



Council of Europe
Conseil de l'Europe

HELP course on key principles for the protection of human rights in the biomedical field

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HELP Network Conference 2015

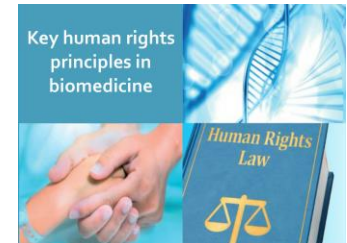
Interactions between *legal* and *other* professionals in human rights training

- Need to provide legal professionals with general training in Human Rights in Biomedicine
- Providing inter-professional trainings for a mixed audience of legal and health professionals, where appropriate

« I wish to underline the need, for legal professionals, to be familiar not only with the European Convention on Human Rights.... I am thinking namely to the Oviedo Convention [Convention on Human rights and Biomedecine] »

Dean Spielmann, President of the ECHR, HELP network Conference 2015

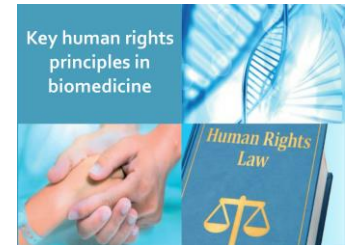
HELP Course: Key human rights principles in Biomedicine



- Increasing number of relevant cases before the **ECtHR**
 - High level seminar on « *International case law in bioethics: Insight and foresight* », December 2016
- Responsibility of both legal and health professionals for the implementation of human rights in biomedecine
 - **Two target audiences**
- Promoting interdisciplinary exchange
- Core principles to be further developed at a later stage



HELP Course: Key human rights principles in Biomedicine



- Finalised in June 2018
- Working group
 - **Prof. Jean-René Binet**, Rennes Faculty of Law, Director of Ecole doctorale SHOS
 - **Prof; Fabio Macioce**, Università di Roma LUMSA
 - **Ivana Roagna**, attorney at law, senior training specialist
 - **Dr Ronals Rozkalns**, attorney at law and medical doctor

With the support of **Ian Culkin**, e-learning designer

- Secretariat support: **HELP** Unit and **Bioethics** Unit

HELP Course: Key human rights principles in Biomedicine

Council of Europe

ECHR

Oviedo
Convention

European Union

EU Directives and
Regulations

United Nations

International
Conventions

Legal framework covered:

- CoE (Oviedo + Protocols; ECtHR)
- UN
- EU
- **8 substantive modules**
- Knowledge checks after each module
- Additional materials available in the links
- **Glossary** – accessible throughout the entire course⁵

Substantive modules

- Introduction: Definitions, international legal sources, principles
- Free and informed consent
- Medical Confidentiality

- Transplantation of Human Organs and Tissues
- Genetic Testing
- Biomedical Research
- Protection of the Embryo and Procreation
- End of Life

Introduction



1.

Introduction

Learning objectives

Welcome to the first substantive module of this Course on Bioethics! By the end of this session you will be able to:

- recognise the multiple ethical issues that arise in medicine, health and biotechnology;
- define the notions of human rights, bioethics and biomedicine and of the main concepts needed to explore the Course further;
- describe the relevance to bioethics of the European Convention on Human Rights (ECHR) and of other international human rights instruments;
- appraise the judicial interpretation of human rights applied to bioethical issues;
- illustrate the scope of application of the Oviedo Convention and recall the main rights and principles it enshrines.



Free and informed consent

2.

What is free and informed consent



Elements of informed consent

Within this module you will have the possibility to explore the key definitions, the international legal framework and the main principles related to bioethics. Choose a topic from the menu below to continue.



Information



Freedom of consent



Ability to make decisions

Learning objectives

Welcome to the second substantive module of this Course on Bioethics! By the end of this session you will be able to:

- define free and informed consent and identify its components
- Internalise the legal and human rights principles applicable to it;
- Discuss the application of the process of informed consent to persons not able to consent and in emergency situations;
- Assess the responsibilities of health professionals in the process of informed consent.;



