The European Research Infrastructure for Bio-Banking and Biomolecular Resources

Partner Charter

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Purpose and applicability

The BBMRI-ERIC Partner Charter should define the most important cornerstones for the participation of biobanks or biological resource centres (Partner) that are associated with BBMRI-ERIC to foster scientific excellence, guarantee interoperability, and compliance with ethical and legal requirements. The Partner Charter is binding for any Partner of the BBMRI-ERIC and shall be agreed between national BBMRI-ERIC nodes and the Partners. Participation of a Partner in BBMRI-ERIC is non-exclusive and has no effect on any activity of a Partner outside of BBMRI-ERIC.

Principles

Primacy

BBMRI-ERIC acknowledges the primacy of national and European legislation and respects the jurisdiction of competent authorities.

Access policy

Samples and data need to be accessible through a clear access procedure compliant with the general access procedures and conditions of BBMRI-ERIC. BBMRI-ERIC will foster the establishment of scientific collaborations between authenticated scientific users and Partners. Special access policies can be established for industrial users.

Access to samples and data will honour commitments to donors and follow the principles of “fair access” and scientific excellence. Access in the context of research projects performed within BBMRI-ERIC will only be provided for specified research projects, in accordance with the terms of the consent given by the participant and after approval of the research project by a Research Ethics Committee (REC). Partners can decide whether access will be granted for a specific project. This decision, however, has to follow transparent decision making procedures.

Data protection and management policy

BBMRI-ERIC and Partners will not make public any information that can be directly related to an individual. Information on individuals will only be made accessible to authenticated scientific users in a coded or anonymized fashion in the context of specific research projects and upon approval by a competent Research Ethics Committee (REC) in compliance with national and EU legislation, and subject to the BBMRI data access conditions. Partners will support integration of their data management system with that of BBMRI-ERIC by complying with the BBMRI-ERIC information requirements. The initial information requirements are realised as the expected minimal common data content and data structure in relevant databases. No access will be provided for non-research purposes (such as forensic, insurance or employment purposes), except pursuant to a court order.

Informed consent

BBMRI-ERIC and Partners will, at any time, honour commitments owed to donors. Partners shall aim at prospectively implementing the OECD Guidelines for Human Biobanks and Genetic Research Databases for issues related to informed consent, as appropriate and subject to the primacy of national and EU legislation.

Infrastructure and management

Partners will commit themselves to future implementation of the OECD best practice guidelines for Global Biological Resource Centres Networks. These guidelines define in particular requirements concerning the following issues:

- Infrastructure (building, facility)
- Management (responsibilities and qualifications)
- Traceability
- Biosecurity
- Data protection
- Minimal and recommended datasets
- Quality management and certification

Quality management

All Partners should commit themselves to implement quality management /assurance procedures compliant with OECD best practice guidelines for Global Biological Resource Centres Networks. SOPs should be established and made publicly available for all processes related to sample collection, processing, storage, retrieval and despatch. It is recommended that SOPs should follow the procedures as specified in the WHO/IARC guidelines for biological resource centres for cancer research whenever feasible. A unique BBMRI biobank (collection) identifier should be provided (see Kauffman, F & Cambon-Thomsen, A. Tracing biological collections: Between books and clinical trials. JAMA 2008, 299: 2316-2318). Criteria for the identifier will be provided by BBMRI-ERIC. Partners should allow external audits by BBMRI-ERIC.

Reporting

Partners will provide annual reports to the National Node Director on which research projects have been supported and information on the outcome that partners have received (e.g., publications, patents). Projects that have been supported by BBMRI-ERIC should acknowledge the contribution of BBMRI-ERIC in any publication according to the principles of good scientific practice. Partners will provide a yearly updated inventory to the National Node Director on the type, content and quality of collections and resources they are holding.

Charges

BBMRI-ERIC will pursue its principal task on a non-economic basis. However, it may carry out limited economic activities, provided that they are closely related to its principal task and that they do not jeopardise the achievement thereof. Biobanking-related services might be subject to cost recovery. Costs can be recovered for staffing, consumables, licensing, equipment servicing/maintenance. No patient samples or data are sold for profit. Supply of samples by or to external commercial organisations shall be conducted in accordance with the Community Framework for State Aid for Research and Development and Innovation (2006/C 323/01).