



BBMRI-ERIC[®]
Biobanking and
BioMolecular resources
Research Infrastructure

2018
**Guidance booklet for new
Member and Observer**

www.bbmri-eric.eu

GUIDELINES FOR NEW BBMRI-ERIC MEMBERS AND OBSERVERS

The purpose of this document is to provide information to the competent authorities of countries and Intergovernmental Organisations wishing to join BBMRI-ERIC (Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium) as Members or Observers. The document is a summary of the official documents (Statutes, Internal Rules and Business Plan) on which the approval of the BBMRI-ERIC application was based in the European Commission on November 22, 2013 and its Statutes published in the Official Journal of the European Union on 30 Nov 2013 (L320/63). The document aims to summarize the process of how to become a Member or an Observer, and to present the rights and responsibilities that membership or observership brings along. The document also presents practical information on the process of establishing National / Organisational Nodes and on the Partner Charter through which individual biobanks in Member Countries join the European biobanking community via BBMRI-ERIC. Two template letters for the official application are also attached as annexes. Finally, a checklist for the application process is included as an additional annex.

1. BACKGROUND INFORMATION

BBMRI was one of the first research infrastructure projects on the ESFRI (European Strategy Forum for Research Infrastructures) Roadmap of 2006. The preparatory phase of BBMRI was funded by the European Commission (EC) in 2008-2011. During this period BBMRI grew into a 54-member consortium with more than 225 associated organisations (largely biobanks) from over 30 countries, making it one of the largest research infrastructure projects in Europe.

During the preparatory phase, it was decided that BBMRI will be implemented under the ERIC (European Research Infrastructure Consortium) legal entity with its Central Executive Management Office in Graz, Austria. For the ERIC application the basic operating principles, the governance structure and a financial plan were drafted in a Business Plan together with the Statutes for BBMRI-ERIC. A total of 12 countries (Austria, Belgium, Czech Republic, Estonia, Finland, France, Germany, Greece, Italy, Malta, Netherlands and Sweden) signed the application to the European Commission with another four countries and one International Organisation as observers (Norway, Poland, Switzerland, Turkey and IARC/WHO).

On the BBMRI-ERIC official web site (www.bbmri-eric.eu) all contact information of the Central Executive Management Office in Graz is available. The web site also contains the official BBMRI-ERIC documents and information for potential new Members and Observers. Any official request for Membership or Observership – signed by an authorized Government or Organisation official - need to be forwarded to the Director General and the chair of the Assembly of Members (A template for such a request letter is attached as Annex 3). Such a request should be accompanied with another letter delegating – if necessary - the authority to be used by the competent ministry for the nomination of delegates and experts (a template in Annex 4). This letter should also contain a description of the Biobanking and Biomolecular Resources field in his/her country or Organisation and nomination of the National Node Director/Coordinator or Organisational Node Director/Coordinator. The Director General will put an item “Joining of a new Member” on the next draft agenda of the Assembly of Members for consideration.

2. HOW TO JOIN BBMRI-ERIC?

The Statutes of BBMRI-ERIC form the legal basis for new Member States, associated countries, third countries other than associated countries, and intergovernmental organisations to seek membership or observer status in BBMRI-ERIC. (Eligible countries and organisations are defined in Article 9 (1) of the ERIC Regulation 723/2009).

Countries or organisations wishing to join BBMRI-ERIC have to decide whether they seek to become a Member or an Observer.

2.1. For Members:

Article 4 of the BBMRI-ERIC Statutes (*Members and Observers*) states:

Member States, third countries as well as intergovernmental organisations may become members of BBMRI-ERIC at any time, subject to approval by the Assembly of Members according to the principles laid down in Article 11(8)(b).

Article 4 (2) further states that “additional requirements concerning Members joining BBMRI-ERIC after the first three years shall be decided by the Assembly of Members.” This refers to a situation where founding Members would have invested in the infrastructure of BBMRI-ERIC to such an extent that additional financing requirements could be justified for new Members gaining access to such infrastructure at a later time. This rule becomes effective when the initial three-year period ends in December 2016.

Article 11(8)(b) states that the acceptance of new Members requires agreement of at least 75% of all the BBMRI-ERIC Members representing at least 75% of the Members annual mandatory contributions.

2.1.1. Benefits for joining BBMRI-ERIC

The many benefits of belonging to BBMRI-ERIC are described in detail in the Business Plan. BBMRI-ERIC will facilitate access to quality-defined human health/disease-relevant biological resources including associated data in an efficient way and ethically and legally compliant manner, and will reduce the fragmentation of the bio-medical research landscape. Important activities of BBMRI-ERIC include harmonization of procedures, implementation of common standards and fostering high-level collaboration and provision of training programmes. BBMRI-ERIC will provide to its Members free access to documents, Standard Operating Procedures (SOP's), IT-solutions and best practices developed by BBMRI-ERIC. Participation in these processes will allow the Members and their biobanks to play an active role within the European biobanking landscape and improve their possibilities to participate in large international research projects. The Members contribute to the establishment of the annual Work Programme through participation of the National or Organisational Coordinator in the work of the Management Committee.

