Faculty of Medicine

Centre for Medical Ethics

Dr. Panagiotis Kavouras

The HYBRIDA Operational Guidelines and Code of conduct for organoid research

CHANGER webinar: Organoid technology: ethical challenges and responsible use | 23 October 2024 | Online event

UNIVERSITY OF OSLO

HYBRIDA

HYBRIDA: Embedding a comprehensive ethical dimension to organoid-based research and resulting technologies

University of Oslo

MANCHESTER 1824

Inserm French National Institute for Health and Medical Research

Université Catholique de Louvain

AARHUS UNIVERSITY

"A person born of a Roman father and foreign mother, or of a freeman and a slave"

National Technical University of Athens

Leiden University Medical Centre

Insubria University

The underlying levels of uncertainty in organoid research

Aim

"To develop a comprehensive regulatory framework for organoid research and organoid-related technologies."

Conceptual

Persons or things?

Epistemological

Quantitative or qualitative uncertainty? Perhaps mere ignorance?

Regulatory

How to merge regulation dealing with persons and things?

The “perfect storm”?

Marcus Woodbridge from Unsplash.com

A co-creative process

Stage 1:
Understanding public opinion (worries, fears, expectations, etc.)
Methods: Mini-publics

Three deliberative workshops were conducted in **Denmark, Greece and Italy**. All deliberations followed and applied the same protocol, design and material. The study engaged a total of **51 participants**.

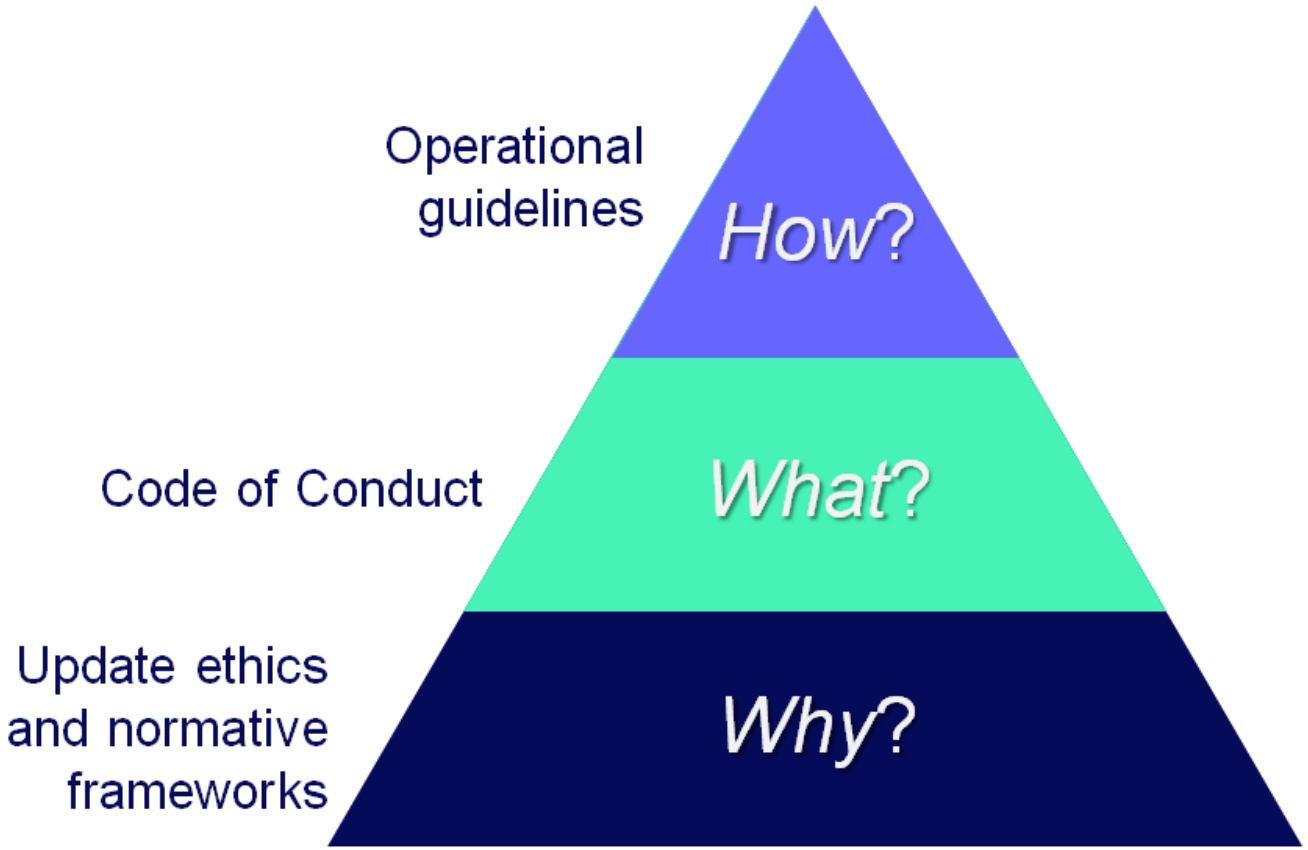
Stage 2: Consultation and co-creation
Methods: Expert interviews + co-creation workshops

