

The European Research Infrastructure for BioBanking and Biomolecular Resources Partner Charter

***Approved by the AoM on 29 April 2014¹
Revised by the AoM on 8 November 2017²***

Version 2.0

Purpose and applicability

The BBMRI-ERIC Partner Charter defines 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 constitutes a declaration of intent for any Partner of BBMRI-ERIC and shall be agreed between the BBMRI-ERIC National 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 following the access procedure as defined in the BBMRI-ERIC Policy for Access to and Sharing of Biological Samples and Data. 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 facilitated 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). Access has to be compliant with regulations of BBMRI-ERIC Partner biobanks, and Partner biobanks have to decide whether access can be granted for a specific project. This decision has to follow transparent and non-discriminating decision-making procedures. Noteworthy, the establishment of high-quality research collaboration is the preferred format for access.

Data protection and management policy

BBMRI-ERIC and Partners will not make public any information of research projects performed through BBMRI-ERIC 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 the integration of their data management system with that of BBMRI-ERIC (IT systems and services such as the BBMRI-ERIC Directory), 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.

¹ In its second session, the AoM followed the suggestion of the Working Group 2: Partner Charter and approved the Partner Charter (draft version 5; 18.06.2012) without any changes as published in the BBMRI Business Plan (v.21.1; 03.12.2012) by Resolution 6.

² Amended during the 10th Session of the AoM with Resolution AoM/10/R3/Rev1

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 strive 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 applicable European and international standards, OECD best practice guidelines for Global Biological Resource Centres Networks and WHO/IARC Common Minimum Technical Standards and Protocols for Biobanks Dedicated to Cancer Research. SOPs should be established and made publicly available for all processes related to sample collection, processing, storage, retrieval and dispatch. 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 biobank (collection) shall be provided a unique persistent identifier as a part of registering the biobank (collection) in the BBMRI-ERIC Directory. Partners are also encouraged to participate and benefit from the quality services of 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).