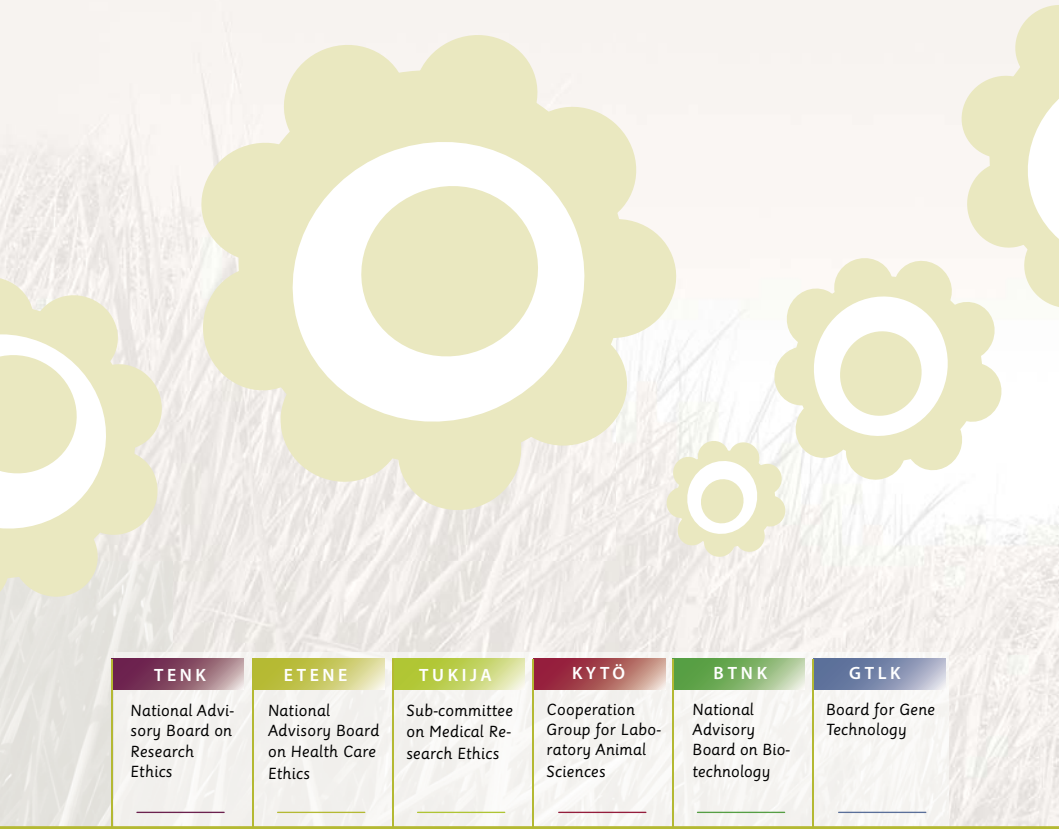
Ethical Evaluation of Research in Finland



TENK	ETENE	TUKIJA	KYTÖ	BTNK	GTLK
National Advisory Board on Research Ethics	National Advisory Board on Health Care Ethics	Sub-committee on Medical Research Ethics	Cooperation Group for Laboratory Animal Sciences	National Advisory Board on Biotechnology	Board for Gene Technology

Ethical Evaluation of Research in Finland

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Ethical Evaluation of Research in Finland

Science and research play an important role in Finnish society. Combined, the government and business investment in research and development represents over 3.5 per cent of the gross national product, which is among the highest rates in the world. Finns have unwavering confidence in science and research. According to the Finnish Science Barometer 2001, Finns trust scientific institutions more than the legal system or the church. A large majority of Finns (80%) give the standard of the sciences and research good overall marks, and most (59%) think that the research community operates responsibly and knows its social responsibilities. Finns (70%) think that cases of misappropriation of research funds are exceptional and that they should not brand the entire scientific community. This trust is confirmed by the statistics compiled by the National Advisory Board on Research Ethics. Although the number of cases of suspected misconduct in science varies, there have only been very few confirmed cases.