Two expert co-creation and consultation workshops and **15 expert interviews**, designed to deepen and supplement the content and results produced in the expert workshops.

Six focus group interviews were conducted, to help validate the latest version of the HYBRIDA products. **35 leading experts** participated (from 17 European countries), representing the research community, industry, patient organizations, biobank networks, stem cell registries, donor organizations, European agencies, RECs and RIOs.

Stage 3:
Assessment and validation
Methods: Assessment focus groups

A high-level description of HYBRIDA's main outcomes



- ***How*** *to implement these new standards and good practices*?
- ***What*** *standards of conduct and good practices to follow to be in line with the enhanced ethics and regulatory frameworks*?
- ***Why*** *is there a need to enhance existing ethics and regulatory frameworks*?

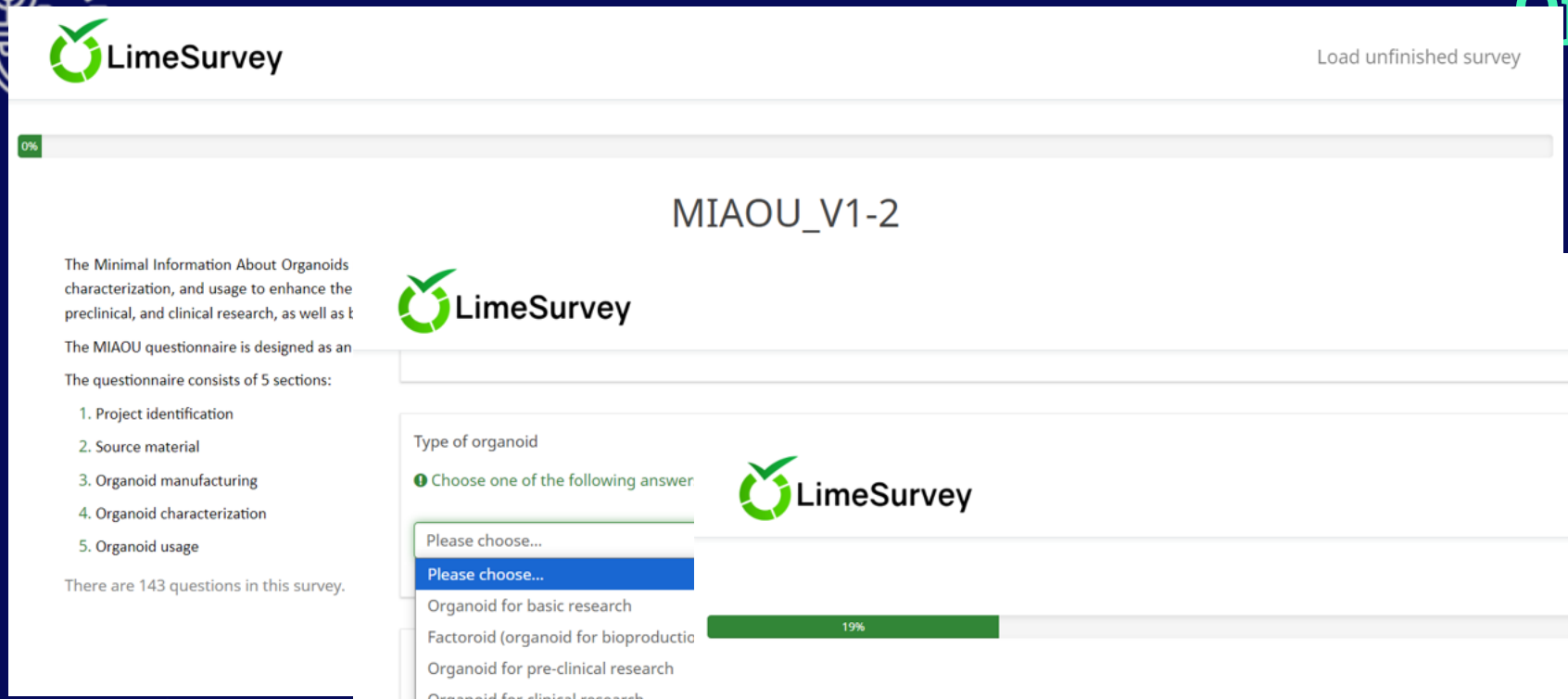
Operational guidelines

Recommendations to organoid researchers, designed to streamline certain working procedures according to best practices. Aim to help researchers ensure reliable research, development and production of organoids and related technologies and provides advice on assessment and evaluation of organoid research projects.

- **MIAOU** (**M**inimal **I**nformation **a**bout **O**rganoids and their **U**se for Researchers)
- **EChOES** (**E**valuator **Ch**ecklist for **O**rganoid **E**xperimental **S**tudies)
- **RICOCheck** (**R**esearch **I**ntegrity **C**ommittee **O**rganoid **Check**list)
- **TRUSTED** (Donor's **T**issue **R**esearch **U**nder **S**ecure **T**ransparent **E**thical **D**onation)

Operational guidelines

reporting,
ard
al metadata)



Operational guidelines

EChOES!

3. Scientific Committees must be well-equipped to evaluate the quality of organoid description in a grant application, in terms of reproducibility and replicability of the proposed research.

RICOCheck

4. Research Ethics Committees (RECs) and Research Integrity Offices (RIOs) should be provided with a tool that will ensure transparency and anticipate ethical issues in organoid research and related technologies.

TRUSTED

5. The impossibility to anticipate all potential uses that might derive from a given biological sample, in the context of organoid research and related technologies, as well as the difficulty to assess the likelihood of a withdrawal of consent, due to the integration of donated biological samples in unanticipated types of biotechnological constructs, renders two types of informed consent as most appropriate: the **dynamic consent** and the **consent for governance model**.

Code of Conduct for researchers

