RESEARCH ETHICS AND DATA PROTECTION LEGISLATION

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De sju som hängdes

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Professor, för med, knust och annat tidiga personliga laga. Kommisarie för huvudvård, och en av de som förvaltade programmet.

Arrests av Himmler personliga staf och vidare av ansvar för utvärdering av friska koncentrationstrappor.

Dra med med Waffen SS och SS medhuggare.

Ibland som ungick

Josef Menges, 1911. Dömd.


1946. Dömd, anmärking 15-60, och mörkexperiment i Dachau, ukänt 1942 på under av Himmler sedan han behärskar skylt till avvikande.

Karl Fischmann, också delad med

Leonardo Donat, 1903. Dömd och av tyska grundvalblöcke.

(Hängas sig, sedan i Himber.

utan på något.)
The Declaration of Helsinki
(http://www.wma.net/e/ethicsunit/helsinki.htm)

• is the World Medical Association’s best-known policy statement. It was first adopted in 1964 and has been amended five times since, most recently in 2000. Notes of clarification were added to para. 29 in 2002 and to para. 30 in 2004. The current (2013) version is the only official one; all previous versions have been replaced and should not be used or cited except for historical purposes

• compliance required by *biomedical journals*
Codes vs. Legislation

• professional codes are not sufficient to guarantee the right’s of research subjects
  • international conventions and national legislation now confirm the principles of the ethical codes and define criminal sanctions for the misuse of research subjects
The European Convention on Human Rights
This international Convention, signed by most of the European States, sets out the fundamental principles applicable in day-to-day medicine as well as those applicable to new technologies in human biology and medicine.

- the additional Protocol on the Prohibition of Cloning Human Beings (adopted by the Committee of Ministers on 6 November 1997, entry into force on 1 March 2001);
- the additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (adopted by the Committee of Ministers on 8 November 2001, came into force on 1 May 2006);
- the additional Protocol on Biomedical Research (adopted by the Committee of Ministers on 30 June 2004, entered into force on 1 September 2007); and

Note: e.g. Germany, Russia and UK have not signed the Convention
Declaration of Helsinki v. Biomedicine Convention

1. the primacy of the well-being of research subject in comparison to benefits for science and society in different documents
2. the requirement for independent review of the research prior its initiation
3. the informed concept requirements and
4. the status of incapacitated subjects and minors in the different documents.
Primacy of the Human Being

**DoH article 8:** While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

**EC Convention on Biomedicine: Art 2:**
The interests and welfare of the human being shall prevail over the sole interest of society or science.

**EU Regulation No 536/2014 on Clinical Trials Art 3:**
A clinical trial may be conducted only if:
(a) the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests…
DoH article 23:

- the research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins

EC Convention on Biomedicine: Research on a person may only be undertaken if all the following conditions are met

- the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability

EU Regulation No 536/2014 on Clinical Trials

- Ethics committee’ means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations

- A clinical trial shall be subject to scientific and ethical review and shall be authorised in accordance with this Regulation…
Consent
Article 5 – General rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.
DoH article 26: In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.

EC Convention on Biomedicine: Research on a person may only be undertaken … if

• the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;

• the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

EU Regulation No 536/2014 on Clinical Trials: A clinical trial may be conducted only where all of the following conditions are met…:

• the subjects, or where a subject is not able to give informed consent, his or her legally designated representative, have been informed in accordance…
Protection of Persons not able to Consent

DoH article 20: Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

DoH article 28: For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.
Finnish Research Legislation

Act on Medical Research (488/1999)
Coverage of ”Medical research”

*Medical research* means research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of health, the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of diseases in general;
Section 3: 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 favorable 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.
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.

- If it is question of research other than clinical drug trial, also another person than a medical doctor or dentist may be responsible for the research, provided that the person has the professional and scientific qualifications required for the research concerned.
Personal data and processing of personal data

For the purposes of this Directive (95/46/EU):

(a) 'personal data' shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity;

(b) 'processing of personal data' ('processing') shall mean any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction;
Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

Article 8
The processing of special categories of data:

1. *Member States shall prohibit* the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of *data concerning health* or sex life.
Genetic data

Recommendation of the committee of ministers of the Council of Europe R (97)5 on the protection of medical data,

medical data" refers to all personal data concerning the health of an individual. It refers also to data which have a clear and close link with health as well as to genetic data. the expression "genetic data" refers to all data, of whatever type, concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals.
Research exemption and genetic data (directive 95/46/EC)

Section 34 of the introduction of the:

Member states are authorized to derogate from the prohibition on processing sensitive categories of data for scientific research. This is possible, when important reasons of public interest so justify, if specific and suitable safeguards of privacy are provided for the processing (see article 8).

Article 8.4:

additional exemptions for processing of sensitive data may be laid down by national law or decision of the supervisory authority in the substantial public interest, but EU commission must be notified on these exemptions
Features of scientific research

• aims to increase knowledge,
• message is aimed for the scientific community (i.e. the results of the research are public)
• non-profitable.
Biobanks

= collections of human biological material (either samples or residual material)

Usually materials are linked with *health data*

Diagnostic samples
Tissue establishments
Research samples

Utilized in medical research, in tissue-based therapies and in commercial product development (diagnostics)
biobank means a unit maintained by an operator engaging in biobanking activities for the purposes of collecting and storing samples and information associated with the samples for future biobank research
Consent

A biobank's right to process samples is based on consent, unless otherwise provided in this act or in another act.

A person may issue consent for the storing of the samples taken or soon to be taken from him or her in a biobank and their use in biobank research, the provision of his or her personal information, the linking of register data concerning him or her and other processing of the samples and information obtained from him or her in connection with the samples to the extent required by biobank research. The consent shall be given in writing.
Exceptions on informed consent

"Old samples"
Research that has been lawfully carried out prior to biobank law

Diagnostic samples
Implied consent and approval of an independent ethics committee (IRB)

Large sample collections
Approval by the ministry of Social Affairs and Health
Data management in biobank

- Registry on samples and data (21 §)
- Registry on consents (22 §)
- Registry on identification codes (23 §)
Freedom of research

- Right of access to information in the sample and information register
  - An institution, company, community or individual performing biobank research has the right of access to information in the sample and information register that is necessary for assessing the usability of the samples and information stored in the biobank and that does not contain sensitive information.

- A biobank may grant access to, study or otherwise process the samples and information stored by it provided that:
  - the intended use corresponds to the research area and the criteria and conditions for the processing of the sample;
  - terms and restrictions provided in this act or elsewhere in law and determined by the biobank are observed in the research;
  - the individual granted access to the samples or information holds the appropriate professional and academic qualifications.
Finnish Act on Biobanks 19 §

Prohibitions and restrictions concerning the processing of samples

Notwithstanding the provisions laid down elsewhere in law on the right of authorities to receive secret information, access to the samples stored in a biobank and the information associated with such samples may not be granted and they may not be used for the purpose of a criminal investigation or in administrative or other decision-making concerning the person.

Samples and information stored in a biobank may not be used to assess or determine the work ability of an individual or for the decision-making of credit or insurance institutions.
Legal Principles in Biomedical Research

- independent ethical evaluation
- informed consent of the research subject
- protection of special groups (e.g. children)
- prohibition of the processing of sensitive data