

A LEGAL METHODOLOGY FOR ADDRESSING THE ETHICAL ISSUES OF NOVEL STEM CELL MODELS

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Introduction

- Novel stem cell models such as neural organoids, stem-cell-based embryo models (SCBEMs), and chimeras, are powerful tools to understand developmental biology, study diseases, and find new cures.

➤ These advances raise distinct ethical and legal challenges:

 - **SCBEMs**: their similarity to embryos, and ability to reproduce late stages of embryo development up to organ formation, raise concerns about their developmental potential;
 - **Neural organoids**: the development of complex biological neural networks, that can interface with mechanical and computer systems, raises concerns about possible sentience;
 - **Chimeras**: the implantation of human cells in animals possibly leading to human features developing in animals, disrupting the boundary between species.
- **The gap**: issues of moral status raised by stem cell models are discussed at length in the ethical literature, but there is almost no legal literature on the subject. There are no conceptual tools to critically analyse existing law and identify regulatory gaps.

➤ **Aim**: to propose a legal method for addressing issues of moral status raised by novel stem cell models.

➤ **Method**: an approach both analytical (systematising existing law) and prospective (resolve gaps identified).

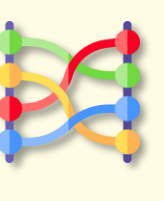
➤ **Results**: a framework that (1) overviews the values attached to stem cell models, (2) situates them within their broader regulatory field, and (3) lists criteria that can be used to legally define and frame them.

(1) The Value-Based Approach to Stem Cell Models

Type of value	What is protected
Intrinsic	The entity's own worth, independent of any use
Relational	The bonds and attachments the entity elicits
Symbolic	What the entity represents
Instrumental	Its scientific, therapeutic, or economic utility

- Drawn from **moral philosophy** and **environmental law** literature, then adapted to biolaw.
- Used to classify values expressed explicitly or implicitly in the legal and ethical literature, statutes, case-law...
- Each value highlights the different interests at stake in regulating stem cell models, and which interests need to be balanced:

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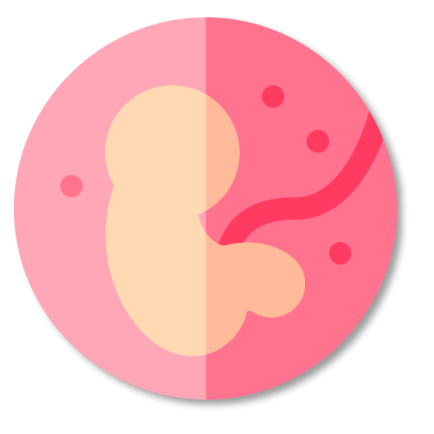
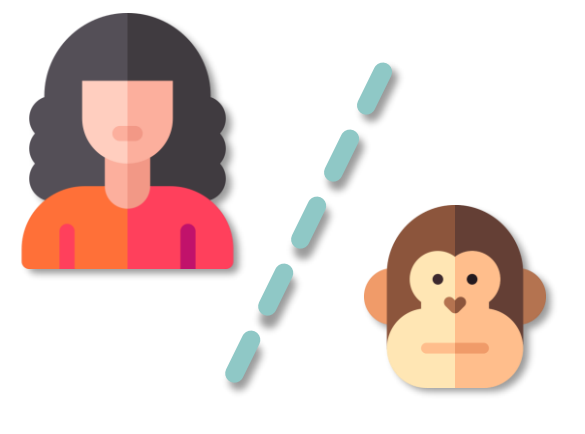
Intrinsic value: when an entity is said to matter in its own right (humans, animals, embryos... and stem cell models?);
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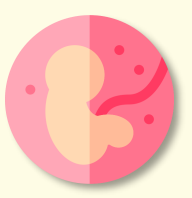
Relational value: when an entity matters because of its bonds with a person, e.g. a donor and their donated cells, linked by genetic ties and by personal meaning projected onto them;
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Symbolic value: when an entity matters because of what it represents in a given cultural context, e.g. the symbolism of human body (blood, organs...) or human features (form, facial features, body plan...);
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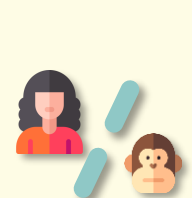
Instrumental value: when an entity matters for its utility in research, therapy, reproduction, or profit-making.

(2) Three at-risk fields of research

		
(a) Human reproduction	(b) Consciousness	(c) Boundary between species
SCBEMs, 14-day rule, ectogenesis, cloning, germline editing	Neural models, "organoid intelligence", neurotechnologies	Chimeras, hybrids, xenotransplantation

- Understanding how a given legal order deals with each of these notions helps situate stem cell models within the broader picture of biotechnology regulation:
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(a) Human reproduction: rapid innovation toward highly sought-after reproductive applications; evolving balance between personal autonomy and public order; emergence of new reproductive and parental models.
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(b) Consciousness: growing influence of sentiocentrisme on legal theory; practical difficulties when dealing with consciousness (measurement problem); convergence with computer science.
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(c) Boundary between species: protecting animals vs. protecting humanity; zoonotic risk; "red-line" or "grey zone"; human traits in animals.
- These fields can overlap, i.e. SCBEMs developing a neural tube (a, b) or human cells growing in the reproductive or nervous systems of a chimera (a, b, c).

(3) Delimitation Criteria for Stem Cell and Embryo Research Regulation

	Ontological	Functional
Makeup	Origin: stem cell reprogramming, fertilisation/cloning of embryo...	Final use: • Research • Reproductive • Therapeutic • Commercial
	Source: human/animal, embryo/adult	
	Composition: adding or subtracting elements such as different cell source, percentages of human cells in the animal, DNA editing	
	Cellular potentiality: totipotency, pluripotency, multipotency...	
Destination	Organismal potentiality: capacity to develop into a fully live and viable being	
	Developmental stages / culture time: primitive streak/14 days, onset of organogenesis/28 days	
	Functional markers: heartbeat, neural activity, sentience, behavior...	

- When defining the scope of biological entities covered by research regulation, different criteria can be used:
- **Ontological criteria**: relating to the entity in itself
 - **Functional criteria**: relating to the uses made of the entity
- Discussions on moral status often revolve around **morally significant ontological features** (equivalence to embryos, sentience, percentage of chimerism...) which are difficult to work with, both conceptually and empirically.
- Some authors call for regulating biotechnologies based on their intended use (**functional approach**).
- Most existing ontological legal criteria revolve around (a) human reproduction. **Gaps** remain for models investigating (b) consciousness and (c) the boundary between species.

Conclusion

- This work presents the first steps to **translate discussions about moral status** of novel stem cell models **into law**:
- Emphasises the **different values** of these models put forward by various stakeholders, their justifications and how they can be balanced against one another;
 - Delineates **three at-risks fields of research**, two of which have had insufficient regulatory attention;
 - Systematises the **types of legal criteria** used to frame embryo and stem cell research.
- This framework:
- Provides a **flexible and actionable methodology** to discuss the moral status and its implication for regulating stem cell models;
 - Systematically highlights **discrepancies** between issues raised in the ethics literature and those actually regulated in law;
 - Offers a model that is both **analytical** (based on existing law) and **prospective** (helps identifying gaps);
 - Takes into account ethical dilemmas and **diverse stakeholders' interests** to balance scientific progress with societal values.
- Though developed for organoid regulation, this methodology is designed to be **transposable to other legal questions concerned with moral status**.