

2003_615

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SFS number 2003:615

Ministry/authority: Ministry of Education and Cultural Affairs

Heading: Statute (2003:615) concerning the ethical vetting of research involving humans

Issued: 9 October 2003

Introductory provisions

Section 1

In this statute there are regulations issued in connection with the act concerning the ethical review of research involving humans (2003:460). The expressions and appellations used in that legislation have the same meaning in this statute.

For ethical vetting in accordance with the law there are regional ethical review boards and the central ethical review board.

The application process

Section 2

When several responsible research bodies participate in the same project, only one of the responsible research bodies is to apply for ethical vetting. The application is to be submitted by the responsible research body that is mainly responsible for the research project in question.

Section 3

The catchment areas for the regional ethical review boards are listed in annex 1.

An application concerning research to be carried out by a state university or a state college is to be vetted by the regional ethical review board in the catchment area to which the responsible research body belongs. An application concerning research to be carried out by someone other than the responsible research body is to be vetted by the regional ethical review board within whose catchment area the responsible research body resides. If the responsible research body is resident in a country other than Sweden , or if the place of residence has not been established, the application is to be vetted by the board within whose catchment area the research will primarily be carried out.

An application concerning research that is to be carried out within the catchment areas of several regional ethical review boards is to be vetted by the board within whose catchment area the responsible research body that is mainly responsible for the research project resides. If a responsible research body is not resident within a catchment area, the application is to be vetted by the board within whose catchment area the research will primarily be carried out.

Section 4

The regional ethical review board that has vetted an original application is also to vet an application that concerns an alteration subsequent to an approval being granted. This applies even if the central review board was the one to vet the original application.

Advisory opinions

Section 4 a

A regional ethics review board may issue advisory opinions regarding research involving research on human subjects in cases of research to which the law on the ethical review of research involving humans (2003:460) does not apply. The board may also issue advisory opinions regarding work that is performed within the framework of higher education on the basic or advanced level. Ordinance (2008:351).

Section 4 b

A request for an advisory opinion must be submitted to the regional ethics review board with jurisdiction over the entity responsible for research according to this ordinance. The board with jurisdiction may also submit a request to a different regional ethics board. Ordinance (2008:351).

Research that includes the donation of ova

Section 4 c

If an ethics review board, within the context of its ethics review, decides to approve research that includes the donation of ova, the board is required to send a copy of the decision to the National Board of Health and Welfare. Ordinance (2008:351).

Processing times for applications

Clinical trials of medicinal products

Section 5

In those cases where the application concerns the clinical examination of people to establish the traits of a pharmaceutical product (clinical trials of medicinal products), the regional ethical review board is to make its decisions within the times given in the table below. The time is calculated from the moment that a complete application is received by the proper regional ethical review board.

The application concerns

Number of days

Pharmaceutical products for gene therapy
or somatic cell therapy or pharmaceutical products
that contain genetically modified organisms

90

- in those cases where there are regulations requiring the board to consult another authority 180

Alteration according to section 4	35
Xenogenic cell therapy	no time limit
Other clinical trials of medicinal products	60

Section 6

One extension to the period of time stipulated in section 5 may be granted if the regional ethical review board requests additional information from the applicant. In such cases the number of days specified in section 6 is extended by the number of days that elapse from the time the information is requested until the time it has been received.

Section 7

The central ethical review board is to make its decision within the number of days specified in section 5 in cases concerning clinical trials of medicinal products that have been referred to it by a regional ethical review board in accordance with section 29 of the act concerning the ethical review of research involving humans (2003:460). This time is calculated from the moment that a complete application has been received by the correct regional ethical review board.

The time needed by the central ethical review board may be extended in the manner described in section 6, unless such a procedure has already been invoked in the case by the board which referred the matter.

Other research

Section 8

When there is ethical vetting of other research than clinical trials of medicinal products, a regional ethical review board should make a decision within 60 days.

When changes are made in accordance with section 4, the board should make a decision within 35 days.

Referral of a case

Section 9

When a case is referred in accordance with section 29 of the act concerning the ethical review of research involving humans (2003:460), the regional ethical review board is to include a statement. The statement is to contain an account of the different opinions for and against an approval, that were expressed when the board met. In those cases where the board procured more information concerning the matter, this information is to be included in the statement.

