



Checklist for legally required ethics review

If you do research involving human participants, information on persons, or human tissues, then please use this checklist to assess whether the Swedish Ethics Review Act applies. If it does, you need an ethics approval from the Ethics Review Authority before the research activities start. Please see the appendix for an overview of the Swedish ethics review system. This checklist does not assess all legal requirements that may apply to your research project. Also, the funder's ethics requirement may differ from what is legally required in Sweden.

Please contact researchethics@kth.se if you need further support.

1. Do you plan to collect, store, analyse, or in any other way process information about human beings that are alive?
 - 1.1. If **yes** on 1, is any information traceable to any specific person through any identifier (name, IP address, email address, etcetera)?
 - 1.2. If **yes** on 1, is any piece of information traceable to any specific person by way of combining the information with one or several other pieces of information?

If **yes** on 1, and any of 1.1 or 1.2, personal information is handled. Required actions include: informing participants and restricting access to the information. The GDPR does apply, and the Ethics Review Act may apply.

2. Is the personal information processed for research purposes?
3. Is the personal information about:
 - 3.1. Ethnic background?
 - 3.2. Religious or philosophical beliefs?
 - 3.3. Political opinions?
 - 3.4. Union membership?
 - 3.5. Health?
 - 3.6. Sexual habits or orientation?
 - 3.7. Genetical or biometrical data?
 - 3.8. Legal offenses?

If **yes** on 2, and any of the questions under 3, an ethics approval is necessary before commencing the planned research. Legal definitions of the terms used in question 3 may differ from definitions used in research.

4. Irrespectively how you reply to the above questions, do you plan to:
 - 4.1. Perform research where research persons are at an *obvious* risk of harm?
 - 4.2. Perform physical procedures on alive or deceased human beings?
 - 4.3. Physically or psychologically affect human beings?
 - 4.4. Use biological samples that are traceable to the alive or deceased human donors?

If **yes** on any of the questions under 4, an ethics approval is necessary before commencing the planned research.



Appendix: Outline of the Swedish Ethics Review-system

The Ethics Review Act (2003:460) mainly regulates research reviews with human participants in Sweden. According to that law, an ethics review is performed by a national agency (the Ethics Review Authority) and is legally required for any scientific or scholarly research activity (1) performed in Sweden that (2) fulfills at least one of the following criteria:

- There is a physical intervention upon the research person (alive or deceased).
- The research method is intended to physically or psychologically affect the research person.
- There is an obvious risk of physical or psychological harm.
- Biological matter from the research persons (alive or deceased) is used and traceable to them.
- Sensitive personal data or personal data concerning the criminal record are handled.

‘Sensitive personal data’ is legally defined by the General Data Protection Regulation (EU) article 9.1 as data that can be traced to a single, identifiable individual and concerns ethnic background, political opinions, religious or philosophical convictions, union membership, health, sexual habits or orientation, genetical or biometrical data, or legal offenses.

Exempted from the scope of the act is work for first and second-cycle studies (unless published in scientific channels), any activities outside Sweden, and arts-based research.

The Ethics Review Authority distributes applications for ethics review to ethics committees consisting of researchers and public representatives, which may approve, approve with requirements, and deny or dismiss applications.

In cases where those criteria are not fulfilled, a legally valid ethics review is unnecessary. As a service, however, the Ethics Review Authority offers an advisory opinion in such cases. Also, Swedish universities are obligated to support their staff on research integrity and research ethics.

The KTH’s Ethics Committee (of the Faculty Council) may provide an advisory opinion on specific projects that may be research-ethically controversial but do not fulfill the above criteria. The application procedure is less demanding than applying for an opinion from the Ethics Review Authority. The KTH’s Ethics Committee provides opinions on projects only before they commence.

The KTH ethics advisor at the Research Support Office primarily offers support on legal requirements.

While, traditionally, the Swedish ethics review system relies on the trust of the researcher’s ethical competence, the research ethics of most projects that do not fulfill the above-listed criteria are handled internally by the group performing the research.