The foundation for science and research is laid in school, and the inculcation of ethical models begins during university studies. The primary responsibility for teaching research ethics rests with universities. Universities, research institutes, polytechnics and other research organisations also create action models in reacting to cases brought to their attention. There are several national advisoryboards which promote research ethics and common practices and follow developments in Finland and abroad.

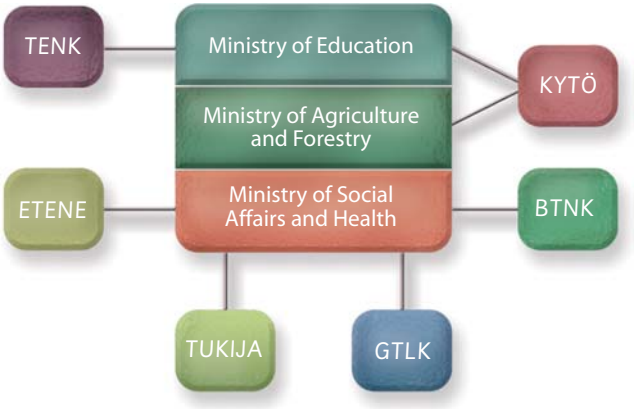
The ethical acceptability of scientific research and the credibility of research findings entail that research is conducted in keeping with good scientific practice. Violations of good practice are either misconduct or fraud in science. Alleged cases of misconduct or fraud are handled by the research organisation with which the researcher is most closely associated. A researcher dissatisfied with the handling of his or her case can request the opinion of the National Advisory Board on Research Ethics, which is an expert body appointed by the Ministry of Education and responsible for disseminating information about and coordinating the promotion of research ethics in Finland.

The single most important issues concerning research with human beings, human embryos are the consent of the research subject and the risks and inconvenience inflicted on him or her compared to the benefits to be gained from the research. The Medical Research Act and Decree regulate research involving human beings. The ethics committees of hospital districts are responsible for ethical pre-evaluation of medical research. The Sub-Committee on Medical Research Ethics of the Advisory Board on Health Care Ethics evaluates the ethical aspects of international multi-centre medicinal trials in cooperation with research ethics committees.

The use of animals in research is regulated by law. At the local level, experiments are supervised by committees on animal experimentation and at the regional level by the provincial state offices. The Ministry of Education has appointed a Cooperation Group for Laboratory Animal Sciences to coordinate research and training in the field and to promote the ethical principles of laboratory animal welfare. Legislation governing the use of laboratory animals is being reformed.

The use of genetically modified organisms is regulated by the Act on Gene Technology (377/1995). The aim of the Act is to promote the safe use and development of gene technology in a way that is ethically acceptable. The Board for Gene Technology attends to the duties laid down in the Act. The National Advisory Board for Biotechnology follows developments in biotechnology, disseminates information, arranges training, and promotes co-operation between authorities, researchers and other operators in the field.

Although both the structure and content for the evaluation of medical research and the use of gene technology are determined in legislation, the primary responsibility for ethical research rests with researchers themselves. Universities must guide researchers towards the responsibility which the freedom of research and science entails.



TENK	ETENE	TUKIJA	KYTÖ	BTNK	GTLK
National Advisory Board on Research Ethics	National Advisory Board on Health Care Ethics	Sub-committee on Medical Research Ethics	Cooperation Group for Laboratory Animal Sciences	National Advisory Board on Biotechnology	Board for Gene Technology

National Advisory Board on Research Ethics

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National Advisory Board on Research Ethics

TENK

The National Advisory Board on Research Ethics was founded in 1991 to address ethical questions relating to research and to the advancement of research ethics in Finland (Decree 1347 of 15 November 1991). The Advisory Board, which is appointed by the Ministry of Education for a term of three years at a time, meets seven times a year. The Secretary General of the Board is attached to the Federation of Finnish Learned Societies. The Board:

1. Makes proposals and issues statements to governmental authorities on legislative and other matters concerning research ethics;
2. Acts as an expert body working towards the resolution of ethical issues relating to research;
3. Takes initiative in advancing research ethics and promotes discussion concerning research ethics;
4. Monitors international developments in the field and takes actively part in international cooperation;
5. Informs the public about research ethics.