2.1.2. Responsibilities of Members

Article 4 (3) of the BBMRI-ERIC Statutes state that each Member shall:

- (a) provide access, within the applicable legal and ethical framework, to BBMRI-ERIC Partner Biobanks, biological and biomolecular resources and/or associated data under a common set of standards and conditions as further specified in the BBMRI-ERIC Partner Charter and approved by the Assembly of Members;
- (b) establish a National/Organisational Node and appoint a National/Organisational Coordinator; [Member countries establish a National Node and appoint a National Coordinator; in case an intergovernmental organisation becomes a Member, it will establish an Organisational Node and appoint an Organisational Coordinator];
- (c) ensure coordination of Partner Biobanks via National/Organisational Nodes that will facilitate access to biological and biomolecular resources and associated data;
- (d) where appropriate, make investments in infrastructure in support of BBMRI-ERIC;
- (e) contribute to capacity development in the field of biobanking;
- (f) support the primary purpose of BBMRI-ERIC and the implementation of the BBMRI-ERIC Work Programme.

The Statutes also stipulate that any Member may, after the initial five years of its accession to BBMRI-ERIC, withdraw from the BBMRI-ERIC by a written notice to the Chair of the Assembly of Members and to the Director General, at the latest three months before the approval of the following year's budget.

2.2. Observers

Article 4.2 of the BBMRI-ERIC Statutes (***Members and Observers***) states:

- (1) Observers of BBMRI-ERIC are Member States of the EU, associated countries and third countries as defined in Article 9 (1) ERIC Regulation and intergovernmental organisations that have applied to become Observers.
- (2) Observer status is granted for a maximum period of three years subject to an approval of the Assembly of Members as laid down in Article 10.5. After the three-year period, Observers shall either apply for membership or withdraw from the BBMRI-ERIC, unless the Assembly of Members decides otherwise.

2.2.1. Benefits for Observers

According to BBMRI-ERIC Statutes the observers are entitled to:

- (a) participate - without voting rights - in the debates of the Assembly of Members;
- (b) participate in certain activities of BBMRI-ERIC identified by the Assembly of Members.

2.2.2. Responsibilities of an Observer

As the Observer status is seen as a first step to join BBMRI-ERIC, participating countries may consider establishing a National Node as described below under 4. A distinct obligation of an Observer is a financial

contribution towards a joint BBMRI-ERIC budget at 70 % discount of the ordinary contribution as detailed below under item 3.

3. FINANCIAL COMMITMENTS OF MEMBERS AND OBSERVERS TOWARDS COMMON BUDGET

According to Article 6 (Resources of BBMRI-ERIC) of the Statutes:

(1) The BBMRI-ERIC budget shall fund the common operation of BBMRI-ERIC including the costs of the Director General, the Central Executive Management Office and the Common Services. It shall be approved by the Assembly of Members through adoption of the Work Programme.

(2) The BBMRI-ERIC budget shall consist of:

- (a) financial contributions of Members and Observers;
- (b) contributions by the Host Member State and the hosting countries of Common Services;
- (c) other income.

(3) Any income generated in the course of BBMRI-ERIC's activities that accrues to its budget shall be used for advancing the Work Programme according to the Assembly of Members' decision.

(4) Members and Observers shall bear their own costs of participation in BBMRI-ERIC meetings.

(5) Each Member and Observer of BBMRI-ERIC shall contribute to the BBMRI-ERIC budget. Unless otherwise agreed by the Assembly of Members, contributions shall be made in cash.

(6) The contribution of each Member shall be in accordance with the membership contribution table that is laid down in Annex 2.

(7) The contribution of each Observer shall be 30% of the full membership contribution as determined in accordance with the membership contribution table that is laid down in Annex 2

3.1. How much does it cost?

The mandatory contributions by the Members and Observers and the contributions by the hosting countries for the Central Executive Management Office as well as for Common Services which are laid down within the budget section of the BBMRI-ERIC annual Work Programme. As detailed in Annex 2, these contributions depend on the population size of the country and on its economic status. The actual size of the joint BBMRI-ERIC budget will be determined annually by the Assembly of Members and thereafter divided between Members and Observers as outlined in Annex 2. For the actual budget figures please refer to the latest Work Programme and Budget on the Website.

4. BBMRI-ERIC NATIONAL NODES

BBMRI-ERIC Statutes define National Node as an entity, not necessarily of legal capacity, designated by a Member State that coordinates the national *Biobanks and Biomolecular Resources*, and links its activities with the pan-European activities of BBMRI-ERIC.

The National Nodes are funded by the respective Member Countries. The BBMRI-ERIC Business Plan lists the minimal requirements for the set-up of the National Nodes. Each National Node has to have a Director (National Coordinator), appointed by an appropriate authority of the Member State. The National Node Director coordinates the participation of national biobanks in BBMRI-ERIC (through signing of a Partner Charter, annex 1) and serves as a member of the BBMRI-ERIC Management Committee chaired by the Director General.

