

DECISION

Reg. no STYR 2023/896*Date* 27 April 2023

Vice-Chancellor

Amended Delegation and Clarification of Responsibility for Ethical Review of Research Involving Humans

Background

Pursuant to Chapter 1 Section 3a of the Higher Education Act (1992:1434), in the course of their operations, higher education institutions shall uphold academic credibility and good research practice. Academic credibility and good research practice includes issues of ethical review. The Swedish Act (2003:460) concerning the ethical review of research involving humans (hereafter referred to as the Ethical Review Act) contains provisions relating to the ethical review of research involving humans and biological material from humans, as well as provisions on consent to such research. The aim of the law is to protect individuals and for research to be conducted with respect for human dignity. According to the Ethical Review Act, an application for ethical review of research must be conducted by the entity responsible for research, also known as the principal investigator. Furthermore, according to the Ethical Review Act, the entity responsible for research has a special responsibility in matters of ethical review.

On 1 April 2004, a decision was made (Reg. no I A 35 1782/2004) regarding delegation to the heads of department of the University to sign applications for ethical review of research involving humans on behalf of the University. At the Faculty of Medicine, the head of department was allowed to delegate this responsibility to the heads of division. The responsibilities assigned to the entity responsible for

research under the Ethical Review Act were not laid out in that decision.

The Internal Audit Office's report "Investigation into the handling of ethical approval" (Reg no. STYR 2022/1445) states that the responsibility of heads of department during ethical reviews should be clarified.

Negotiations were conducted in compliance with Section 11 of the Swedish Employment (Co-Determination in the Workplace) Act on 18 April 2023.

Decision

The Vice-Chancellor delegates to the deans or their equivalents at Lund University, within their respective faculties or equivalents, the responsibility to complete tasks associated with the entity responsible for research in accordance with the Ethical Review Act and its related regulations.

The named tasks that the deans are to be responsible for are:

- that measures are taken to prevent research, which under the Ethical Review Act requires approval in an ethical review, from being carried out without an approval or in breach of a condition issued in connection with such an approval,
- that procedures are in place for information, follow-up and checks on issues of ethical review,
- that there is an internal organisation to monitor that applications for ethical review of research are submitted to the extent necessary and to verify compliance with an approval and conditions that may be associated with it,
- that those conducting third-cycle studies participate in compulsory education on research ethics and thereby acquire relevant knowledge of the ethical review process,

- that lecturers and research staff at the faculty/equivalent receive the necessary training on the Ethical Review Act and other regulations relevant to the issue,
- that those conducting third-cycle studies, lecturers and research staff receive information on where in the University they can seek advice and support on issues regarding good research practice and deviations from such practices, including issues of ethical review,
- upon request, to provide the Ethics Review Appeals Board with the necessary assistance to carry out its supervisory role under the Ethical Review Act, and
- compliance with orders and prohibitions issued by the Ethical Review Board of Appeal.

Furthermore, the Vice-Chancellor delegates to the deans or their equivalent to decide, within their respective faculties or equivalent, to

- apply for an ethical review of research and amendment of an approval in accordance with the Ethical Review Act and the Statute (2003:615) concerning the ethical review of research involving humans,
- request an advisory opinion pursuant to Sections 4a and 4b of the Statute concerning the ethical review of research involving humans,
- together with other entities responsible for research involved in the same research project, instruct one of them to apply for ethical review of the project on behalf of all of them and to apply for ethical review on behalf of the other entities responsible for research, and inform the others of the decision reached by the Swedish Ethical Review Authority, and
- appeal against the decision made by the Swedish Ethical Review Authority in cases concerning ethical review and represent the University in such appeal cases.

Deans or their equivalent may, within their respective areas of activity or equivalent, delegate the above tasks and decisions to heads of department or equivalent. These tasks and decisions may not be further delegated.

This decision enters into force on 27 April 2023 and replaces the previous decision “Delegation of decisions on signing applications for ethical review of research involving humans” (Reg. no I A 35 1782/2004).

The decision on this matter was taken by the undersigned pro vice-chancellor in the presence of University Director Susanne Kristensson, following a consultation with a representative of the Lund University Students’ Unions and a presentation by policy officer Jessica Salomonsson Enetoft at the Office of the Vice-Chancellor.

Lena Eskilsson

Copies sent to:

- All faculties
- The University Library
- Internal Audit Office
- Staff organisations
- FSI
- University Specialised Centres
- University Cultural and Public Centres
- MAX IV Laboratory
- Lund University Student Unions Association