

ETHICS COMMITTEES IN FINLAND

Biomedicine and Research

Finland has four major national ethics committees concerning biomedicine and research. The Board for Gene Technology, the Advisory Board for Biotechnology, and the Advisory Board on Health Care Ethics function under the Ministry of Social Affairs and Health whereas the National Research Ethics Council is subordinate to the Ministry of Education. The functions and the scope of activity of these committees is mainly based on governmental legislation. In addition to the national committees, there is a wide network of regional and institutional ethics committees, especially in the field of biomedical research and animal research.

NATIONAL ETHICS COMMITTEES

Board for Gene Technology

The Board for Gene Technology is constituted by the Gene Technology Decree (No. 821/1995). In addition to being a national authority, the Board functions as a competent authority towards the European Community, processing notifications concerning the use and release of genetically modified organisms as defined in Directives 90/219/EEC and 90/220/EEC and responding to them within its authority to make legally binding decisions. The Board aims to ensure safe and ethically acceptable use of gene technology and to prevent any harm gene technology may inflict to human health, animals, property or the environment. Its priorities include processing notifications, issuing instructions and regulations, acting as a registration authority, preparing opinions and recommendations, monitoring, restricting or prohibiting the use of potentially dangerous organisms and imposing administrative sanctions to ensure its provisions are complied with. The Board consists of a chairman, a vice chairman and five members who represent the Ministry of Trade and Industry, the Ministry of Agriculture and Forestry, the Ministry of Social Affairs and Health and the Ministry of the Environment. Ethical expertise shall also be represented on the Board.

The Board is appointed for five years by the Council of State. The present Board is chaired by Professor Pirjo H. Mäkelä, the vice chairman being Professor Dennis Bamford. The Board has three secretaries, Secretary General Irma Salovuori, Secretary Hannele Leiwo and Senior Officer Kai Korpela.

Contact information: Secretary General Irma Salovuori, Ministry of Social Affairs and Health, P.O. Box 267, FIN-00171 Helsinki, Finland. Fax. +358-9-160 3876, e-mail: irma.salovuori@stm.vn.fi.

National Advisory Board for Biotechnology

The Gene Technology Decree (No. 821/1995) states the functions of the Advisory Board for Biotechnology as follows:

1. to promote the cooperation between authorities, research in the field and establishments concerning matters related to biotechnology and in particular to gene technology,
2. to monitor and promote international cooperation on biotechnology,
3. to monitor the progress in biotechnology and the research on biotechnology as well as health and environmental effects of biotechnology,
4. to develop and promote the research, information and education in biotechnology,

5. to promote the consideration of ethical issues in biotechnology, and
6. to see to other assignments related to biotechnology issued by the ministries.

The Advisory Board does not give legally binding decisions. The opinions of the Advisory Board may be issued by request or by its own initiative. The Board has selected monitoring the development and the public safety of gene technology and informing the general public as its main duties. It publishes a journal and organises debates and seminars related to the field. The Advisory Board consists of a chairman, a vice chairman and 18 members who represent researchers, relevant authorities and non-governmental organisations. The Board has been divided into five working groups which each cover a specific area: EC legislation, national legislative work, environmental issues, bioethics, and information services.

The Advisory Board is appointed for three years by the Council of State. The present Board (1.1.1999 - 31.12.2001) is chaired by Professor Matti Sarvas (National Public Health Institute) and the vice chairman is Director Marja Sorsa (Ministry of Education). The Board has two secretaries, Ms. Helena von Troil and Dr. Susanne Somersalo.

Contact information: Secretary Helena von Troil, Rikhard Nymanintie 9 B, FIN-00370 Helsinki. Tel. +358-40-544 9981, fax +358-9-556 383, e-mail: helena.troil@clarinet.fi.

National Advisory Board on Health Care Ethics (ETENE)

The Advisory Board on Health Care Ethics was founded by an amendment to the Parliamentary Act on the Status and Rights of Patients (No. 333/1998) as an expert committee concerning ethical issues related to health care and patients' status on a principle level and issuing recommendations. Its purpose and functions are, however, stated more specifically in the Decree on the Advisory Board on Health Care Ethics (No. 494/1998) as:

1. to take initiative and to submit opinions and recommendations on ethical questions arising in health care, including nursing ethics, as well as to initiate societal discussion on health care issues,
2. to give expert assistance in developing health care and the relevant legislation,
3. to collect and to distribute information on ethical health care issues and international discussions,
4. to follow the development in health care and related technologies and on their connections with ethical issues,
5. to see to other assignments issued by the Ministry of Social Affairs and Health.

The Advisory Board does not issue legally binding decisions. The opinions of the Advisory Board may be issued by request or by its own initiative. The Board consists of a chairman, vice chairman and 18 members who represent patients, providers of health care services, health care professionals, jurisprudence, health sciences and ethics. The Advisory Board also includes four Members of Parliament who shall be conversant with ethical issues related to health care. The Board has the opportunity to appoint sub-committees to assist in its assignments.

The Decree on the Advisory Board on Health Care Ethics includes provisions concerning the **Sub-Committee on Medical Research Ethics**, which states the functions of the Sub-Committee as following:

1. to support the regional ethics committees in ethical principle issues concerning medicine and other research of health care and in organising training in these fields,
2. to submit national opinions on international multicentre trials after hearing regional ethics committees related to the matter, unless the National Sub-Committee has not delegated this assignment to one of the regional ethics committees.

