**REQUEST FOR AN ETHICAL REVIEW STATEMENT CONCERNING A RESEARCH PROJECT**

This form is used when applying for an ethical review statement for a research project **from The Human Sciences Ethics Committee of the Helsinki Region Universities of Applied Sciences**, unless legislation stipulates that the ethical review must conducted by another party. An ethical review of research subject to the Medical Research Act must always be conducted by the regional committee on medical research ethics. For clinical medical research, an opinion is always sought primarily from the National Committee on Medical Research Ethics (TUKIJA), based on which the ethical review is conducted either by TUKIJA or by a regional ethics committee.

You can use this form to document your consideration of matters related to research ethics in your own research/thesis even if it does not require an ethical review.

1. **Information on the research/thesis**

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| **Researcher/author of the thesis** |  |
| Organisation |  |
| Email |  |
| Telephone |  |
| **Person responsible for the research /**  **thesis supervisor** |  |
| Name |  |
| Qualification, job position |  |
| Organisation |  |
| Email |  |
| Telephone |  |
| **Name of the research**  (also in English if an English-language statement is required from the committee) |  |
| **Short description of the research**  (What problem are you aiming to solve? Detailed research question, methods to be used, desired outcome, how results will be utilised and by whom. What new information will the research offer? The importance of this new information? If this is a large project, describe the areas for which you are requesting an opinion from the committee.) Maximum 300 words. |  |
| Estimated start date of the study |  |
| Estimated duration |  |
| Collection of material will be started on [date] |  |
| What kind of a whole is this research a part of?  Participants in the project (research institutes, higher education institutions, their units/departments and researchers; other participating units and their researchers) |  |
| Project funders and funding amounts |  |

**This is...**

New research   
 Research that has been revised and we are requesting a new statement

Date of previous statement: \_\_\_\_\_\_\_\_\_\_\_\_

What revisions have been made to the research after the previous ethical review statement was given? Short description of the revisions as a list, maximum 200 words.

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1. **Statement requester’s assessment of the need for an ethical review**

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|  | **Is this research subject to the Medical Research Act, i.e.:** | **Yes** | **No** |
| **1.** | **Is this a scientific study?**  Research as referred to in the Medical Research Act is considered scientific if:   * the person responsible for it has the professional and scientific qualifications required by the research in question * a scientific research plan has been prepared for the study * the purpose is to increase knowledge through the use of a scientific method * the outcomes of the research are intended to be made available to the public through a publication channel approved by the scientific community   **Note!** A UAS Bachelor’s thesis rarely fulfils the criteria for scientific research. If the thesis is a part of a larger research project, a request for an ethical review should be submitted for the entire research plan. |  |  |
| **2.** | **Is the purpose of the research to increase knowledge about health or the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of diseases in general?** |  |  |
| **3.** | **Does the research involve intervention in the physical integrity of a person?**  Intervention in the physical integrity of a person includes, for example, taking blood samples, biopsies or similar, research involving physical strain and research which seeks to influence health or the risk or symptoms of a disease. |  |  |
| **4.** | **Does the research involve intervention in the psychological integrity of a person?**  Intervention in the psychological integrity of a person is when the research may cause a risk to the mental wellbeing of the research participant. |  |  |
| If you answered “yes” to questions 1 **and** 2 **and** to question 3 **or** 4, you must obtain a favourable opinion from the local medical ethics committee before you can start the research.  For further information, see: [web pages of the HUS Ethics Committees](https://www.hus.fi/tutkimus-ja-opetus/tutkijan-ohjeet/eettisen-lausunnon-hakeminen)  **Note!**   1. If your research is a not a scientific study but an anonymous survey, you don’t need an ethical review. 2. If your research consists of a personal interview survey in which you will collect particularly personal data or sensitive data on people’s health with the intention of studying diseases and their treatment, your research could be considered medical research that involves intervention in the psychological integrity of a person. In this case, the ethical review must be conducted by the local medical ethics committee. 3. You don’t need an ethical review if your research is based solely on registered information or patient documents (the research subjects will not be contacted). 4. Service development and observation studies as well as quality and process projects conducted in the health care sector, when they don’t involve intervention in the integrity of a person, are not covered by the scope of the Medical Research Act. | | | |

