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HARMONISED ACCESS PROCEDURE TO SAMPLES AND DATA

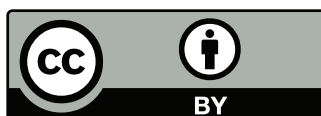
Executive Summary

This framework document describes basic access criteria and procedures under which the access and use of samples and data facilitated by BBMRI-ERIC are realized.

The access procedure is described step-by-step, from registration to the completion of access, at the Pan-European and national levels. BBMRI-ERIC operates as a facilitator in the provision of access; while the local biobanks stay in control of granting access based on their existing access policies, proper peer review and ethical assessment of research proposals. By introducing and further implementing these access criteria and procedures, BBMRI-ERIC offers the service of taking the European collections of biological resources to a new level of coordination, efficiency and usage for the health of EU citizens and beyond.



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DOCUMENT LOG

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1 Background

The ADOPT BBMRI-ERIC project aims to boost and accelerate the BBMRI-ERIC activities of establishing, operating and developing a Pan-European distributed research infrastructure that facilitates access to biological resources as well as supports high quality biomolecular and biomedical research. In this context, we developed this framework document, in order to specify access criteria and procedures when users are requesting BBMRI-ERIC associated samples/data via the BBMRI-ERIC IT services. BBMRI-ERIC provides a one-stop access to the collections of the European biobanking community; building on the outcome of the Preparatory Phase (GA212111). By this facilitator service, BBMRI-ERIC will foster access to the biobank infrastructure capacities to and for the European academic community, as well as the private sector, and stimulate the collaboration between academia and industry. The latter will typically take shape as public-private partnerships.



2 BBMRI-ERIC Access Criteria and Procedures

2.1 Preamble

This document is intended to harmonize the procedure of requesting Samples/Data via BBMRI-ERIC. Therefore it is a binding document for BBMRI-ERIC itself, BBMRI-ERIC linked biobanks, and any Requesters who request Samples/Data from BBMRI-ERIC linked biobanks via BBMRI-ERIC. It is not intended to supersede access policies and procedures of BBMRI-ERIC linked biobanks, but as a framework with which BBMRI-ERIC linked biobanks need to be compatible for requests coming to them via BBMRI-ERIC.

Definitions. The following terms are used in this document:

BBMRI-ERIC Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium.

Samples/Data Biological samples or data stored in, and under custodianship of, one of the BBMRI-ERIC linked biobanks. Note that BBMRI-ERIC does not act as a biobank itself and only facilitates access to the biobanks.

BBMRI-ERIC linked biobank Biobanks participating in BBMRI-ERIC infrastructure as a part of National/Organisational Node that has BBMRI-ERIC Partner Charter signed. Note that biobanks remain in control to ultimately grant/deny access to potential users.

Requester A qualified person requesting Samples/Data. Needs to be registered as specified in Step-1

National/Organisational Node A National Node or an Organisational Node as defined in the Statutes of BBMRI-ERIC.

Provider A BBMRI-ERIC linked biobank providing Samples/Data.

MTA A contract between the requester and the biobank specifying conditions under which the biological material and/or data is transferred from the biobank to a recipient. Data-only transfer agreement is sometimes called a Data Transfer Agreement (DTA).

Project Outcome Can be published research papers, patents, new therapies and other types of commonly acknowledged medical research achievements. This also includes report on use of samples and data.

Availability Information Availability information for Samples/Data is provided by the Provider to the Requester via BBMRI-ERIC. It is used before the Requester starts direct interaction with the Provider, in order to get access to the Samples/Data. Availability informations are treated as confidential by BBMRI-ERIC, i.e., not disclosed to other providers.

2.2 Access Criteria

The following principles form part of the basis for the governance of the access to and use of Samples/Data, of which BBMRI-ERIC facilitates the access:

- The Samples/Data remain under the custodianship of the BBMRI-ERIC linked biobanks as the original source, unless otherwise specified under a separate agreement. Consequently, BBMRI-ERIC only facilitates access, while BBMRI-ERIC linked biobanks actually grant and provide the access.