Right to charge fees

Section 10

A regional ethics review board is entitled to charge fees for its consideration of cases according to the law on the ethical review of research involving humans (2003:460). The provisions on Sections 11 to 14 of the Fee Ordinance (1992:191) shall apply to these fees. A regional ethics board is entitled to charge fees for advisory opinions as described in Section 4. The provisions on Sections 11 to 13 of the Fee Ordinance (1992:191) shall apply to these fees. Ordinance (2008:351).

Section 11

Fees in accordance with section 10 are divided into categories depending on what type of application is to be vetted. The fees are set out in annex 2 of this statute.

Directives

Section 12

The Swedish Research Council may issue directives concerning exemptions to the requirement that approval should be granted during the course of the ethical vetting

of research or the treatment of personal data in accordance with the act concerning the ethical review of research involving humans (2003:460) if it is clear that the research does not involve any noteworthy risk to the health or safety of an individual or any intrusion with respect to an individual's personal integrity.

The Swedish Research Council may issue additional directives concerning the implementation not only of the act concerning the ethical review of research involving humans (2003:460), but also of this statute.

Appeals

Section 13

An advisory opinion pursuant to Section 4 a may not be appealed.

Decisions regarding application fees in a matter of an advisory opinion pursuant to Section 4 a may be appealed to the Central Ethics Review Board. Ordinance (2008:351).

Transitional provisions

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- This statute comes into force on 1 January 2004
- The regulations in sections 5-7 are not to be applied to applications submitted prior to 1 May 2004 .

Annex 1

This annex lists the geographical catchment areas for the regional ethical review boards. For universities and colleges with another principal there are regulations in section 3 paragraph 2.

The regional ethical review board in Gothenburg

Counties

Västra Götaland county

Universities and colleges

The University of Gothenburg
Borås University College
Skövde University College
Trollhättan/Uddevalla University College

The regional ethical review board in Linköping

Counties

Östergötland County
Jönköping County
Kalmar County
Kronoberg County
Gotland County
Universities and colleges
The University of Linköping
Växjö University College
Gotland University College
Kalmar University College

The regional ethical review board in Lund

Counties
Blekinge County
Scania County
Halland County
Universities and colleges
The University of Lund
Blekinge Institute of Technology
Halmstad University College
Kristianstad University College
Malmö University College

The regional ethical review board in Stockholm

Counties

Stockholm County
Södermanland County
Universities and colleges
Stockholm University
Karolinska Institut
The Royal Institute of Technology
The University College of Dance
The University College of Film, Radio, Television and Theatre
The University College of Physical Education and Sports
The University College of Arts, Crafts and Design
The Royal University College of Fine Arts
The Royal College of Music
The Stockholm Institute of Education
The University College of Opera
Södertörn University College
The National Academy of Mime and Acting

The regional ethical review board in Umeå

Counties

Västernorrland County
Jämtland County
Norrbotten County
Västerbotten County
Universities and colleges
Umeå University
Luleå University of Technology
Mid Sweden University College

The regional ethical review board in Uppsala

Counties

Uppsala County

Värmland County
 Örebro County
 Västmanland County
 Dalarna County
 Gävleborg County
 Universities and colleges
 Uppsala University
 Karlstad University
 Örebro University College
 Dalarna University College
 Gävle University College
 Mälardalen University College
 The Swedish University of Agricultural Sciences

Annex 2

In this annex is listed the fees for reviewing an application for ethical vetting.

Application which	Fee
concerns research in which only one responsible research body participates	5,000 Kronor
concerns research in which more than one responsible research body participates	16,000 Kronor
concerns research in which more than one responsible research body participates, but in which all the researchers or subjects of research according to section 4 of the ethical review act concerning research involving humans (2003:460) have an immediate link to only one of the responsible research bodies	5,000 kronor
only involves processing personal data	5,000 Kronor
concerns research involving clinical trials of medicinal products	16,000 Kronor
concerns changes in accordance with section 4	2,000 Kronor

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