

Unofficial translation

© **Ministry of Social Affairs and Health**

No. 488/1999

Medical Research Act

Chapter 1

General provisions

Section 1

Scope of application

This Act applies to medical research carried out on persons, human embryos and human foetuses, unless otherwise provided by legislation.

Section 2 (23.4.2004/295)

Definitions

For the purposes of this Act:

- (1) *medical research* means research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of disease in general;
- (2) *embryo* means a living group of cells resulting from fertilisation not implanted in a woman's body;
- (3) *foetus* means a living embryo implanted in a woman's body;
- (4) *researcher* means a medical doctor or dentist with adequate professional and scientific qualifications who is in charge of carrying out a clinical trial at a research site; if a trial is carried out at a research site by a research group, *researcher* refers to the medical doctor or dentist acting as the leader of the group;
- (5) *commissioning party* means the person, company, institution or organisation that is in charge of starting, directing or financing a clinical trial; if an outside party takes part in carrying out the trial only by financing it, the researcher and financier may agree between themselves that the researcher is also the commissioning party; if the trial is not commissioned by an outside party the researcher is the commissioning party; and
- (6) *clinical trial on medicinal products* means intervention research on persons for the purpose of finding out effects of a medicinal product in a human being as well as its absorption, distribution, metabolism or excretion in the human body.

Section 3 (23.4.2004/295)

General conditions governing medical research

Medical research shall respect the inviolability of human dignity.

Before any research referred to in this Act is undertaken, the ethics committee shall have given a favourable opinion on the research plan. When conducting clinical trials on medicinal products the provisions of Chapter 2 a and of the Medicines Act (395/1987) shall be taken into account, in addition.

Where the commissioning party alters the research plan so that the alteration may affect the safety of the research subjects or the alteration has a bearing on the interpretation of the scientific documents used in support of the research or where the alteration is otherwise considerable, the party shall inform the ethics committee about it. The research may not be continued in accordance with the altered plan until the ethics committee has delivered a favourable opinion on it. If the committee's opinion is negative, the plan shall be adjusted in the way called for in the opinion before continuing the research or, alternatively, the research can be continued according to the original plan unless the safety of the research subjects requires that the research is suspended or terminated. In addition, the National Agency for Medicines shall be informed about any alteration to the research plan regarding a clinical trial on medicinal products as laid down in the Medicines Act.

Where the ethics committee delivers a negative opinion, the commissioning party may bring the matter before the committee for reconsideration. The ethics committee shall then seek the opinion of the relevant sub-committee of the National Advisory Board on Health Care Ethics.

Chapter 2

Medical research on persons

Section 4

Weighing up benefits and harmful effects

In medical research the interests and well-being of the research subject shall always be put before any benefits to science or society. Measures shall be taken to prevent any risks or harmful effects to the research subject, as far as possible.

Research subjects may be exposed only to measures where the expected health or scientific benefit is unequivocally greater than the potential risks or harm to the research subject.

Section 5

People in charge of research

Medical research may be undertaken only under the responsibility of a medical doctor or dentist with the adequate professional and scientific qualifications.

The person in charge of the research shall ensure that there are competent staff and suitable tools and equipment available for the research and that the research is otherwise conducted under safe conditions. The person in charge shall also ensure that the research is conducted in accordance with the provisions of this Act, the international obligations concerning the status of research subjects and the rules and guidelines that govern research.

The person in charge of the research shall suspend the research immediately where required for the safety of the research subject. If new knowledge related to the carrying out of the research or the medicinal product used in the research that has a bearing on the safety of the research subjects emerges in the course of the research, the person in charge of the research and the commissioning party shall immediately undertake precautionary measures to protect the research subjects. The commissioning party shall immediately inform the ethics committee of such new knowledge and of the measures undertaken based thereon. In addition, information and measures regarding clinical trials on medicinal products shall be immediately communicated to the National Agency for Medicines. (23.4.2004/295)

Section 6 (23.4.2004/295)

Consent of research subjects

Medical research on persons may not be conducted without the research subject's informed consent in writing. Exceptions to this may be made where consent cannot be obtained owing to the urgency of the matter and the patient's state of health and the measure is expected to be of immediate benefit to the patient's health. If the research subject is not able to write he or she can give the consent orally in the presence of at least one witness who is not dependent on the research. It is allowed to deviate from the requirement for written consent in research other than clinical trials on medicinal products also when giving personal data would be in contrary to the research subject's interests and the research will only involve minor stress to the research subject and is not harmful to the research subject's health. Oral consent may then be given without the presence of a witness, and the personal data of the research subject are not recorded in the research documents.