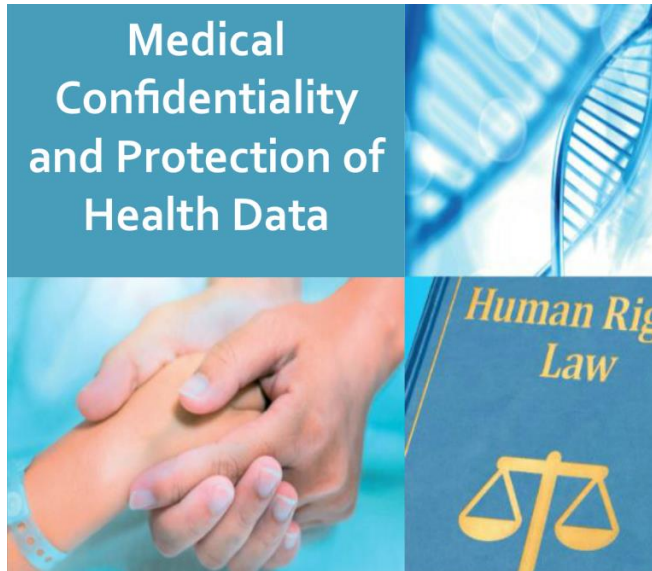
The sources of the principle of informed consent

You can review the sources that the principle of informed consent is based on by clicking the buttons below.

Council of Europe		European Union	United Nations
ECHR	Oviedo Convention	EU Directives and Regulations	International Conventions



Medical confidentiality and protection of health data



Learning objectives

Welcome to the fifth substantive module of this Course on Bioethics! By the end of this session you will be able to:

- Describe why medical confidentiality and protection of health related data are important;
- List key principles of data protection law applied to the biomedical field;
- Differentiate situations where confidentiality is interfered with and assess the compliance of such situations with legal obligations;
- Illustrate the boundaries within which processing of medical data is allowed.



Click next
to continue



Transplantation of human organs and tissues

Definitions

Review some of the main definitions relating to this topic below.

Review and then click 'Next' to continue.

Transplantation

Donor

Recipient

Transplantation: the complete process of removal of an organ or tissue from one person and implantation of that organ or tissue into another person, including all procedures for preparation, preservation and storage.

Case law of the ECtHR

Generally speaking, the deceased's family or close relatives are informed of or involved in the decision. The requirement here is connected with the need for respect for private and family life. This matter has been the subject of several decisions of the European Court of Human Rights. You can explore two key examples by selecting the headers below.

Petrova v. Latvia **Elberte v. Latvia** **More information**



Legal Framework

The regulatory framework for health related data processing is composed by legal instruments developed by the CoE and the EU.

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

EUROPEAN UNION


World Health Organization


ECHR **Directives** **Guiding Principles**

Oviedo Convention

Anti-trafficking Convention


Non Binding Principles



Genetic testing

Genetic tests: different types

Genetic tests are of different types, and they are aimed at different purposes. Click on the buttons to explore the differences between them.



- Diagnostic genetic tests**
Diagnostic genetic tests are intended to diagnose a genetic disorder in a person who already has symptoms.
The results of this test may help to make choices about how to treat or manage health problems. They may also help solve the problem of diagnostic uncertainty, enabling individuals at least to know from what disorder they are suffering.
- Predictive genetic tests**
- Carrier Tests**
- Pharmacogenomic tests**

Genetic tests and personal data



Mark Bale, former Chair of the Council of Europe Committee on Bioethics, talks about the [Recommendation CM/Rec\(2016\)02](#) of the Committee of Ministers on the processing of personal health-related data for insurance purposes, including data resulting from genetic tests.

Learning Objectives

Welcome to the third substantive module of this course on Bioethics! By the end of this session you will be able to:

- list the different types of genetic tests;
- identify the general principles and human rights obligations applicable to genetic testing;
- appraise the judicial interpretation of such obligations by the ECtHR;
- apply the rules connected to the detention and processing of genetic samples and data, including for insurance purposes, in your daily work.



Click next to continue



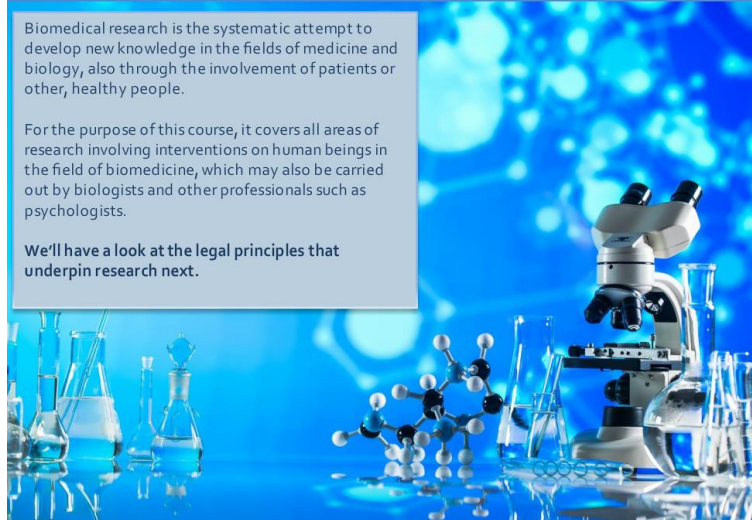
Biomedical research

What is biomedical research?