The Board issues guidelines for good scientific practice and procedures for handling misconduct and fraud in science. The third, revised version of the guidelines came out in 2002. The Board organises seminars and takes initiative for academic and societal discussion on research ethics.

The Board has an advisory role and does not issue legally binding decisions.The Board is composed of a chairman, a vice chairman and eight members. They represent the most important disciplines in terms of research ethics and authorities primarily responsible for research ethics.

National Advisory Board on Health Care Ethics (ETENE)

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National Advisory Board on Health Care Ethics

ETENE

The Advisory Board on Health Care Ethics was established by an amendment to the Act on the Status and Rights of Patients (No. 785/1992, amendment No. 333/1998). It is forum representing different parties and its task is to deal with ethical issues related to health care and rights and status of patients. According to the Decree on the Advisory Board on Health Care Ethics (No. 494/1998) it among others:

1. takes initiatives and issues statements and recommendations on ethical issues in health care, as well as raises societal discussion on ethics,
2. acts as an expert body in development of health care legislation;
3. collects and shares information about ethics in health care and about international ethical discussion on health care;
4. follows the development of health care and related technologies from an ethical point of view.

The Advisory Board is a forum for ethical discussion and debate. It can submit recommendations and statements and advisory opinions but not legally binding orders or decisions. The Board consists of a chairperson, vice chairperson and 18 members. They represent patients, providers of health care services, health care professionals, law and research. At least four members must be Members of Parliament.

National Advisory Board on Health Care Ethics
The Sub-Committee on Medical Research Ethics

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The Sub-Committee on Medical Research Ethics

TUKIJA

The Board has a SUB-COMMITTEE ON MEDICAL RESEARCH ETHICS (TUKIJA). It:

1. Gives national ethical opinions on international multi-centre clinical trials on medicinal products. This can also be forwarded to the ethics committees of hospital districts;
2. Supports the ethics committees of hospital districts in fundamental ethical issues concerning medical and other health care research and assist in arranging training concerning these issues.

More information:

National Advisory Board on Health Care Ethics
The Sub-Committee on Medical Research Ethics
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http://www.etene.org/tukija/index.shtml

Ethics Committees of Hospital Districts

According to Medical Research Act (488/1999, amended 295/2004) an independent ethics committee has to pre-evaluate and give a favourable opinion on a clinical trial prior to the start of study. A study that has got a negative opinion given by an ethics committee can be forwarded to the Sub-Committee on Medical Research Ethics of the National Advisory Board on Health Care Ethics.

The ethics committees are nominated by hospital districts and registered by Provincial State offices. The size, composition and duties of ethics committees have been determined in the Medical Research Act. Finland has 21 hospital districts and there 25 ethics committees.

The ethics committees pre-evaluate research projects based on 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 most important of these are the Convention of Human Rights and Biomedicine by the Council of Europe (CETS 164) and the Directive 2001/20/EC on the implementation of good clinical practice on clinical trials on medicines.

Institutional Ethics Committees

Institutional research ethics committees evaluate research not covered by Medical Research Act. Very often the composition and size of these ethics committees is similar to ethics committees of hospital districts. When necessary the ethics committees of the hospital districts may also evaluate research not covered by Medical Research Act.

Cooperation Group for Laboratory Animal Sciences (KYTÖ)

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Cooperation Group for Laboratory Animal Sciences

KYTÖ

The tasks of the joint Cooperation Group for Laboratory Animal Sciences of the Ministry of Education and Ministry of Agriculture and Forestry are:

1. to coordinate research and education involving laboratory animals
2. to promote ethical principles in animal experiments and welfare of laboratory animals
3. to promote education in fields involving animal experiments.

