
Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Decision of 22 November 2013 on setting up the Biobanks and Biomolecular Resources Research Infrastructure Consortium (BBMRI-ERIC) as a European Research Infrastructure Consortium (2013/701/EU), ANNEX I. (See end of Document for details)

ANNEX I

STATUTES OF THE BIOBANKING AND BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURES EUROPEAN RESEARCH INFRASTRUCTURE CONSORTIUM ('BBMRI-ERIC')

THE KINGDOM OF BELGIUM,
THE CZECH REPUBLIC,
THE FEDERAL REPUBLIC OF GERMANY,
THE REPUBLIC OF ESTONIA,
THE HELLENIC REPUBLIC,
THE FRENCH REPUBLIC,
THE ITALIAN REPUBLIC,
THE REPUBLIC OF MALTA,
THE KINGDOM OF THE NETHERLANDS,
THE REPUBLIC OF AUSTRIA,
THE REPUBLIC OF FINLAND,
THE KINGDOM OF SWEDEN,
HEREINAFTER REFERRED TO AS 'THE MEMBERS',

and:

THE KINGDOM OF NORWAY,
THE REPUBLIC OF POLAND,
THE SWISS CONFEDERATION,
THE REPUBLIC OF TURKEY,
HEREINAFTER REFERRED TO AS 'THE OBSERVERS'.

WHEREAS the Members are convinced that biological human samples including associated medical data and biomolecular research tools are a key resource in unravelling the interplay of genetic and environmental factors causing human diseases and impact on their outcome, identification of new biomarkers and targets for therapy as well as contributing to reduce attrition in drug discovery and development.

WHEREAS the biomolecular resources include antibody and affinity binder collections, cell lines, clone collections, siRNA libraries and other research tools needed for analysis of biobanked samples. Also repositories of model organisms are considered biomolecular resources when relevant to human diseases.

WHEREAS the pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) will build on existing sample collections, resources, technologies and expertise, which will be specifically complemented with innovative components and properly embedded into European scientific, ethical, legal and societal frameworks.

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CONSIDERING that the Members seek to increase the scientific excellence and efficacy of European research in the biomedical sciences as well as to expand and secure competitiveness of European research and industry in a global context and to attract investments in pharmaceutical and biomedical research facilities, by establishing the Biobanking and Biomolecular Research Infrastructure — European Research Infrastructure Consortium — hereinafter referred to as ‘BBMRI-ERIC’.

EMPHASISING the Members’ commitment to the Charter of Fundamental Rights of the European Union as proclaimed by the Council and European Commission in Nice in December 2000 and in particular European and national data protection legislation.

WHEREAS the Members request the European Commission to set up BBMRI according to the ERIC Regulation as a European Research Infrastructure Consortium (ERIC) legal entity.

HAVE AGREED AS FOLLOWS:

CHAPTER I

GENERAL PROVISIONS

Article 1

Definitions

For the purpose of these Statutes:

- (1) ‘Biobanks (and Biomolecular Resources Centres)’ means collections, repositories and distribution centres of all types of human biological samples, such as blood, tissues, cells or DNA and/or related data such as associated clinical and research data, as well as biomolecular resources, including model- and micro-organisms that might contribute to the understanding of the physiology and diseases of humans;
- (2) ‘Member’ means an entity according to Article 4(1);
- (3) ‘Observer’ means an entity according to Article 4(7);
- (4) ‘Defaulting Member’ means a Member, which
 - (a) is in default of the payment of its annual contribution, if the outstanding amount equals or exceeds the amount of contributions due for the preceding financial year;
 - (b) seriously fails in its obligations; or
 - (c) causes or threatens to cause serious disruption in the operation of BBMRI-ERIC;
- (5) ‘Common Service’ means a facility of BBMRI-ERIC according to Article 15(1);
- (6) ‘National Node’ means an entity, not necessarily with 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;
- (7) ‘National Coordinator’ means the director of a National Node, appointed by the competent authority of a Member State;