Biomedical research is the systematic attempt to develop new knowledge in the fields of medicine and biology, also through the involvement of patients or other, healthy people.

For the purpose of this course, it covers all areas of research involving interventions on human beings in the field of biomedicine, which may also be carried out by biologists and other professionals such as psychologists.

We'll have a look at the legal principles that underpin research next.



Biomedical research: legal principles

Legal principles affirm the need to respect and protect human dignity and the principle of primacy of the human being (if you do not remember what these principles are about, you can review them in the **Module 1 - Introduction**.)

In accordance with these aims, even if the freedom of research is of utmost importance, the interests and welfare of the human being participating in research must always prevail over the sole interest of science and society.

Have a look at the principles by selecting the arrow and then click 'Next' to continue.

More

These principles require that:

- biomedical research shall never be carried out contrary to human dignity;
- the protection of the human being must always be of paramount concern;
- where there is a conflict, the interests and welfare of the people participating in research prevail over the interest of society or science;
- every person has a right to accept or refuse to participate in biomedical research and no one shall be forced to do it; and
- particular protection shall be given to human beings vulnerable in the context of biomedical research.

Consent: specific situations

The Protocol also addresses the issues arising from biomedical research in specific situations. If you want to explore these rules, click on the buttons below.

Click 'Next' to continue



Protection of the Embryo and Procreation

Beginning of life and beginning of rights

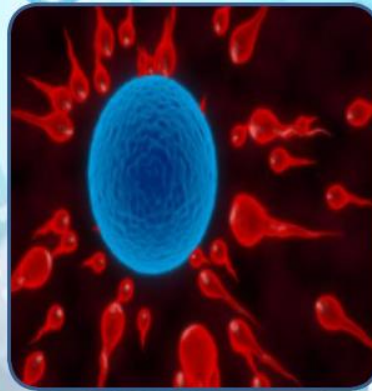
In the case of [Vo v. France](#) mentioned above, the ECtHR considered that it was “neither desirable, nor even possible as matters stand, to answer in the abstract the question whether the purposes of Article 2 of the Convention justify the interference (in the text).”

In its subsequent case-law, the Court has held that, although the ECtHR does not determine whether the right to life, the ECtHR affirms a certain degree of respect which would be required.

Thus in a judgment of 2015, in which the Court held that the prohibition to donate her embryos for research was property protected by Article 1 of the Convention, the ECtHR stated that “human embryos are to be regarded as ‘possessions’ within the meaning of Article 1 of the Convention.”

In the same case, the ECtHR acknowledged that “the ‘protection of the embryo’s potential for life’ may be linked to the aim of protecting morals and the rights and freedoms of others” and can thus justify a prohibition on donating human embryos for research.

Click 'Next' to continue.



Medically Assisted Procreation



Pre-Natal Diagnosis



Surrogacy

End of life



Legal instruments

Even if end-of-life situations are not expressly regulated in international legal instruments, a number of principles and norms are relevant in those cases

Binding Instruments

European Convention on Human Rights

Oviedo Convention

Non-binding Instruments

Recommendations of the Committee of Ministers of the Council of Europe

End of life: Introduction

Progress in the health field and advances in medicine – particularly developments in medical technology – enable life to be prolonged and increase prospects of survival. By turning what used to be regarded as acute or rapid progression illnesses into chronic or slow progression illnesses, they give rise to complex situations and are unquestionably rekindling the debate on the end of life and the framework in which decisions are taken on medical treatment in end-of-life situations. Click 'Next' to continue.

Next steps

- 2018 :
 - Free availability as an online-learning tool on the HELP platform <http://help.elearning.ext.coe.int/>
 - Launching in Belarus (Belarus Action Plan)

- Expression of interest by national institutions: Russian authorities, Armenia, Moldova, Romania, Italy, ...
 - Budget: voluntary contribution, including in kind

- Contact with training institutions in the health field

- Future: Development of course on specific topics



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