BIOETHICS IN RESEARCH

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Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine

Oviedo, 4.IV.1997

Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research

Strasbourg, 25.I.2005

Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes

Strasbourg, 27.XI.2008
Main legal instruments

**LEGALLY BINDING TEXTS**

**THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE (OVIEDO CONVENTION)**

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, the Convention on Human Rights and Biomedicine (ETS No. 164), which was opened for signature on 4 April 1987 in Oviedo, Spain, is the only binding international legal instrument on the subject of bioethics. It draws on the principles established by the European Convention on Human Rights, in the field of biology and medicine. This text is a framework convention for the protection of fundamental rights. States ratifying it undertake to apply its provisions. Its aim is to protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other fundamental freedoms with regard to the application of biology and medicine. It is regarded as the European treaty on patients' rights and deals specifically with biomedical research, genetics and transplantation of organs and tissues.

The tenth anniversary of the entry into force of the convention was celebrated in 2009.

[www.conventions.coe.int](http://www.conventions.coe.int)

The provisions of the convention are elaborated upon and fleshed out by additional protocols on specific subjects.

**ADDITIONAL PROTOCOLS**

- Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 189), 2002
- Additional Protocol on Biomedical Research (ETS No. 195), 2005
- Additional Protocol concerning Genetic Testing for Health Purposes (ETS No. 203), 2008

**NON-LEGALLY BINDING TEXTS**

- Committee of Ministers Recommendation on xenotransplantation Rec(2003)10
- Committee of Ministers Recommendation on the protection of the human rights and dignity of persons with mental disorder Rec(2004)10
- Committee of Ministers Recommendation on research on biological materials of human origin Rec(2006)4

**PRACTICAL INFORMATION**

**WHERE TO FIND FURTHER INFORMATION?**

- The Council of Europe bioethics site
  [www.coe.int/bioethics](http://www.coe.int/bioethics)
- Factsheets on the case-law of the European Court of Human Rights in the field of bioethics
  [www.echr.coe.int](http://www.echr.coe.int)

The aim of the Council of Europe, which is made up of 47 states, is to promote a greater unity between its members. It works in particular for respect for human rights, pluralist democracy and the rule of law and the promotion of peace through culture.
WHERE TO FIND FURTHER INFORMATION?

- The Council of Europe bioethics site
  http://www.coe.int/bioethics

- Factsheets on the case-law of the European Court of Human Rights in the field of bioethics
  www.echr.coe.int
WHO guidelines on ethical issues in public health surveillance
Global Bioethics: What for?

20th anniversary of UNESCO’s Bioethics Programme

UNESCO Publishing

Global Bioethics: What for?

20th anniversary of UNESCO’s Bioethics Programme

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Bioethical issues – Educational fact sheets

Train your pupils in a participatory approach, fundamental to education for citizenship, by organising an informed, multidisciplinary debate on bioethical issues.

This teaching aid is designed in particular for fourth form to upper sixth form teachers of biology, philosophy and civic education.

Five initial themes are addressed in this publication:
- organ donation;
- medically-assisted procreation;
- genetic testing;
- biomedical research on human beings;
- cloning.
Biomedical research on human beings

Find out more

... ABOUT QUESTIONS RAISED BY BIOMEDICAL RESEARCH

- Convention on Human Rights and Biomedicine (Oviedo Convention), Council of Europe, 1997
  http://conventions.coe.int/Treaty/EN/Treaties/Html/164.htm

- Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Council of Europe, 2005
  http://conventions.coe.int/Treaty/EN/Treaties/Html/195.htm

- Bioethics at the Council of Europe
  www.coe.int/bioethics

- Opinions of the French National Council on Ethics (Nos. 2; 7; 11; 34; 38; 58; 73)
  www.ccne-ethique.fr


... ABOUT QUESTIONS RAISED BY BIOMEDICAL RESEARCH IN DEVELOPING COUNTRIES

  http://ec.europa.eu/european_group_ethics/avis/index_en.htm

- The Ethics of Research Related to Healthcare in Developing Countries, report of the Nuffield Council on Bioethics, 2002
  www.nuffieldbioethics.org
Research will be taken care in accordance with Helsinki declaration. The research will be conducted in accordance with the Oviedo convention. There will be no cloning. The researcher will take care for the rights of the participants in the study.

