

# “The Development of International Biolaw by the Council of Europe: an initial approach”



UNIVERSIDAD  
DE MÁLAGA

María Isabel Torres Cazorla (mtorres@uma.es)



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- ▶ The labour of the Council of Europe on Biomedicine: the Oviedo Convention and Additional Protocols
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# The labour of the Council of Europe on Biomedicine

- ▶ First step: the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine
- ▶ Known as Oviedo Convention or Convention on Human Rights and Biomedicine (1997, opening for signature; 1999: entry into force)

<https://www.coe.int/en/web/bioethics/home>



# Some preliminary concepts to be defined

- ▶ Biomedicine: **Biomedicine** is a branch of medical science that applies biological and physiological principles to clinical practice. Biomedicine also can relate to many other categories in health and biological related fields. It has been the dominant health system for more than a century.
- ▶ It includes many **biomedical** disciplines and areas of specialty that typically contain the "bio" prefix such as molecular biology, biochemistry, biotechnology, cell biology, embryology, nanobiotechnology, biological engineering, laboratory medical biology, cytogenetics, genetics, gene therapy, bioinformatics, biostatistics, systems biology, neuroscience, microbiology, virology, immunology, parasitology, physiology, pathology, anatomy, toxicology, and many others that generally concern life sciences as applied to medicine.



# Some preliminary concepts to be defined

- Bioethics: **Bioethics** is the study of the [ethical issues](#) emerging from advances in [biology](#) and [medicine](#). It is also moral discernment as it relates to medical policy and practice. Bioethics are concerned with the ethical questions that arise in the relationships among [life sciences](#), [biotechnology](#), [medicine](#) and [medical ethics](#), [politics](#), [law](#), and [philosophy](#).
- Biolaw: **Biolaw** is a branch of law, emerged as a consequence of the advance of life sciences, medicine and biotechnology. The traditional basis of law (at the municipal and international spheres) must be reconsidered, taking into account the field of human rights, ethics (body and human dignity), environmental questions, health issues, medical sciences and surrounded areas. [Article on Biolaw](#)



## **COMMON ASPECTS TO BE CONSIDERED (BIOMEDICINE, BIOETHICS AND BIOLAW)**

- Multidisciplinary approach
- Pluralist study of sciences of life (bio) and technologies, related to human beings
- Changing nature
- Human rights, dignity, biology, medicine, health, ethics and law are intertwined

# A group of international instruments...

Number	Title	Opening of the Treaty	Entry into force
164	<a href="#"><u>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</u></a>	04/04/1997	01/12/1999
168	<a href="#"><u>Additional Protocol to the Convention, on the Prohibition of Cloning Human Beings</u></a>	12/01/1998	01/03/2001
186	<a href="#"><u>Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin</u></a>	24/01/2002	01/05/2006
195	<a href="#"><u>Additional Protocol, concerning Biomedical Research</u></a>	25/01/2005	01/09/2007
203	<a href="#"><u>Additional Protocol concerning Genetic Testing for Health Purposes</u></a>	27/11/2008	01/07/2018

# The Oviedo Convention: two official languages (English and French)

Together with unofficial translations:

Czech – Dutch – Estonian – Finnish – Georgian – German – Hungarian – Icelandic – Italian – Latvian – Lithuanian – Polish – Romanian – Russian and Explanatory Report – Slovak – Slovenian – Spanish and Corrective – Ukrainian



# With great impact in the field of Human Rights

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?

- 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?



# First step: the Oviedo Convention in a few words

- ▶ The first legally-binding international text designed to preserve human dignity, rights and freedoms, through a series of principles and prohibitions against the misuse of biological and medical advances.
- ▶ Starting point: the interests of human beings must come before the interests of science and society.
- ▶ The Convention recognises the importance of promoting a public debate and consultation on these questions.
- ▶ The only restrictions are those prescribed by law and which are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.
- ▶ Additional Protocols are foreseen to clarify, strengthen and supplement the overall Convention.
- ▶ The Steering Committee on Bioethics (CDBI), or any other committee designated by the Committee of Ministers of the Parties may request the ECHR to give advisory opinions on legal questions concerning the interpretation of the Convention.



