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SFS number: 2007:1069

Ministry/authority: Ministry of education and cultural affairs

Heading: Statute containing instructions for regional ethical review boards (2007:1069)

Issued: 22 November 2007

Changes implemented: Up to and including SFS 2008:352

Tasks

General tasks

Section 1

According to the Act concerning the Ethical Review of Research Involving Humans (2003:460), there are to be regional ethical review boards whose task is to vet applications for ethical review.

The boards also have the task of vetting certain issues in accordance with the Biobanks in Medical Care Act (2002:297).

Advisory statements

Section 2 /Ceases to be applicable on 1 July 2008/

A regional ethical review board may issue advisory statements concerning research involving humans in those cases where the research is not encompassed by the act concerning the ethical review of research involving humans (2003:460).

Section 2 /Comes into force on 1 July 2008/

A regional ethical review board may issue advisory statements concerning research involving humans in accordance with the regulations in statute (2003:615). Statute (2008:352).

Section 3 /Ceases to be applicable on 1 July 2008. Superseded by statute (2008;352)/

A request for an advisory statement shall be submitted to the regional ethical review board to which the responsible research body belongs, in accordance with the statute concerning the ethical vetting of research involving humans (2003:615). A board that is qualified to do so may refer the request to another regional ethical review board.

General information about the organization

The regional ethical review boards

Section 4

The regional ethical review boards are:

The regional ethical review board in Gothenburg

The regional ethical review board in Linköping

The regional ethical review board in Lund

The regional ethical review board in Stockholm

The regional ethical review board in Umeå and

The regional ethical review board in Uppsala

The structure of the boards

Section 5

A regional ethical review board consists of two or more departments in accordance with the annex to this statute. There are regulations concerning the composition of the departments in section 25 of the act concerning the ethical review of research involving humans (2003:460).

There are to be personal substitutes for all members of the board.

The management of the authority

Section 6 /Ceases to apply on 1 July 2008/

A regional ethical review board is led by the chairmen of the board's departments (the board of management). The management of the board has the responsibility stipulated in section 3 and section 4 paragraphs 1-4 of the authorities act (2007:515). The management of the board is also to make decisions concerning the annual report and the budget, together with other decisions of major significance. However, decisions concerning matters stipulated in sections 1-3 of this statute are to be made by a department within the board.

The government appoints one of the department chairmen to be the chairman of the board of management.

If an issue that is to be decided by the board of management is so urgent that a decision cannot be delayed without significant inconvenience, it may be decided by the person responsible for the administrative management of the board.

Section 6 /Comes into force on 1 July 2008/

A regional ethical review board is led by the chairmen of the board's departments (the board management). The management of the board is to carry out the tasks stipulated in section 3 and section 4 paragraphs 1-4 of the authorities act (2007:515) are the responsibility of the management of the authority. The management of the board is also to make decisions concerning the annual report, interim report and the proposed budget, together with other decisions of major significance. However, decisions concerning matters stipulated in sections 1 and 2 of this statute are to be made by a department within the board.

The government appoints one of the department chairmen to be the chairman of the board of management.

If an issue that is to be decided by the board management is so urgent that the management of the board does not have time to meet in order to deal with the matter, it may be decided by the chairman of the board of management. Statute (2008:352).

Organization

Members with scientific qualifications

Section 7

Those universities listed in section 9 are to submit proposals to the government concerning members and substitutes with scientific qualifications for the regional ethical review board for which the university is to fulfil its obligations in accordance with the same regulation. Before proposals are submitted, each university is to confer with the seats of learning within each board's catchment area in accordance with annex 1 of the statute concerning the ethical vetting of research involving humans (2003:615).

/The heading comes into force on 1 July 2008/

Members who represent the interests of the public

Section 7a /comes into force on 1 July 2008/

Those county councils listed below are to submit proposals to the government concerning members and substitutes who represent the interests of the public in the respective regional ethical review boards. Before proposals are submitted, each county council is to confer with other county councils in those counties which are located within each respective board's catchment area in accordance with annex 1 of the statute concerning the ethical vetting of research involving humans (2003:615).

Board	County Council
Regional ethical review board in Gothenburg	Västra Götaland County Council
Regional ethical review board in Linköping	Östergötland County Council
Regional ethical review board in Lund	Scania County Council
Regional ethical review board in Stockholm	Stockholm County Council
Regional ethical review board in Umeå	Västerbotten County Council

Statute (2008:352)

Scientific Secretary

Section 8

The chairman is to appoint one member in each department to be the scientific secretary for a fixed period of time.