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|  |  | **Yes** | **No** |
| **5.** | **Is your project something other than research with human participants that is covered by the scope of the Medical Research Act?**  Besides humanities and social sciences, this research includes research with human participants in natural sciences and technology, artistic research, and also non-invasive health or medical research, including sports science and nutritional science. |  |  |
| **6.** | **Does participation in the research deviate from the principle of informed consent?**  Informed consent means that:   1. the research participant knows they are participating in the research 2. the research participant receives understandable and truthful information on the research 3. the research participant has sufficient time to make a decision and the opportunity to ask for further information 4. the research participant never feels coerced to participate in the research or fears any negative consequences if they refuse to participate 5. the research participant actively shows their willingness to participate in the research 6. the research participant has the right to interrupt their participation or withdraw their consent without stating a reason before the research is completed |  |  |
| **7.** | **Do the research participants include population groups whose voluntary participation in the research may be disputed?**  Vulnerable population groups or people who are dependent on the researcher or the organisation conducting the research, for example people performing military services, prisoners, the researcher’s subordinates, students or pupils. |  |  |
| **8.** | **Does the research involve intervention in the physical integrity of the research participants?**  For example, measuring physical condition, taking physiological samples, consumption of food or other ingested products, or restricting physical freedom so that the research participants have no opportunity to stop their participation in the research of their own free will within a reasonable period of time. |  |  |
| **9.** | **Will the research involve participants under the age of 15 who participate without the separate consent of their guardian and without the guardian being informed, based on which the guardian would have the opportunity to forbid the child from participating?**  In general, the guardian’s consent is needed for the participation of minors under the age of 15. However, it is enough if the guardian is merely informed if:   * the research is a survey targeted at a minimum of 400 people * the research participants are observed without recording equipment or processing of personal data |  |  |
| **10.** | **Will the research participants be subjected to exceptionally strong stimuli?**  For example, material containing violence or pornography, or ideas and data that are completely incompatible with the participants’ values. |  |  |
| **11.** | **Does the research involve the 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?**  For example, if the research is associated with traumatic experiences of research participants or their family members or other closest to them. |  |  |
| **12.** | **Can the research pose a threat to the safety of the research participants or the researchers, or their family members or others closest to them?**  For example, research into domestic violence or research conducted in crisis situations or areas. Data security risks can also form a safety threat, e.g. if the research participants’ personal data is collected and combined from several different sources. |  |  |
| If you answered “yes” to question 5 **and** one of questions 6–12, you must obtain an ethical review statement from the Ethics Committee for Human Sciences before you start collecting data.  If no ethical review statement is requested or the researcher does not comply with the guidelines in the statement they have received, this may constitute a violation of responsible conduct of research (RCR) and, where necessary, it may be resolved through the process of handling allegations of research misconduct.  For further information, see: [website of the Finnish National Board on Research Integrity TENK](https://www.tenk.fi/fi/htk-loukkaukset%20%20%5bSIVUA%20EI%20LÖYTYNYT%5d) | | | |
| **13.** | **Do you have any other reason to request an ethical review than those stated in questions 6–12?**  For example, requirement by a funder, partner, research subject or publisher. |  |  |
| In this case, instead of issuing a statement, the ethics committee may provide a description of the ethical review processes in Finland and of the instances in which an ethical review is required in Finland. | | | |
| **14.** | **Is the research based on public information, data from registers and documents or archived data?** |  |  |
| If you answered “yes”, you don’t need an ethical review statement from the Ethics Committee for Human Sciences. Please check whether you need any other permits or statements! | | | |

1. **The statement requester’s view of the ethical issues related to the research and of the means for resolving them**