# State Parties to the Convention

- ▶ On 2017 celebrated the 20th Anniversary.
- ▶ States Parties: [Full-list](#)
- ▶ Some significant absences: Austria, Belgium, Germany, Ireland, Italy, Liechtenstein, Luxembourg, Malta, Monaco, Netherlands, Poland, the Russian Federation, Sweden, Ukraine or the United Kingdom.
- ▶ Followed by some reservations and declarations: [See](#) (most of them referred to article 20, par.2, sub-paragraph ii, concerning the removal of regenerative tissue and the limitations of the Convention to certain categories of relatives).



# Main goals of the Oviedo Convention

- ▶ Primacy of the human being (prevailing over the sole interest of society or science).
- ▶ Free and informed consent (to carry out an intervention in the health field).
  - ▶ Appropriate information as to the purpose and nature of the intervention, its consequences and risks.
  - ▶ The person concerned may freely withdraw consent at any time.
  - ▶ Arts. 6 and 7 deals with the protection of persons not able to consent and protection of persons who have a mental disorder. Emergency situations (art. 8) and previously expressed wishes shall be taken into account (art. 9).




# Main goals of the Oviedo Convention (II)

- ▶ Private life and right to information (art. 10), including the right to be/not to be informed.
- ▶ The human genome issues (non-discrimination, predictive genetic tests, intervention on the human genome, and non-selection of sex).
- ▶ And scientific research together with protection of persons undergoing research, and research on embryos in vitro.
- ▶ Organ and tissue removal from living donors for transplantation purposes and, in particular, protection of persons not able to consent to organ removal (RESERVATIONS TO ART. 20, par.2, ii).
- ▶ The prohibition of financial gain and disposal of a part of the human body are aspects to be considered.



# An open and unfinished text...

- ▶ Open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration and by the EU (European Community when the Oviedo Convention was adopted). [Council of Europe member States](#)
- ▶ After the entry into force, there is a possibility to invite any non-member State of the Council of Europe to accede to this Convention (art. 34).



# Followed by some Additional Protocols..

- 1. On the Prohibition of Cloning Human Beings (Paris, 12/01/1998, entered into force the 01/03/2001).[See](#)
- The first legal instrument developed in this area. [State parties](#)
- The cloning of human beings may become a technical possibility.
- A question to be answered: what is a human being? Example: the declaration from the Netherlands (at the time of signature). A human being is a human individual (who has been born).
- The Protocol explicitly restricts genetic identity to sharing the same nuclear gene set, meaning that any intervention by embryo splitting or nuclear transfer techniques seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.



# Followed by some Additional Protocols (II)

- ▶ 2. Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin. [See](#)
- ▶ Adopted in Strasbourg the 24 of January 2002. Entered into force the 1 of May 2006. In Spain the 1st April 2015 (ratified in 2014). [State Parties](#)
- ▶ It contains specific provisions regarding the transplantation of organs and tissues (including cells) of human origin for therapeutic purposes, and the promotion of donation of organs and tissues
- ▶ It includes equitable access to transplantation services for patients, transparent rules for organ allocation, health and safety standards, the prohibition of financial gain by donors, and the need for donors, recipients, health professionals and the public to be properly informed.
- ▶ Some additional aspects: tissues shall be allocated only among patients on an official waiting list (transparency principle) and traceability of organs and tissues must be ensured.