PRILOGA 9:
Izjava mentorja raziskovalca

Spodaj podpisani mentor raziskovalca prof. dr. Danijel Petrovič, dr. med. potrjujem, da so raziskovalci, vključeni v raziskavo, usposobljeni za delo v zvezi z raziskavo, da so zmožni pravočasno prepoznati morebitne zaplete, ki bi lahko ogrožali zdravje ali življenje oseb v raziskavi, in da so zmožni pravilno ukrepati. Potrjujem, da je na ustanovi je poskrbljeno za strokovnost dela in varnost oseb v raziskavi, da bom nadziral raziskovalce in da bodo upoštevali načela Helsinške deklaracije o biomedicinskih raziskavah na človeku, določila Konvencije Sveta Evrope o varovanju človekovih pravic in dostojanstva človeškega bitja v zvezi z uporabo biologije in medicine (Oviedské konvencie in protokolov k njej – o prepovedi kloniranja človeških bitij; o presaditvi človeških organov in tkiv; o človekovih pravicah v zvezi z biomedicino glede biomedicinskih raziskav; o človekovih pravicah v zvezi z biomedicino glede genetskega testiranja za zdravstvene namene) ter določila slovenskega Kodeksa medicinske deontologije.

PRIOLOGA 10:
Izjava odgovornega nosilca raziskave, da stroški morebitnih preiskav, ki so
namenjene izključno raziskavi, ne bodo bremenili sredstev zdravstvenega
zavarovanja

Pregledi in preiskave ne bodo opravljeni na napotnico in torej ne bodo bremenili
sredstev zdravstvenega zavarovanja. Zaradi raziskave se ne bo zmanjšala
dostopnost do zdravstvenih storitev pacientom zunaj raziskave.

prof. dr. Danijel Petrovič, dr. med.

Resources of health insurance will not be used.
Raziskava bo opravljena v skladu z načeli Helsinške deklaracije o biomedicinskih raziskavah in načeli slovenskega Kodeksa medicinske deontologije. Vaši podatki bodo ostali anonimni.

Podpisani(a) ____________________________ , roj. ____________________________, sem seznanjen(a) z namenom in potekom raziskave. V njej sem pripravljen(a) prostovoljno sodelovati. Seznanjen(a) sem z možnimi tveganji za zaplete. Vem, da lahko katerikoli trenutek tekom raziskave sodelovanje v njej prekinem, ne da bi mi bilo potrebno razloge za odločitev pojasnjevati.

Podpis preiskovanca ____________________________
Podpis priče ____________________________

V Murski Soboti, dne ____________
Genetic Tests for Health Purposes

Under what circumstances is genetic testing foreseen?

Professional genetic counselling

What is a genetic test looking for?

Your decision
The Council of Europe has 47 member states, covering virtually the entire continent of Europe. It seeks to develop common democratic and legal principles based on the European Convention on Human Rights and other reference texts on the protection of individuals. Ever since it was founded in 1949, in the aftermath of the Second World War, the Council of Europe has symbolised reconciliation.
OPINION NO. 29 OF THE EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES

The ethical implications of new health technologies and citizen participation

Brussels, 15 October 2015
In response to the rapid advancements in genetics and genomics, and within the framework of its work programme for 2014-2015, the International Bioethics Committee (IBC) decided to update its reflection on the issue of the human genome and human rights, building upon the considerable work done on this topic by the IBC in the past, and in particular, taking into account the Universal Declaration on the Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003), and the Universal Declaration on Bioethics and Human Rights (2005). Prior to the 21st Session of the IBC and the Joint Session of the IBC and the Intergovernmental Bioethics Committee (IGBC) in September 2014, a concept note was prepared by a small working group of the Committee, providing a preliminary outline of potential areas of reflection for this topic. Members of the IBC, the IGBC, the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), and the UN Interagency Committee on Bioethics (UNIACB) were invited to submit written comments and suggestions on the concept note. Both the concept note and written submissions were then discussed during the sessions in September 2014. Following this discussion, the IBC established a larger working group to prepare a draft report on the topic, which was discussed during the 9th Session of the IGBC in July 2015. The draft report was then revised to take into account the comments of the IGBC. The final draft of the report was further discussed, revised and adopted during the 22nd Session of the IBC in October 2015.
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