

Council of Europe



- Intergovernmental organisation established in 1949
- 46 member states
- Observers: Canada, Holy See, Japan, Mexico, USA, (*Israel, Australia*)
- Based in Strasbourg, France
- Role: **strengthening human rights, democracy and the rule of law**
- Means: standards setting, monitoring, cooperation activities



Convention on Human Rights and Biomedicine (Oviedo Convention)

- **Only international legally binding instrument** in this field
 - Ethical and legal principles applicable to any medical act: « Patients rights treaty »
 - Principles applicable to new biomedical technologies: transplantation, research, **genetics**
- Close **link** with the **European Convention on Human Rights**
 - European Court of Human Rights: reference instrument
 - EU: European Charter of Fundamental Rights
 - UN instruments

Oviedo Convention

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

- Concern about **misuse and abuse**, in particular intentional modification of human genome to produce individuals or entire groups endowed with particular characteristics and required qualities (e.g. enhancement,...)
 - Limitation to medical purposes
- Concern about **safety**: owing to the unknown risks inherent to the introduction of modification in the genome that would be passed on to descendants
 - Prohibition of interventions aiming to deliberately introduce modification in the genome that can be passed on to descendants

November 2018 Statement : “Ethics and Human Rights must guide any use of genome editing technologies in human beings” (DH-BIO intergovernmental committee)



“.....The Convention on Human Rights and Biomedicine (“[the Oviedo Convention](#)”, 1997) - the only international legally binding instrument addressing human rights in the biomedical field - provides a unique reference framework to that end”

*.....There is **strong support** for the **better understanding** of the causes of **diseases** and their future **treatment** and these technologies have considerable **potential for research** in this field and to improve human health.*

However, the application of genome editing technologies to human gametes or embryos raises many ethical, social and safety issues, particularly from any modification of the human genome which could be passed on to future generations.

Re-Examination of Article 13 by the intergovernmental committee responsible under the Oviedo Convention

- Analysis of technical and scientific aspects of developments
- Examination of their ethical and human rights implications
- June 2021 conclusions:
 - remaining relevance of the underlying principles and provisions of Article 13
 - **need for clarifications**, in particular on the terms “preventive, diagnostic and therapeutic” and to avoid misinterpretation of the applicability of this provision to “research”

Clarifications - “Preventive, diagnostic and therapeutic purposes”

Intervention seeking to modify the human genome only permissible for medical purposes



- **Preventive** purpose: aim at avoiding the occurrence of a disease or disorder defined in accordance with internationally accepted medical standards.



- **Diagnostic** purpose: undertaken to identify a disease or disorder, or a genetic variant or factor associated with the development of a disease or disorder as defined.



- **Therapeutic** purpose: aim at controlling symptoms of a disease or disorder, slowing or reversing its progression, or providing a cure, for example by removing its underlying cause.



Clarifications - Research

- Article 13 also **applies to** any intervention seeking to modify the human genome in **research**
- **Purposes limitation** i.e. "preventive, diagnostic, therapeutic", also applies in research
- Interventions seeking to modify the human genome for the **acquisition of knowledge** relevant to the permitted purposes may be carried out
- Intervention on individuals or cells then introduced into an individual: to respect **protection standards for research participants**

Clarifications added value

- increased understanding of the relevance of the provisions of Article 13
- greater certainty to researchers working with human cells
- ensure that new treatments can be developed within clear ethical limits
- put down a clear marker in the renewed international debate about heritable genome editing – societal debate

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