# Followed by Additional Protocols (III)

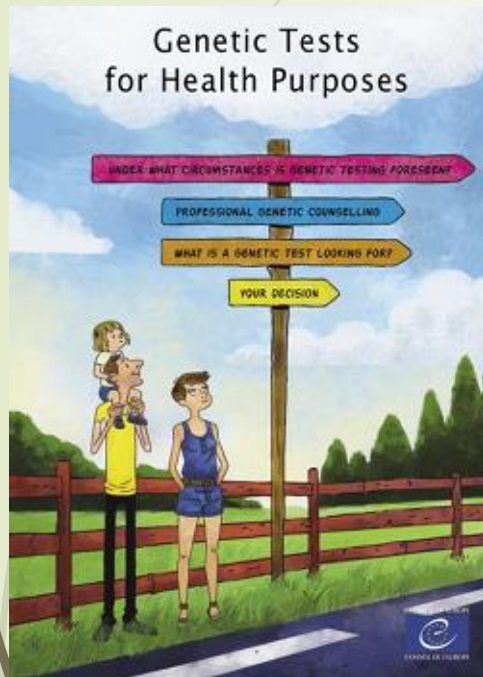
- ▶ 3. Additional Protocol concerning Biomedical Research. [See](#)
- ▶ Strasbourg, 25 of January 2005, entered into force the 1st September 2007. [State Parties](#)
- ▶ Define and safeguard fundamental rights in biomedical research, in particular of those participating in research.
- ▶ Fundamental principle for research involving human beings: free, informed, express, specific and documented consent of the person(s) participating.



# Followed by Additional Protocols (IV)

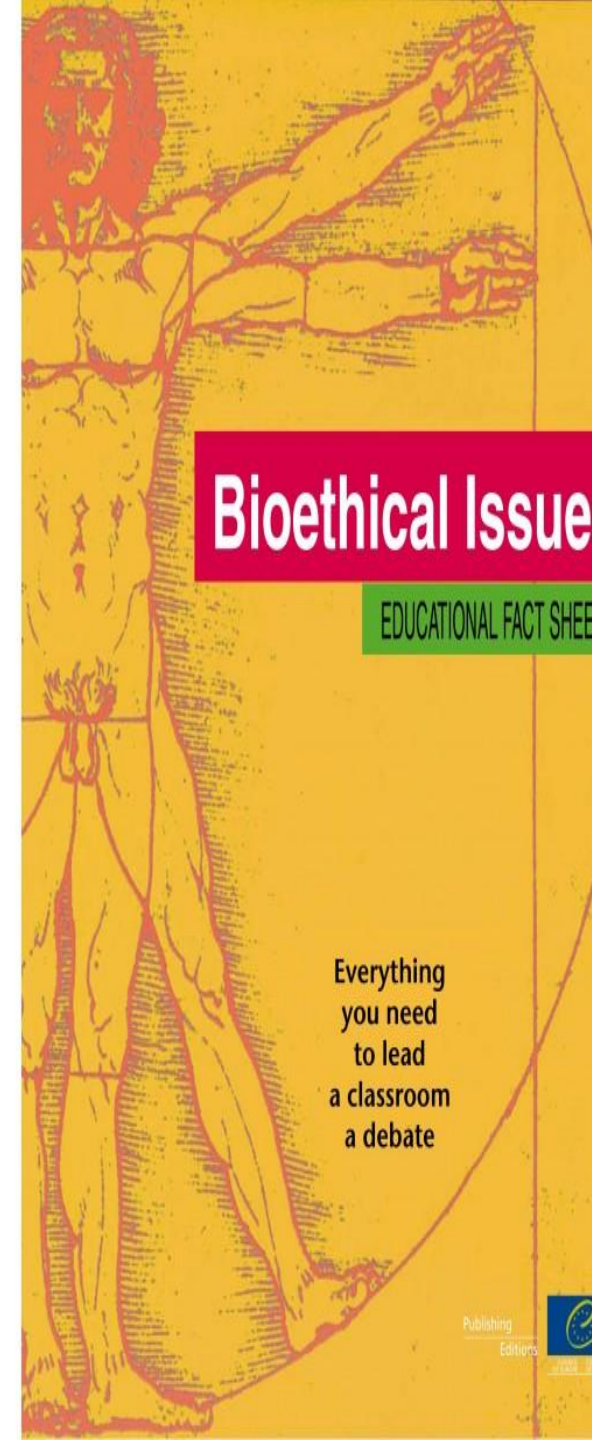
- Concerning Genetic Testing for Health Purposes. [See](#)
- Strasbourg, 27 November 2011, entered into force the 1st July 2018. [State Parties](#)
- Genetic tests (general rules to conduct them), directly accessible genetic tests for which a commercial offer could develop in future.
- Protection of private life and right to be/not to be informed must be preserved.

