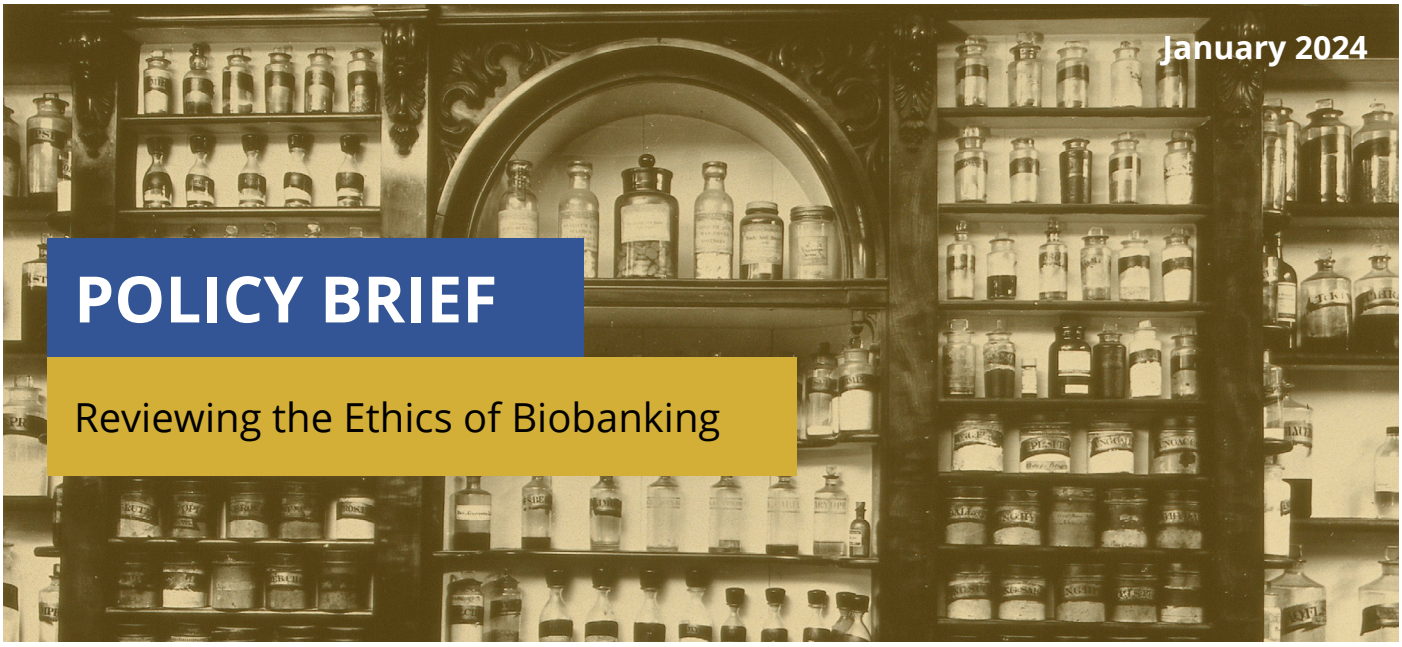
POLICY BRIEF

Reviewing the Ethics of Biobanking

January 2024

Funded by the European Union

Funded by the European Union. UK participants in Horizon Europe Project irecs are supported by UK Research and Innovation grant numbers 10055935 (University of Central Lancashire) and 10037820 (De Montfort University). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Research Executive Agency or UKRI. Neither the European Union nor the granting authority nor UKRI can be held responsible for them.



January 2024

POLICY BRIEF

Reviewing the Ethics of Biobanking

Why this policy brief on Ethics of Biobanking?

Biobanking refers to collecting and storing biological materials and their associated data. As biobanking practices continue to evolve, it is essential to address the changing nature of ethical considerations associated with the collection, use, and sharing of these valuable resources. This policy brief highlights three key issues and provides recommendations for risk mitigation, specifically targeting ethics experts and members of Research Ethics Committees (RECs).

