THE IMPACT OF THE DECLARATION OF HELSINKI ON EUROPEAN HUMAN RIGHTS DEVELOPMENT

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Year 1964: The Declaration of Helsinki is approved

U.S. military forces launch attacks on North Vietnam on the basis of Tonkin Gulf resolution

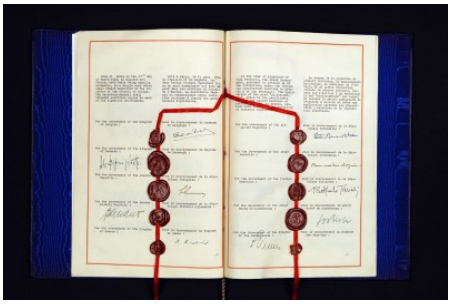
Beatles 1st US #1,

"I Want to Hold your Hand"

Al Oerter wins in Tokyo Olympics the discus for the third time in straight

Konrad E. Bloch and Feodor Lynen win Nobel Prize for research on mechanism and regulation of cholesterol and fatty-acid metabolism

The European Convention on Human Rights



Convention on Human Rights and Biomedicine (entry into force on Dec. 1, 1999) and its additional Protocols

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
- the Protocol concerning Genetic Testing for Health Purposes (adopted by the Committee of Ministers on 7 May 2008, opened for signature on 27 November 2008).

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…

Ethical Review of the Research Protocol

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…*

Independence of the Ethics Committee

The committee must be transparent in its functioning, must be **independent of the researcher, the sponsor and any other undue influence** and must be duly qualified.

Even though the committee must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards **but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration**.

ECHR 2012: Case of Gillberg v. Sweden

The Swedish Parliamentary Ombudsman brought criminal proceedings against Mr. Gillberg, and short time later he was convicted of misuse of office. Mr. Gillberg was given a suspended sentence and a fine of the equivalent of 4,000 euros. The university's vice president and the officials who had destroyed the research material were also convicted.

Mr. Gillberg's conviction was upheld by the Court of Appeal and leave to appeal to the Supreme Court was refused. Short time later Mr. Gillberg lodged an application with the Strasbourg Court of Human Rights. He complained in particular that his criminal conviction breached his rights under Articles 8 and 10, because **his promise of confidentiality to the participants in the research was allegedly imposed on him by the university's ethics committee,** as a precondition for carrying out his research.

The Court considered itself only being in a position to examine whether Mr. Gillberg's criminal conviction for refusing to execute a court order granting access to official documents was compatible with the Convention. **The conviction of professor for refusal to grant access to sensitive research data was not in breach of ECHR**

Informed Consent

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…

Information for the Research subjects in Clinical Trials with Medicinal Products (article 29)

Information given to the subject or, where the subject is not able to give informed consent, his or her legally designated representative for the purposes of obtaining his or her informed consent shall:
(a) enable the subject or his or her legally designated representative to understand:
i. the nature, objectives, benefits, implications, risks and inconveniences of the clinical trial;
ii. the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical trial at any time without any resulting detriment and without having to provide any justification;
iii. the conditions under which the clinical trial is to be conducted, including the expected duration of the subject's participation in the clinical trial; and
iv. the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical trial is discontinued;
(b) be kept comprehensive, concise, clear, relevant, and understandable to a layperson;
(c) be provided in a prior interview with a member of the investigating team who is appropriately qualified according to the law of the Member State concerned;
(d) include information about the applicable damage compensation system
(e) include the EU trial number and information about the availability of the clinical trial results

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

Clinical trials on incapacitated subjects (article 31)

In the case of incapacitated subjects, a clinical trial may be conducted only where all of the following conditions are met:

a)the informed consent of their legally designated representative has been obtained;

b)the incapacitated subjects have received the information referred to in Article 29(2) in a way that is adequate in view of their capacity to understand it;

c)the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to in Article 29(2) to refuse participation in, or to withdraw from, the clinical trial at any time, is respected by the investigator;

d)(no incentives or financial inducements are given to the subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial;

e)the clinical trial is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in clinical trials on persons able to give informed consent, or by other research methods;

f)the clinical trial relates directly to a medical condition from which the subject suffers;

g)there are scientific grounds for expecting that participation in the clinical trial will produce:

i. a direct benefit to the incapacitated subject outweighing the risks and burdens involved; or

ii. some benefit for the population represented by the incapacitated subject concerned when the clinical trial relates directly to the life-threatening or debilitating medical condition from which the subject suffers and such trial will pose only minimal risk to, and will impose minimal burden in comparison with the standard treatment

Conclusions

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European Commission

- Both the Convention on Biomedicine of the Council of Europe and EU regulation on clinical trials follow the principles that have their origin in the Declaration of Helsinki.
- New issues, however, may rise when IT-technology (e.g. big data analysis) and whole-genome sequencing are becoming widely used research methods

The compliance of research methodology with the principles of the Declaration has to be constantly monitored