

REASSESSING THE LEGAL STATUS OF THE EMBRYO IN LIGHT OF A COMBINATION OF NEW TECHNOLOGIES: A RENEWED DEBATE

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Acknowledgement: this work has been supported by the ANR-funded Organact project (ANR-22-CE41-0012) and I-BioLex project (ANR-20-CE26-0007-01).

Introduction

- Old debates about the legal status of the human embryo have been reignited with the rapid advancement of several novel reproductive and genetic technologies: the **challenge of the '14-day rule'** for embryo research; **Stem Cell-Based Embryo Models (SCBEMs)**; **In Vitro Gametogenesis (IVG)**; **aneuploidy detection**; **mitochondrial donation**; and break of the **taboo on heritable germline modification**.
- Each technology has been studied at length by the ethical literature. But their **combined effect** on the embryo's legal status remains underexplored.
- This study evaluates whether and how these innovations potentially transform the legal status of the human embryo.
- Method:** analysis of ethical and legal literature, based on an accepted literature review paper (Bottacci, Mahalatchimy, Nicolas, 2026), as well as of regional and international instruments (Oviedo Convention, Charter of Fundamental Rights of the EU, Universal Declaration on Bioethics and Human Rights etc.). The analysis was further expanded by comparative examples identified from the literature. The selected examples were then updated where necessary and explored through further research on the web and targeted literature.
- Key question:** Is there a **cumulative effect of these technologies** on the embryo's legal status? If so, how does it reshape the balance between competing interests?

Ethical issues and legal challenges associated with new research into reproductive technologies

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The '14-Day Rule' Challenge

The 14-day rule limits *in vitro* embryo culture to 14 days post-fertilisation. Recent scientific advances now make culturing beyond 14 days technically feasible, prompting calls for revision.

Ethical Issues

To extend the period of embryos culture, raise concerns about commodification and the moral status attributed to the embryo as it develops. A 28-day limit is suggested (neurulation, blood circulation, beating heart cells) but is far from consensual.

Legal Challenges

Calls from literature and international soft-law to revisit the rule. Relaxing it often conflicts with existing statutory prohibitions; any reform requires parliamentary or regulatory action.

Stem Cell-Based Embryo Models (SCBEMs)

SCBEMs are structures derived from stem cells that mimic early embryonic development without using gametes or fertilisation. They can replicate key developmental stages of a real embryo.

Ethical Issues

Blurs the line between a 'model' and a 'real' embryo, raising the question of their equivalency and moral status. Some uses are deemed unethical (transfer *in vivo*, ectogenesis...)

Legal Challenges

Legal frameworks diverge sharply: some countries (e.g. Australia, Netherlands) assimilate SCBEMs to embryos; others regulate them separately. For signatories of the Oviedo Convention, the prohibition on creating embryos for research purposes will impact this debate.

In Vitro Gametogenesis (IVG)

IVG derives functional gametes (eggs and sperm) from stem cells. It could revolutionise infertility treatment and enable genetically related children for individuals otherwise unable to produce gametes.

Ethical Issues

The instrumental production of gametes raises concerns about commodification and clinical safety. IVG enables new parental models: same-sex biological, multiplexed and solo reproduction.

Legal Challenges

Validating IVG-derived gametes requires fertilisation, which conflicts with prohibitions on creating embryos for research purposes. Regulatory frameworks vary greatly: France permits IVG research but not creation of embryos for research purposes; the UK restricts clinical use; the US applies a patchwork of States and federal rules.

Aneuploidy Detection (PGT-A)

Pre-implantation Genetic Testing for Aneuploidies (PGT-A) screens embryos fertilised *in vitro* for abnormal number of chromosomes before transfer, aiming to improve implantation success rates.

Ethical Issues

Where PGT-A is banned, aneuploid embryos can be transferred to the uterus despite low chances of success. Concerns about the selection and discard of embryos with perceived anomalies, echoing eugenics debates.

Legal Challenges

Acceptance varies widely across jurisdictions: some forbid PGT-A, others limit its use, others permit broader use or do not regulate it at all. The practice feeds into broader debates on the criteria for embryo selection and their impact on the rights of persons with disabilities.

Mitochondrial Donation

Mitochondrial donation involves replacing defective mitochondria in an egg or embryo with healthy ones from a donor, preventing heritable mitochondrial diseases, which are often fatal.

Ethical Issues

Involves three genetic contributors ("three-parent baby"), unsettling conventional notions of parenthood and genetic identity. Long-term effects on the child's identity and health remain uncertain.

Legal Challenges

Most countries lack specific legislation; only the United-Kingdom and Australia have legalised mitochondrial donation. The modification of the germline in embryos raises concerns regarding the prohibition of heritable genome editing.

Germline modification

Germline modification (e.g. via CRISPR-Cas9) alters the DNA of embryos, eggs, or sperm, with changes that future generations will inherit. It holds potential for eliminating hereditary diseases.

Ethical Issues

Poses profound questions about the acceptability of 'designer' children, eugenics, and intergenerational consent. The irreversibility and heritability of changes heighten moral concerns.

Legal Challenges

The He Jiankui affair prompted calls for strengthened international governance: World Health Organisation, International Commission (IC) and European Group on Ethics. No new international treaties or national reforms. IC report explicitly considered how to organise a responsible pathway for clinical use of heritable genome editing.

Conclusion

- Long-standing **consensuses** have been challenged, particularly regarding the 14-day rule and germline modification, **without a clear path toward new ones**. Meanwhile, **regulatory fragmentation** persists for SCBEMs, IVG, mitochondrial donation and PGT-A, driven by diverging national positions on the **ethical acceptability** of each technology.
- These technologies require revisiting existing prohibitions, enact new ones, and adapt governance and oversight frameworks. They place several **values in tension**, notably:
 - The **protection of the embryo and human germline integrity**,
 - Research freedom** and the **right to access to innovative therapies**
- Yet, the most significant legal challenge is to analyse their **cumulative effect**, so as not to undermine the **coherence of legal systems**. No single technology alone captures the full transformation of the embryo's legal status:
 - Broken taboos:** heritable germline modification in multiple ways through rogue actors but also concerted scientific action. Ethical acceptability now recognised by certain National Ethics Committees (FR, UK, DE).
 - A reconfiguration of reproduction:** in the number and biological sex of genetic contributors.
 - Blurring boundary:** between therapy, enhancement and eugenics, compounded by 'medical tourism'.
- The combined trajectory points towards a **liberalisation of the embryo's legal status**: accelerate pursuit of therapeutical promises, and a prioritisation of subjective individual rights over an objective moral *ordre public*. What remains deeply unclear is where the **new limits** ought to be drawn, and by whom.