The Cooperation Group consists of a chairman, a vice-chairman and nine members, who are researchers and experts of animal experiments from universities, research institutes and industry.

Three working groups have been set up under the Cooperation Group. The working group on education and training focuses on developing education in all job categories involving animal experiments. Another objective is to harmonise Finnish education in the field with the European standards. The working group on ethics promotes discussion on animal welfare and ethical principles of animal experiments. The group has also prepared guidelines for the assessment of the ethical aspects of research plans. The information group compiles and produces information material on animal experiments.

More information

on the legislation on animal experimentation is available from the Ministry of Agriculture and Forestry http://www.mmm.fi/ or from the provincial state offices.

Committees on Animal Experimentation

Under the Decree on Animal Experimentation (1076/1985, amended in 1996), all institutions conducting animal experiments must have a committee to evaluate research plans which involve the use of animals in experiments. Each committee consists of a chairman, who is in charge of experimentation within the institution, a member of the animal care staff and at least two other members familiar with animal experimentation. The main duty of the committee is to scrutinise the research proposals in terms of compliance to animal welfare regulations.

The committee may grant a licence to a class 2 experiment. In the case of the more intrusive and painful class 1 experiments, it gives its opinion on the proposal and refers it to the provincial state office, which either approves or rejects the proposal. Both the institutional committee and the provincial state office may request more information before granting a permission, or they can add specific conditions to the licence. New legislation on animal experimentation is presently under preparation at the Ministry of Agriculture and Forestry.

Biotekniikan neuvottelukunta

National Advisory Board on Biotechnology

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National Advisory Board on Biotechnology

BTNK

The main duties of the Advisory Board are to promote communication between stakeholders within the field of bio- and gene technology, to promote research in the field, to follow the development of health and environmental effects and risk assessment, and to advance information exchange and education. The primary task of the Advisory Board is to consider ethical issues, follow public debate, and promote public participation and perception of gene technology. The Advisory Board does not give legally binding decisions. The Board may issue opinions by request or on its own initiative.

Under the Gene Technology Decree (928/2004), the duties of the Advisory Board on Biotechnology in its capacity of an advisory body are as follows:

1) The duties of the Advisory Board on Biotechnology in its capacity of an advisory body are as follows (Gene Technology Decree 928/2004);
2) to monitor and promote international cooperation in biotechnology;
3) to monitor in particular the developments and research in gene technology, as well as its health and environmental effects;
4) to promote the taking into account of ethical considerations in gene technology; and
5) to attend to other duties relating to biotechnology as assigned to it by the relevant ministries.

The Government appoints the Advisory Board for Biotechnology upon the submission of the Ministry of Social Affairs and Health for a term of three years. The Advisory Board shall include representatives of at least the authorities most relevant to the control of gene technology, of the most representative organizations of trade, consumers and industry, as well as of research in the various fields of gene technology.

The Board for Gene Technology

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Board for Gene Technology

GTLK

The use of genetically modified organisms is regulated by the Act on Gene Technology (377/1995). The aim of the Act is to promote the safe use and development of gene technology in accordance with the precautionary principle and in a way that is ethically acceptable; and to protect human and animal health and the environment when carrying out the contained use or deliberate release into the environment of genetically modified organisms. The competent authority established by the Act is the Board for Gene Technology which is subordinate to the Ministry of Social Affairs and Health. The Board is appointed for five years by the Council of State upon the submission of the Ministry of Social Affairs and Health. The members 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 among others. Ethical expertise shall also be represented. The board has a full-time Secretary General.

The first term of office of the Board begun in 1995 when the Act on Gene Technology also came into force, and the third term started in the summer of 2005. The priorities of the Board include processing notifications concerning the use and release of genetically modified organisms as defined by the Act and to lead and co-ordinate the supervision of compliance with the Act. The Board co-operates with different Ministries, the supervisory authorities referred to in the Act, the Advisory Board for Biotechnology and governmental expert authorities and institutions.

The primary responsibility for ethical research rests with researchers themselves.