The scientific secretary is to prepare the cases prior to the meetings of the departments and is also to make use of their scientific expertise in order to assist the chairman and the rest of the department.

Departmental matters etc

Section 9

The following universities are to provide premises and be responsible for ensuring that departmental matters, the preparation of cases and related matters are carried out on behalf of the boards in question.

Board	University
Regional ethical review board in Gothenburg	Gothenburg University
Regional ethical review board in Linköping	Linköping University
Regional ethical review board in Lund	Lund University
Regional ethical review board in Stockholm	Karolinska Institutet
Regional ethical review board in Umeå	Umeå University
Regional ethical review board in Uppsala	Uppsala University

The management of cases

Circumstances in which rulings can be made

Section 10

In sections 25 and 27 of the act concerning the ethical review of research involving humans (2003:460), there are regulations about when the departments of the board are quorate.

The presentation of cases

Section 11

Cases are decided after they have been presented. Members of the board, their substitutes or such members of staff at a university who carry out tasks specified in section 9 may make presentations to the board.

Cases as defined in the third paragraph of section 6 may be decided without the presentation of reports. Decisions made in such cases are to be notified at the next meeting of the board of management

Ethical issues of a novel and fundamental character

Section 12

When ethical issues of a novel and fundamental character are being dealt with, all members should be present if possible.

Special expertise when certain cases are reviewed

Section 13

In cases concerning the vetting of research involving minors or persons referred to in section 20 of the act concerning the ethical review of research involving humans (2003:460), there is either to be special expertise within the department when the vetting is carried out, or a statement from an expert on the issue is to be obtained.

The special expertise referred to in the first paragraph must

1. include qualifications in the field of pediatrics, psychiatry or geriatrics in departments that vet applications concerning medical research and
2. include qualifications in the field of research that is relevant to the case in question in departments that vet applications concerning other research.

Referral of certain cases

Section 14

A special decision is to be made with respect to referrals in accordance with the third paragraph of section 27 of the act concerning the ethical review of research involving humans (2003:460). Decisions made with the support of such a referral are to be notified at the next meeting.

/Heading ceases to apply on 1 July 2008/

Remuneration

Section 15 /Ceases to apply on 1 July 2007 as a result of statute (2008:352)/

A regional ethical review board is entitled to remuneration for advisory statements of the type specified in section 2. The board is to apply those fees listed in annex 2 of the statute concerning the ethical review of research involving humans (2003:615). With respect to such fees, the regulations in sections 11-13 of the Ordinance Act (1992:191) are to be applied.

In sections 10 and 11 of the statute concerning the ethical review of research involving humans it states that the board is entitled to charge remuneration for the vetting of cases in accordance with the act concerning the ethical review of research involving humans (2003:460).

Exceptions to the Swedish Authorities Act

Section 16 The following regulations in the Swedish Authorities Act (2007:515) are not applicable to the regional ethical review boards:

Section 2 - concerning management of the authority,

Sections 4 and 5 - concerning the responsibility of the management,

Section 5 - concerning delegation,

Section 14 - concerning the composition of a board

Sections 15 and 16 - concerning quorum issues

Section 27 - concerning the right to represent the state in a court of law.

/The heading ceases to apply on 1 July 2008/

Appeals

Section 17 /Ceases to apply on 1 July 2007 as a result of ordinance (2008:352)/

An advisory statement issued in accordance with section 2 may not be appealed against.

Appeals against decisions concerning the application fee in cases involving an advisory statement issued in accordance with section 2 may be appealed against to the central ethical review board.

Annex

In this annex is stated which departments there are to be within the regional ethical review boards. By medical research is also meant pharmacy, clinical psychology, odontology and nursing science.

The regional ethical review board in Gothenburg:

- two departments for the vetting of medical research.

- one department for the vetting of other research

The regional ethical review board in Linköping:

- one department for the vetting of medical research.
- one department for the vetting of other research

The regional ethical review board in Lund :

- two departments for the vetting of medical research.
- one department for the vetting of other research

The regional ethical review board in Stockholm :

- four departments for the vetting of medical research.
- one department for the vetting of other research

The regional ethical review board in Umeå:

- one department for the vetting of medical research.
- one department for the vetting of other research

The regional ethical review board in Uppsala

- two departments for the vetting of medical research.
- one department for the vetting of other research