Current callenges

1. Difficulty to choose a consent model

RECs struggle to determine if individuals who provided consent in the past have agreed – or would have agreed – to the use of their material or data (e.g. stem cells or genomic data) in research projects that emerged later in time. This problem has been addressed via 'broad' or 'dynamic' consent but no single model has been universally accepted. Commercial use in a future project unknown at the time of initial consent is of particular concern. It is a challenge for RECs to evaluate the reasonable and necessary scope of consent at the time of ethics review. Additionally, the evolving nature of biological research means that the types of useful information cannot always be foreseen and potential future risks (e.g. in privacy protection) may remain unknown. Managing these uncertainties requires an approach that puts forward trust and ongoing normative assessment and offers clear information on possible future use to the subjects.

2. Difficulty to understand complex and diverse regulation

Ethics reviews in biobanking can be challenging due to narrow definitions of biobanks vs. other health data in national regulation. There is also a lack of guidance on assessing collections of human biological materials or data that resemble, or are similar to, biobanks (e.g. archaeological remains or patient databases). In some countries,

irecs www.irecs.eu

Funded by the European Union

Funded by the European Union. UK participants in Horizon Europe Project irecs are supported by UK Research and Innovation grant numbers 10055935 (University of Central Lancashire) and 10037820 (De Montfort University). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Research Executive Agency or UKRI. Neither the European Union nor the granting authority nor UKRI can be held responsible for them.

legal provisions are primarily focused on large population or disease-oriented biobanks, making it difficult to evaluate smaller collections created in research studies. Cross-border evaluation is also difficult in the case samples are sent to biobanks in different countries. Integrating older collections originally collected for non-research purposes can pose additional challenges.

3. Difficulty to monitor incidental findings

With the advancement of next-generation sequencing technologies, incidental individual findings often result from biobank samples or data. RECs may not have the necessary tools to address ethical issues in communicating such findings back to the subject. There is an increasing recognition of the moral and legal duty to report such findings. However, many biobanks lack policies on the return of individual health-related findings, and existing policies vary in terms of when and under what circumstances results should be returned. Determining the utility of findings is complex and involves considerations of medical treatment relevance, family implications, reproductive decisions, and personal preferences. Policy and legal uncertainties, both internationally and nationally, contribute to disagreements among RECs on actionable findings and return criteria. Inconsistencies in the interpretation of this issue exist not only across different countries but also at the national level.

Recommendations

1. Implement a standard consent model across EU member state

It is crucial to elaborate an appropriate consent model at the creation stage of a biobank. Ethical considerations should include the implementation of dynamic consent options, allowing biobank participants to object to specific types of research and providing a clear explanation of the scope of biobank research. To facilitate cross-border sharing of biobank resources and improve transparency in cross-border use of biobanks, there should be efforts to standardize consent model across EU member states and internationally (to avoid ethics dumping).

2. Address regulatory disparities between biobanks and secondary data use across EU member states

RECs need homogenized guidance at the EU level to elaborate reasonable but flexible requirements that do not hinder cross-border research projects and allow researchers to address regulatory challenges effectively at all levels. Biobank regulations are typically highly demanding, with ethics reviews common across European countries. In contrast, secondary data use initiatives have more permissive ethical review policies and optional governance. Policy makers should determine the circumstances under which biobank research could be exempted from ethical review to align with secondary data use initiatives. Specific criteria should be established to guide the regulatory distinctions, if any, between biobank regulation and other secondary data use initiatives. A coordinated and consistent approach to ethical review for various data initiatives should be implemented at the national and international levels.

3. Refine and homogenize the scope of reportable incidental findings

RECs should establish unified criteria for reporting incidental findings to subjects. To achieve this goal, the EU should devise and implement a coherent approach to determining the level of importance of incidental findings. In the short term, refining the scope of reportable incidental findings can be achieved by adopting one of the existing gene lists or by following a set of general criteria. This will help to determine the findings to be reported with a clear benefit for medical institutions and for subjects.

What is Biobanking?

Biobanks are large-scale collections of biological material like DNA or tissue samples. They can be used for research, genealogy, studying diseases and much more.

