EUROPE BIOBANK WEEK 2020

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BIOBANKING FOR GLOBAL CHALLENGES

Mapping European RECs & ethics review processes for biobank-based research

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INTRODUCTION

Facilitating the use and exchange of biological samples and associated health data in large cross-border collaborations is essential to promoting biomedical research. However, practices for the ethical review of research projects are not harmonized across European countries and there are no systems for mutual recognition of ethical approval decisions (**RECgnition**). Variations in legal frameworks provide an additional level of complexity to this landscape.

Thus shared information on Research Ethics Committee (REC) requirements in different EU countries is a critical element for a **harmonized and collaborative environment**. It leads to a need for an updated mapping of ethics review processes for biobank-based research at European level. To promote a framework of mutual RECgnition, it is key to understand the common needs and challenges and the national level REC workflows, needs and requirements.

The **Task Force REC,** as a part of the ELSI Services of BBMRI-ERIC dedicated to RECs' needs and issues, has launched a pilot survey targeting nine EEA Countries (Austria, Czech Republic, Germany, Greece, Italy, Latvia, Malta, Norway, United Kingdom) as the first step of an extensive European REC mapping of practices and legal landscapes for ethical approval.

AIM

To collect and analyse information on the regulatory and procedural framework of the ethical review process of biobank-based research

→ support the scientific community applying for REC review of collaborative biobank-based research

→ induce a harmonization-process among the RECs involved

METHOD

1) Establishment of definitions of the key terms

2) A questionnaire with 7 sections aimed to to gather objective data on national requirements highlighting the following critical issues:

- ✔ the ethical and regulatory framework for biosample/data-based research
- ✔ the ethics committees in charge of evaluating the biobank-based research
- ✔ the rules of operation of RECs for the ethical review of:
  - a. biosample/data-based research projects
  - b. the establishment of a human research biobank
- ✔ the expected process for submitting this type of biomedical research for REC review

EUSurvey Platform as an online survey management system

- 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

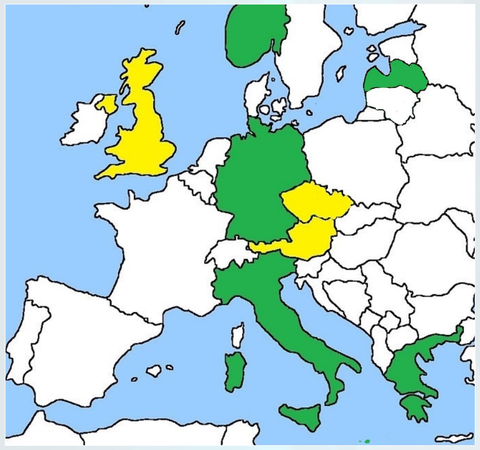
Preliminary engagement exercise involving National Node Directors & the BBMRI ELSI community

National RECs gatekeepers, the main addressees: people with a key role in the operation of Research Ethics Committees (RECs) on a national level such as for example the chairman of the national ethics commission or of the national REC network.
Engaged at least two respondents representing RECs for each of the 9 countries represented in the Task Force REC.

Duration of data collection: from 10th August to 30th September 2020 (This proved too short a timeframe for response from all invited countries, possibly due to work pressure in the ongoing Covid pandemic).
The participants will be acknowledged in any publication.

FIRST RESULTS

EEA countries involved in the pilot phase



9 countries invited but only 6 responded (green), due to Covid work pressure.

SHARING

Definitions

Research Ethics Committees - "RECs": (independent*) accredited Research Ethics Committees that review research proposals and/or clinical studies with human participants to ensure that they conform to internationally and locally accepted ethical guidelines. Depending on the Member State legal framework, their review may also include projects aiming at a "secondary use" of human data/human biological samples.*

Institutional Ethics Committees- "IECs" *(IRB): Institutional Ethics Committees/Institutional Review Boards that review research proposals using 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.*

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 in the respect of ELSI requirements.*

MORE IN COMMON

- ❏ all (responding) countries have RECs and institutional RECs
- ❏ all countries have legislation to set up independent RECs but not for institutional ECs
- ❏ RECs set their own procedures on which supporting documents to collect
- ❏ accredited RECs can review prospective and retrospective research in all countries

Biobank-based research is evaluated
- ✔ **by both RECs and IECs, depending on the EEA countries**
- ✔ **without a specific regulatory framework for biobank-based research (except for Norway)**
- ✔ **with different processes for submitting, depending on the country and the ethics committee**

Biobank establishment
- ✔ **not all the EEA involved countries require the ethical evaluation of a new biobank**

Access to biobank samples
- ✔ **only Germany has dedicated access committees. Italian biobanks may have access committees**

PRELIMINARY CONCLUSIONS

- **Confusion as to what independence and accreditation are.**
  - Our definition of REC mentions independent and accredited. This created problems for those countries that do not have formal accreditation processes in place.
- **Fragmented situation, within the same country and between European countries.** RECs and IECs review biobank-based research without a common regulatory framework, without sharing common rules as well as not asking for specific ELSI competencies for biobank-based research reviewing.
- **Few countries have a National Commission aimed at standardizing RECs activities** (Italy, Norway, Latvia) or a National REC Network (Germany, Italy, Norway), and these seem not to operate within a common pan-European harmonized framework.
- **Need of**
  - **harmonization of both legislation** (often biobank-based research is evaluated by analogy, adopting principles and criteria from regulatory frameworks designed for other specific areas, for example for data processing or clinical trials) **and procedures**
  - **sharing of best practices and common rules** (i.e. for submitting/establishment/access processes)
  - **dedicated training**
- **Expressed need for support by**
  - **ELSI help desk**
  - **Website with the live updated regulatory framework**
  - **Webinar to tackle critical issues**

Between November and December 2020, the survey will be extended to the other BBMRI ERIC partner states.

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