

The Moral and Legal Status of Organoids: Closing Governance Gaps

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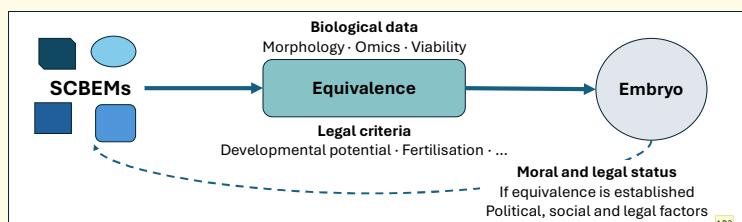
Introduction

- The rapid development of **organoid technologies** poses challenges to existing ethical and legal frameworks. Their moral and legal status remains largely unsettled.
- Two types of models raise particularly pressing concerns
 - **Stem Cell-based Embryo Models (SCBEMs)** raise questions about their possible **equivalence to embryos**
 - **Neural organoids** raise questions about possible **sentience**.
- This poster draws from **three types of sources** addressing the status of organoids:
 - Current guidance from the **International Society for Stem Cell Research (ISSCR)**,
 - Recent **national policy developments**,
 - A **systematic literature review** of legal academic scholarship on the status of organoids
- We identify **three main regulatory discussions**:
 - i. Should SCBEMs be **assimilated to embryos** under existing regulatory frameworks?
 - ii. Should **animal research regulation** inspire or even be extended to possibly sentient neural organoids?
 - iii. Are **broadier oversight approaches** needed to address biotechnological innovations?

The Status of SCBEMs

Core question:
Should SCBEMs be legally assimilated to embryos? If so, on what basis?

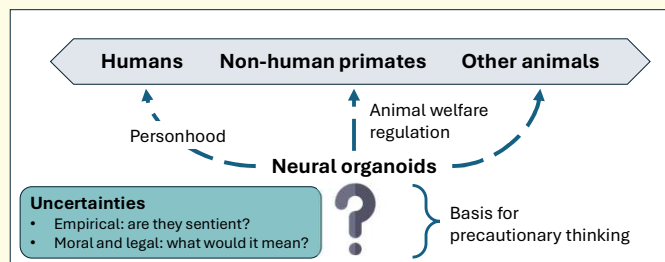
- **International soft law, ISSCR Guidelines**
 - Adequate Review Processes (review, approval, and ongoing monitoring, as appropriate)
 - SCBEM research requires specialised oversight (category 2). It must demonstrate: **scientific rationale**, merit of research proposals, relevant expertise, ethical permissibility and justification, use of the minimum necessary materials, a less complex model is not appropriate, defined time limits that can be extended if safe, never open-ended time limits. The review must be proportionate to the complexity of the model. Iterative approval process with regular reporting.
 - Transfer of human SCBEMs *in utero* or ectogenesis is **prohibited** for any purpose.
 - **Normative influence of ISSCR Guidance**: the now retired "Integrated/Non-Integrated model" distinction influenced soft law in several jurisdictions (FR, NL, SE...).
- **Diverging national regulations**
 - SCBEM regulation face global fragmentation as it is emerging from embryo and stem cell research regulation, already fragmented.
 - Some jurisdictions define embryos by **developmental potential** (Belgium, Netherlands, Australia). Others rely on **fertilisation** as defining criterion (Spain, France).
- **Debates in the literature**
 - Law does not have to follow definitions from biology.
 - **In favour of assimilation**: conferring SCBEMs the moral status of embryos might be desirable under the right circumstances, in particular where developmental potential is the defining criterion. Not all rules applicable to embryo research translate to SCBEMs (i.e. **14-day rule**).
 - **Against assimilation**: practical and theoretical difficulties with the potentiality as a criterion. Alternatives include classification by biological complexity, developmental stage, or research purpose.
 - **National guidelines** are needed.



The Status of Neural Organoids

Core question:
Should neural organoid regulation be modelled after research on sentient beings?

