

Rules of Procedure for the Research Ethics Committee at Karlstad University

Approved by the Vice-Chancellor on 31 January 2022

1. Establishment

The research ethics committee at Karlstad University was established by order of the university board 12 June, 2001. The need for a research ethics committee is based on the stipulations of the Ethical Review Act concerning research involving humans, as well as on those of the Higher Education Act (Chap. 1, Sec. 3a), requiring higher education institutions to uphold academic credibility and good research practice. However, it is always the responsibility of the researcher and entity responsible for research to ensure compliance with good research practice and applicable laws and regulations. From 1 January 2020 and in accordance with the Ethical Review Act concerning research involving humans (2003:460, Sec. 6 and 8), there are stricter regulations in place regarding the obligation of the entity responsible for research to prevent that research in the organisation is conducted without an approval following an ethics review or in violation of the terms established in connection with such an approval.

The research ethics committee is part of Karlstad University's internal research ethics review process and preventive work in matters related to ethical review by providing an advisory and review function with research, legal and information security expertise to support both researchers and the authorised representative of the entity responsible for research.

2. Ethical Review Act

The Ethical Review Act (2003:460) concerning research involving humans came into force 1 January, 2004. The Act stipulates that certain research projects involving humans may only be conducted after they have been approved by the Swedish Ethical Review Authority.

According to the Act, Sec. 2,

research is defined as scientific experimental or theoretical work or observational research studies, if the work or studies are carried out to acquire new knowledge, and/or development work on a scientific basis, excluding work performed as part of first- or second-cycle higher education programmes,

entity responsible for research is defined as a government agency or a natural or legal person under whose auspices the research is conducted,

human subject is defined as a living individual about whom an investigator conducts research, and

processing of personal data is defined as the processing specified in Article 4.2 of the General Data Protection Regulation.

The Act shall, in accordance with Sec. 3, apply to research including the processing of

1. personal data as specified in Article 9.1 of the General Data Protection Regulation (sensitive personal data), or

2. personal data on transgressions of the law, including crime, judgments in criminal cases, coercive measures or administrative deprivation.

Sensitive personal data include data that disclose racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union affiliation and the processing of genetic data, biometric data to unequivocally identify a physical person, data concerning health, a physical person's sexuality or sexual preference.

In addition to what applies pursuant to Sec. 3, the Act shall also apply, according to Sec. 4, to research that

1. involves physical procedures on a research participant,
2. is conducted using a method that aims to influence the research participant physically or mentally, or which involves an evident risk of harming the research participant physically or mentally,
3. concerns studies of biological material taken from a living person and which can be traced back to this person,
4. involves physical procedures on a deceased person, or
5. concerns studies on biological material taken from a deceased person for medical purposes and which can be traced back to this person.

An application for ethical review of such research covered by the Ethical Review Act shall be submitted by the entity responsible for research, Karlstad University, to the Swedish Ethical Review Authority. The Swedish Ethical Review Authority may also upon request provide advisory opinions on research and student projects that do not fall under the Ethical Review Act. The power to represent Karlstad University as the entity responsible for research in applications for ethical review and requests for advisory opinions has been delegated to the dean, who can in turn can delegate to the head of department or a research centre director.

3. The role of the research ethics committee

The research ethics committee is tasked with assisting the entity responsible for research and the individual researcher with assessments of whether a research project fall under the Ethical Review Act, as well as recommendations with the aim of strengthening and assuring the quality of the applications that are submitted to the Swedish Ethical Review Authority. The research ethics committee is also responsible for conducting risk analyses and offering advice to the entity responsible for research and the individual researcher regarding data protection and information security, and whether an impact assessment regarding data protection is required.

3.1 Research that may fall under the Ethical Review Act

All research at Karlstad University that may be covered by the regulations in the Ethical Review Act shall be reported to the university's research ethics committee before the commencement of a project. The responsible researcher assesses – sometimes in consultation with an expert in the event of any uncertainty – whether a project needs to be reported to the research ethics committee. The research ethics committee reviews and assesses whether an application falls under the Ethical Review Act or not. The research ethics committee also formulates an advisory opinion that will function a guide for the researcher and the representative of the entity responsible for research in the drawing up of an application to the Swedish Ethical Review Authority. In cases where the research ethics committee finds that the research project does not fall under the Ethical Review Act, an advisory opinion is still be provided.

Student projects are generally not subject to ethical review but could be viewed as research, for example, when the projects are conducted as part of a larger research project intended for scientific publication. In such cases, the supervisor is the person in charge of ensuring that the student project undergoes a research ethical review and that the project is reported to the research ethics committee in cases where the research is covered by the Ethical Review Act.

3.2 Research that does not fall under the Ethical Review Act

In addition to research subject to ethical review according to the Ethical Review Act, ethical decisions frequently need to be made regarding aspects of other research projects and student projects. These aspects may include prioritisation, methodology, or striking a balance between the benefits and possible negative results of the research. This type of research is primarily reviewed by the faculty ethical advisors and registered internally in Karlstad University's registry. The research ethics committee may in some cases review research projects that do not fall under the Ethical Review Act but where the responsible researcher still wants their research to be ethically reviewed. This may, for example, apply in connection with the publication of a research paper in a scientific journal that requires that the research has been preceded by an ethical review. In such, and similar, cases, the research ethics committee must provide an advisory opinion if the researcher or the authorised representative of the entity responsible for research requests it.

