UNIVERSITY OF EASTERN FINLAND

Committee on Research Ethics

INSTRUCTIONS FOR FILLING OUT A REQUEST FOR STATEMENT REGARDING AN ETHICAL REVIEW OF A STUDY

The request for a statement with the required appendices should be submitted by email as one PDF file to the address: tuetto (at) uef.fi

The request should be sent according to the deadlines set by the Committee.

The person in charge of the study (for a doctoral dissertation research, the supervisor acts as the person in charge of the study) has to sign:

- the request for statement (item 14.) and
- the mandatory appendix 2. (the assessment of the ethical aspects of the study by the person in charge)

If needed, the signed request for statement with appendices can also be sent by mail to the Secretary of the Committee to the address:
University of Eastern Finland / Mika Saikkonen
P.O.Box 111
80101 Joensuu

The UEF Committee on Research Ethics issues statements relating to the ethical aspects of non-medical research projects on human subjects and other research projects, unless the review has been assigned to be carried out by some other body by law. Statements are given on research projects which are carried out at the University of Eastern Finland. As regards the ethical review of medical studies on human subjects, the ethical committee of the hospital district concerned is the only competent body to issue a statement (see the Act on Medical Research 488/1999).

The primary task of the UEF Committee on Research Ethics is to carry out ethical reviews of studies and research projects on the basis of research proposals. When assessing the need for a review, researchers should refer to the guidelines of the National Advisory Board on Research Ethics entitled “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).

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Committee on Research Ethics

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.

An ethical review statement may also be requested when a funding body, collaborative partner, research object or publisher so requests. However, it must be noted that a statement cannot be requested once the research has commenced.

1) **Notes of the UEF Committee on Research Ethics**
   Filled in by the Secretary of the Committee. The request for statement becomes pending when the documents are received by the Secretary of the Committee, who enters them into records and registers their arrival. As a rule, the matter is given an identification number on the basis of the code of the study (the Secretary gives the request a code). The Committee may use experts and the Committee and the experts of the Committee shall act in confidence.

2) **Object of the statement**
   Indicate whether the statement is requested on a new study or on an alteration made to an earlier study.

   A new statement is required if the research proposal is altered in a manner which can affect the safety of the subjects or the interpretation of the scientific documents used in the study, or if the alteration is otherwise significant. Essential and significant alterations referred to above are such which can affect, e.g., the following things:
   - the physical and mental integrity of the subjects
   - the damages possibly caused by the study
   - the stressfulness and risks of the study
   - the scientific value and significance of the study
   - the implementation of the study (e.g. a new sub-project will be added to the project or new research material will be included in the project)

   In requests for statement relating to an alteration to an earlier study, the dates of the earlier meetings and statements of the UEF Committee on Research Ethics should be given. The alterations made to the study as well as the justifications for making them should be explained in detail to the UEF Committee on Research Ethics. An assessment of the ethics of the study by the person in charge is also required in case of an alteration to the research proposal: the request should include the researcher's own assessment of the significance of the alterations for the benefits and risks of the study. Furthermore, all

altered and revised documents, including the summary of the original research proposal, should be provided as an appendix to the request for statement. The documents must indicate the alterations made (e.g. removed text crossed out and added text n italics): the version number and date of the appendices must also be changed.

3) Reason for requesting a statement

Indicate the reason for requesting a statement. The reasons for requesting a statement are presented on the first page of these instructions. According to the guidelines of the National Advisory Board on Research Ethics, studies in the humanities and social and behavioural sciences are, in certain cases, always required to undergo an ethical review. The reason for requesting a statement should refer to one of the examples in the guidelines of the National Advisory Board on Research Ethics.

The reason for requesting a statement can also be other than that specified in the guidelines of the National Advisory Board on Research Ethics. The reason can be, for instance, an ethical review demanded by an external party, e.g. the funder or the publisher of the study.

4) Name of the research proposal / study, date and possible version number

Indicate the official name of the study both in the original language and in Finnish. If the name of the study contains confidential information, the UEF Committee on Research Ethics should be notified of this. In these cases, the Committee will only use the code of the study when processing the research proposal.

Furthermore, the date of the research proposal and, whenever possible, also the version number of the research proposal should be given. The version number changes if alterations are made to the research proposal (e.g. version 1, 2, etc.). It is highly recommended that the date and version number be included in all documents and appendices delivered to the Committee. This also makes it easier for the researcher to manage his or her documents.