- **International soft law, ISSCR Guidelines**
 - **Currently** no biological evidence of consciousness or pain perception in central nervous system (CNS) models. However, researchers are urged to **monitor emerging ethical issues** as organoid models become more **complex** (long-term maturation or assembloids).
- **Debates in the literature**
 - **Consciousness as the basis for moral status?** Symbolism of the brain also matters.
 - Moral status implies limitation on what can be made to them.
 - Which criteria: complexity, structures and functions, brain areas modelled...
 - Legal concepts: Interests to not suffer? Dignity? Personhood?
 - **Sentience does not prohibit from conducting experiments**: e.g. animal research
 - A utilitarian balance may still permit research.
 - This point towards **adapting the 3Rs framework** (*Replace, Reduce, Refine*) to neural organoids.
 - Other principles inspired from animal research: *Sufficient Value to Justify Harm, No Unnecessary Harm, Basic Needs, Upper Limits to Harm*.
 - **Precautionary thinking**: there is no certainty about sentience in organoids contrary to animals. Yet, if it is a possibility, then we should anticipate that risk to mitigate unnecessary suffering. Is it an appropriate measure or is stifling innovation?
 - **Dedicated guidelines** are needed for research involving potentially sentient entities.



The Need for Broader Oversight Approaches

Core challenge:
How do we design a decision-making framework for biotechnological innovations that is robust, pluralistic and forward-looking ?

- **ISSCR recommendations**
 - The community should promote **accurate, current, balanced, and responsive public engagement** to maintain public trust.
- **Consent as a corner stone of responsible innovation**
 - Existing consent frameworks are often ill-adapted to organoid research. **New oversight structures must make consent a central issue**.
 - **Key challenges**: overly broad consent, risks of infringement, ensuring appropriate return of information to donors, managing anonymisation and reidentification.
 - These point toward the need for **new consent models**, allowing greater consideration of donor's interests (governance models, dynamic models etc.)
- **Methodological needs for assessing moral status**
 - Regulating organoids requires engaging with **abstract moral characteristics derived from biology**.
 - Without robust methodologies, the field of developmental biology will face increasing levels of ethical risks, which could have adverse repercussions on society and lead to regulatory backsliding.
- **Reflexive, Anticipatory, and Deliberative (RAD) approach** (Ankeny, Munsie, and Leach, 2022):
 - researchers, regulators, funders, and publics should engage in **reflexive** (critically examining their own assumptions and practices), **anticipatory** (systematically asking "what if?" about possible outcomes before they arise), and **deliberative** (openly debating the values and ethical implications underlying research) processes
- **Public engagement**
 - Decision-making must incorporate **legal, political, sociological and philosophical knowledge**.
 - Broader and more systematic public engagement is needed to ensure that regulatory frameworks reflect **pluralistic societal values**, not only scientific consensus

Conclusion

- Regulatory discussions started with **SCBEMs** and are progressively expanded to **neural organoids**. As increasingly later developmental stages are reproduced *in vitro*, questions relating to **CNS tissues complexity** are now arising for SCBEMs as well. Confronting the question of **sentience** across organoid models appears inevitable.
- While some regulatory challenges are model-specific, others are shared across organoid types, pointing toward the need for a **broadier oversight strategy**:
 - Moving beyond a model-by-model approach, toward governance frameworks grounded in **precautionary and risk-based thinking**.
- To date, only SCBEMs have seen momentum toward **international regulatory structuring** through soft-law guidelines. Neural organoids ought to be next.
- Public engagement with the **broadier public remains critically lacking**.
- Emerging policies targeted at organoid models are **redefining the boundaries of human material research**. A coherent framework looking at morally relevant features and involving the public is urgently needed to develop adequate regulatory instruments that will support **responsible organoid research and maintain public trust**.

Diapositive 1

AB1 Probablement à raccourcir

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AB2 Meilleure formulation? Place?

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