The Advisory Board on Health Care Ethics is appointed for four years by the Council of State. The present Board (1.10.1998 - 1.10.2002) is chaired by Docent Martti Lindqvist, the vice chairman being Archiatre Risto Pelkonen. The Secretary General of the Board is Dr. Ritva Halila.

Contact information: Secretary General Ritva Halila, Ministry of Social Affairs and Health, P.O.Box 267, FIN-00171 Helsinki, Finland. Tel. +358-9-160 3834, fax. 160 4312, e-mail: ritva.halila@stm.vn.fi.

The National Research Ethics Council of Finland

In the Decree on the National Research Ethics Council of Finland (1347/1991) the Council was assigned the following tasks:

1. to make proposals and to issue statements to governmental authorities on legislative and other matters concerning research ethics,
2. to contribute, in its expert capacity, to resolving issues of research ethics,
3. to take initiative in promoting research ethics and discussion on research ethics,
4. to follow international developments in the field and to take an active part in international co-operation,
5. to raise awareness of research ethics in society at large.

The Council has issued guidelines for the prevention, handling and investigation of misconduct and fraud in scientific research in pursuit of fulfilling its duties. The first set was issued in 1994 and in 1998 the revised version of the guidelines was adopted. The Council organises seminars and has been actively involved in academic discussion in the field. One of its main duties, however, is to process claims of fraud and scientific misconduct presented to the Council after they have been processed at the research institution related to the matter. The role of the Council is advisory and it does not issue legally binding decisions. The opinions of the Council may be issued by request or by its own initiative.

The National Research Ethics Council of Finland is appointed for three years by the Council of State. The present Council (1.2.1998 - 31.1.2001) is chaired by Chancellor Keijo Paunio (University of Turku) and the vice chairman is Professor Matti Sarvas (National Institute of Public Health). The Council has two secretaries, Secretary General Veikko Launis and Secretary Salla Lötjönen.

Contact information: Secretary General Veikko Launis, Department of Philosophy, FIN-20014 University of Turku, Finland. Tel. +358-2-333 6338, fax. +358-2-333 6270, email: veikko.launis@utu.fi.

REGIONAL AND INSTITUTIONAL ETHICS COMMITTEES

The legislation on medical research on humans imposes restrictions on medical research requiring an ethical preview of research protocols concerning human subjects (Medical Research Act (No.

488/1999), entry into force 1 November 1999). Animal research is governed by the Decree on Animal Experimentation (No. 1076/1985).

Ethics committees on research on humans

According to Section 17 of the Medical Research Act the functions of research ethics committees include prior evaluation of research projects based on conformity to the provisions of the Medical Research Act, data protection legislation, the international obligations covering the status of research subjects and the rules and guidelines that govern medical research. The Act requires every health care district to have an ethics committee, although the districts may also combine their efforts by forming one joint ethics committee. Ethics committees shall also contain representatives from other fields than medicine, and at least two members shall be laypersons. Currently there are many local ethics committees in hospitals, research institutes, and universities etc.

Research ethics committees do not make final decisions on the conduct of research but they issue an opinion on its approval. However, without the approval of the committee, the research cannot be conducted. If the ethics committee issues a negative opinion, the researchers may present the matter to the committee for reconsideration. The ethics committee shall then ask for the opinion of the National Advisory Board on Health Care Ethics and its Sub-Committee on Medical Research Ethics.

More information on the research ethics committees in Finland is available from the Advisory Board on Health Care Ethics.

Contact information: Secretary General Ritva Halila, Ministry of Social Affairs and Health, P.O.Box 267, FIN-00171 Helsinki, Finland. Tel. +358-9-160 3834, fax 160 4312, e-mail: ritva.halila@stm.vn.fi.

Research ethics committees on animal experiments

According to Section 11 of the Decree on Animal Experimentation, every institution conducting experiments on animals shall have a committee on animal experimentation although the institution may also form a committee together with another institution. The committee shall consist of a chairman who is in charge of experimentation within the institution, a member who is responsible for the care of animals in the institution, and at least two other members who are conversant with animal experimentation. The main duty of the committee is to process and scrutinise the research protocols in terms of their necessity and compliance to the animal welfare regulations and to decide on the classification of the experiments according to the Decision (No. 477/1986) of the Ministry of Agriculture and Forestry. New legislation on animal experimentation is being prepared. Depending on the classification, the committee may grant a licence to the experiment or must refer the protocol to the Provincial State Office, which has the authority to grant the licence for more intrusive and painful experiments. The Provincial State Office can in turn refer the case to the Ministry of Agriculture and Forestry for decision-making. Both the institutional committee and the Provincial State Office may add specific conditions to the licence.

More information on the legislation on animal experimentation is available from the Ministry of Agriculture and Forestry.

Contact information: Ministry of Agriculture and Forestry, Veterinary and Food Department, Unit of Animal Health and Welfare, P.O.Box 232, FIN-00171 Helsinki, Finland. Tel. +358-9-1601, fax +358-9-160 3338 or +358-9-160 4447.

Information compiled and edited by Salla Lötjönen, LL.M., M.A., Secretary for the National Research Ethics Council of Finland, 1999.