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, the course examiners needs to be consulted.**

Research that falls within the EtRAct must be reviewed by the Swedish Ethical Review Authority[[3]](#footnote-4).

The distinction and boundary between research and degree projects are described in Part A.

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

**The Self-Assessment of Ethical Issues in Degree Projects should always be approved by the course examiner before the degree project is started.**

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 usually considered as 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.

**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 questions in Part B aim to examine;

1. if the degree project has such ethical problems that if it were research - it would require to be reviewd by the Ethics Review Authority. In these cases, the degree project must not be completed.
2. how ethical principles are handled in the degree project.

If any of the questions are answered with "not sure" or "yes" (questions 1-13) and with "not sure" or "no" (questions 14-23), an in-depth ethical reflection involving students and supervisors should be carried out on how these ethical risks and problems must be managed or how the study can be modified to counteract identified risks. In these cases, the course examiner should also be involved in the self-assessment and the ethical reflection to make a final decision on the implementation of the degree project. **The ethical self-assessment must always be approved by the examiner before the degree project begins.**

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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 any 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? | [ ]  | [ ]  | [ ]  |
|  |  | **Yes** | **Not sure** | **No** |
| 3 | Does the study intend to include people who can be identified as vulnerable groups and / or people who are dependent on the person who recruits or carries out the data collection | [ ]  | [ ]  | [ ]  |
| 4 | Does the study intend to include children (persons under the age of 18) | [ ]  | [ ]  | [ ]  |
| 5 | Does the study involve a physical intervention on the participants, eg some type of physical examination or sampling (also something that is part of normal routines, but is also part of the study) | [ ]  | [ ]  | [ ]  |
| 6 | Is the purpose of the study to affect the participants physically or psychologically eg, ? | [ ]  | [ ]  | [ ]  |
| 7 | Are there an apparent risk to harm the participants physically or psychilogically? | [ ]  | [ ]  | [ ]  |
| 8 | Will the study use biological material that can be traced to an identifiable individual or deceased person (e.g., blood samples or tissue specimens)? | [ ]  | [ ]  | [ ]  |
| 9 | 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)?  | [ ]  | [ ]  | [ ]  |
| 10 | 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** |  |  |  |
| 11 | Do the participants belong to a particularly vulnerable or disadvantaged group in society (a minority group)? | [ ]  | [ ]  | [ ]  |
| 12 | Will the study involve the establishment of a personal register where data can be linked to a physical person?  | [ ]  | [ ]  | [ ]  |
|  | **Informed consent** |  |  |  |
| 13 | 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”)? | [ ]  | [ ]  | [ ]  |
| 14 | 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)? | [ ]  | [ ]  | [ ]  |
| 15 | Is it clearly stated in the written information to the participant that the participation in the study is entirely voluntary? | [ ]  | [ ]  | [ ]  |
| 16 | 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?  | [ ]  | [ ]  | [ ]  |
| 17 | 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** |
| 18 | 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** |  |  |  |
| 19 | Are there procedures in place to ensure confidentiality in the collection of data? | [ ]  | [ ]  | [ ]  |
| 20 | 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)? | [ ]  | [ ]  | [ ]  |
| 21 | Are there procedures to ensure confidentiality? | [ ]  | [ ]  | [ ]  |
| 22 | Are there clear routines for ensuring that the collected data material is handled according to GDPR? | [ ]  | [ ]  | [ ]  |
|  | **Degree project results and/or findings** |  |  |  |
| 23 | Are there reasons to offer participants the opportunity to obtain a copy of or otherwise gain access to the degree project 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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 **Signature Examiner**

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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)