



ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

Bioethics

Silvia Zullo

Department of Legal Studies

– CIRSFID - silvia.zullo@unibo.it

Bioethics and biolaw

-the interdisciplinary structure of bioethics **requires** the continuous updating of the operators and the opportunity for discussing with the experts of different disciplines, with heterogeneous languages and methodologies. One of this language is the **language of law**

-the **need of juridical categories** to define and classify phenomena that depart from the usual context of analysis

-**prudence (or precaution) of the legislator**, in the fear that certain techno-scientific intervention on life may cause unforeseeable and irreversible effects



Bioethics and biolaw

Prominent (bio)ethical codes

- 1. Oath of Hippocrates: one of the most widely known of Greek medical texts**
- 2. Nuremberg Code (1947): issue of human experimentation**
- 3. Universal Declaration of Human Rights (1948)**
- 4. Declaration of Helsinki (World Medical Association, 1964): issue of human experimentation**
- 5. CIOMS (the Council for International Organizations of Medical Sciences) Guidelines (1993): International Ethical Guidelines for Biomedical Research Involving Human Subjects**
- 6. Declaration on the Human Genome and Human. Rights, adopted by the General Conference of UNESCO at its 29th session (1997)**
- 7. Universal Declaration on Bioethics and Human Rights (UNESCO) (2005).**



Bioethics and biolaw

Council of Europe

Intergovernmental organisation founded in 1949, to achieve greater unity between its members with a view to defend :

- Human rights
- Parliamentary democracy
- Rule of law

Unlike the EU, the Council of Europe cannot make binding laws, but it does have the power to enforce select international agreements reached by European states on various topics. The best known body of the Council of Europe is the **European Court of Human Rights**, which enforces the European Convention on Human Rights.



Bioethics and biolaw

Activities of the Council of Europe in the field of bioethics

To find the necessary **balance between scientific/medical progress and protection of the human being:**

-Normative activities: defining fundamental principles ensuring this balance reflecting European consensus, but International dimension of research taken into account.

-Values and derived principles contribute to general consideration at international level.

-Cooperation activities: helping country implementing those principles (e.g. meetings, publication, expertises).



Bioethics and biolaw

Tools of the Council of Europe in the field of bioethics:

- **Legal instruments**
- **Cooperation activities**

Objective:

Raising awareness on ethical principles and facilitating their effective implementation

- Regional/bilateral meetings
- Comprehensive programme focusing on one country
- Developments of guide(s) intended for research ethics committee members, scientists, health professionals
- Pedagogical tools on ethics of biomedical research



European relevant legal instruments

Convention on Human Rights and Biomedicine

(Council of Europe, Oviedo, 04.04.1997)

Fundamental principles

- Free, informed, express, specific and documented consent
 - Research shall be carried out freely, subject to provisions ensuring protection of the human being.



European relevant legal instruments

Additional Protocol on Biomedical Research (Strasbourg, 25/01/2005)

Covers full range of research activities involving interventions on human being (including recruitment of research participants); builds on the principles of the Convention and complements its provisions.

In particular:

- Informed consent: type of information to be communicated to the person
- Confidentiality
- Research in specific situations: emergency situation, persons deprived of liberty...
- Transparency: publication of all results



Biolaw aims to:

-Development of a whole set of legal instruments addressing bioethical issues raised by scientific and biotechnological research which are the only legally binding instruments at international level

-Definition of a framework for the protection of human rights and fundamental freedoms in the field of biomedical research

-Normative activity accompanied by cooperation activities in Central and Eastern European countries to promote ethical principles in biomedical research

**Council of Europe ready to share its experience in this field
and to collaborate with other organisations and bodies**



Bioethics and biolaw

In order to regulate bioethical issues we have also (bio)ethical committees, their role is :

- **scientific updating activity, interdisciplinary dialogue, ethical pluralistic and dialectic discussion in-depth examination of legal aspects at the national and international level**
- **recommendations to government in biolaw and identification of shared principles and values public involvement**



International Committees

Unesco:

- International Committee for Bioethics
- Intergovernmental Committee for Bioethics
- World Commission on the Ethics of Scientific Knowledge and Technology (Comest)

WHO, Department of ethics and health



European Bioethics Committees

**The European Group on Ethics in Science and in
New Technologies (EGE)**

<https://ec.europa.eu/research/ege/index.cfm>

Bioethics Committee (Council of Europe)

<https://www.coe.int/t/dg3/healthbioethic/>



National organism

-The Italian Committee for Bioethics

<http://www.governo.it/BIOETICA/>

born in 1990:

It's an interdisciplinarian pluralistic structure: is giving advice to Parliament and Government, information to society opinions, motions.

-**Ethical committees** in hospitals, medical institute.



The need of a global harmonization in biolaw

**Emergence of transnational problems
(i.e. pandemics, human genome
mapping, international trials,
environmental issues)**

**International biolaw sources:
deontological codes, documents of
international organizations, national law
and rules**



Bioethics and biolaw

When we have (bio)legal and bioethical controversies we refer to:

1. At National level: Courts and Tribunals
2. At European Level: **European Court of Human Rights** (Strasbourg), **Court of Justice of the European Union (“CJEU”)** based in Luxembourg
3. At International Level: **Courts and Tribunals**



Bioethics and biolaw

The Hastings Center



The Hastings Center addresses fundamental ethical and social issues in health care, science, and technology.

In addition to producing original research, the Center is committed in a public engagement and service to the field of bioethics.

<https://www.thehastingscenter.org/>



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