

# 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 1997 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 rights and 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 on the Prohibition of Cloning Human Beings (ETS No. 168), 1998
- ▶ Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186), 2002
- ▶ Additional Protocol on Biomedical Research (CETS No. 195), 2005
- ▶ Additional Protocol concerning Genetic Testing for Health Purposes (CETS 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

ENG

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## PRACTICAL INFORMATION

### WHERE TO FIND FURTHER INFORMATION?

- ▶ The Council of Europe bioethics site

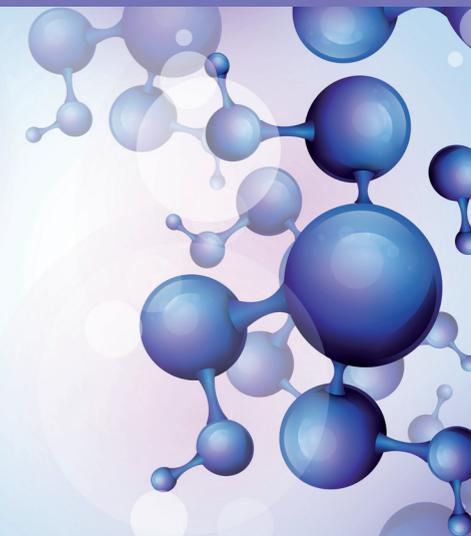
[www.coe.int/bioethics](http://www.coe.int/bioethics)

- ▶ 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.

## BIOETHICS AT THE COUNCIL OF EUROPE



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



# Bioethics at the Council of Europe

” Science without conscience is but the ruin of the soul ”  
Rabelais

## SOME QUESTIONS ...

- ▶ Can I refuse to undergo a genetic test requested by a future employer or my insurance company?
- ▶ What information should a doctor provide to a person suffering from an illness who wishes to take part in a clinical trial for a new medicine?
- ▶ Can samples taken from a person during treatment be used for research purposes?
- ▶ Is it possible for me to use medically assisted procreation techniques to choose the gender of my child?
- ▶ If an examination on a patient brings to light information that is relevant to the health of other family members, should they be informed accordingly?
- ▶ Do I have the right to sell one of my kidneys, or my sperm or ova?

Bioethical issues concern us all, as patients or professionals, but also as members of a society facing new choices as a result of scientific progress. What are the principles on which we all need to agree? What framework do we need to establish to prevent abuses and promote advances that are of benefit to humankind?

Since the end of the Second World War, biomedical research has resulted in major advances in areas such as the transplantation of organs, procreation, genetics and cell therapy.

The Nuremberg Code and the Helsinki Declaration laid the foundations for the principles to be applied to biomedical research. Intense discussions arose in many countries, then at international level, on the ethical principles that should apply to biomedical activities, whether in day-to-day medicine, research or new technologies.

**In 1985**, with the Parliamentary Assembly providing the impetus, bioethics was included among the Council of Europe's activities. The aim of this new work was to establish a framework for the protection of human beings and to promote scientific progress for the benefit of humankind.

**In 1992**, the Steering Committee on Bioethics (CDBI) was established. Its mission is to study ethical problems, in particular the challenges for human rights, raised by progress in the biomedical sciences, and to frame legal instruments to deal with such problems.

**In 1997**, the first international legally binding instrument in the field, the Convention on Human Rights and Biomedicine (Oviedo Convention, ETS No. 164), was adopted. It established a legal framework for the protection of rights applying both to day-to-day medicine and to new technologies in human biology and medicine.

**In 2012**, the CDBI became the Committee on Bioethics (DH-BIO) and is now directly attached to the Steering Committee for Human Rights (CDDH). Its tasks are still to assess new ethical and legal issues in the ever-changing field of biomedical science and technologies, such as those relating to genetics and biobanks, to develop the principles enshrined in the Convention on Human Rights and Biomedicine in specific fields and to help to raise awareness about its principles and facilitate their implementation.

## THE SPECIAL FEATURES OF BIOETHICAL ACTIVITIES

Bioethics is primarily a multidisciplinary, pluralist study of sciences and technologies in the biomedical field, which must take account of their constantly changing nature.

The composition of the DH-BIO, which comprises representatives of the 47 member states, reflects this multidisciplinary approach by bringing together experts from the different fields concerned, including human rights, biology and medicine.

## QUESTIONS WHICH AFFECT ALL CITIZENS

For the Council of Europe there is a crucial need for public debate, which is referred to specifically in Article 28 of the Oviedo Convention. Symposia, hearings and public consultations are an integral part of the DH-BIO's working methods.

At the same time, the DH-BIO helps to stimulate public debate by producing information material and discussion aids, such as education sheets aimed at young people.