Request for statement arrived

Date sent to reviewers

Date draft statement received

Meeting date of the Committee

Aalto University Research Ethics Committee

Secretary Jari Söderström

P.O.Box 18000

FI-00760 Aalto

**REQUEST FOR STATEMENT REGARDING ETHICALITY OF RESEARCH**

Please write the request on this form under the headings below. Use other presentation styles only if the nature of the research requires additions or alterations.

**1. DETAILS OF RESEARCH GROUP**

* 1. Name of study
  2. Research group and unit
  3. Aalto school
  4. Department
  5. Researcher in charge:
  6. Name
  7. Academic degree, Academic title
  8. Relation to Aalto University:

|  |  |
| --- | --- |
|  | Employee |
|  | Post graduate student |
|  | Grant researcher, working on Aalto visitor agreement |
|  | Research group member, working on Aalto visitor agreement |
|  | Other relation, what, working on permission by Aalto |

* 1. Contact details (address, telephone, e-mail)

**2. BACKGROUND AND OBJECTIVES OF STUDY**

1. Summary of the research proposal, also to be included in the statement form
2. General description of the research question using lay terms as much as possible
3. Methodological expertise of research unit
4. Test series
5. Objectives of study, reasons for necessity of study
6. Utilization of research results (for example basic research, method development, applied research etc.)
7. Duration of the research

**3. RESEARCHERS AND RESEARCH GROUP**

1. Researcher in charge: educational background and experience in the field
2. Other researchers involved in proposed research project: Name of researcher; Academic title; Field of education; Workplace; Special role or activity in the project
3. Funder of research (or client)

**4. NATURE OF STUDY**

The study represents the research field of\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(e.g. technical sciences, economics, art & design, neuroscience, psychology).

The study involves:

|  |  |
| --- | --- |
|  | Researcher´s scientific work in connection to University research, |
|  | Research in connection to a doctoral thesis |
|  | A joint research effort of different research organizations |
|  | Contract research |

The Aalto University Research Ethics Committee gives statements on studies:

* which are of non-medical nature,
* which do not aim to increase knowledge of human health or of the reasons, symptoms, diagnostics, treatment or prevention of diseases or of the nature of diseases in general, and
* where no drugs are administered to the study subjects during the study.

If this applies to your study, add the following text to the request with possible additional information:

“The studies conducted are of non-medical nature. This study does not aim to increase knowledge of health or of the reasons, symptoms, diagnostics, treatment or prevention of diseases or of the nature of diseases in general. No drugs are administered to the study subjects during the study.”

**5. STUDY** **SUBJECTS**

1. Study subjects, gender and age distribution
2. Possible pre-screening of subjects and exclusion criteria and other justification for choice of subjects
3. Compensation to be paid for study subjects

**6. RESEARCH METHOD**

**6.1. Principles of measurement(s)**

* Description of measurement(s)
* Type of data obtained by measurement(s)

**6.2. Arrangement of measurements**

* Time of study: time for starting and ending
* Place of study
* Staff arrangements for measurement, persons present during the implementation of the study

**6.3. Procedure of measurements**

* Description of study procedure
* Quality and quantity of tasks, stimuli etc.
* Accurate number of study subjects
* Duration of test series and of the study per study subject

**6.4. Risks and security**

* Which factors may present a risk in the measuring situations, how risks are prevented
* How can the study subject contact the measuring staff during measurement
* Possible safety training for staff
* Safety precautions for possible unexpected situations

**7. ASSESSMENT OF RESEARCH ETHICALITY**

* Overall impression of researcher on risks to study subjects
* Voluntary nature
* Measures taken in cases of unexpected incidental findings: In case the tests would happen to reveal a markedly non-typical unexpected finding, which the study subject is not aware of, a specialist doctor of the appropriate field will be consulted about this finding. Based on his/her estimation, the study subject may be recommended, if necessary, to seek appropriate further examinations.

**8. GROUNDS FOR REQUEST**

The study and the request for statement:

* have not been considered previously; or
* complement a prior statement (date of prior statement shall be given).

Statement is requested because (please mark where appropriate):

|  |  |
| --- | --- |
|  | a study subject requires an ethical evaluation |
|  | a possible financier requires an ethical evaluation |
|  | a study partner requires an ethical evaluation |
|  | a possible publisher requires an ethical evaluation |
|  | the study involves strong stimuli, causes mental stress, or the research situation otherwise requires an ethical evaluation (to be described separately) |

**9. INFORMATION TO THE DATA SUBJECTS**

**9.1. Information required by the EU General Data Protection Regulation GDPA (Privacy Notice)**

Instructions can be found on the Aalto University web site:

<http://www.aalto.fi/en/research/research_data_management/data_management_planning/research_ethics/>

**9.2. Information sheet for study subjects**

Information on the research may be provided in connection with the Privacy Notice (9.1.) or separately.