# Useful materials...



<https://www.coe.int/en/web/bioethics/information-brochure-on-genetic-tests-for-health-purposes>

<https://edoc.coe.int/en/educational-tools/5506-bioethical-issues-educational-fact-sheets-pdf-2009-.html>

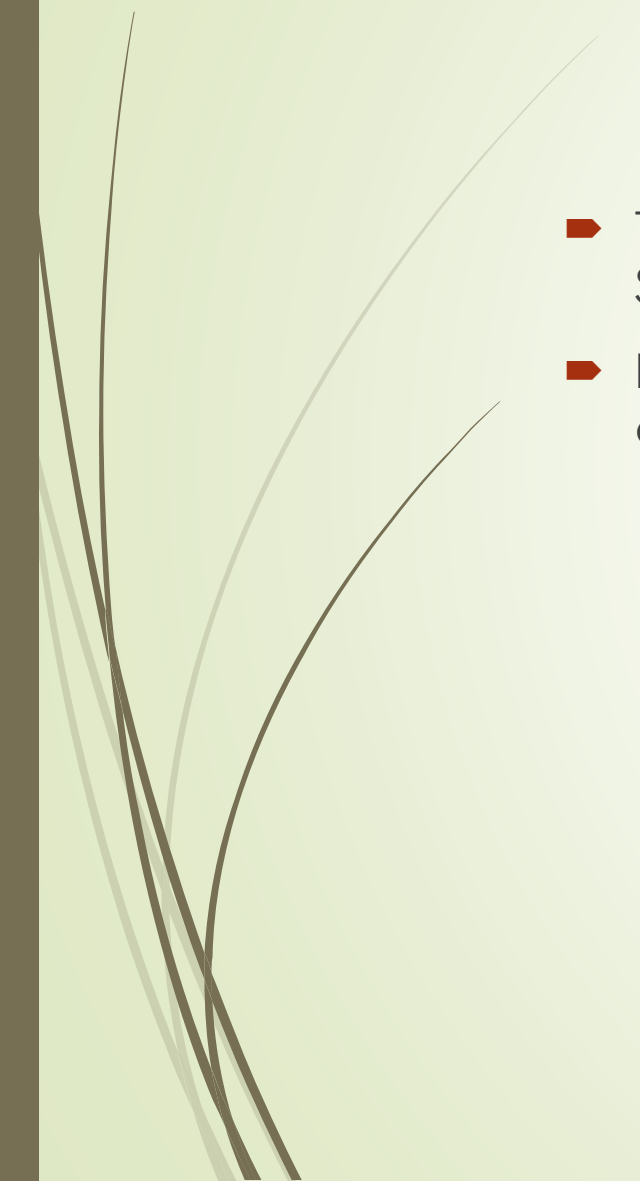




The “right not to be informed” in the  
Biomedicine Convention and the Additional  
Protocols: *Some initial remarks*

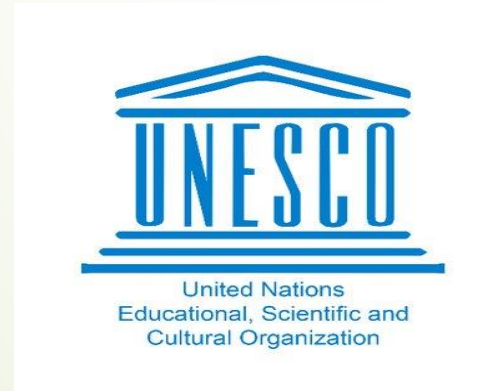



# A key point...

- ▶ The relationship between ethics, science and freedom (new frontiers of the Science, new dimensions for human rights)
  - ▶ International instruments: declaratory instruments and international conventions (in the sphere of the Council of Europe).
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# From the *Aristotelic* view to biomedicine recent contributions...