Overall the size of the National Nodes will obviously depend on the complexity of the biobanking infrastructure in the respective countries. Examples of existing National Nodes can be found at <http://bbmri-eric.eu/national-hubs>

5. BBMRI-ERIC ORGANISATIONAL NODES

In case an intergovernmental organisation becomes a Member of BBMRI-ERIC, a structure analogous to a National Node, called an Organisational Node will have to be established with a Director, called Organisational Coordinator, who will have a similar position as a National Coordinator.

ANNEX 1. PARTNER CHARTER:

The European Research Infrastructure for Bio-Banking and Biomolecular Resources Partner Charter - 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.

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 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).

ANNEX 2. MEMBERSHIP CONTRIBUTION TABLE

- (1) This annex lays down the mechanism of calculation of the contributions by Members/Observers. The overall amount of contributions by Members/Observers shall be defined in the annual Work Programme and Budget.
- (2) The membership contribution shall be composed of a fixed contribution and a variable share.
- (3) Concerning the fixed contribution there shall be two categories,
 - (a) Members with less than 3 million inhabitants or which are international organisations shall pay a fixed contribution according the lower category; and
 - (b) Members with equal or more than 3 million inhabitants shall pay a fixed contribution according the higher category.
- (4) At the time these Statutes come into effect the fixed contribution shall be
 - (a) 20.000 EUR for Members of the lower category; and
 - (b) 25.000 EUR for Members of the higher category.
- (5) The fixed contribution for Observers shall be 30% of the respective category.
- (6) International organisations shall pay a variable share that will be decided by the Assembly of Members on case by case basis.
- (7) The overall amount of the variable share proportion of Member/Observer States is determined by subtracting the overall amount of fixed contributions of Members/Observers and the variable share of international organisations from the overall amount of contributions by Members/Observers.
- (8) The overall amount of the variable share is split among Member States based on their percentage of total GDP of all Member States.
- (9) The calculation of the variable share of Observer States is based on 30% of their respective GDP.
- (10) None of the Members shall pay more than 25% of the overall amount of contributions by Members/Observers. In case that according to the above membership contribution model the contribution of a Member would exceed this level, the difference is then distributed among the other Member/Observer States according to their percentage levels of GDP.

ANNEX 3. TEMPLATE FOR THE FORMAL REQUEST TO BECOME MEMBER

Biobanking and BioMolecular resources
Research Infrastructure – European Research
Infrastructure Consortium (BBMRI-ERIC)
Neue Stiftingtalstrasse 2 / B /6
A-8010 Graz, Austria

Subject: Request for becoming a Member of the Biobanking and Biomolecular Resources Research Infrastructure

Dear Director General,

<<Name country>> hereby requests to formally to become a Member of the Biobanking and Biomolecular Resources Research Infrastructure - European Research Infrastructure Consortium according to Article 4 of the Statutes of BBMRI-ERIC published 30 Nov 2013 in the Official Journal of the European Union (L320/68). I ask to forward this request to the Assembly of Members of BBMRI-ERIC.

The initial commitment as a member will be for the first five years as of the approval of the Assembly of Members of BBMRI-ERIC.

The representing entity to the Assembly of Members shall be <<full name and abbreviation>>.

<<Name country>> has nominated <<name of legal entity>> as the National Node and <<name>> as the National Coordinator.

For the Government of <<name country>>

Signature:

<<name person authorized to sign>>

<<function>>

ANNEX 4. TEMPLATE FOR THE FORMAL DELEGATION OF POWERS

To whom it may concern

<<date>>

The <<name of legal entity>> has full authority to represent <<name country>> in all dealings relating to the Biobanking and Biomolecular Resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI-ERIC) application for membership.

Signature:

<<name person authorized to sign>>

<<function>>

<<details of delegated entity>>

CHECKLIST FOR THE APPLICATION PROCESS FOR NEW MEMBERS AND OBSERVERS OF BBMRI-ERIC

- For a biobank in an eligible country not yet a Member or Observer in BBMRI-ERIC: contact the appropriate Ministry (Ministries) in the country and encourage them to initiate the application process to become a Member or an Observer. .
- The appropriate Ministry contacts the Director General of BBMRI-ERIC to discuss the time schedule of the application process, the estimated cost of becoming a Member or Observer and other pertinent issue. .
- Filing of an official application to become a Member or an Observer by the Ministry, Government or Parliament of the country (see template letters).
- Decision on the application by the Assembly of Members.
- For Members: establishment of a National Node (if not yet in existence) and appointment of a National Coordinator and delegates to the Assembly of Members (Each Member shall be represented by up to two delegates officially appointed by the competent authority. They may be accompanied by a maximum of three advisors who may act as alternates to the delegates. Members shall state in the appointment letter the name of the delegate with voting rights and the order of representation).
- National Nodes: to recruit BBMRI-ERIC Partner Biobanks within the country to sign the Partner Charter and to provide access, within the applicable legal and ethical framework, to biological and biomolecular resources and/or associated data under a common set of standards and conditions as further specified in the BBMRI-ERIC Partner Charter and approved by the Assembly of Members;
- For Observers: appointment of up to two representatives with official endorsement may attend the Assembly of Member's meetings in an observing capacity.

