

European Regulation of Embryo Research

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Introduction

Embryos through the lens of European law

Instruments from the Council of Europe (CoE) and from the European Union (EU)
(hard law and soft law)

I – Types of embryos

II – Types of research

III – Funding and patentability of embryo research

IV – Cross-border movements of embryos for research purposes

No integrated approach but a diffracted approach resulting from specific interventions by different European actors



Introduction

Council of Europe (CoE) (47 Member States)



Convention on Human Rights and Biomedicine (1997) signed and ratified by some of the 47 Member States

Resolutions and recommendations by the **Parliamentary Assembly of the Council of Europe (PACE)**

Decisions made by the **European Court of Human Rights (ECtHR)** on the basis of the provisions of the European Convention on Human Rights (ECHR) signed and ratified by all the 47 Member States

Introduction

European Union (EU) (28 Member States)



European Treaties (freedom of circulation and support to research)

EU Charter of fundamental rights (protection of human dignity)

Directives and regulations on funding and patentability of research

Directives and regulations on quality and security of human tissues and cells

Decisions made by the **General Court of the European Union (GCUE)** or the **Court of Justice of the European Union (CJUE)**

I – Types of embryos

Creation of embryos for research purposes

Oviedo Convention (art. 18)
(Explicit) prohibition of the creation of embryos for research purposes

Non-signature/ratification by several CoE Member States

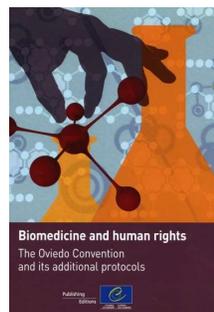
Among these, various States which allow the creation of embryos for research purposes (Belgium, UK, Russia, Sweden)

Resolution 1352(2003) of the PACE

Resolution 1934(2013) of the PACE

Recommendation 2115(2017) of the PACE

The CoE keep asking to sign and ratify the Convention and to make the prohibition effective



I – Types of embryos

Donation of supernumerary embryos

Oviedo Convention (art. 18)
(Tacit) authorisation of research on supernumerary embryos

Parrillo v Italy decision of the ECtHR (2015)

The ability to make a choice regarding the fate of one's embryos relates to the right to private life (art. 8 § 1)

The protection of embryos may be linked to the aim of protecting morals and the rights and freedoms of others (art. 8 § 2)

States enjoy a wide "margin of appreciation" (MoA) as there is no European consensus

European States may exclude the possibility of donating supernumerary embryos to a research programme



174. [...] While it is of course important, **the right invoked by the applicant to donate embryos to scientific research is not one of the core rights attracting the protection of Article 8 of the Convention, as it does not concern a particularly important aspect of the applicant's existence and identity.**

175. Consequently, [...] **the respondent State should be afforded a wide margin of appreciation in the present case.**

176. Furthermore, it observes that **the question of the donation of embryos not destined for implantation clearly raises "delicate moral and ethical questions"** (see *Evans*; *S.H. and Others v. Austria*; and *Knecht*, all cited above) and that the comparative law materials available to the Court (see paragraphs 69-76 above) show that, contrary to the applicant's affirmations, **there is no European consensus on the subject** (see paragraph 137 above).

II – Types of research

Modification of the human genome

Oviedo Convention (art. 13)
Only for preventive, diagnostic or therapeutic purposes

Only if it does not introduce modifications in the genome of descendants
No interdiction in Belgium

Recommendation 2115(2017) of the PACE

Ban pregnancy with embryos having undergone genome editing
Develop a common regulatory and foster a broad and informed public debate
Article 13 could be revised (art. 32 + 28)

ESHRE supports the call for a moratorium published in 2019 in the journal Nature by a group of scientists



II – Types of research

Human embryonic stem cell (hESC) research

Oviedo Convention (art. 18)

Where the law allows research on embryos it must ensure adequate protection

Resolution 1352(2003) of the PACE

Promote stem cell research as long as it respects life in all states

Encourage techniques that are not divisive in order to use cell pluripotency

Promote research on adults stem cell

If accepted, research involving the destruction of embryos must be authorised and monitored and structures bringing together scientists and civil society must examine research projects

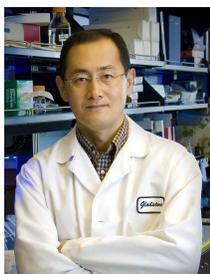


TABLE 1

Number of projects per area of research, 2007–2015.