If a person taking part in a clinical trial on medicinal products is not able to give consent on taking part in the trial, the person may not, deviating from the provision in paragraph 1, be research subject unless the person's close relative or other person closely connected with the person or his/her legal representative, after having been informed about the nature, meaning, effects and risks of the clinical trial, gives consent to taking part in the trial. The consent must be in accordance with the research subject's supposed will.

Research subjects shall have their rights, the purpose and nature of the research and the procedures it involves properly explained to them. The potential risks and harm shall also be properly explained to them. This information shall be given so that research subjects are in a position to give their informed consent as regards issues connected with the research that have a bearing on their decision-making.

Research subjects shall be entitled to withdraw their consent at any point prior to the completion of the research. They shall be informed of this right before the start of the research. Withdrawal of consent and resulting withdrawal from the research shall not involve any negative consequences for the research subject.

Further provisions on the content of the document giving consent and on the information concerning oral consent to be recorded in the research documents are issued by Government Decree.

Section 7

Research involving persons not able to consent

People who, owing to a mental health disorder, retardation or other similar reason, do not have the capacity to give their consent to research may be research subjects only where it is not possible to obtain the same scientific results using other research subjects and where the risk of harming or distressing the research subject is only very slight.

It shall be further required that:

- (1) the research should be likely to be of direct benefit to the research subject's health;
or
- (2) the research should be likely to be of special benefit to the health of people in the same age group or with the same state of health.

Persons not able to consent as referred to above may be research subjects in the cases set out in paragraphs 1 and 2 above only where written consent for this has been given by their close relative or other person closely connected with the person or legal representative after being provided with the information referred to in section 6 (2). The consent must be in accordance with the research subject's supposed will. Consent may be withdrawn on the same terms as laid down in section 6 (4). (23.4.2004/295)

In addition, the research subjects shall be given, taking into account their capacity of understanding, information about the research as well as of its risks and benefits. Where a person not able to consent opposes a research measure, it may not be performed on the person. (23.4.2004/295)

Section 8

Research involving minors

Minors may be research subjects only where it is not possible to obtain the same scientific results using other research subjects and where the risk of harming or distressing the research subject is only very slight.

It shall be further required that:

- (1) the research should be likely to be of direct benefit to the research subject's health;
or
- (2) the research should be likely to be of special benefit to the health of people in the same age group or with the same state of health.

Where the minor has reached the age of 15 and, in view of his/her age and maturity and the type of illness and research, is capable of understanding the importance of the research procedure and the research is likely to be of direct benefit to the minor's health, it shall be sufficient for the minor to give his/her informed consent in writing. In such

cases the guardian shall be informed of this. In other cases minors may be research subjects only where written consent for this has been given by their guardian or legal representative after being provided with the information referred to in section 6 (2). The consent must be in accordance with the minor's supposed will. Consent may be withdrawn on the same terms as set out in section 6 (4). (23.4.2004/295)

Minors shall receive within their capacity of understanding information about the themes of the research as well as about its risks and benefits from staff with experience from working with minors. Where minors who, in accordance with paragraph 3, are not entitled to be research subjects without the consent of their guardian or other legal representative, are capable of understanding the importance of the research procedure to be carried out on them, their written consent shall also be required. (23.4.2004/295)

Where a minor opposes a research or a research measure, the minor's opinion shall be complied with, taking account of his/her age and maturity. (23.4.2004/295)

Section 9

Research involving pregnant women and nursing mothers

Pregnant women and nursing mothers may be research subjects only where it is not possible to obtain the same scientific results using other research subjects and:

- (1) the research is likely to be of direct benefit to the health of the woman or the unborn child; or
- (2) the research is likely to be of benefit to the health of people related to the woman, or to pregnant women or nursing mothers, or to foetuses, newborn children or unweaned children.

Section 10

Research involving prisoners

Prisoners may be research subjects only where the research is likely to be of direct benefit to their own health or the health of people related to them or the health of other prisoners.

Chapter 2 a (23.4.2004/295)

Clinical trials on medicinal products

Section 10 a (23.4.2004/295)

Good clinical research practice

All clinical trials on medicinal products shall be planned, conducted and reported on observing the principles of good clinical research practice.

Section 10 b (23.4.2004/295)

Insurance or other guarantee

The party commissioning a clinical trial on medicinal products shall see to it that there is an insurance policy or other appropriate guarantee to cover the liability of the party and the researcher.