- ▶ The right not to know, and the need to take into account this idea: contributions of the Council of Europe, the UNESCO, the WHO and the European Union...






To begin with it...as a departure point, Recommendation R (90) 3 of the Committee of Ministers of the Council of Europe 1990:

Principle 3


- ▶ 1. No medical research may be carried out without the informed, free, express and specific consent of the person undergoing it. Such consent may be freely withdrawn at any phase of the research and the person undergoing the research should be informed, before being included in it, of his right to withdraw his consent.
- ▶ 2. *The person who is to undergo medical research should be given information on the purpose of the research and the methodology of the experimentation. He should also be informed of the foreseeable risks and inconveniences to him of the proposed research. This information should be sufficiently clear and suitably adapted to enable consent to be given or refused in full knowledge of the relevant facts. (Emphasis added)*
- ▶ 3. The provisions of this principle should apply also to a legal representative and to a legally incapacitated person having the capacity of understanding, in the situations described in Principles 4 and 5.



# Followed by different declarations at the international sphere...

- ▶ Art. 5 c) of the UNESCO Universal Declaration on the Human Genome and Human Rights (1997) ([Text](#))
- ▶ Art. 10 of the UNESCO International Declaration on Human Genetic Data (2003) ([Text](#))
- ▶ Together with the work of the World Medical Association (Declaration of Lisbon on the Rights of the Patient) and the WHO






# The “real right”: full, understandable information. What does it mean?

- ▶ Art. 5 of the Biomedicine Convention and art. 8 of the Additional Protocol concerning Genetic Testing for Health Purposes:
  - ▶ “When a genetic test is envisaged, *the person concerned shall be provided with prior appropriate information in particular on the purpose and the nature of the test, as well as the implications of its results*” (emphasis added).



# Art. 5 of the Biomedicine Convention

- ▶ “(...)an intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.
- ▶ This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.
- ▶ The person concerned may freely withdraw consent at any time”.



# Relevant step: art. 10 of the Oviedo Convention...


➤ **Article 10 –Private life and right to information**

1. *Everyone has the right to respect for private life in relation to information about his or her health.*

**2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.**


3. *In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.*

«la volontà di una persona di non essere informata deve essere rispettata»; «droit de ne pas savoir» «right not to know»



# ...that is strongly emerging in the field of biomedical research and genetics

- ▶ In particular, being included in the Additional Protocol concerning Genetic Testing for Health Purposes, of 27 November 2008 (art. 16).
- ▶ Or in art. 27 (Duty of care) of the Additional Protocol concerning Biomedical Research, of 25 January 2005. (In communication of such information, due care must be taken in order to protect confidentiality and to respect any wish of the participant not to receive such information).



# Article 16 of the Protocol on Genetic Testing

- ▶ **Article 16 – Respect for private life and right to information**

*1. Everyone has the right to respect for his or her private life, in particular to protection of his or her personal data derived from a genetic test.*

*2. Everyone undergoing a genetic test is entitled to know any information collected about his or her health derived from this test.*

*The conclusions drawn from the test shall be accessible to the person concerned in a comprehensible form.*

**3. The wish of a person not to be informed shall be respected.**

*4. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraphs 2 and 3 above in the interests of the person concerned.*



# A right connected with the right to be informed and submitted to limitations

- ▶ Limited by the “health of the patient, of third persons, the collectivity and the therapeutic needs of the case”
- ▶ *The delegation to the respective internal laws of the exercise and limitations of this right.*



# A relevant limit...


- ▶ ...the right not to be informed is not presumed: it must be “activated” in an explicit way by the person who tries to exercise it. Is this more a “right” *stricto sensu*, or just a possibility connected with free autonomy?