Funded by the European Union

Funded by the European Union. UK participants in Horizon Europe Project irecs are supported by UK Research and Innovation grant numbers 10055935 (University of Central Lancashire) and 10037820 (De Montfort University). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Research Executive Agency or UKRI. Neither the European Union nor the granting authority nor UKRI can be held responsible for them.

Further Reading

BBMRI-ERIC (Biobanking and Biomolecular Resources Research Infrastructure - European Research Infrastructure Consortium)
An international organization that provides resources and support for biobanking, including guidelines, ethical considerations, and educational materials
https://www.bbmri-eric.eu

Global Alliance for Genomics and Health (GA4GH)
Aims to accelerate progress in genomics research by promoting data sharing, collaboration, and the development of ethical guidelines
https://www.ga4gh.org

Ethics Committee (Human Genome Organisation)
Provides resources and recommendations related to the ethical, legal, and social implications of genomics research, including biobanking
https://www.hugo-international.org/ethics

World Medical Association Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks
Offers guiding principles for ethical biobanking practices
https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks

American College of Medical Genetics (ACMG) Recommendations for Reporting of Secondary Findings in Clinical Exome and Genome Sequencing
https://www.ncbi.nlm.nih.gov/clinvar/docs/acmg

Berg, Jonathan S et al. "A semiquantitative metric for evaluating clinical actionability of incidental or secondary findings from genome-scale sequencing." *Genetics in medicine: official journal of the American College of Medical Genetics* vol. 18,5 (2016): 467-75. doi:10.1038/gim.2015.104
https://pubmed.ncbi.nlm.nih.gov/26270767

How we did it

This policy brief is based on research conducted in *Task 2.2: Development of recommendations for addressing ethical challenges from research in new technologies.* Using desk research, expert consultation and a leadership roundtable, irecs identified ethical issues in Biobanking as well as challenges faced by REC members and ethics appraisal experts. Recommendations were drafted with iterative input from irecs partners. The Stakeholder Advisory Board gave feedback and a dedicated focus group was organized by EUA to discuss and refine the recommendations.

Funded by the European Union

Funded by the European Union. UK participants in Horizon Europe Project irecs are supported by UK Research and Innovation grant numbers 10055935 (University of Central Lancashire) and 10037820 (De Montfort University). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Research Executive Agency or UKRI. Neither the European Union nor the granting authority nor UKRI can be held responsible for them.

About irecs

"Improving Research Ethics Expertise and Competencies to Ensure Reliability and Trust in Science"

irecs aims to advance research ethics expertise and competences in new and emerging technologies. The project will focus on 4 emerging technologies (AI in health and healthcare; Extended reality; Genome editing (human/non-human); Biobanking) and will develop, implement and disseminate training material for research ethics reviewers and (early career) researchers.

Funding: European Research Executive Agency (HORIZON-WIDERA-2021-ERA-01)
Duration: 3 years (October 2022 to September 2025)
Grant: 3.8 M€
Coordinator: Rheinische Friedrich-Wilhelms-Universität Bonn (Bonn, Germany)
Consortium: 17 organizations from 11 countries

Authors
Etienne Aucouturier (CEA-Saclay)
etienne.aucouturier@cea.fr
Alexei Grinbaum (CEA-Saclay)
alexei.grinbaum@cea.fr

Contributors
Vygintas Aliukonis (VU)
Eugenius Gefenas (VU)
Jurate Lektutiene (EUREC)
Tom Lindemann (EUREC)

Layout design
Radboud University

Image credits
Wellcome Collection

www.irecs.eu
@irecs_eu
contact@irecs.eu
irecs Project

www.irecs.eu

Funded by the European Union

Funded by the European Union. UK participants in Horizon Europe Project irecs are supported by UK Research and Innovation grant numbers 10055935 (University of Central Lancashire) and 10037820 (De Montfort University). Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the Research Executive Agency or UKRI. Neither the European Union nor the granting authority nor UKRI can be held responsible for them.