The ethical Review Act

Please note that errors may occur in the wording of statutes. In most cases the annexes are included. However, given the technology currently in use, annexes consisting of images, maps and listings in many columns cannot be entered into the database. The text should therefore always be checked against the printed version.

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Heading: The Act concerning the Ethical Review of Research Involving Humans (2003:460)
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Section 1
This statute contains regulations concerning the ethical vetting of research concerning humans and biological material from humans. It also contains regulations concerning consent to such research.

The purpose of the act is to protect individuals and human dignity when research is conducted.

Definitions

Section 2
In this statute, the terms listed below shall be construed as follows:

Research: Scientifically experimental or theoretical work intended to result in new knowledge and development outcomes on a scientific basis, excluding work that is performed within the framework of higher education on the basic or advanced level.
Responsible research body: A government authority or a physical or legal entity under whose auspices the research is conducted
Research subject: A living person who is the subject of research.

Handling of personal data: Handling as defined in Section 3 of the Personal Data Act (1998:204). *Law (2008:192)*.

Applicability

Research to which the law applies

Section 3

This law shall apply to research that includes the handling of:

1. Sensitive personal data pursuant to Section 13 of the Personal Data Act (1998:204), or
2. Personal data regarding violations of law that include crimes, judgments in criminal cases, penal law sanctions, or administrative deprivation of liberty, as defined in Section 21 of the Personal Data Act. *Law (2008:192)*.

Section 4

In addition to that which follows from Section 3, the law shall apply to research that:

1. Subjects a research subject to a physical intervention,
2. Is performed according to a method with the purpose of affecting a research person physically or mentally, or includes an apparent risk of injuring the research subject either physically or mentally
3. Relates to studies of biological material that has been taken from a living person, and can be traced to that person
4. Constitutes a physical intervention on a deceased person, or
5. Relates to studies of biological material that has been taken from a deceased person for medical purposes, and can be traced to that person. *Law (2008:192)*

Geographical applicability

Section 5

This statute is applicable to research that is conducted in Sweden.

Approval

Section 6

Research that is referred to in sections 3-5 may only be conducted if it has been approved subsequent to an ethical vetting. An approval may be subject to conditions. An approval is to refer to a certain project or a part of a project or research defined in a similar fashion. The research may only involve dealing with personal data of the kind referred to in section 3 if the ethical vetting process has resulted in an approval.

An approval ceases to be valid if the research has not commenced within two years of the final decision gaining legal force.
An approval granted in accordance with this statute does not entail that the research may be carried out if it is in conflict with another statute.

The basis of ethical vetting

Section 7
The research may only be approved if it can be conducted with respect for human dignity.

Section 8
Human rights and fundamental liberties must always be taken into account during ethical vetting, while at the same time giving consideration to the fact that there can be a growth of knowledge as a result of research. The welfare of people should always be given precedence over the needs of society and science.

Section 9
Research may only be approved if the risks to which the subject of the research is exposed are counterbalanced by its scientific value.

Section 10
Research cannot be approved if the anticipated result can be achieved by some other means that entails fewer risks for the health, safety and personal integrity of the subject of the research.

An approval may only be given with respect to handling personal data in the manner intended in section 3 if this is necessary in order to carry out the research.

Section 11
The research may only be approved if it is to be conducted by or under the supervision of a researcher who has the necessary scientific competence.

Section 11a

Over and above what follows from this statute, during the ethical vetting of the clinical examination of people to determine the qualities of a pharmaceutical product (clinical trials of medicinal products), the provisions of 13 e and f of the Medicinal Products Act (1992:859) are to be applicable. Law (2004:198).

Disclosure of personal data

Section 12
Personal data may be disclosed for research purposes unless other conditions apply as a consequence of regulations concerning confidentiality and professional secrecy.

Information and consent

Section 13
With respect to research as described in section 4 paragraphs 1-3, the provisions in sections 16-22 concerning information and consent are to be applied. However, with respect to research as described in section 4 paragraph 3, special provisions in section 15 apply. If there are special regulations in any other statute concerning information and consent in the course of research as described in section 4 paragraphs 1-3, those regulations are to apply instead of the provisions in this statute.

With respect to research as described in section 4 paragraphs 4 and 5, the provisions concerning information and consent in the Transplant Act (1995:831) and the Autopsy Act (1995:832) respectively are to be applicable instead of this statute.

Especial prerequisites for approval

Section 14
Research as described in section 4 may only be approved if it can be assumed that the appropriate provisions concerning information and consent will be observed or if the prerequisites for research without consent in sections 20-22 are fulfilled.