At least the following information shall be included in the fact sheet:

1. Name or topic of the research project
2. General description of study method, research group´s experience of the method
3. Purpose of the study
4. Funding or financier(s) of the study
5. Compensation paid to study subjects
6. Voluntary nature of participation
7. Right to discontinue participation at any time without obligation to disclose any specific reasons
8. Possible risks and their prevention
9. Communication with the research staff during testing
10. Description of study situation
11. Measures to be taken in cases of unexpected incidental findings. **The following clause shall be included:** The tests have not been designed to provide any clinical information. Nonetheless, in case the tests would happen to reveal a markedly non-typical unexpected finding, which the study subject is not aware of, a specialist doctor of the appropriate field will be consulted about this finding. Based on his/her estimation, the study subject may be recommended, if necessary, to seek appropriate further examinations.
12. Insurance coverage: **The following clause shall be included:** The study subjects are covered by Aalto-level insurances for accidents and damages during the tests.

The information sheet shall be signed by the researcher in charge (with his/her contact information) on behalf of the research group.

**9.3. Informed consent of study subjects**

**NOTE!** Processing of personal data is lawful, if it is required for the performance of a task carried out in the public interest, namely scientific research and academic expression. No consent is required for the processing of personal data. However, participation in research must always be voluntary.

If a consent is required, the following information shall be included in the consent document:

1. Name of study
2. Research method:
3. Research group and unit
4. Consent clause (minimum clause, to be complemented if necessary):

I have read and understood the study information sheet given to me and I have sufficient information on the process of the study. I understand that my participation in the study is completely voluntary and that I have the right to discontinue my participation at any stage without any consequences. It has been explained to me that a designated researcher will, at my request, provide me with additional details of the general principles of the study and its progress or of the results concerning myself.

I have understood that the research data is gathered for scientific purposes only and it will not be given even in part to the study subject him/herself.

The research data and measurements related to me are only available to the researchers of the research group and they will not be presented to a third party without my written consent. The researcher in charge of the study may, however, give permission to his/her other cooperation partners to analyse the research data and results for scientific purposes or ask for a professional consultation on possible unexpected incidental findings without separate consent provided that the anonymity of the results has been ensured. Any type of commercial exploitation of the research data is prohibited.

The research data and measurements related to me may be used in Aalto University, without a new separate consent, to another study related to the same research area conducted by the same researcher.

I am not aware of any medical condition preventing me to attend the tests. I approve that in case there appears an unexpected incidental finding I will be informed about this.

By my signature, I confirm my participation in this study and agree to volunteer as a study subject.

5. Signature of the study subject with his/her personal and contact information

6. Signature of the researcher in charge

**10. SIGNATURE OF THE RESEARCHER IN CHARGE**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Signature

Type or print name

**STATEMENT REGARDING ETHICALITY OF RESEARCH BY THE AALTO UNIVERSITY RESEARCH ETHICS COMMITTEE**

**Researcher in charge fills out (Sections with grey background):**

**Title of the research proposal**

|  |
| --- |
|  |

**Researcher in charge**

*Name:*

*Academic title:*

*Affiliation:*

*Tel:*

*E-mail:*

**Other involved members of the research group (name, affiliation)**

**Funding of the study**

**Grounds for statement request (For example request by financier, publisher or study subject; requirement for research permit; nature of research)**

**Short summary of the research proposal**

**The evaluators fills out:**

**Matters to be reviewed (Add if needed)**

1. *Research method:*
2. *Number of study subjects, age distribution; exclusion criteria:*
3. *Validity of the ethical evaluation:*
4. *Compensation for study subjects:*
5. *Managing of data gathered of study subjects:*
6. *Information sheet for study subjects:*
7. *Possible risks:*
8. *Medical vs. non-medical research:*
9. *Research data form:*

**Ethical evaluation of the study**

**Recommendation**

**Date and signature (reviewers of the statement)**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Signature

Type or print name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature

Type or print name

**Reviewers**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Reviewer in charge** |  | **Other reviewer** |
|  | Ossi Naukkarinen |  | Ossi Naukkarinen |
|  | Iiro Jääskeläinen |  | Iiro Jääskeläinen |
|  | Riitta Salmelin |  | Riitta Salmelin |
|  | Juhani Orkas |  | Juhani Orkas |
|  | Tuija Takala |  | Tuija Takala |
|  | Juan José Valle-Delgado |  | Juan José Valle-Delgado |
|  | Seppo Ovaska |  | Seppo Ovaska |
|  | Wojciech Solowski |  | Wojciech Solowski |
|  | Hanna Renvall |  | Hanna Renvall |