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- (8) ‘Organisational Node’ means an entity, not necessarily with legal capacity, designated by an intergovernmental organisation that coordinates the Biobank(s) and Biomolecular Resources of the organisation, and links its activities with those of the pan-European infrastructure, BBMRI-ERIC;
- (9) ‘Organisational Coordinator’ means the director of an Organisational Node, appointed by an intergovernmental organisation;
- (10) ‘Partner Biobanks’ means Biobanks collaborating with BBMRI-ERIC that comply with the BBMRI-ERIC Partner Charter⁽¹⁾;
- (11) ‘Work Programme’ means the description of the strategy, planned activities, staffing and funding of BBMRI-ERIC;
- (12) ‘Mandatory contributions’ mean the contributions by Members/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.

Article 2

Creation, Duration and Statutory Seat

1 A Biobanking and Biomolecular Research Infrastructure-European Research Infrastructure Consortium (BBMRI-ERIC) is established. It shall be established for an unlimited period of time as from the date when the decision of the European Commission establishing the infrastructure takes effect.

2 The statutory seat of BBMRI-ERIC shall be located in the city of Graz on the territory of the Republic of Austria, hereinafter referred to as ‘Host Member State’.

3 The Host Member State shall provide the location, facilities and services for the Central Executive Management Office of BBMRI-ERIC as described in a written statement in the application for ERIC status.

Article 3

Tasks and Activities

1 BBMRI-ERIC shall establish, operate and develop a pan-European distributed research infrastructure of Biobanks and Biomolecular Resources in order to facilitate the access to resources as well as facilities and to support high quality biomolecular and medical research. BBMRI-ERIC shall implement its Work Programme as adopted by the Assembly of Members.

2 BBMRI-ERIC shall operate the infrastructure on a non-economic basis. BBMRI-ERIC may carry out limited economic activities, provided that they:

3 To fulfil its tasks, BBMRI-ERIC shall in particular:

4 The activities of BBMRI-ERIC shall be politically neutral and guided by the following values: pan-European in scope, combined with scientific excellence, transparency, openness, responsiveness, ethical awareness, legal compliance, and human values.

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Article 4

Members and Observers

1 In accordance with Article 9(1) of Regulation (EC) No 723/2009, Member States, associated countries, third countries other than associated countries, and intergovernmental organisations that have agreed to these Statutes are Members of BBMRI-ERIC. The founding members are set out in Annex II.

2 Member States, third countries as well as intergovernmental organisations may become members BBMRI-ERIC at any time, subject to approval by the Assembly of Members according to the principles laid down in Article 11(8)(b). Additional requirements concerning Members joining BBMRI-ERIC after the first three years shall be decided by the Assembly of Members.

3 Each Member shall:

4 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.

5 The Director-General may propose to the Assembly of Members that a defaulting Member should be excluded.

6 The initial list of Members is set out in Annex II and shall be kept updated online by the Central Executive Management Office.

7 Observers of BBMRI-ERIC are Member States, associated countries and third countries as defined in Article 9(1) ERIC Regulation and intergovernmental organisations that have applied to become Observers.

8 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 11(8)(c). After the three-year period, Observers shall either apply for membership or withdraw from the BBMRI-ERIC, unless the Assembly of Members decides otherwise.

9 Observers are entitled to:

10 The initial list of Observers is set out in Annex II and shall be kept updated online by the Central Executive Management Office.

CHAPTER II

FINANCIAL PROVISIONS

Article 5

Resources of BBMRI-ERIC

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

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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:

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 III.

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 III.

8 The scale of contributions based on the membership contribution table laid down in Annex III may be modified in case of accession of a new Member or Observer or in case of withdrawal or exclusion of a Member or Observer. The new scale shall take effect as from 1 January of the following financial year.

9 The Assembly of Members may decide to take into account any special circumstances of a Member or Observer and adjust its contribution accordingly.

10 When in accordance with the Work Programme and the relevant rules as approved by the Assembly of Members, Members may contribute partly in-kind to the common BBMRI-ERIC budget.

11 BBMRI-ERIC is entitled to accept grants, special contributions and payments from any individual, public or private body for the purposes set out in these Statutes. They are subject to approval by the Assembly of Members.

