; risks to research participants
    - Confidentiality and data security
        - Specific information about all data records, including possible registry data to be gathered later on (research participants are to be informed if the data gathered from them as part of the research (by means of, for example, a questionnaire) will be combined with data from other sources, such as registry data, including the origin of such data)
        - They must also be informed of possible later use of research data (e.g., possible data transfers)
        - Confidentiality of research data and management of materials (incl. secure storage and processing of data)
        - Information about the further access, archiving or destruction of data
        - NOTE! In addition to the above, research participants are to be given any other information required by the General Data Protection Regulation, in the form of a data protection statement.
    - Contact details of the principal researcher (Principal Investigator) and the person providing further information.

6. Consent form to be given to research participants

- If the legal basis for the processing personal data of research participants is consent, a consent must be requested from participants for both the participation in research and the processing of personal data.
- Research participants are requested to give their consent for the gathering of data records for use in research, including possible registry data to be obtained later on.
- The consent given by research participants determines the conditions for processing their personal data, in other words, in what ways their personal data can be managed (e.g., if data may be archived for further access).
- Consent must be given in a way that keeps it clearly separate from other possibly coinciding activities (such as rehabilitation).
- The consent shall be a voluntary, active expression of intent by a research participant.

- Consent for the processing of sensitive data shall be explicit and primarily be given in writing.
- The consent form shall be dated and signed by the research participant and the researcher, including their name clarifications (and if there is a justified ground, also the date of birth and address or the personal ID of the research participant).

7. **Data protection statement for scientific research**

8. **Other material to be given to research participants**
    - For example, questionnaire forms, interview outline, journals, tests, etc.

General instructions concerning the documents

When drawing up an information leaflet, consent document or questionnaire form, it is a good idea to observe, among other things, the following aspects:

- Use of language that is polite and respectful towards the target group, as well as family and gender-sensitive;
- Use of linguistic style that is clear and can be easily understood by the target group;
- If there are several target groups, the information leaflet and consent form must be drawn up separately for each target group.

Submission of the request for an ethical review statement

The statement request and necessary appendices shall be sent as a single PDF file via email no later than 2 weeks before the meeting of Kela's Research Ethics Committee to: kirjaamo(a)kela.fi The dates of Committee meetings are available on the pages of Kela's Research Ethics Committee. The Committee can only process written statement requests that arrive prior to the stated deadline. The statement request, research design, project plan and appendices should be carefully considered and finalised. Submitting a statement request prematurely often leads to supplementary processes that may unnecessarily delay the start-up of the project.

Instructions for resubmission of the statement request

Kela's Research Ethics Committee may, upon handling a request for an ethical review statement at its meeting, ask that it be resubmitted once the corrections and additions required by the Committee have been made. Possible modifications must be stated clearly in the following manner: 1) all changes are highlighted (e.g., with a colour) in the statement request documents, and 2) all changes are listed point by point in the reply or cover letter.