# Development of this “right” by municipal law in Spain


- Firstly, in general acts, being applied in the State as a whole:
  - Basic Act 41/2002, of 14 November, on free autonomy of the patient and rights and duties concerning information and clinic documentation (art. 9).[Text](#)
  - Act 14/2007, of 3 July on Biomedical Research (art. 4.5 *in fine* and art. 49.2).[Text](#)





# Basic Act on free autonomy of the patient, art. 5.4 (therapeutic needs)


- ▶ “The right to sanitary information of the patients may be limited by the **accredited existence of a situation of therapeutic needs**. A therapeutic need will be understood as the **possibility of the doctor to act in a professional way without giving the information to the patient, in case of, due to objective reasons, the knowledge of his own situation could produce a serious prejudice to his health**. If it is the case, the doctor will explain in a reasoned and formal way of the clinic history circumstances and **will communicate his decision to the persons connected with the patient by familiar or factual reasons**”.



# Basic Act on free autonomy of the patient, art. 9.1 (limits)

➤ This provision says:


➤ “The waiver of the patient to receive information is **limited by the health of the patient, of third persons, the collective and the therapeutic needs of the case**. When the patient will express his **desire not to be informed**, his wish will be respected, and it **must be expressed in a documentary way**, without prejudice of the need to obtain his consent before the intervention.”



# Spanish Act 14/2007, of 3 July on Biomedical Research

➤ Art. 49.2:

- “When the person concerned have exercised the right not to be informed of the results of a genetic analysis, he will receive just the necessary information in order to follow the doctor’s prescription and accepted by the patient. When this information is necessary to avoid a relevant prejudice for the health of biological relatives, the affected persons or legal authorized representatives could be informed. Anyway, the communication will be exclusively limited to the necessary data to obtain the mentioned result”.

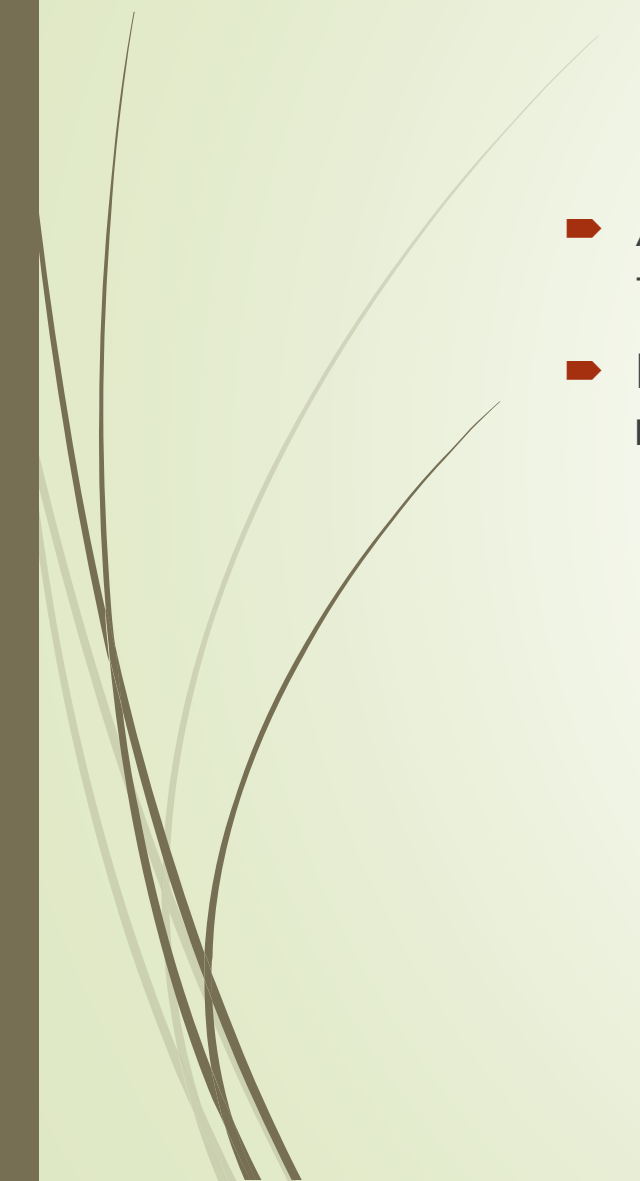


This is the general view, completed by a great number of municipal laws of the Autonomous Communities, dealing with rights and duties of the health system users