12 Assets acquired for the account and at the expense of BBMRI-ERIC shall be its property. In case of contributions in kind, property issues shall be agreed in a specific agreement to be concluded between the Member or Observer concerned and BBMRI-ERIC pursuant to a decision by the Assembly of Members.

Article 6

Procurement and Tax Exemption

1 BBMRI-ERIC shall treat procurement candidates and tenderers equally and without discrimination, regardless whether or not they are based within the European Union. The BBMRI-ERIC procurement policy shall respect the principles of transparency, non-discrimination and competition. Internal rules on procurement procedures and criteria shall be adopted by the Assembly of Members.

2 Freedom from taxation based upon Articles 143(1)(g) and 151(1)(b) of Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax⁽²⁾ and in accordance with Articles 50 and 51 of Council Implementing Regulation (EU) No 282/2011 of

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15 March 2011 laying down implementing measures for Directive 2006/112/EC on the common system of value added tax⁽³⁾ shall be limited to the value added taxes for such research and development goods and services which are:

3 Procurement by individual members shall not benefit from tax exemptions. No further limits shall apply.

Article 7

Liability

1 The Members' financial liability shall be limited to their respective contributions as set forth in Annex III.

2 BBMRI-ERIC shall take appropriate insurances to cover the risks specific to its construction and operation and not covered according to paragraph (1).

Article 8

Budgetary Principles, Accounts and Audits

1 All items of revenue and expenditure of BBMRI-ERIC shall be included in estimates to be drawn up for each financial year and shall be shown in the budget section of the Work Programme. The revenue and expenditure shown in the budget shall be in balance.

2 The Members shall ensure that the appropriations are used in accordance with the principles of sound financial management.

3 The budget shall be established, implemented and the accounts presented in compliance with the principle of transparency.

4 BBMRI-ERIC shall keep account of all income and expenses. The accounts shall be accompanied by a report on budgetary and financial management for the financial year.

5 BBMRI-ERIC shall be subject to the accountings standards as set forth in the applicable law in the Host Member State.

6 The financial year of BBMRI-ERIC is the calendar year.

7 The Assembly of Members shall appoint external auditors to examine the accounts. The external auditors' appointment shall be periodically renewed according to the specific provision stated in the Financial Rules as approved by the Assembly of Members.

8 The external auditors shall submit a report on the annual accounts through the Finance Committee to the Assembly of Members. The Director-General shall provide the auditors with the information necessary for the performance of their duties.

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CHAPTER III

GOVERNANCE AND MANAGEMENT

Article 9

Governance Structure

The governance structure of BBMRI-ERIC shall comprise the following bodies:

- (a) the Assembly of Members;
- (b) the Finance Committee;
- (c) the Director-General supported by the Management Committee;
- (d) the Scientific and Ethical Advisory Board.

Article 10

Assembly of Members

1 The Assembly of Members shall be the body by which the Members take collective decisions on matters relating to BBMRI-ERIC. Those decisions shall then be implemented by the Director-General, together with the staff of the Central Executive Management Office and the Management Committee.

2 The Assembly of Members shall be constituted through the first meeting of the Members after establishment of BBMRI as an ERIC.

3 The Assembly of Members shall be composed of all Members of BBMRI-ERIC. 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.

4 Up to two representatives with official endorsement from each Observer may attend the Assembly of Member's meetings in an observing capacity.

5 Other observers may attend meetings of the Assembly of Members in accordance with the Rules of Procedure adopted by the Assembly of Members.

6 The Assembly of Members shall:

Article 11

Decision-making by the Assembly of Members

1 For the purposes of this Article 'present' shall mean face-to-face, by telephone, video conference or other practical means as determined in the Rules of procedure.

2 Quorum shall be formed when the following conditions are met:

3 Each Member shall have one vote. Defaulting Members shall have no vote.

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4 On all decisions the Assembly of Members shall use their best efforts to achieve consensus.

5 Failing consensus a simple majority of those Members present and voting shall be sufficient to pass a decision unless explicitly stated otherwise in these Statutes or in the Rules of Procedure.