Section 10 c (23.4.2004/295)

Start of research

A clinical trial on medicinal products may be started only after the ethics committee has delivered an opinion in favour of it, and on the condition that the National Agency for Medicines has granted it the licence required in the Medicines Act or it has not informed of any obstacle to starting the research as laid down in the Medicines Act.

Section 10 d (23.4.2004/295)

Opinion of the ethics committee

The provisions of sections 3 and 17 shall apply to the opinions of the ethics committee. In addition, an opinion on a clinical trial on medicinal products shall take into account in particular the following circumstances:

- 1) appropriateness of the trial and its planning;
- 2) appropriateness of the assessment of its benefit and risks and justifiability of any conclusions regarding them;
- 3) the research plan;
- 4) suitability of the researcher and staff;
- 5) the researcher's information package containing clinical and other information on the medicinal product or products used in the trial that is of significance when testing those medicinal products on people;
- 6) quality of the premises and equipment to be used in the trial;
- 7) sufficiency and coverage of the written information given to obtain the informed written consent and the procedure for obtaining the consent, and grounds for trials to be carried out on persons not able to give their consent;
- 8) the grounds on which damages possibly caused by the trial are compensated and insurance policies and other arrangements for covering a compensation payable on account of damages or death;
- 9) amount of the fee or remuneration to be paid to researchers and research subjects or the criteria for determining it and procedures possibly related to the matter, as well as the main content of the agreement to be concluded between the commissioning party and the research site; and
- 10) detailed procedures relating to choosing the research subjects.

The ethics committee shall give its opinion to the body asking it within 60 days of having received an appropriate request for opinion as well as communicate it to the National

Agency for Medicines for information. If the trial concerns medicinal products meant for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms, the opinion must be delivered within 90 days. The committee can however extend this time limit by up to 90 days, if the giving of the opinion requires extensive further investigations. The ethics committee may ask once additional information from the party asking for opinion. There is no defined period for giving an opinion on xenogenic cell therapy.

The ethics committee shall deliver its opinion on an alteration to the research plan within 35 days of having received the notification of alteration.

The period of time during which further information is requested or delivered shall not count for the purposes of calculating the time limits referred to in paragraphs 2 and 3.

Section 10 e (23.4.2004/295)

Notification of adverse events

The researcher shall immediately notify the commissioning party of any serious adverse events, except for those adverse events that it is not necessary to notify according to the research plan or the researcher's information package. After the notification a written detailed report shall be given on the adverse event. In the notification and report the research subjects are identified by code numbers.

The commissioning party shall be notified within the defined periods laid down in the research plan of any adverse events and deviating laboratory results that are defined in the research plan to be significant from the point of view of safety evaluation.

The researcher shall communicate to the commissioning party and the ethics committee any information requested by them about deaths of research subjects.

Section 10 f (23.4.2004/295)

Notification of serious adverse effects

The commissioning party shall notify the National Agency for Medicines, the relevant ethics committee and the competent authorities of the Member States of the European Union which the matter concerns of any fatal or life threatening unexpected adverse effects as soon as possible, at the latest in seven days from the day on which the commissioning party received information on such an adverse effect. Significant additional information on the matter shall be notified within eight days from the day on which the first notification of the adverse effect was made.

The commissioning party shall notify any other suspicions of serious adverse effects than those referred to in paragraph 1 to the National Agency for Medicines and the ethics committee, as well as to the competent authorities of the Member States of the European Union which the matter concerns as soon as possible and at the latest in 15 days from the day when the commissioning party for the first time received information on them.

The commissioning party shall also notify other researchers of the circumstances referred to in paragraphs 1 and 2.

Section 10 g (23.4.2004/295)

List of adverse events and effects

The commissioning party shall draw up separately detailed lists of all the notifications made by the researcher or researchers to it on the basis of sections 10 e and 10 f. The information on a list of adverse events shall be communicated, at request, to those Member States of the European Union in whose territory the trial is being conducted.

The list of suspected serious adverse effects shall be forwarded once a year all through the period a clinical trial goes on to those Member States of the European Union in whose territory the trial is being conducted, as well as to the relevant ethics committee. A report on the safety of the research subjects shall be furnished in addition.

Section 10 h (23.4.2004/295)

Notification of termination of research

The commissioning party or the researcher shall within 90 days from the termination of a clinical trial on medicinal products notify the National Agency for Medicines and the ethics committee that the research has been terminated. If the research has been terminated before planned, the notification shall be made within 15 days from the termination. The reasons for the premature termination must be specified in the notification.