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| **Informing the research participants and obtaining consent**  If the information material and consent forms intended for the research participants clearly describe the matters below, you may leave questions 15–19 unanswered. | |
| **15.** | **How will you recruit participants for your research?** |
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| **16.** | **How will you inform the participants of the research and their participation in it in an understandable and truthful manner?**  Please consider particularly cases where the research participants are underage, people with limited capacity or vulnerable people, or where communication is challenging due to language skills, sensory impairments etc. |
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| **17.** | **If the research participants are under 15 years of age, how will you inform their guardians of the research and participation in it?** |
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| **18.** | **How will you ensure that participation is truly voluntary? Do the research participants include population groups whose voluntary participation may be disputed? How will you ensure that these persons will give their consent voluntarily? The research participant must not be made to feel that they will suffer negative consequences if they refuse to participate in the research or if they wish to withdraw their consent later.**  For example, if the research participant is a vulnerable person or you have another relationship with them besides being a researcher (e.g. colleague, service provider etc.), the research subject must not be made to feel that refusing to participate would affect their treatment or rights or the service/medical care they receive. You also may not appeal to the research participants’ emotions, or solicit or bribe them to participate. If the research is conducted as part of studies, the student must have the opportunity to complete the credits in question in an alternative manner to participating in the research. |
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| **19.** | **How will you prove the informed consent of the research participants?**  **Please note that even if a guardian or legal representative may give permission for participation in the research, the decision to participate must be made personally by the research participant.**  For example, providing a signed form, pressing the “accept” button in an electronic survey or showing up at a research situation based on material received in advance. Note that consent cannot be given passively, for example by remaining silent, by accepting a pre-selected checkbox or by not doing something. |
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| **20.** | **Are you going to deviate from the principle of informed consent for participation in the research? Do you plan on not giving the research participants sufficient or truthful information about the research? Please provide a justification for your decision.**  This is for cases where the research is justified but it can’t be conducted by asking the research participants for their consent to participate. For example, when the research outcome might be affected if the participants are aware they are a part of a study, or if you are using old data for which you are no longer able to ask for consent from the research participants. |
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| **21.** | **Do you intend to conduct research on minors aged under 15 without asking for permission from their guardians or informing their guardians? Please provide a justification for your decision. How will you ensure that those you ask to participate in the research understand the subject of the research and what participation entails from them?**  For example, if you are researching subjects in which the guardians’ knowledge will influence the outcome of the research (incl. domestic violence) or the research participants themselves don’t want their guardians to know (incl. substance abuse, sexuality and similar). |
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| **Processing of personal data in the research**  If you have appended a data management plan and a data protection statement for scientific research which clearly present the information requested below, you can leave questions 22–30 unanswered. | |
| **22.** | **Will you process personal data in your research? What data and why?**  Personal data means any information relating to an identified or identifiable natural person. Research data contains personal data if they can be directly or indirectly used to identify a person or persons through reasonable means. |
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| **23.** | **Will you process special categories of personal data (sensitive data) in your research? What data and why?**  Special categories of personal data means personal data that reveals racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, biometric data processed for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person’s sex life or sexual orientation. |
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| **24.** | **What is your legal basis for processing personal data?**  There must be a legal basis for processing personal data.  Scientific research in the public interest  Consent of the research participant (data subject)  Other, please specify. |
| **25.** | **If your legal basis for processing personal data is the consent of the research participant (data subject), how will you prove consent?** |
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| **26.** | **Who will be the data controller(s)?**  The data controller determines the purpose for which personal data will be used and how they will be processed and is responsible for the data protection of the data register. |
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| **27.** | **Please describe how personal data will be processed when data is analysed and the outcomes of the research are reported. Who will process the data? When and how will the data be pseudonymised and/or anonymised? Will personal data be stored for the purpose of combining them?**  Personal data must as a general rule be erased from the research data when they are no longer necessary for conducting the research or verifying the outcome of the research. |
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| **28.** | **Is it possible that individual research participants will be identifiable in the published research, for example, due to the small sample size or the public profile of the research participants?**  Research participants and people who have provided information for the research must not be promised complete anonymity if this can’t be guaranteed. |
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| **What will happen to the research data once the research is concluded?** | |
| **29.** | **Is the research data useful for further research and could it be stored in accordance with the principles of open science so that it is available to other researchers? Who will anonymise the data and make it accessible to other researchers?**  Note! The research participants must be informed at the data collection stage that the data will be stored for future use. |
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| **30.** | **If the data can’t be stored and made available to other researchers, who will erase the data, and how and when?** |
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| **Other risks and potential harm that may be caused to the research participants, the researchers or their family members or others close to them.** | |
| **31.** | **If the research participants will be subjected to exceptionally strong stimuli or there is 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, how have you prepared for potential negative consequences?**  For example, if the research deals with traumatic experiences, will there be help on offer for the research participants? How have you arranged this help? |
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| **32.** | **Can the research pose a threat to the safety of the research participants or the researchers, or their family members or others closest to them? What will you do to minimise this risk?** |
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| **33.** | **In your opinion, can this research pose any other risks or cause other harm to the research participants? How will you prevent or minimise this risk or harm?** |
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| **34.** | **If you find something unexpected in measurements, imaging etc. included in the research (e.g. signs of a disease the research participant is unaware of), how will you act?** |
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1. **Assessment by the person responsible for the research / the thesis supervisor of the potential risks or harm caused to the research participants, the researcher or their family members or others closest to them, and of the researcher’s plan to prevent these (maximum 300 words)**

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| **Signatures** | | |
|  | I assure that I have considered the potential risks or harm caused to the research participants, the researcher or their family members or others closest to them and I have provided a truthful account of them above.  I assure that the research/thesis will be conducted according to the plan. | |
| **AND** | | |
|  | I believe that this research/thesis **will not cause** risks or harm to the research participants, the researcher or their family members or others closest to them that would require an ethical review by the ethics committee. | |
| **OR** | | |
|  | I believe that this research/thesis **could cause** risks or harm to the research participants, the researcher or their family members or others closest to them that require an ethical review by the ethics committee. | |
| **Signature of the researcher / thesis supervisor:** | | **Date:** |
| **Signature of the person responsible for the research / the thesis supervisor:** | | **Date:** |

**Appendices to the request for a statement**

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| **Mandatory appendices** | |
| Research plan |  |
| Data management plan |  |
| **Depending on the research design:** | |
| Recruitment notice to be given to the research participants |  |
| Information material to be given to the research participants |  |
| Consent form for the research participants |  |
| If identifiable personal data are collected from the research participants: privacy notice of the research and, if necessary, a DPIA |  |
| Other material provided to the research participants, such as a questionnaire, interview outline etc. |  |
| Other, please specify. |  |
|  |  |