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EXECUTIVE OFFICE

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Dnr C2013/430

## Rules of procedure for the research ethics committee at Karlstad University

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### 1. Establishment

The research ethics committee at Karlstad University was established by decision of the university board on 12 June 2001. The need for a research ethics committee is based on the stipulations of the Act concerning the ethical review of research involving humans, as well as on those of the Higher Education Act, requiring higher education institutions to uphold academic credibility and good research practice (s.1, §3a).

### 2. Mandate

The Ethical Review Act (SFS 2003: 460) concerning research involving humans came into force on 1 January 2004. The Act stipulates that certain research projects involving humans may only be conducted after they have been approved by a regional ethical review board. As from 1 June 2008, the following applies:

According to the Act (§ 2), *research* is defined as scientifically experimental or theoretical work intended to result in new knowledge and development on a scientific basis, excluding work performed as part of first- or second-cycle higher education programmes. The *responsible research body* is the government authority, or physical or legal entity, under whose auspices the research is conducted.

The Act shall apply, according to § 3, to research that includes the handling of:

1. Sensitive personal data pursuant to § 13 of the Personal Data Act, or
2. Personal data regarding violations of the law, including crimes, rulings in criminal cases, penal law sanctions, or administrative deprivation of liberty, as defined in § 21 of the Personal Data Act.

*Sensitive personal data* is defined as personal data that reveal race or ethnic origin, political views, religious or philosophical persuasion, labour union membership, or information about health or sex life.

In addition to what follows from § 3, the law shall apply to research that

1. Involves a physical intervention on a person,

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2. Is performed according to a method that aims to affect someone physically or psychologically, or that includes an apparent risk of physical or psychological damage to the person,
3. Relates to studies on biological material taken from a living person and traceable to that person,
4. Involves a physical intervention on a deceased person, or
5. Relates to studies on biological material taken from a deceased person and traceable to that person.

An application to review research falling under the Ethical Review Act shall be submitted to one of six regional ethical review boards. On request, the regional review boards may also give advisory opinions on research and student projects that do not fall under the Act. When Karlstad University is the responsible research body, applications are reviewed by the regional review board in Uppsala.

The vice-chancellor has delegated the power to represent Karlstad University as responsible research body in applications for ethical review and requests for advisory opinions to the chair and vice-chair of the research ethics committee.

### **3. Research falling under the Ethical Review Act**

All research conducted at Karlstad University that may fall under the stipulations of the Ethical Review Act shall be reported to the research ethics committee before the commencement of a project. The committee then decides whether the proposed research is subject to review according to the Ethical Review Act. If the research is found to fall under the Ethical Review Act, the application shall be sent to the regional ethical review board. Should the research ethics committee find that the research is not subject to review according to the Ethical Review Act, it may give an advisory opinion on the project.

### **4. Research not falling under the Ethical Review Act, and student projects**

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.

Generally student projects performed as part of first- or second-cycle programmes are not subject to ethical review, if they do not form part of larger research projects. This does not mean, however, that good research practice should not be followed. However, projects done by students as part of first- or second-cycle programmes ought to be ethically sound. According to government bill 2007/08:44 ("Certain Ethical Reviewing Issues, etc."), the government is of the opinion that it is unreasonable to expect first- and second-cycle students to have attained the knowledge and insight needed to ensure that people participating in research are adequately protected. Students should therefore not be tasked with research involving people that risks harming participants physically or psychologically, or damaging their integrity. Nevertheless, the government works under the assumption that student projects done as part of first- or second-cycle higher education programmes are conducted under ethically sound conditions, and it is the responsibility of the educational institution to ensure that this is the case.

The research ethics committee reviews research projects and second-cycle student

projects that do not fall under the Ethical Review Act in cases where the responsible researcher or supervisor desires an ethical review. If the aim is to publish research results in an academic journal, the journal may require that an ethical review had been done prior to the research being conducted. In these and similar cases, the research ethics committee shall give an advisory opinion.

## **5. Matters handled by the research ethics committee**

In conclusion, the research ethics committee at Karlstad University has to:

1. Decide whether research projects with Karlstad University as responsible research body fall under the stipulations of the Ethical Review Act (an application shall be submitted before project commencement). Should the research ethics committee decide that a project falls under the Ethical Review Act, the application needs to be submitted to the regional ethical review board. Should the research ethics committee find that a project does not fall under the Ethical Review Act, the committee may give an advisory opinion.
2. Review the research ethics of research projects and second-cycle student projects that do not fall under the Ethical Review Act, if the responsible researcher or supervisor requests an ethical review (an application for review may be made to the committee). In these cases the research ethics committee shall give an advisory opinion.

When necessary, the committee handles matters in consultation with the involved researcher or supervisor. The committee may recommend changes to the project design or may request supplementary material before a decision is taken.

## **6. Composition**

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. Staff members have to be at least employed at 50%, either until further notice or on time-limited 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 is elected by the representative body for graduate students for a term of one year.
- Students are entitled to representation by a representative elected by the student representative body for a term of one year.
- The university's legal expert employed by the executive office has the right to attend and speak at meetings.

## **7. Rules of procedure**

### **7.1 Calling meetings**

Meetings are called by the chair. The final agenda is set at the 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.

### **7.2 Proceedings**

A quorum is reached when more than half the members of the research ethics committee are present. Most 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 included in the Administrative Procedure Act (§ 18). In the case of a tie, the chair has the deciding vote.

According to the Administrative Procedure Act (§ 19), members involved in committee decisions have the right to make a reservation against decisions by having a dissenting opinion noted. This means that the dissenting opinion is recorded in the minutes, and that the member concerned is not deemed responsible for the decision. Rapporteurs and other officials who have not been involved in the 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.

### **7.3 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. All members should be given the opportunity to participate in the decision. If this is deemed inappropriate, the chair may take the decision alone. Matters decided in this matter have to be reported during the next committee meeting.