A report on the outcome of a clinical trial on medicinal products shall be submitted to the National Agency on Medicines and the ethics committee within one year of completion of the trial.

Section 10 i (23.4.2004/295)

Guidelines and regulations by the National Agency for Medicines

The National Agency for Medicines issues necessary guidelines and regulations on the good clinical practice referred to in section 10 a, on the content, drawing up, verification and presentation of the notifications referred to in sections 10 e - 10 h, and on the procedures for analysis of unexpected and serious adverse effects. Furthermore, the National Agency for Medicines may issue guidelines and regulations for observance of international scientific guidelines and practices.

Chapter 3

Research involving embryos and foetuses

Section 11

Conditions governing research involving embryos

Research on embryos outside a woman's body may be carried out only by agencies that have been granted the appropriate licence by the National Authority for Medicolegal Affairs. The conditions for the granting of the licence shall be laid down by Decree.

Medical research on embryos is permitted only if no more than 14 days have passed from their formation. The time during which an embryo is kept frozen shall not count for the purposes of calculating this time limit.

Section 12

Consent for research on embryos

Research on embryos outside a woman's body may not be undertaken without the written consent of the persons who donated the gametes. The donors shall be provided with the information referred to in section 6 (2). Consent may be withdrawn on the same terms as set out in section 6 (3).

Embryos produced from donated gametes may not be used for research once the withdrawal of consent has been received.

Research on an embryo inside a woman's body may not be undertaken without her written consent.

Section 13

Restrictions on research on embryos

The production of embryos exclusively for the purpose of research shall be forbidden.

Embryos that have been used for research may not be implanted in a human body or be kept alive for longer than 14 days from their formation, not including any time during which they have been kept frozen.

Research may use embryos that have been stored for up to 15 years, after which the embryos must be destroyed.

Section 14

Consent for foetal research

Research on a foetus may not be undertaken without the written consent of the pregnant woman.

The conditions governing the consent procedure and the research subject are as laid down in sections 6-10, as applicable.

Section 15

Prohibited research

Research on embryos and gametes for the purpose of developing procedures for modifying hereditary properties shall be prohibited, unless the research is for the purpose of curing or preventing a serious hereditary disease.

Chapter 4

Ethics committees

Section 16

Establishment

Each hospital district shall have at least one ethics committee. There may also be joint ethics committees.

Section 17 (23.4.2004/295)

Duties

Ethics committees are responsible for prior evaluation of research projects and delivering opinions on them. Projects shall be considered by the ethics committee of the region where the person in charge of the research is based or of the region where the research is to be principally conducted. In their opinions ethics committees shall give their reasoned view on whether or not the research is ethically acceptable.

An opinion on the clinical trials on medicinal products that are carried out as international multicentre research shall be delivered by the relevant sub-committee of the National Advisory Board on Health Care Ethics, unless the task has been delegated to a regional ethics committee.

For the purposes of delivering the opinion, ethics committees shall examine whether the research plan has taken account of the provisions of this Act, the provisions on data protection, the international obligations concerning the status of research subjects and the regulations and guidelines that govern medical research.

Ethics committees shall also monitor and guide the handling of issues in research ethics in their region.

Provisions on fees to be charged in respect of opinions shall be laid down by decree of the Ministry of Social Affairs and Health.

Section 18

Composition

Ethics committees shall have a chairperson and at least six other members, one of whom shall be the deputy chairperson. There shall be an appropriate number of substitutes for the members.

Apart from medicine, ethics committees shall also contain representatives from other areas. At least two members shall be laypersons.

Decisions on opinions shall be taken with the participation of the chairperson or the deputy chairperson and at least half the other members or at least four of the other members, whichever is the greater. When decisions on opinions are taken, the members shall include at least one layperson and two people from outside the research unit.

When dealing with a clinical trial on medicinal products to be conducted on minors ethics committees shall have as a member or consult a specialist in paediatrics. When dealing with a clinical trial on medicinal products to be conducted on an adult not able to give consent ethics committees shall have as a member or consult a specialist in the illness and patient group concerned. Instead of consulting, ethics committees may request a written opinion from a specialist representing the area in question. (23.4.2004/295)

Section 19 (23.4.2004/295)

Disqualification of a member

Disqualification of a member of an ethics committee shall be governed by the provisions on the disqualification in regard to civil servants laid down in the Administrative Procedure Act (434/2003).