If a person who is a subject of the research is in a situation of dependency with respect to the responsible research body, or a person conducting the research, or if the person who is a subject of the research can be presumed to have difficulties in asserting their rights; issues concerning information and consent should be given particular attention during the course of an ethical vetting.

Section 15
In cases where the research concern studies of biological materials that have previously been removed from a living person, if approval is granted it should be decided which requirements should apply concerning information and consent with respect to the use of the material.

Information

Section 16
The subject of the research is to be informed about

- the overall plan for the research
- the purpose of the research
- the methods that will be used
- the consequences and risks that the research might entail
- the identity of the responsible research body
- the fact that participation in the research is voluntary, and
- the right of the research subject to cease participating at any time

If the subject of the research is less than 18 years old, section 18 is applicable.

Consent

Section 17
The research may only be carried out if the subject of the research has consented to the research that concerns him or her. Consent is only valid if the subject of the research has previously been given information concerning the research in accordance with section 16. The consent is to be voluntary, explicit and specific to particular research. The consent is to be documented.

If the subject of the research is less than 18 years of age, section 18 is applicable.

Research subjects less than 18 years of age

Section 18
If the subject of the research is over 15 years of age, but has not attained the age of 18 and realises what the research entails for his or her part, he or she shall personally be given information about the research and shall consent to the research in the manner described in sections 16 and 17.

In other cases when the subject of the research has not attained the age of 18, the subject's guardians are to be informed and their consent is to be acquired in the manner described in sections 16 and 17. As far as possible, however, the research persons themselves are to be informed about the research. Even if the consent of guardians has been obtained, research

may not be carried out if a person who is the subject of the research is younger than 15 years of age, understands what it entails for his or her part and objects to it being carried out.

With regard to a married person who is the subject of research, what is laid down for a person who has attained the age of 18 is to be applicable in such cases.

Withdrawal of consent

Section 19
Consent may be revoked at any time and with immediate effect. Data that has been collected prior to this may be used in the research, however.

Research without consent

Section 20
Research may be carried out without consent if illness, mental disorder, weakened state of health or some other similar circumstance prevents the subject of the research from expressing an opinion. The research may only be carried out under the conditions specified in sections 21 and 22, however.

Section 21
Research with respect to a person who is a subject of research as described in section 20, may be carried out if

1. the research can be expected to result in knowledge that is not possible to obtain by means of research using informed consent, and
2. the research can be expected to be of direct benefit to the person who is the subject of the research.

Even if the condition in the paragraph 2 above are not fulfilled, the research may be carried out if

- the purpose is to contribute to a result that can be of benefit to the person who is the subject of the research or someone else who suffers from a similar illness or disorder, and
- the research entails an insignificant risk of injury and insignificant discomfort for the person who is the subject of the research.

Section 22
As far as is possible, a person who is a participant in the research as described in section 20 is to be personally informed about the research. There is to be consultation with the closest

relatives of the person who is participating in the research. There is also to be consultation with a custodian or other legal representative as defined in chapter 11 of the Parental Code, if the issue forms part of their mandate. The research may not be carried out if the subject of the research has indicated in any way that they do not wish to participate or if anyone they have consulted is opposed to the undertaking.

Application

Section 23
The application for ethical vetting of the research is to be made by the responsible research body.

Duties

Section 24
There are to be regional boards whose duty is to examine applications as stated in section 23 .

It is also the duty of the boards to examine certain questions in connection with the establishment of biobanks in accordance with the Biobanks in Medical Care Act (2002:297).

Departments

Section 25
A regional board is to be divided into two or more departments. A department is to vet cases within certain areas of research.
A department is to consist of a chairman and fifteen other members. Of the other members, ten are to have scientific qualifications and five are to represent the general public.
Substitutes are to be appointed for the members. The chairman and the chairman's substitute must be a judge or former judge.
All members and their substitutes are to be appointed by the government for a fixed period of time.

Competence to make decisions

Section 26
A department within a regional board has a quorum and is able to make a decision when the chairman and at least eight other members are present. Of the other members, at least five are to have scientific qualifications and at least two are to represent the general public.
Members with scientific qualifications should always be in a majority when a case is decided.

Section 27
A department is quorate if the chairman alone is present when

- preparatory measures are being taken
- typing errors and similar corrections are being made
- other decisions are being made that do not constitute the final decision concerning a case, and
- it is being decided whether to reject or write off a case

The chairman may hand over information as described in the first paragraph to someone presenting the case to the board.
In certain cases, after reviewing the facts of a case, a department can entrust the decision to the chairman or another member if the case is such that previous decisions that constitute precedents are deemed applicable or if they are of such a nature in other respects that the decision need not be made by the department.