Aims to develop and support Research Integrity (RI) within an ethical research ecosystem. While this framework must be operationalized locally and/or nationally in addition to the EU level, this document offers recommendations for institutions to consider for fostering a culture of research integrity.

1. Sensitive domains of RI more specific to organoid research

- **Ethical procurement and use of biological materials**: Guidelines on the ethical procurement of human tissues and cells for creating organoids must emphasize informed consent procedures and respect for donor rights.
- **Transparency and public engagement**: Initiatives to enhance public understanding of organoid research, including its potential benefits and ethical considerations, must foster an informed dialogue between researchers and the public.

2. Good Research Practices in organoid research

- **Data practices and management**: Confidentiality and privacy concerns, related to genetic information derived from organoids, should align with GDPR and other relevant data protection frameworks.

Code of Conduct for researchers

3. Violations of RI specific to organoid research

- **Misuse of organoids in research and therapy**: Potential misapplications of organoid technology, such as creating organoids with sentient potential or for purposes not aligned with ethical guidelines and societal values must be addressed.
- **Inequitable access to benefits**: Risks related to the commercialization of organoids, must be recognized and mitigated to ensure equitable access to advancements in organoid-based therapies and diagnostics.

4. Engagement with Stakeholders

- **Inclusion of Patient Advocacy Groups and Ethical Committees**: Ensure that organoid research addresses patient needs and ethical considerations by engaging with patient and donors advocacy groups and ethical committees in the research design and review process.
- **Regulatory and Legal Frameworks**: Develop specific guidelines for organoid research with collaboration with regulatory bodies, considering the rapid technological advancements and their societal implications.

Supplement to the European Code of Conduct for Research Integrity

"The European Code of Conduct for Research Integrity serves the European research community as a framework for self-regulation across all scientific and scholarly disciplines and for all research settings"

To complete the criteria for appropriate behavior in research, quality, and robustness of research, we propose an addition to the ECoC **about the responsibilities of researchers relevant to human biological samples and associated data, one of the fundamental principles of which is respect for the donor and their consent**.

https://allea.org/code-of-conduct/

Thank you for your attention!

https://hybrida-project.eu/

panagiotis.kavouras@medisin.uio.no