Section 20

Duty of notification

Hospital districts shall notify the relevant State Provincial Office of the setting up or dissolution of ethics committees, their composition and any changes to them and contact details for them. On the basis of these notifications the State Provincial Offices shall keep a register of ethics committees in their area.

Chapter 5

Miscellaneous provisions

Section 21

Remuneration of research subjects

No payment shall be made for participating in the research to the research subjects, their guardians, close relatives, any other persons closely connected with them, or to their legal representative. However, an appropriate remuneration may be paid in respect of expenses or loss of earnings or for any other inconvenience suffered as a result of the research.

Grounds on which payment may be made are laid down by the relevant ministry.

Section 22

Supervision and withdrawal of licence

The National Authority for Medicolegal Affairs can revoke the licence referred to in section 11 if the research organisation fails to observe the provisions or regulations which apply. In the event of defects or irregularities, the National Authority for Medicolegal Affairs may decide that the research shall be suspended until the defects or irregularities have been rectified or may withdraw the licence previously granted.

The decision to revoke a licence shall be complied with even if an appeal has been lodged against the decision.

For the purposes of overseeing this Act and the provisions and regulations laid down in virtue of it, the National Authority for Medicolegal Affairs shall have the right to inspect the premises and activities of establishments which have been granted a licence as referred to in section 11 and to inspect any documents required for the exercise of this supervision.

Section 23

Official accountability and duty of confidentiality

Those responsible for research and the members of the ethics committees shall be governed by the principle of official accountability.

Confidential information obtained in the course of activities in relation with this Act and relating to research plans, personal information concerning other persons, their state of health, personal circumstances or financial status or business or trade secrets, must not be disclosed to a third party.

Section 24 (23.4.2004/295)

Further provisions

Further provisions on the implementation of this Act are laid down as necessary by Government decree.

If necessary, further provisions concerning the drawing up and keeping of research documents, the form for the request for opinion to be made to the ethics committee and the documents to be attached to it, delegating requests for opinion to regional ethics committees and on the information to be given to research subjects are laid down by decree of the Ministry of Social Affairs and Health.

Chapter 6

Penal provisions

Section 25

Unlawful research on embryos and gametes

Any person who undertakes research on embryos without the licence referred to in section 11 or in contravention of the restrictions laid down in sections 11 and 13, or who in contravention of the prohibition in section 15 conducts research on embryos or gametes, shall be fined or imprisoned for a period not exceeding a year for *unlawful research on embryos and gametes*.

Section 26

Unlawful intervention on the genome

Any person who undertakes research with the aim of :

- (1) cloning human beings;
- (2) creating a human being by combining embryos;
- (3) creating a human being by combining human gametes and genes from animals,

shall be fined or imprisoned for a period not exceeding two years for *unlawful intervention on the genome*.

Section 27 (23.4.2004/295)

Breach of the Medical Research Act

Any person who conducts medical research

- (1) without the consent referred to in sections 6-8, 12 or 14,
- (2) without the favourable opinion of the ethics committee in violation of section 3,
- (3) in violation of the conditions laid down in sections 5-10,
- (4) without observing the provisions of sections 10 b, 10 c and 10 e – 10 g in the research,

shall be fined for *breach of the Medical Research Act*.

Section 28

Breach of confidentiality

Upon conviction of any breach of the duty of confidentiality laid down in section 23 a penalty may be imposed under Chapter 38, section 1 or 2, of the Penal Code (39/1889), unless the action is punishable under Chapter 40, section 5, or a more severe penalty is laid down by other legislation.

Chapter 7

Entry into force and transitional provisions

Section 29

Entry into force

This Act enters into force on 1 November 1999.

Measures necessary for the implementation of the Act may be undertaken before its entry into force.

Section 30

Transitional provision

The provisions of this Act shall, where applicable, apply to research projects already under way when the Act enters into force. The provisions of the Act shall also apply to the specimens taken of people, human gametes and human embryos that are being stored when the Act enters into force.

Every hospital district in which research covered by this Act is being conducted shall submit a notification in accordance with section 20 within six months of entry into force of this Act.

Any institution where research of the type referred to in section 11 is being conducted when the Act enters into force shall apply to the National Authority for Medicolegal Affairs for a licence for its activities within six months of entry into force of this Act. The work may continue until the application has been processed. The National Authority for Medicolegal Affairs shall decide on a licence application within one year of the date on which the application was received.

Entry into force of amended statute:

23.4.2004/295:

This Act enters into force on 1 May 2004.