Form for Self-Assessment of Ethical Issues in Degree Projects[[1]](#footnote-2) at the School of Health and Welfare

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| --- | --- |
| Date: |       |
| Title of the degree project  |       |
| Student(s)[[2]](#footnote-3): |       |
| Student’s/Students’ e-mail address: |       |
| Degree programme: |       |
| Education cycle: |       |
| Supervisor: |       |
| Supervisor’s e-mail address: |       |

Degree projects at the School of Health and Welfare, Jönköping University, must comply with the ethical principles expressed in the Act concerning the Ethical Review of Research Involving Humans (Etikprövningslagen, “EtRAct”). This form is a tool for reviewing ethical issues related to the degree project.

**The student and the supervisor carefully go through the form together, identify potential ethical problems, and agree on how these should be addressed. If there is still doubt, an application for an advisory opinion must be submitted to the Research Ethics Committee (see Part C).**

Research that falls within the EtRAct must be reviewed by the Swedish Ethical Review Authority[[3]](#footnote-4). There are two types of studies that usually are not considered as research, and that must be dealt with specially. One is degree projects and the other is quality improvement projects in health care and social welfare.

The distinction and boundary between research and these two types of studies are initially touched on in Part A.

Part B deals with what falls under the EtRAct and ethical principles that are important to consider before conducting a study.

Part C contains procedures for obtaining an advisory opinion from the Research Ethics Committee.

If the degree project is already included in a project that has been reviewed and approved, it is not necessary to conduct a Self-Assessment of Ethical Issues.

Part A: Is this a research study?

The purpose of the questions in Part A is to determine if the study is to be regarded as research. A degree project is not ordinarily considered research and thus cannot be reviewed by the Swedish Ethical Review Authority. Under certain circumstances, however, a degree project may be research, namely if:

1. the intention is to publish it in a scientific journal
2. it addresses a scientific question and has a design that can answer that question
3. it is led by researchers within the discipline, either as part of a larger project or with a researcher as the supervisor.

All of these three must be fulfilled for the study to be considered research and be able to be reviewed by the Swedish Ethical Review Authority.

Is the study research in these three respects?

 [ ]  YES (The study needs to be reviewed by the Swedish Ethical Review Authority.)
 [ ]  NO (Proceed to Parts B and C.)

Part B: Does the degree project contain what is regarded as ethically sensitive according to the Ethical Review of Research Involving Humans?

The purpose of the questions in Part B is to explore whether the degree project raises any ethical issues that, *if it were research*, would require a review by the Swedish Ethical Review Authority, and whether the degree project complies with ethical principles.

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| --- | --- | --- | --- | --- |
|  |  | **Yes** | **Not sure** | **No** |
| 1 | Does the study intend to process what the General Data Protection Regulation (GDPR) considers to be sensitive personal data, i.e., data that at some stage can be linked to a person and that reveals racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, or information about an individual’s health or sex life? | [ ]  | [ ]  | [ ]  |
| 2 | Does the study intend to collect and process personal data relating to violations of the law that involve criminal offences, convictions in criminal proceedings, penal law sanctions, or administrative deprivation of liberty? | [ ]  | [ ]  | [ ]  |
| 3 | Does the study entail a physical intervention on the participants (also that which is included in standard procedures, but also part of the research)?  | [ ]  | [ ]  | [ ]  |