3.3 Risk analysis and impact assessment related to data protection

In connection with an ethical review, the research ethics committee completes a risk analysis regarding data protection and information security, and assesses whether a complete impact assessment needs to be carried out before the processing of personal data can begin. The data protection officer and the chief information security officer have the main responsibility for drafting and presenting the risk analysis to the research ethics committee.

If the personal data processing, especially in terms of use of new technology and the nature, scope and purpose of the processing, is likely to lead to high risk to the rights and freedoms of natural persons, the data controller must carry out a impact assessment in accordance with Article 35 of the General Data Protection Regulation.

The purpose of an impact assessment is to mitigate any negative effects of a research project. An impact assessment includes:

- identifying any risk with the personal data processing
- creating routines and measures in response to these risks
- showing that the requirements of the General Data Protection Regulation are met.

3.4 Matters handled by the research ethics committee

In conclusion, the research ethics committee at Karlstad University is tasked with the following duties:

1. Deciding whether research projects with Karlstad University as the entity responsible for research fall under the stipulations of the Ethical Review Act and submitting their assessment as well as an advisory opinion on the application to the responsible researcher and the authorised representative of the entity responsible for research. Should the research ethics committee decide that a project falls under the Ethical Review Act, an application shall be submitted before project commencement. Should the authorised representative disagree with the research ethics committee's assessment that a project falls under the Ethical Review Act, it is up to the vice-chancellor to decide whether an application for ethical review should be

submitted or not. The fact that the research ethics committee has made the assessment that a research project does not fall under the regulations of the Ethical Review Act does not prevent an application to the Ethical Review Authority. The authorised representative of the entity responsible for research is in consultation with the responsible researcher responsible for the final version of the application.

2. Research ethically reviewing research projects at Karlstad University that do not fall under the Ethical Review Act but where the responsible researcher or the authorised representative of the entity responsible for research still wants the research project to be ethically reviewed. In such cases, the research ethics committee shall provide an advisory opinion.
3. Conducting risk analyses, together with the data protection officer and chief information security officer, regarding the issue of data protection and assessing whether a complete impact assessment needs to be made in relation to personal data processing in the research projects reviewed by the committee. The assessment is submitted to the responsible researcher and to the authorised representative of the entity responsible for research, who then decide whether an impact assessment regarding data protection should be carried out.

When necessary, the committee handles matters in consultation with the involved researcher and the authorised representative of the entity responsible for research, whereby the committee can recommend that the structure of the research project be changed or that the application be supplemented before a decision is made.

4. The composition of the research ethics committee

The research ethics committee has the following composition and terms of office:

- Five members of the teaching staff and two supplementary members that are professors or hold posts requiring a doctorate (or equivalent). The faculty boards and faculty board for teacher education each nominates two or three candidates mainly working in the faculty's area of responsibility. Teaching staff members have to be at least employed at 50 %, either until further notice or on fixed-term contracts covering their terms in office. The vice-chancellor appoints members, with one appointed as chair and another as vice-chair. The term of office is three years.
- Two external members with experience of executive or investigative work that may involve research ethical decisions. The dean of each faculty and of teacher education shall each nominate an external member to the vice-chancellor, who then vets and appoints two external members. The term of office is three years.
- One doctoral student representative and one supplementary doctoral student representative are elected by the representative body for graduate students for a term of one year.
- Students are entitled to representation by one representative and one supplementary representative elected by the student representative body for a term of one year.
- The university's data protection officer and chief information security officer have the right to attend and speak at meetings.
- The ethical advisors of each faculty have the right to attend and speak at meetings.

5. Rules of procedure

5.1 Calling meetings

Meetings are called by the chair. The final agenda is set at the board meeting. Usually, the invitation, agenda and material pertaining to points are sent to members and those with the right to speak and attend at least six workdays before the meeting. The chair may call non-scheduled meetings.

Members unable to attend meetings have to inform the committee secretary. Members also have to inform the secretary of changes of address.

5.2 Proceedings

The research ethics committee makes decisions in relation to assessments and advisory opinions. A quorum is reached when more than half the members of the research ethics committee are present. The majority of those present should be teaching staff from Karlstad University, including the chair or vice-chair.

The committee's secretary and researchers whose projects are under review have the right to attend and to speak at meetings.

In addition, the chair or vice-chair may decide to give someone the right to attend and to speak for a specific meeting or in connection to a specific matter.

The chair appoints rapporteurs for specific matters from among the committee members.

The committee secretary keeps the minutes. At meetings, the committee appoints one of its members to check the minutes together with the chair.

Decisions are made by acclamation, unless voting is required. Voting shall be open and decisions are based on simple majority. The voting regulations are stipulated in Section 29 of the Administrative Procedures Act, APA. In the event of a tie, the chair has the deciding vote.

According to Section 30 of the APA, members involved in committee decisions have the right to make a reservation against decisions. This involves having a dissenting opinion noted in the minutes, so that the member is seen not to have participated in the decision. Rapporteurs and other officials who have not been involved in a decision, but who have been involved in the handling of a matter, also have the right to have dissenting opinions noted. Dissenting opinions have to be recorded before the decision is dispatched or announced in another way. If the decision is not to be announced, the notification of dissent has to be made at the latest when the minutes are adjusted. Dissenting opinions ought to be registered and noted already at the meeting where the decision in question is taken.

5.3 Urgent matters

If a matter is so urgent that the committee does not have time to meet for discussion, the matter may be handled by way of messages between the chair and as many members as needed for a quorum. However, all members must be given the opportunity to participate in the decision. If this is deemed inappropriate, the chair may take the decision alone on behalf of the research ethics committee. Matters decided in this matter have to be reported during the next committee meeting.