

FRENCH INSTITUTIONS' PERSPECTIVES ON THE REGULATORY ADOPTION OF ORGANOID TECHNOLOGIES

BRIDGING INNOVATION AND GOVERNANCE GAPS

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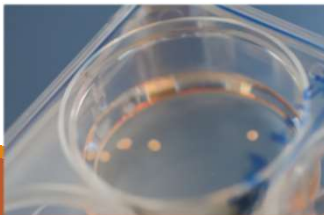
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Organoids

A Scientific Revolution With Regulatory Challenges

What are organoids?	What are they used for?	What is the French legal context?	What are the regulatory challenges?	What are the institutional perspectives?
• Self-organising 3D structures • derived from stem cells, • reproducing structural and functional features of organs	• From basic research to clinical applications • Closer model of in vivo biology • Reduce animal experimentation	• No specific legal framework • Certain aspects are covered by various legal text and practices	How do legal institutions integrate them into existing legal frameworks and their implementation?	• 5 qualitative interviews with French institutions • September – December 2024 • Proactive monitoring and systemic gaps



Credits:
Fabien Milanovic

French Institutions

Proactive But Segmented Approaches

Institution	Focus	Proactive Measures	Limitations
Ministry of Research (MESR) : • Research and Innovation Strategy • Regulated Research Practices	Research & Industrial sectors	Coordination via public-private partnerships	• Limited in-house expertise • Reduced efficacy in implementation due to knowledge gaps
National Agency for Medicines and Health Products Safety (ANSM)	Organs-on-a-chip (OOCs)	• Permanent Scientific Committee on non-clinical data (since 2020) • Position paper	• Technical focus • Dependency on EU developments • Lack of data sharing from industry
Biomedicine Agency (ABM)	Embryoids, stem cells, organs...	• Orientation Council for ethical position-taking • Evolutive interpretation	• No legal definition • Unclear remit (neuroscience)
Research Ethics Committee (CPP)	Human participants protection in research	Ethics reviews for research protocols	• No centralised expertise • Volunteer-based

Systemic Gaps

Ambiguities, Overlaps, and Blind Spots



Ambiguities

- Scope of applicable laws
- No legal definition for organoids and embryoids
- Biomedical Agency vs. Ethics committee: No cross-reporting mechanism → risk of gaps



Overlaps

- Medicines agency vs. ethics committee: despite procedures described in law, tensions in practice over clinical research authorisation processes.
- All four institutions possibly competent on different aspects of organoid research



Blind Spots

- No full explicit regulation of chimeras (e.g., human organoids in animals).
- No framework for neural organoids and "organoid intelligence".

Uncertainty for researchers and broader stakeholders

Adapting the Framework

Ethics/Safety vs. Innovation



"Ethics-Focused" Institutions (ABM, CPP):
There are gaps in the current framework for
embryoids and neural organoids.

→ Proposal: Revisable guidelines every 3
years (wished by ABM).



"Innovation-Focused" Institutions (MESR,
ANSM): the overall legal framework suffices;
procedures need to be streamlined;
regulatory criteria are needed for OOCs.

→ Proposal: Shift to ex-post control for human
biomaterial storage procedures (considered
by MESR).

Ethics/Safety vs. Innovation: How to balance protection with progress?

Conclusion

Balancing Flexibility and Protection



Key Points

- French institutions proactively monitor organoids but face systemic gaps.
- Ambiguities, overlaps, and blind spots hinder regulatory adoption.
- Ethics/Safety vs. Innovation debate shapes adaptation efforts.



Call to Action

- ✓ Periodical bioethics law revision
- **Updatable sectorial guidelines**
- **A formal legal coordination mechanism** (inter-institutional platform)
- **A risk-based tiered research review framework:**
 - Prior control for higher tier of risk (e.g. embryoid, neural organoid), ex-post control for lower tier of risk.



Outlook

- We hope this work contributes to the discourse on the next **Bioethics Law revision** and the future of emerging biomedical technologies.



Thank you for your attention!

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