- The rights, privacy and consent of participants must be protected and respected at all times.
- All use of Samples/Data should be compliant with national and European law. It is the national law of the BBMRI-ERIC linked biobank that applies to the processing of data, irrespective of where the data is used. Processing must be compliant with the provisions of the informed consent and/or decision of an Ethical Review Board, or else compliant with national law.
- Samples/Data can only be used for academic or industrial research purposes, depending on the legislation of the member states or organisations, as specified in a MTA between the Requester and the BBMRI-ERIC linked biobank.
- BBMRI-ERIC encourages BBMRI-ERIC linked biobanks to use the European Charter for Access to Research Infrastructures¹ as a reference when updating existing or defining new access policies. Because of diversity of BBMRI-ERIC linked biobanks, the access units and access modes are to be defined by each biobank. Suggested access units are samples and resources consumed for preparation and delivery of data sets and recommended access mode is excellence-driven access, but biobanks can adjust these recommendations to their preference.
- All extensions to the use of human biological material beyond the aims and objectives for which samples/data were initially collected and provided, subject to the above overarching principle, must also be evaluated by the appropriate Ethical Review Board.
- Requests issued by Requesters for access to Samples/Data will be required to follow the Request Procedure for Samples/Data via BBMRI-ERIC IT Services below.
- In order to stay accountable for use of the infrastructure providing Samples/Data, Requesters are required to acknowledge the Provider in relevant Project Outcomes and inform the Provider about achieved Project Outcomes.
- In order to maximize value of the biobank resources, the Providers may request that data derived from Samples/Data are transferred back to the respective Provider free of charge (so called Return of Data). If the Provider does not have capacity to store the data, the Provider may contact BBMRI-ERIC to facilitate storage.
- Access will be cost neutral to BBMRI-ERIC and BBMRI-ERIC linked biobanks. It may be that BBMRI-ERIC linked biobanks require from the Requesters to partially or fully cover the cost of providing samples and data. Cost aspects have to be regulated in the MTA between the Requester and the BBMRI-ERIC linked biobank.

2.3 Request Procedure for Samples/Data via BBMRI-ERIC IT Services

The basic framework for the request procedure for accessing Samples/Data via BBMRI-ERIC IT services comprises the following steps outlined below:

- Step-1 *Registration*: BBMRI-ERIC verifies the identity of each Requester and his/her institutional affiliation (employee status).
- Step-2 *Request of Samples/Data*: A Requester files a Request for Samples/Data via BBMRI-ERIC IT services. Each Request must include information about the approved/proposed research project including its ethical approval status, expected properties of Samples/Data and their anticipated use. A Provider may either request refinement of the Request or provide an Availability Information to the Requester. Availability Information is treated as confidential by BBMRI-ERIC, i.e., not disclosed to other Providers.

¹ *European Charter for Access to Research Infrastructures Principles and Guidelines for Access and Related Services*. March 2016. https://ec.europa.eu/research/infrastructures/pdf/2016_charterforaccessto-ris.pdf



Requests are not used by the Providers for any other purpose than assessing availability of the Samples/Data and providing Offers.

- Step-3 *Access control & samples/data delivery:*** After receiving adequate Availability Information, the Requester follows up directly with the Provider (biobank) in order to provide any additional information needed for assessment as to whether the access can be granted. As a part of this process, the Provider must comply with the regulatory and ethical conditions (e.g., data protection regulations, assessment of compliance of the informed consent with the approved/proposed project, check whether the amount of depletable sample required is scientifically justified) and transfer liability to the Requester using MTA as appropriate. Approval of Samples/Data release for the project requested is decided by the Provider and access to depletable samples may be subject to prioritisation. For approved Requests, the MTA will need to be executed and access charges paid before release of Samples/Data to the Requester.
- Step-4 *Return of results:*** Providers need to collect reports on Project Outcomes for accountability regarding BBMRI-ERIC infrastructure utilization. Providers are encouraged to require return of the data to the Provider (see Access Criteria above) and require this as a part of MTA.
- Step-5 *Request completion notification:*** For each request obtained via BBMRI-ERIC, for which Availability Information was provided in the Step-2 followed by Step-3, the BBMRI-ERIC linked biobanks are required to inform BBMRI-ERIC whether the request has been completed successfully, or whether it failed and specify reason for failure. For successfully completed Requests, report on Project Outcomes will be reported by the Provider to BBMRI-ERIC.

As access facilitator BBMRI-ERIC provides infrastructure implementing Step-1, Step-2 and Step-5. BBMRI-ERIC is not directly involved in Step-3 and Step-4.



3 Implementation of BBMRI-ERIC Access Procedure

The access procedure Step-1, Step-2 and Step-5 will be implemented by a tool called “BBMRI-ERIC Negotiator”,² to be delivered by BBMRI-ERIC Common Service IT by the end of 2016. Step-1 will use federated authentication mechanism in conjunction with the Negotiator.

² BBMRI-ERIC Negotiator is expected to be available at <https://negotiator.bbmri-eric.eu/>.