5) Contact person relating to the request for statement and his or her contact information

The name and contact information of the contact person are needed for the purposes of communication relating to the processing of the request for statement. The contact person will be notified whether the request for a statement is duly filled out or whether it is incomplete. The contact person will also be sent information relating to the processing of the request as well as the eventual decision of the UEF Committee on Research Ethics. The person in charge of the study may act as the contact person.

6) Person in charge of the study

Indicate the name of the person in charge of the study, his or her contact information, and academic and occupational title/ organisation. When ethical review is requested for a doctoral dissertation research, the supervisor acts as the person in charge of the study. The supervisor signs the request for the statement. As regards research groups, the members of the group select a person to act as the person in charge of the study. The person is usually the principal investigator, who is also responsible for the adherence to good scientific practice and for the legal, safe and competent implementation of the study. The person in charge of the study shall make sure that the study has access to a

competent staff and adequate equipment and devices, and that the study also otherwise can be implemented safely and in accordance with quality standards. The person in charge of the study shall also ensure that the EU's General Data Protection Regulation, GDPR (EU 2016/679, other data protection regulations, international obligations relating to the position of the subjects, and other regulations and guidelines relating to the study are followed. The request for statement must include an assessment of the ethical aspects of the study by the person in charge (see appendices, Appendix 2).

7) Project participants (research institutes/ universities, their units/departments and researchers; other participating units and their researchers)

Indicate the names of the research institutes participating in the study and their units/ departments and researchers. The academic and occupational titles of the researchers involved should also be given. In international research projects, the countries participating in the study should also be indicated in the request for statement. Use a separate appendix when necessary.

8) Brief summary of the research proposal

The summary of the research proposal must be clear and understandable also to other people than those representing the field in question. The summary, which is recommended not to exceed one page, should briefly describe the following things:

- the purpose of the study and grounds for its implementation;
- the research setting, research material, data sources, data collection methods and evaluation methods used;
- the main selection criteria of the subjects;
- the estimated number of subjects and an explanation of the sufficiency of the extent of the research material in regard to the question setting; and
- the processing of personal data in the study and the data protection arrangements of the study.

9) Estimated start and end of the study

Indicate the estimated schedule of the study, take into account the time needed for processing of personal data.

10) Processing of personal data

Describe shortly how personal data will be processed in the study, identify the data controller, and the person drafting the privacy notice for scientific research, and the person or organisation in charge of matters relating to data protection.

11) Subjects and research material

Indicate the subjects and/or research material and the number of subjects.

Subjects: Indicate whether the study is planned to involve a certain group of people. If the study uses children (under 15 years of age) or people placed in an institution (e.g. a prison or a retirement home), this should always be mentioned separately.

If the study involves people who are unable to give their informed consent in writing, the procedure must be described and justified in an appendix.

Separate fact sheets, consent forms and other materials must be prepared for under-aged children/ children of different ages and their guardians. The fact sheet and consent form must be drafted for each subject group in clear language and they must observe the level of development of the children in question.

Research material: In addition to humans, the research material and subject can be, e.g., a personal data register, animals (other than laboratory animals), the environment, documents.

NB! The statement of the Committee on Research Ethics not a permission to conduct the study. The permission to actually conduct the study will be given by the organization/research target where the research material will be collected, or where the research will be conducted in practice. The individual research subjects will give their consent to participate in the study.

NB: The use of laboratory animals is subject to separate permission, see http://www.uef.fi/en/kek/tietoa-elainkokeista for further information. The permission is granted by the National Animal Experiment Board.

12) Information relating to the study's finances, commissioner, financier, fees and compensations payable to the subjects

Indicate the sponsor of the study and the financier of the study, if the financier is not the same as the sponsor. The sponsor may be a person, a company, a department or an association, which is responsible for the launch, administration and funding of the study. In researcher-driven studies, the researcher is usually the sponsor. The financing should be indicated in these cases as well (e.g. a grant awarded by the Academy of Finland, a foundation or a company, or a funding agreement).

In order to assess the ethical aspects of research projects and studies, the UEF Committee on Research Ethics requires a summary of the budget. Itemised estimates of the compensations payable to the researchers and research institutes involved should be indicated here or on a separate appendix. In addition, the costs caused by the study to the subjects and the compensations payable to them should be indicated.

13) Insurance policies

Insurance policies possibly taken out for the subjects should be indicated here.

14) Date and signature

The request should be signed and dated by the person in charge of the study.

15) Appendices to the application:

1. **Research proposal and abstract.** For research proposals written in English, the abstract should be written in Finnish. Date the document and, whenever possible, add a version number (e.g. version 1, 2). It is recommended that the final research proposal be verified by the signature of the person in charge of the study.

