

Glossary

Mapping European Research Ethics Committees

& ethics review processes for biobank-based research

A pan-European REC mapping of practices and legal landscapes for ethical approval promoted by the Task Force REC of BBMRI-ERIC.

The recently established Task Force REC (Research Ethics Committees), part of the *ELSI Services and Research Unit* of BBMRI-ERIC dedicated to RECs' needs and issues, set up a pan-European inquiry with a specific focus on ethics review processes regarding biobank-based research. Our aim is to share information on REC workflows, requirements and needs in different EU countries as a critical element for a harmonized and collaborative environment.

A critical step in the data collection process is the prior sharing of definitions central to the content of the survey. This glossary aims to support the respondents throughout the data collection process, within a landscape where the heterogeneity of language use and terminology may otherwise cause misunderstanding and misinterpretation.

Here are the shared definitions:

- **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.*
- **National RECs Commission:** *Entity in charge of RECs representation/support/standardisation at a national level. This must be understood as a different organisation than National Ethics/Bioethics Committees issuing a more general opinion on broad ethical issues, such as the Nuffield Council on Bioethics, Comité National Consultatif d'Ethique, Deutscher Ethikrat, Comitato Nazionale di Bioetica, etc. (Note that such a National RECs Commission might not exist within your country).*
- **RECS Network:** *a network of RECs organized at the national level either on a voluntary basis (I.e., Ricerc@ for Italy) or by law (I.e., ak-med-ethik-komm.de for Germany) aimed at sharing information, best practices and harmonize procedures of the RECs.*
- **Use & Access Committees (UACs)/Scientific Review Boards:** *Biobank Bodies that review the request of access to stored human biological samples for research uses.*
- **Rules:** *a set of explicit regulations or principles governing the ethics review of biomedical research (projects) and human research biobanks.*
- **Tools:** *instruments prefigured or recommended to facilitate the ethical review process of biomedical research (projects) and biobank-based research.*
- **Sample-based research:** *research using human biological samples and related data.*
- **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*

- **Data-based research:** *a structured way of analysing already existing health data, whether the data is provided by a biobank or not.*

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