6 In the event of tie vote the majority of mandatory contributions shall have the casting vote.

7 Decisions to submit a proposal to the Commission to amend the Statutes shall require unanimous approval.

8 The following decisions shall require agreement of at least 75 % of all the Members representing at least 75 % of the Members annual mandatory contributions:

9 The following decisions shall require agreement of at least 75 % of Members present and voting representing at least 75 % of the Members annual mandatory contributions:

10 The Chair and Vice-Chair of the Assembly of Members and of the Finance Committee shall be elected among the Members' delegates with at least 75 % of the Members present and voting for a term of one year with the possibility to be re-elected twice. The Vice-Chair shall, in the absence or incapacity of the Chair, represent the Chair.

11 The Assembly of Members shall meet at least once a year. It may also meet in extraordinary session at the Chair's request or at the request of one quarter of its Members.

Article 12

Finance Committee

1 The Finance Committee shall be an advisory and preparatory committee of the Assembly of Members to:

2 External auditors shall report directly and in person to the Finance Committee after having addressed their reports to the Director-General.

3 The Finance Committee shall operate in accordance with the Rules of Procedure and the Financial Rules adopted by the Assembly of Members.

Article 13

Director-General

1 The Director-General shall be appointed by the Assembly of Members for a term of at least three years, with the possibility to be reappointed. The Director-General may be dismissed following the same procedure. The Director-General shall be employed by BBMRI-ERIC. The Director-General shall be assisted in performing the managerial functions by the staff of the Central Executive Management Office and the Common Services.

2 The Director-General shall be responsible to the Assembly of Members for:

3 The Director-General shall:

4 The Director-General shall be the Chief Executive Officer and legal representative of BBMRI-ERIC and shall represent BBMRI-ERIC in any litigation. The Director-General may

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delegate powers, in accordance with the guidance and directions provided by the Assembly of Members, to the BBMRI-ERIC staff.

Article 14

Management Committee

1 The Management Committee shall be established by the Director-General and shall comprise the Coordinators of National/Organisational Nodes and Common Services.

2 The Management Committee shall be chaired by the Director-General. The Management Committee may elect among its members a vice-chair to support the Director-General in performing the managerial duties.

3 The Management Committee shall be responsible for:

Article 15

Common Services

1 Common Services shall consist of the facilities of BBMRI-ERIC that provide expertise, services and tools relevant for the pursuance of BBMRI-ERIC's tasks and activities, laid down in the Work Programme.

2 Common Services shall be established under BBMRI-ERIC and under the responsibility of the Director-General.

3 Common Services shall be hosted in countries that are BBMRI-ERIC Members. The selection procedure for hosting Common Services shall follow the principles set out in Annex IV.

4 Each of the Common Services shall be managed by a director, appointed by the Director-General after consultation with the national delegates of the hosting Member State.

Article 16

Scientific and Ethical Advisory Board

1 The activities of BBMRI-ERIC shall be periodically evaluated by an independent Scientific and Ethical Advisory Board (SEAB). The SEAB shall also advise the Assembly of Members with regard to proposals of the Director-General on the implementation of the Work Programme.

2 The SEAB shall be composed of distinguished scientists or experts appointed in their own right, not as representatives of their respective background organisations or of Members.

3 The Assembly of Members shall appoint the SEAB members and decide on their rotation and on the terms of reference of SEAB.

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Article 17

Staff

1 BBMRI-ERIC may employ staff which shall be appointed and dismissed by the Director-General. The appointment and dismissal of high-level staff as defined in the internal rules shall require approval by the Assembly of Members.

2 The Assembly of Members shall approve the staff establishment plan prepared by the Director-General while approving the Work Programme.

3 The selection procedures of applicants for BBMRI-ERIC staff positions shall be transparent, non-discriminatory and respect equal opportunities.

Article 18

Access

1 BBMRI-ERIC shall make samples and data in databases affiliated with or developed by BBMRI-ERIC Partner Biobanks available to researchers and research institutions according to the access procedure and criteria as approved by the Assembly of Members. Access shall respect conditions set by sample and data providers that affiliate their databases to BBMRI-ERIC. No provision in these Statutes should be understood as seeking to restrict the right of owners of Biobanks or Biomolecular Resources affiliated with BBMRI-ERIC to decide on providing access to any samples and data.