2. **An assessment of the ethical aspects of the study by the responsible scientist**. Assess here the appropriateness of the objectives and planning of the study as a whole, and compare the benefits and risks of the study from the viewpoint of the different parties involved. Explain also what kind of material or mental damage the study may cause to the subjects and which principles are adhered to in the meeting and treatment of the subjects or informants. The explanation should take the field of science concerned into consideration. If the study deviates from the principle of informed consent, the justifications for this should be explained in the ethical assessment. The assessment of the ethical aspects needs to be signed by the responsible scientist.

3. **Participant information sheet** (also in English when necessary). The fact sheet should always include a date and, whenever possible, also a version number (see Section 3). The research proposal may define that several fact sheets are needed, e.g. separate ones for the subjects and their family members and close relatives/ friends as well as for the persons in the control group. Separate fact sheets and other materials must be drafted for under-aged children/ children of different ages and their guardians. The fact sheet must be drafted for each subject group in clear language and it must observe the level of development of the children in question. The language used in the fact sheet must be understandable to the subjects and the clarity and readability of the fact sheet should be invested in.
If you are not able to inform the participants, a data protection impact assessment should be performed.

   Instructions for drafting the fact sheet:

   The information given to the subjects must indicate the following things:
   1. The person in charge of the study and his or her contact information.
   2. The research organisation(s) and the financing of the study.
   3. The purpose, objectives and significance of the study.
   4. Possible benefits and risks of taking part
   5. The method of collecting data / implementing the study (what the participation of the subjects in the study concretely requires, how much time will the participation in the study take, etc.).
   6. The rights of the subjects: voluntariness of participation, right to ask additional information about the study and right to discontinue the participation in the study.
   7. Purpose of use of the research material, safeguarding of confidentiality (possible anonymity) and archiving of the material for further research purposes.
   8. Processing of personal data (personal data means any kind of data that may be used to identify a person directly or indirectly): see appendix to the Participant Information Sheet: Processing of personal data in the study. Appendix is available at the page http://www.uef.fi/en/web/guest/research/instructions-and-forms

   9. When information received from the subjects is combined with information in the registers of authorities, the subjects must be informed of the registers used in the study.

4. Consent form to be signed by the subjects (also in English when necessary) and **an explanation on how the consent is obtained**.

   The consent form should always include a date and, whenever possible, also a version number (see Section 3). The research proposal may define that several consent forms are needed, e.g. separate ones for the subjects and their family members and close relatives/ friends, as well as for the persons in the control group. The consent form must be drafted separately for each subject group in clear language and it must observe the level of development of the children in question. The language used in the consent form must be understandable to the subjects.

   An explanation of the procedure for selecting the subjects and obtaining their consent.

   a) A description of how the subjects are invited to take part in the study (e.g. newspaper ads and ads on bulletin boards, random selection from a register). The procedure by which the calls/ visits/ interviews of the persons taking contact through the ads are handled. Provide the newspaper ads and other possible ads as an appendix to the request for statement.

   b) A description of the procedure for obtaining the informed consent of each subject before the study. Informed consent refers to a process by which the subject voluntarily confirms his or her willingness to participate in a certain study, after having received sufficient information, both in writing and orally, on all the significant aspects of the study which are relevant for the decision to participate. The subject must be given an opportunity to discuss the possibility of participating in the study with his or her family and close relatives/ friends, and the potential participant must be given enough time for making the decision.

5. **Other material to be given to the subjects** (interview template, journals, questionnaires, etc,)

6. **Data management plan** (processing, storage and archiving plan for the data, plan for further use)
   Research material is to be stored in a locked space in the university. If material is stored elsewhere, describe how the material is stored and give your reasons for not storing the material in the university.
   A data management plan should be devised according to the instructions of the University of Eastern Finland: http://www.uef.fi/web/open-uef/avoimen-tutkimuksen-suunnittelu

   UEF instructions on information processing:
   https://studentuef.sharepoint.com/sites/heimo_en/services/information-security/Pages/information-protection-and-processing-instructions.aspx

   Further information on data management planning: Data Management Guidelines of the Finnish Social Science Data Archive: http://www.fsd.uta.fi/aineistonhallinta/en/

7. **UEF Privacy notice for scientific research**
   Privacy notice can be found at https://www.uef.fi/en/research/instructions-and-forms
   If you need help with filling in the UEF Privacy notice for scientific research, please contact the UEF data protection officer Helena Eronen, helena.eronen@uef.fi

8. **Other possible appendices**