Area of research	No. of projects	%
Embryo development and implantation	13	29
Human embryonic stem cells	11	24
Genetic abnormalities	9	20
Cryopreservation/vitrification/storage/freezing	7	16
Oocytes	5	11

Note: Nine research projects belonged to more than one area of research. Pennings. Human embryo research in Belgium. Fertil Steril 2017.

III – Funding and patentability

European funding and the « One of Us » case

Framework Programme for Research and Innovation “Horizon 2020” (Regulation 1291/2013)

Research on hESC may be financed depending on the scientific proposal and the legal framework of the Member States

Destruction of embryos cannot be funded but ulterior steps may be

One of US decision of the EU Tribunal (2018)

The European Commission has legitimately refused to follow the European Citizen’s Initiative “One of Us” and to ban the funding of hESC research

The ECJ is seized of an appeal and must now confirm that European funding can be allocated to hESC research programmes



III – Funding and patentability

Patentability and the « ISCO » case

Directive 98/44/CE on the legal protection of biotechnological inventions

Uses of human embryos for industrial or commercial purposes shall be considered unpatentable

This is so even when destruction took place much earlier

Brüstle decision of the ECJ (2011)

A parthenote is an embryo as it can trigger the development process of a human being

ISCO decision of the ECJ (2014)

A parthenote is an embryo only if it has the intrinsic capacity to develop into a human being

No patent except if the aim is therapeutic or diagnostic





28 As the Advocate General observed, in essence, in point 73 of his Opinion in the present case, that term must be understood as meaning that, **in order to be classified as a 'human embryo', a non-fertilised human ovum must necessarily have the inherent capacity of developing into a human being.**

29 Consequently, where a non-fertilised human ovum **does not fulfil that condition**, the mere fact that that organism commences a process of development is not sufficient for it to be regarded as a 'human embryo'; within the meaning and for the purposes of the application of Directive 98/44.

30 By contrast, where such an ovum **does have the inherent capacity of developing into a human being**, it should, in the light of Article 6(2)(c) of that directive, be treated in the same way as a fertilised human ovum, at all stages of its development.

IV – Cross-border movements of embryos Embryo transfer for assisted reproduction

Directive 2004/23 (« Tissue and Cell »)

Comparable level of quality and safety
Applicable to reproductive cells and adult and embryonic stem cells

Not applicable to research for purposes other than human application

Applies to ART procedures with cross-border movements of gametes and embryos

Directive 2015/565 (« Cloning »)

Directive 2015/566 (« Import »)

Member States have taken measures in line with European directives



IV – Cross-border movements of embryos Embryo transfer for research

Directive 2004/23 (« Tissue and Cell »)

Applies to clinical research involving hESC

Regulation 1394/2007 (« Advanced therapy medicinal products »)

Provides for additional requirements

Commission's response to « One of Us »

European favour for collaborative and cross-border hESC research

Creation of an European register (hPSCreg)

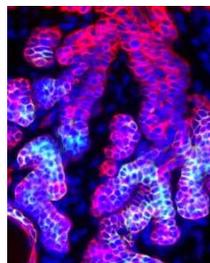
Existing lines of ESC + lines of ISC

Including non-European lines

Ethical requirements

Movements of embryos for research

purpose = regulation by national authorities ?



Conclusion



A **clear European consensus** against the creation of research embryos and germline edition ... but Belgium sees things differently

A **much more nuanced approach** of research on supernumerary embryos : no interdiction but funding, patentability and mobility easier with existing cell lines, induced stem cells or cells obtained through parthenogenesis

Strong **European preference for the development of (these) alternatives** to embryo research