- ▶ Act 21/2000, of 29 December, on rights of information on the health and the autonomy of the patient and clinic documentation, of the Autonomous Community of Catalonia, as amended by Act 16/2010, of 3 June.[Text](#)
- ▶ Act 11/2007, of 26 November, on the Genetic Council, protection of rights of persons submitted to genetic tests and human DNA Banks of Andalusia.[Text](#)




# Together with...

- ▶ Act 3/2009, of 11 May, on rights and duties of users of the health system of the Autonomous Community of Murcia.
  - ▶ Foral Act 17/2010, of 8 November, of the Foral Community of Navarra on rights and duties of persons dealing with health matters.
- 



# With recent rules on rights and guarantees of person's dignity in death throes

- ▶ Merely as examples of some laws adopted on this field: Act 2/2010, of 8 April, of the Autonomous Community of Andalusia (BOE n. 127, 25 May 2010), the Foral Act 8/2011, of 24 March of the Foral Community of Navarra (BOE n. 99, of 26 April 2011), or the Act 10/2011, of 24 March, of the Autonomous Community of Aragón (BOE n. 115, of 14 May 2011).



# And opening the door to initial conclusions...


- The discussion between the “right not to be informed”: an open question.
- This new debate try to have an answer in the most recent municipal legislation in Spain, following the international standards.
- An open question, because not all the Autonomous Communities have developed this topic.



# Related Instruments of the Council of Europe under review


- ▶ Rec (2016) 8 on the processing of personal health-related data for insurance purpose, including data resulting from genetic tests
- ▶ Rec (2016) 6 on Research on Biological Materials of Human Origin
- ▶ Rec (2004) 10 concerning the Protection of the Human Rights and Dignity of Persons with Mental Disorder
- ▶ Rec (2003) 10 on Xenotransplantation





## When Science, Human Rights and Law are intertwined...

- Surrogacy,
- assisted reproductive techniques,
- the end of life issues,
- genetic engineering,
- the use of vaccines,
- organ trafficking,
- pandemics,
- new diseases,
- new medical treatments (...)



## Together with Legal challenges and new technologies

- Big data
- the development of artificial intelligence in unexplored areas,
- robotics development, ...
- We have more questions than answers

[https://www.coe.int/fr/web/portal/videosroom/-/asset\\_publisher/1TjV7lheskiu/content/bioethics?\\_101\\_INSTANCE\\_1TjV7lheskiu\\_languageId=en\\_GB](https://www.coe.int/fr/web/portal/videosroom/-/asset_publisher/1TjV7lheskiu/content/bioethics?_101_INSTANCE_1TjV7lheskiu_languageId=en_GB)



# Tentative conclusions: a long way to go...

- ▶ Opinion of the Judge Marcus-Helmons (Cyprus v. Turkey case, 10 May 2001, application 25781/94):
  - ▶ “With the rapid evolution of biomedical techniques, new threats to human dignity may arise. The Convention on Human Rights and Biomedicine, signed at Oviedo in 1997, seeks to cover some of those dangers. However, to date only a limited number of States have signed it. Moreover, this Convention only affords the European Court of Human Rights consultative jurisdiction. In order this “fourth generation rights” to be taken into account so that human dignity is protected against possible abuse by scientific progress, the Court could issue a reminder that under Article 2 of the European Convention on Human Rights the States undertook to protect everyone’s right to life by law”.



*"Science without conscience is but the ruin of the soul"*  
Rabelais