2 BBMRI-ERIC shall provide access to samples and related clinical data based on the scientific excellence of the proposed project as determined by an independent peer review and after ethical review of the research project proposal.

3 BBMRI-ERIC shall seek to ensure that the source of samples and data be appropriately acknowledged and shall request that such attribution be maintained in subsequent use of the samples and data.

Article 19

Intellectual Property Rights

1 No provision in these Statutes should be understood as seeking to alter the scope and application of Intellectual Property Rights and Benefit-Sharing Agreements as determined under relevant laws and regulations of the Members and international agreements to which they are a Party.

2 BBMRI-ERIC may claim appropriate Intellectual Property Rights available within applicable national and international jurisdictions over tools, data, products or any other results developed or generated by BBMRI-ERIC while carrying out the Work Programme.

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Article 20

Reporting and Control

BBMRI-ERIC shall issue an annual report, containing in particular the scientific, operational and financial aspects of its activities. It shall be approved by the Assembly of Members and transmitted to the European Commission and relevant public authorities within six months after the end of the corresponding financial year. This report shall be made publicly available.

CHAPTER IV

FINAL PROVISIONS

Article 21

Linguistic Regime and Working Language

- 1 All versions of these Statutes in the official languages of the European Union shall be deemed authentic. No linguistic version shall prevail.
- 2 When language versions are not provided for through the *Official Journal of the European Union* in case of amendments to these Statutes that do not require a Commission Decision, BBMRI-ERIC shall provide translations into the official languages of its EU Members.
- 3 The working language of BBMRI-ERIC shall be English.

Article 22

Rules of Procedure

The Assembly of Members shall adopt at its first meeting the Rules of Procedure for BBMRI-ERIC according to the voting procedure laid down in Article 11(8)(a). The Rules of Procedure may be modified in accordance with the same procedure.

Article 23

Consolidated version of the Statutes

- 1 The Statutes shall be kept up to date and made publicly available on the website of the ERIC and at its statutory seat.
- 2 Any amendment to the Statutes shall be clearly indicated with a note specifying whether the amendment concerns an essential or non-essential element of the Statutes in accordance with Article 11 of Regulation (EC) No 723/2009 and the procedure followed for its adoption.

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Article 24

Winding Up of BBMRI-ERIC

1 The Assembly of Members may decide to terminate BBMRI-ERIC, subject to a vote according to Article 11(8)(e).

2 Subject to any agreement which may be made between Members at the time of dissolution, the Host Member State shall be responsible for the liquidation.

3 The Members shall decide transfer any crediting of income and properties of BBMRI-ERIC to one or more public or other not-for-profit legal entities based on a vote according to Article 11(9)(e).

Article 25

Applicable Law — Settlement of Disputes

1 The setting-up and internal functioning of BBMRI-ERIC shall be governed by:

2 The Members shall make their utmost effort to settle by amicable means any dispute which may arise from the interpretation or application of these Statutes.

3 The Court of Justice of the European Union shall have jurisdiction over litigation among the Members in relation to the BBMRI-ERIC, between the Members and BBMRI-ERIC and over any litigation to which the European Union is a party.

4 European Union legislation on jurisdiction shall apply to disputes between BBMRI-ERIC and third parties. In cases not covered by European Union legislation, the law of the Host Member State shall determine the competent jurisdiction for the resolution of such disputes.

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- (1) To be adopted by the Assembly of Members.
- (2) [OJ L 347, 11.12.2006, p. 1.](#)
- (3) [OJ L 77, 23.3.2011, p. 1.](#)
- (4) In case of Council adoption of the amendment of Regulation (EC) No 723/2009, Article 9(3), in regard to enabling participation of associated countries in ERIC's on the same footing as EU Member States, from the day of the amendment entering into force condition (c) shall read 'Of the Members present Member States of the European Union and associated countries must have the majority of the votes'.

Changes to legislation:

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