



# Role of the Council of Europe

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## The Oviedo Convention

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<http://www.coe.int/bioethics>

# Council of Europe



- Intergovernmental organisation established in 1949
- **47 European member states,**
- Observers: Canada, Holy See, Japan, Mexico, USA
- Role: strengthening **human rights**, democracy and the rule of law
  - European Court of Human Rights
- Means: standards setting, monitoring, cooperation activities



# Council of Europe and Bioethics

- Objective of the activities of the Council of Europe in bioethics:
  - *Protecting human rights in the field of biology and medicine*
  - *Promoting thereby scientific and technical developments for the benefit of present and future generation*

# Medically Assisted Procreation (MAP)

- ❑ Sensitive and complex issues
- ❑ Divergence of views among member states
  - Status of the embryo
- CoE Parliamentary Assembly (starting in the 80's): concern for use of embryo and foetus, abortion, prenatal sex selection
- Ad Hoc Committee of experts on progress in biomedical sciences:
  - 1989: Report on human artificial procreation – 15 principles
- Committee on Bioethics (DH-BIO)
  - 2003: Report on the protection of the embryo in vitro
- European Committee on transplantation of organs (CD-P-TO)
  - 2017: 3rd Edition Guide to the quality and safety of tissues and cells for human application - Includes reproductive tissues and cells (ESHRE contribution)



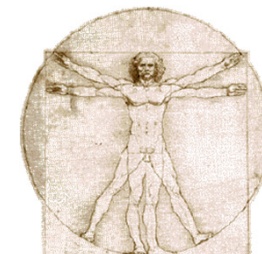
# Medically Assisted Procreation (MAP)

- Questionnaires/Studies
  - 1998: Comparative study among member states
  - 2004: Access to MAP (updated in 2017)
  - 2015: Background document on preimplantation and prenatal genetic diagnostic (clinical and legal situation)
- Legal instruments
  - Non legally binding
    - Recommendation (90)13 on prenatal genetic screening, prenatal genetic diagnostic and associated genetic counselling
  - Legally binding
    - **Convention on Human Rights and Biomedicine**  
(Oviedo Convention, ETS No164, 1997)

# Oviedo Convention

- **Convention on Human Rights and Biomedicine** (Oviedo Convention, ETS n°164, 1997)
  - Principles applicable to **any medical act**
  - Principles applicable to « **new** » **biomedical technologies** (transplantation, biomedical research and **genetics**)
- **Framework convention** further developed in **Additional Protocols** on
  - prohibition of **cloning** human beings (ETS n°168, 1998)
  - transplantation of organs and tissues of human origin (ETS n°186, 2002)
  - biomedical research (ETS n° 195, 2005)
  - genetic testing for health purposes (ETS n° 203, 2008)

Impact: **National, European (ECHR, EU) and Global**



# Oviedo Convention

- Common framework for the protection of human rights and dignity in **both longstanding and developing areas** concerning the application of biology and medicine.
- Acknowledged need to take into account rapid developments in medicine and biology
  - **Regular re-examination** of the provisions of the Convention **in the light of new scientific developments** (Art. 32)  
*Re-examination in 2004: No development justifying reconsideration of the provisions*

# Intergovernmental Committee

- **Committee on Bioethics (DH-BIO)** (Art. 32)
  - Representatives of the 47 Members States
  - Non member states: Australia, Canada, Holy See, Israel, Japan, Mexico, USA
  - Other intergovernmental committees dealing with: e.g. data protection, organ transplantation, blood transfusion, rights of persons with disabilities, children rights
  - CoE bodies: PACE, Conference of INGOs, CoE Commissioner for Human Rights
  - Intergovernmental organisations: EU, WHO, UNESCO, OECD
- **Responsibilities**
  - To re-examine the Convention in the light of scientific developments – To propose amendment and additional protocol
  - **To assess ethical and legal challenges** raised by developments in the biomedical field and address them, where appropriate



# Oviedo Convention and MAP

- Article 14 – Non selection of sex
  - Prohibition to use **MAP** to select the sex of an embryo, except to avoid serious hereditary sex-related disease
- *General provisions*
  - Article 2 – Primacy of the human being
  - Article 3 - Equitable access to health care : Obligation to take measures to that effect
  - Article 5 – General rule: Free and informed consent
  - Article 10 – Private life and right to information
    - Respect for private life in relation to health-related information
    - Right to know any information collected about his/her health
  - Article 11 – non discrimination on grounds of genetic heritage
  - Article 21 - Prohibition of financial gain
    - The body and its parts, as such, not to give rise to financial gain
- Article 28- Public debate

# Oviedo Convention and MAP

- *Specific provisions*
  - Article 18 – Research on embryo in vitro
    - Where allowed by law, to provide adequate protection
    - Prohibition of creation of embryo for research purposes
  - Article 13 – Intervention on the human genome

« *An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.* »

    - limitation of purposes: clinic and research
    - prohibition of modification of gametes/embryo for procreation



# Genome Editing Technologies

- **December 2015: DH-BIO statement on genome editing technologies**
  - Considerable potential for research for the benefit of human health and strong support for the better understanding of the causes of diseases and for future treatmentbut also,...
  - safety issues and possible misuse and abuses, particularly for any modification of the human genome which could be passed on to future generations
  - Oviedo Convention: Expectations and concerns remains very relevant;
  - Oviedo Convention laid down reference principles;
  - DH-BIO, as part of its mandate, to examine ethical and legal challenges raised by these technologies
- **2017 : Recommendation 2115(2017) of the PACE - “The use of new genetic technologies in human beings”**
  - Committee of Ministers : welcome PACE text and support work of the DH-BIO<sub>11</sub>

# 20<sup>th</sup> anniversary of the Oviedo Convention

- **International conference:** “Oviedo Convention: relevance and challenges”  
(24-25 October 2017)

<https://www.coe.int/fr/web/bioethics/20th-anniversary-of-the-oviedo-convention>

- **Prospective approach**
  - **assessment of relevance** of existing legal principles with regard to developments in the biomedical field **and possible challenges**;
  - basis for a **Strategic Action Plan**: framework for the Council of Europe’s action to address the human rights issues identified – to be developed in 2018-2019

# Role of the Council of Europe

- **Reference** international **legal framework**
  - Oviedo Convention and related instruments
  - Art.32: regular re-examination
- Well established **cooperation** with the different fields and stakeholders concerned
- Development of **relevant instruments to address them**:  
guidelines, implementation tools, information leaflet ...
- **Unique international forum** to discuss ethical and legal issues raised by developments in biomedical field, exchange of good practices
- **Relevant thematic work** already undertaken at intergovernmental level

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