EUROPE BIOBANK WEEK 2021

A WORKABLE REGULATORY FRAMEWORK FOR MULTICENTRE AND MULTINATIONAL BIOBANK-BASED RESEARCH: WHERE ARE WE IN 2021?

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BBMRI-ERIC

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Regulatory Implications

INTRODUCTION

Institutional &/or Research Ethics Committees (IECs &/or RECs) are strongly involved in the ethical review of biobank-based research.

The "BBMRI-ERIC ELSI Services REC Task Force" carried out a pan-European IEC/REC mapping **to help enable collaborative multinational biobank-based research.**

The two mapping steps:

- **A pilot round in 2020** comprised 6 BBMRI partners (Germany, Greece, Italy, Latvia, Malta, Norway), involving at least 2 "gatekeepers" with a critical role in operating RECs on a national level.
- In a **second round in 2021,** the engagement conditions and methodological framework were extended to all the BBMRI-ERIC partners and observers.

AIM

To gain an **overview of the European landscape** of ethical review processes regarding biobank-based research involving human biological samples and related data.

To highlight

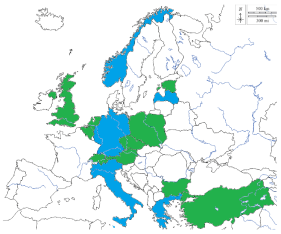
- ✓ the **regulatory framework** for the ethical review of biobank-based-research;
- ✓ the institutionally endorsed (recognized and competent) and/or accredited (legally recognized) **ethics committees for the ethical review of biobank-based-research**, and the establishment of a human research biobank; and
- ✓ the **path for submitting research review applications.**

RESULTS

In a nutshell:
We share the preliminary results of the two phases involving respondents from **17 countries**.
All the 38 respondents provided in-depth explanations.
Detailed assessment revealed some difficulties in answering; **respondents from only two countries agreed consistently on all questions.**

The overall results largely confirmed the pilot results shared during the EBW2020

- ➢ the lack of a specific regulatory framework for biobank-based research (except for Norway and Finland),
- ➢ different processes for submitting applications, depending on the country and the ethics committee,
- ➢ and that not all the involved EEA countries require the ethical evaluation of a new biobank.



- ✓ **A complex regulatory patchwork including soft laws**
  - All countries have a regulatory framework for clinical trials, but there is a wide-ranging patchwork of legislation for the ethical review of biosample/data-based-research.
  - The legislation in some countries is controversial.
  - **Divergent interpretations of definitions, functions, and differences regarding which laws and regulations mattered** (nationally and internationally); one such difference relates to whether regulations for the processing of personal data also apply to samples.

➡ **the importance of soft laws emerged.**

- ✓ **RECs and/or IECs: who is responsible for what? what can they review?**
  All countries have legislation for RECs covering clinical trials. But in some countries, **there is lack of clear legal regulation for IECs.**
- ✓ **ECs accreditation is a problem** – countries have a different understanding of what this is. Some interpret accreditation by law, others by institutional policies.
- ✓ **Variable documentation is requested and reviewed by ECs.**
- ✓ **Request for access**
  Respondents from 9 countries (Austria, Belgium, Finland, Germany, Netherlands, Sweden, Switzerland, Turkey, UK) provide for access committees. **Access is handled in a variable manner** by other countries.
  It seems to be a Biobank decision how to proceed in Italy, Switzerland, Czech Republic, Poland.

Challenges in emergency times: the difficulty to identify the legal basis for biobank-based research data processing, with particular concern regarding the application of GDPR.

Data analysis revealed different answers within countries. This might indicate that the ethical review of biobanking can also differ within countries. However, discrepancies could also be due to different interpretation of the survey questions.
Moreover, the number of respondents per country differed.

METHOD

Difficulties arose in the pilot phase in interpreting:

- ✓ terms such as "accredited committee," "independent committee,"
- ✓ the question "Is the legal framework the same for samples and for data?".

➡ In the 2nd phase, **the same online format was used with some clarifications regarding definitions of key terms and question setting.**

***** Critical definitions agreed by the REC Task Force**

Biobank-based research:
Research using human biological samples and related data, collected, stored and provided by (or mediated through) a biobank, operating in accordance with standard procedures, that ensure sample integrity, quality control, quality assurance and with respect to ELSI requirements.

Research Ethics Committees - RECs:
Independent Research Ethics Committees that review research proposals with human participants. These RECs must be set up in line with the EU Clinical Trials Regulation and national legislation, which may authorize /accredit them to assess different types of research (not just clinical trials).

Institutional Ethics Committees - IECs/Institutional Review Boards - IRBs:
Institutional Ethics Committees that review research proposals aiming to use human biological samples and associated personal data. Usually, they are affiliated to research Institutions and endorsed by the same Research Institutions to comply with ELS international requirements.

Sect. 1 - Regulatory Framework
Sect. 2 - REC/IEC/other ethics committees involved in the Review-Process of biobank-based research
Sect. 3 - Ethics review process for biobank-based research
3A. Prospective collection of human samples
3B. Retrospective collection of human samples
3C. Biobank establishment
3D. Access and transfer
Sect. 4 - National Body Coordinating RECs activities
Sect. 5 - National body and biobank-based research
Sect. 6 - RECs Network
Sect. 7- Challenges in emergency time

NOVELTIES:

- ✓ National node directors and ELSI experts identified respondents playing a key role in the operation of RECs on a national level.
  This action enlarged the composition and the representativeness of the REC Task Force.
- ✓ **Glossary** - https://zenodo.org/record/4580480#.YV21i6DONpQ

CONCLUSIONS

The mapping highlights

- ➢ **a fragmented ethical review process for biobank-based research in Europe**, notably also within Member States. Ethical review relies on interpretation of a patchwork of regulations, possibly due to a lack of a specific regulatory framework for biobank-based research, creating difficulties for collaborative national and multinational research. Scientists are willing to develop cross-border collaborations, but the differences in legal frameworks often make such collaborations difficult.
- ➢ **GDPR can conflict with applicable biobank legislation in a few cases, but sometimes confuses IEC/REC representatives** (they don't understand the interplay with the biobank legislation, if any). The issue of applying the same legislation for samples and data remains unclear.
- ➢ **Different ethical bodies have different responsibilities in reviewing research applications.**

Recommendations:
Harmonisation of terminology in the field of IEC/RECs is needed.
Practical support in emergencies (but not only) such as ELSI helpdesk, a website with live update of regulatory framework, webinars for critical issues.

OUR NEXT STEPS

- ❖ A third round of verification of discrepancies between respondents.
- ❖ Tailored deliverables for the 3 identified targets (RECs, National Nodes, Policymakers)

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List of respondents: https://bit.ly/3Bl52qK

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