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|  |  | **Yes** | **Not sure** | **No** |
| 4  | Is the purpose of the study to affect the participants physically or psychologically? | [ ]  | [ ]  | [ ]  |
| 5  | Are there any risks for the participants (for example, the risk of physical harm or the risk of awakening traumatic memories)? | [ ]  | [ ]  | [ ]  |
| 6  | Will the study use biological material that can be traced to an identifiable individual or deceased person (e.g., blood samples or tissue specimens)? | [ ]  | [ ]  | [ ]  |
| 7 | Can voluntariness be questioned (e.g., vulnerable groups, such as children, people with cognitive impairment or mental disabilities, or individuals in a dependent relationship to the principal investigator, such as a patient or student)?  | [ ]  | [ ]  | [ ]  |
| 8 | Will the study involve individuals with limited autonomy (for instance individuals with cognitive difficulties, minors), whose understanding of the meaning of the consent is limited? | [ ]  | [ ]  | [ ]  |
|  | **Selection of participants and social vulnerability** |  |  |  |
| 9 | Do the participants belong to a particularly vulnerable or disadvantaged group in society (a minority group)? | [ ]  | [ ]  | [ ]  |
| 10 | Will the study involve the establishment of a personal register where data can be linked to a physical person?  | [ ]  | [ ]  | [ ]  |
|  | **Informed consent** |  |  |  |
| 11 | Will informed consent be obtained as a part of the study (in other words, will the participants receive full information about the study and/or the opportunity to opt out from participation?  | [ ]  | [ ]  | [ ]  |
| 12 | Is the study described in such a manner so that the participants understand its purpose and structure, and what participation in the project entails (e.g., number of visits, duration of the project, and written in easy-to-understand Swedish without technical terms or professional jargon)? | [ ]  | [ ]  | [ ]  |
| 13 | Is it clearly stated in the written information to the participant that the participation in the study is entirely voluntary? | [ ]  | [ ]  | [ ]  |
| 14 | Does the information letter contain persuasive formulations (implying that the person must or should participate, without showing full respect for the choice, for example mildly persuasive formulations, such as “thanks in advance”)? | [ ]  | [ ]  | [ ]  |
| 15 | Is it clearly stated that the participants may choose not to participate, without prejudice to the participants’ being offered care or treatment or, if relating to students, it affecting their grades? | [ ]  | [ ]  | [ ]  |

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| --- | --- | --- | --- | --- |
|  |  | **Yes** | **Not sure** | **No** |
| 16 | Is it clearly stated that the participants may discontinue the participation at any time and without the need to state any reason, without prejudice to the participants’ being offered care or treatment or, if relating to students, it affecting their grades? | [ ]  | [ ]  | [ ]  |
|  | **Confidentiality and the security of the participants** |  |  |  |
| 17 | Are there procedures in place to ensure confidentiality in the collection of data? | [ ]  | [ ]  | [ ]  |
| 18 | Are the results/findings described in such a manner so that the participants’ identity remains confidential, meaning that they cannot be identified afterwards (including a minimal potential for reverse identification)? | [ ]  | [ ]  | [ ]  |
| 19 | Are there procedures to ensure confidentiality? | [ ]  | [ ]  | [ ]  |
| 20 | Are there clear routines for ensuring that the collected data material is handled according to GDPR? | [ ]  | [ ]  | [ ]  |
|  | **Research results and/or findings** |  |  |  |
| 21 | Are there reasons to offer participants the opportunity to obtain a copy of or otherwise gain access to the research results/findings? | [ ]  | [ ]  | [ ]  |

**The questions under section B, have been responded truthfully and discussed with supervisor.**

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| Place and date: |       |
|  | **Signature Student** |  | **Signature Supervisor** |
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Part C: Application for an Advisory Opinion

Follow the instructions in the bulleted list. The application must be written under supervision and signed by the student(s) and supervisor. The text may not exceed 1,000 words, excluding the project plan (Times New Roman, 12 pt, 1.5 line spacing).

* Describe the ethical risks and problems identified in Part B.
* Describe and explain how these ethical risks and problems could be addressed.
* Attach the project plan and relevant attachments, such as questionnaires and information letters.

Sign the “Self-Assessment of Ethical Issues” form, scan it, and e-mail it along with what is requested in Part C to the Research Ethics Committee's secretary. All documents must be in PDF format. The dates for the meetings of the Research Ethics Committee can be found on [the university’s website](https://ju.se/en/about-us/school-of-health-and-welfare/research/research-ethics-committee.html).

The above questions have been carefully reviewed, truthfully answered, and discussed with the supervisor.

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| Place and date: |       |

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|  | **Printed name** |  | **Signature** |
| Student/implementer: |       |  |  |
| Student/implementer: |       |  |  |
| Student/implementer: |       |  |  |
| Supervisor: |       |  |  |

1. The form also applies to quality improvement projects in health care and social welfare. [↑](#footnote-ref-2)
2. Alternatively, the implementer of quality improvement projects in health care and social welfare. [↑](#footnote-ref-3)
3. https://etikprovning.se/ [↑](#footnote-ref-4)