Referral

Section 28
If the board finds that the research gives rise to ethical issues that are new and fundamental in character, the board should obtain an opinion from the Swedish Research Council and other authorities involved.

Transferral

Section 29
If the board is not in agreement about the outcome of an ethical vetting, the board is to transfer the case to the central board for it to decide the matter in accordance with section 31. However, this only applies if at least three of the members request that such a transfer should take place. However, if only nine members participate in the vetting, the transfer should take place if at least two members make such a request.
When the board refers a case, it is to include its own comments on the matter.

Decisions

Section 30
The decisions of a regional board are immediately applicable unless the board itself decides otherwise.

Central Board

Section 31
There is to be a central board for the ethical vetting of research.

The central board is to review both cases that a regional board has transferred to it in accordance with section 29 and appeals against the decisions of a regional board in accordance with section 36. It is also the task of the board to review certain issues in connection with the inauguration of biobanks in accordance with the Biobanks in Medical Care Act (2002:297).

The board also has a supervisory role in accordance with sections 34 and 35.

Composition

Section 32
The central board is to consist of the chairman and six other members. Of the other members, four are to have scientific qualifications and two are to represent the general public. Substitutes may be appointed for the members. Both the chairman and the chairman's substitute are to be judges or former judges.

All members and substitutes are appointed by the government for a fixed period of time.

Competence to make decisions

Section 33
The central board is quorate when the chairman and at least three members with scientific qualifications and at least one person representing the general public are present. Members with scientific qualifications are always to be in the majority when a matter is decided.
The board is quorate if the chairman alone is present when

- preparatory measures are being taken
- typing errors and similar corrections are being made
- other decisions are being made that do not constitute the final decision concerning a case, and
- it is being decided whether to reject or write off a case

The chairman may hand over information as described in the second paragraph to someone presenting the case to the board.

Supervision

Section 34

The central board is to supervise the observance of this legislation and the regulations that have been issued with the support of the act. However, this does not apply in the event that supervision is within the remit of another authority.

The central authority may decide if a supervision order is to apply immediately.

Section 35

The central board is entitled to request to be given on demand the information and documentation needed for the supervision in question and is also entitled to be given access to those premises that are being used for the purposes of research. The responsible research body is to give the board on demand any assistance needed in order for such supervision to be carried out.

The board may communicate the orders and prohibitions that are needed to ensure that this act and the regulations that have been issued with the support of the act are followed. The board may also issue orders when information or documents are not submitted or when access or assistance is denied. In addition to such an order or a prohibition, a fine may be levied. Such an order or prohibition may also be directed towards the state when it is the responsible research body.

If there are reasonable grounds to suspect that a crime of the kind referred to in section 38 has been committed, the board is obliged to report the matter to the prosecutor.

Appeals

Section 36

The decisions of a regional board in a matter concerning ethical vetting may be appealed against to the central board if the regional board has concluded the matter and the decision has gone against the responsible research body. Other decisions made by a regional board in matters concerning ethical vetting may not be appealed against.

Section 37

The decisions of the central board in matters concerning ethical vetting may not be appealed against.

Directives or prohibitions issued by the central board in accordance with section 35 may be appealed against to the general administrative court. Other decisions of the court concerning matters of supervision may not be appealed against.

A review dispensation is required when appeals are made to the administrative court of appeal.

Penalties

Section 38
Anyone who intentionally breaches the first paragraph of section 6 or a condition that has been stipulated with the support of the first paragraph of section 6 is to be sentenced to fines or a prison sentence lasting no more than six months. In trivial cases nobody will be deemed liable.
Nobody will be deemed liable in accordance with the first paragraph if the deed is subject to penalties in accordance with the regulations in any other statute.
Anyone who infringes a directive that is subject to the penalty of a fine in accordance with section 35 may not be deemed liable for an action that is subject to the directive.

Authorisation

Section 39
The government or the authority decided upon by the government may issue regulations concerning fees for ethical vetting in accordance with this law.

Section 40
The government or the authority decided upon by the government may issue regulations concerning exceptions to the requirement of approval subsequent to ethical vetting for research or processing of personal data in cases where it is obvious that the research does not entail any noteworthy risk to the health or safety of an individual or risk to the personal integrity of an individual.

Information about more detailed regulations

Section 41
The government issues more detailed regulations concerning the regional boards and the central board.
The government or the authority decided upon by the government issues more detailed regulations concerning ethical vetting.
Transitional regulations
2003:460
This law comes into force on 1 January 2004 . However, the law is not to be applied to research that has already commenced or research that has been subjected to ethical vetting by a state authority.