No. 986/1999

Medical Research Decree

Issued in Helsinki on 29 October 1999

Section 1
Submitting a research plan to the ethics committee

The research plan shall be submitted for the opinion of the ethics committee referred to in section 3 of the Medical Research Act (488/1999) to the ethics committee of the hospital district in whose area the person responsible for the research operates and in whose area the major part of the research is to be carried out. The ethics committee of some other public or private health care unit, institution, community or company cannot deliver such an opinion by an ethics committee as is referred to in the Act.

Section 2 (29.4.2004/313)
Deliverer of opinion in certain cases

Opinions referred to in section 3 (4) and section 17 (2) of the Medical Research Act are given by the Sub-Committee on Medical Research Ethics of the National Advisory Board on Health Care Ethics.

Section 3 (29.4.2004/313)
Content of the document where consent is given

The document of consent referred to in section 6 of the Medical Research Act shall include the following:

1) the research subject's name, personal identity code or date of birth, and address;
2) that the information referred to in section 6 (2) has been given to the research subject and data about the giver of the information;
3) which other sources information concerning the research subject will be gathered from;
4) whom the information gathered in the context of the research can be delivered to and how the confidentiality of the information is protected;
5) the research subject's voluntary consent; and
6) a mention of the right to withdraw the consent without it affecting the research subject's right to receive the care he or she is in need of.

The document of consent shall be dated, and it shall be signed by both the person who gives and the person who receives the consent. If the research subject has given the consent orally because he or she is not able to write, a witness not dependent on the research shall sign the document of consent. The witness' signature shall be appended with clarification of the name and contact information. In case the ethics committee has approved the carrying out of the research so that no written consent is

required on the basis of the 4th sentence in section 6 (1) of the Medical Research Act, the information referred to in paragraph 1 (1) is not recorded in the document of consent and the research subject need not sign the document if he or she forbids recording the information and refuses to sign the document. Such information on the research subject that is necessary for the research shall however be recorded in the document of consent. A copy of the document shall be given to the giver of the consent.

The Ministry of Social Affairs and Health will issue, if necessary, separate instructions concerning the information that shall be given to the research subject and appended to the document of consent.

Section 4

Conditions governing institutions that are carrying out research involving embryos

The condition for granting a licence referred to in section 11 of the Medical Research Act is that the institution has appropriate research facilities and equipment, as well as the staff needed for the activity.

When an institution applies for a licence referred to in paragraph 1 from the National Authority for Medicolegal Affairs, the institution shall append to the application information about:

1) the content and extent of the research;
2) the facilities used for the research;
3) devices and equipment used for the research;
4) staff engaged in the research;
5) quality assurance of the research; and
6) the ethics committee assessing the research.

If the applicant is an institution referred to in the Private Health Care Act (152/1990), to the application shall be attached, in addition, information about the licence granted to the institution.

The National Authority for Medicolegal Affairs will issue, if necessary, further instructions for the application procedure.

Section 5

Persons outside the research unit

By a person outside the research unit referred to in section 18 of the Medical Research Act is meant a person who is not employed by or otherwise dependent on the unit, clinic or department of the hospital or institution in which the research is chiefly carried out.

Section 6

Entry into force

This Decree enters into force on 1 November 1999.