INSTRUCTIONS FOR COMPLETING THE COMMENT REQUEST FORM FOR NON-MEDICAL HUMAN SUBJECT RESEARCH

The Ethics Committee addresses non-medical human subject research conducted at the University of Turku. Only the Ethics Committee of the hospital district is competent to comment on medical research subjected to persons (see the Medical Research Act 488/1999).

1. 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. 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 subjects 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 subjects
- 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 information on the previous processings of the Ethics Committee: date of the comment, which is to be found in the previous extract of the minutes. The Ethics Committee must be given detailed clarifications on and justifications for the changes in the research. The statement on the ethical aspects of the research by the person responsible for the study 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 strikethrough and an added text with italics). The version number and date of the attachments must be changed at the same time.

3. 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.

4. 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.

5. 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).

6. The name and contact information of the contact person of the study or the commissioning party is needed for communication related to the research plan. The contact person is sent a notification about the appropriateness of or possible flaws in the comment 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 assessment 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 study.

7. 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. S/he must make sure that the research is compliant with the Personal Data Act (523/1999), other data protection regulations, international obligations related to the research subjects' position and other regulations and guidelines related to research. The comment request must contain an assessment by the person responsible for the study on the ethical aspects of the research (see the attachments; attachment number 2). This assessment may be a part of the summary of the research plan.

8. The Finnish or Swedish-language summary of the research plan 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:

- the purpose of the research and the justification for conducting it
- study design, sources of information and data collection and evaluation methods to be used
- the most important research procedures and plans related to the monitoring of the research subjects
- the most important criteria for the exclusion or inclusion of research subjects
- estimated number of research subjects and justifications for whether the data is large enough relative to the research question
- the processing of personal data in the study and data protection arrangements

9. The estimated timetable for the study.

10. Research centres and their units / departments and researchers participating in the study. At the same time, the researchers' education and occupation should be mentioned. The curriculum vitae of the person responsible for the study and the principal researcher of each centre should be delivered as attachments to the comment request form. If the study is an international multicentre study, the form should also state the participating countries. A separate attachment can be used if needed (attachment 10).

11. This section should state the unit, department or organisation in which the research register is maintained and stored; identify the controller, the person who draws up the description of the file, and the person or organisation in charge of data protection matters.

12. 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 subjects belonging to other special groups) or whether the research subjects are healthy volunteers. Also the number of research subjects and their lower and upper age limit should be marked. If the study includes research subjects who are unable to give their written informed

voluntary consent, the proceedings for recording consent must be described and justified in attachment 6.

Under-aged children/children of different ages and their guardians must receive their own notifications, consent forms and other material (see also 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.

13. 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 11), indicate estimates for the compensations to both researchers and research centres as individualised calculations. In addition, indicate possible costs and compensations for research subjects.

14. In this section, indicate the possible insurance cover of the research subjects.

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

16. Attachments of the application.

1. Research plan, which can be written in English. Mark the document with a date and a version number (e.g. version-1, version-2). It would be good to verify the final research plan with the signature of the person responsible for the study. *Mandatory attachment.*

2. Statement by the person responsible for the study on the ethical aspects of the research; appropriateness of the goals and planning of the study and a comparison of risks and benefits. Also a clarification on possible harm that the study may cause the research subjects. *Mandatory attachment.*

3. Study subject information / notification for the research subject (if needed, also in Swedish or in English). Always mark the date and preferably also the version number (see Section 3 in this instruction) on the notification. Several notifications may be needed depending on the research plan, for example for the research subject, for control subject, or for a relative. Under-aged children/children of different ages and their guardians must receive their own notifications and other material. The notification 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 notification must be understandable to the research subject. Pay special attention to the clarity and readability of the notification. *Mandatory attachment.*

4. Informed consent form (if needed, also in Swedish or in English). Always mark the date and preferably also the version number (see Section 3 in this instruction) on the document. Several different informed consent forms may be needed depending on the research plan, for example for the research subject, control subject, or for a relative. 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 subject. *Mandatory attachment.*

5. Clarification on the proceedings for obtaining the informed consent. Describe the proceedings used for acquiring the informed consent from each research subject before commencing the research procedures. Informed consent is a process, in which the research subject 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 subject 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.

6. Justifications for the research, when research subjects are persons unable to give their informed consent.

7. Clarification on the detailed proceedings related to choosing the research subjects. Describe how research subjects are recruited for the study (e.g. advertisements in newspapers and on noticeboards, random sample from a certain register). At the same time, indicate the procedure for carrying out the telephone calls/visits to persons who have announced their interest due to an advertisement. Enclose newspaper advertisements and other possible announcements.

8. Other material given to the research subject (questionnaires, journals, etc.; if needed, also the documents in Swedish or in English).

9. Description of the personal data file (in Finnish or in Swedish) as stipulated in Section 10 of the Personal Data Act (523/1999) (see http://tietosuoja.fi/1560.htm). *Mandatory attachment.*

10. List of the research centres and their researchers in Finland.

11. Clarification on the funding of the research and on the possible compensations and rewards to be paid for the research subjects. In order to make it simpler to make the clarification required by the Ethics Committee it is worthwhile to familiarise oneself carefully with the instruction issued by the National Committee on Medical Research Ethics (TUKIJA http://www.tukija.fi/c/document_library/get_file?folderId=18753&name=DLFE-682.pdf (available only in Finnish). The instruction deals with economic clarifications of medical research. *Mandatory attachment.*

12. Other possible attachments, such as a notification for the personnel.