

## 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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) <sup>(1)</sup>, and in particular point (a) of Article 6(1) thereof,

Whereas:

- (1) 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 and the Kingdom of Sweden requested the Commission to set up BBMRI as a European Research Infrastructure Consortium (BBMRI-ERIC). The Kingdom of Norway, the Republic of Poland, the Swiss Confederation and the Republic of Turkey will participate in BBMRI-ERIC as Observers.
- (2) The Republic of Austria has been chosen by 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 Finland and the Kingdom of Sweden as the Host Member State of BBMRI-ERIC.

- (3) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 20 of Regulation (EC) No 723/2009,

HAS ADOPTED THIS DECISION:

*Article 1*

1. A European Research Infrastructure Consortium for the Biobanks and Biomolecular Resources Infrastructure named BBMRI-ERIC is hereby established.
2. The statutes of BBMRI-ERIC are set out in the Annex. These Statutes shall be kept up to date and made publicly available on the website of BBMRI-ERIC and at its statutory seat.
3. The essential elements of BBMRI-ERIC Statutes for which amendments shall require approval by the Commission in accordance with Article 11(1) of Regulation (EC) No 723/2009 are provided for in Articles 2, 3, 6, 7, 16, 17, 18, 19 and 24.

*Article 2*This Decision shall enter into force on the third day following its publication in the *Official Journal of the European Union*.

Done at Brussels, 22 November 2013.

*For the Commission**The President*

José Manuel BARROSO

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<sup>(1)</sup> OJ L 206, 8.8.2009, p. 1.

## 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.

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;
- (8) 'Organisational Node' means an entity, not necessarily with legal capacity, designated by an inter-governmental 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 inter-governmental organisation;
- (10) 'Partner Biobanks' means Biobanks collaborating with BBMRI-ERIC that comply with the BBMRI-ERIC Partner Charter <sup>(1)</sup>;
- (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:
  - (a) are closely related to its principal tasks;
  - (b) do not jeopardise their achievement.
3. To fulfil its tasks, BBMRI-ERIC shall in particular:
  - (a) grant effective access to its resources and services in accordance with the rules defined in these Statutes to the European research community, composed of researchers from Members;
  - (b) improve the interoperability between Biobanks and Biological Resource Centres of Members;
  - (c) implement quality management including standardised procedures, best practices and appropriate tools to increase the quality of the resources collected and their associated data;
  - (d) promote continuous enrichment of resources in Biobanks and associated data in order to maintain an adequate supply of specimens to keep up with the demands of the scientific community as well as to ensure continuous enrichment of the information associated with and generated by the analysis of biobanked samples. It shall contribute to increased use and dissemination of knowledge as well as optimisation of the results of biobank-based research activities throughout Europe;

<sup>(1)</sup> To be adopted by the Assembly of Members.

- (e) establish and operate Common Services for the European biobanking community;
  - (f) perform research services for public and private institutions;
  - (g) establish and implement technological developments related to the resources and services;
  - (h) provide training and facilitate mobility of researchers to support the establishment of new Biobanks and Biomolecular Resource Centres to strengthen and structure the European Research Area;
  - (i) establish international relationships and launch joint activities with other European and non-European organisations concerned with its activities and in related fields, and when appropriate become a member of such organisations;
  - (j) undertake any other activity necessary to fulfil its tasks.
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.

#### 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 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). Additional requirements concerning Members joining BBMRI-ERIC after the first three years shall be decided by the Assembly of Members.
3. 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;
  - (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.
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:
  - (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.
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 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 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 <sup>(1)</sup> and in accordance with Articles 50 and 51 of Council Implementing Regulation (EU) No 282/2011 of 15 March 2011 laying down implementing measures for Directive 2006/112/EC on the common system of value added tax <sup>(2)</sup> shall be limited to the value added taxes for such research and development goods and services which are:

- (a) in direct relation to the management and services of BBMRI-ERIC; and
- (b) closely related to the aims and activities laid down in Article 3; and
- (c) benefiting the entire scientific community; and
- (d) exceeding the value of EUR 250; and
- (e) wholly remunerated and procured by BBMRI-ERIC.

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.

<sup>(1)</sup> OJ L 347, 11.12.2006, p. 1.

<sup>(2)</sup> OJ L 77, 23.3.2011, p. 1.

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.

### 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:
  - (a) adopt the annual Work Programme and budget, together with a preliminary Work Programme and budget for the following two years;
  - (b) adopt the Rules of Procedure, the Financial Rules and Internal Rules according to Article 11(8)(a);
  - (c) adopt all rules, regulations and policies necessary for the sound management of the Work Programme, in particular the access procedure to biological resources, data in Biobanks and services developed by BBMRI;
  - (d) define the assignments of the Finance Committee;
  - (e) elect and dismiss the Chair and Vice-Chair;
  - (f) elect and dismiss the Chair and the Vice-Chair of the Finance Committee;
  - (g) appoint and dismiss the Director-General;
  - (h) approve hiring and dismissal of other high-level staff according to the Internal Rules;
  - (i) establish the Scientific and Ethical Advisory Board and any other committee, board or body such as the Stakeholders Forum and define their assignments and ruling;
  - (j) provide guidance and direction to the Director-General;
  - (k) approve the annual report, the annual accounts and reports of any advisory committee of the BBMRI-ERIC;
  - (l) consider any matters pertaining to BBMRI-ERIC or its operation submitted by any Member;
  - (m) admit Members and terminate the membership of any Member according to Article 11(8)(b);
  - (n) admit Observers and terminate the partnership of any Observer according to Article 11(8)(c);
  - (o) adjust the scales of financial contributions according to Article 5(8);
  - (p) decide on amendments to the Statutes according to Article 11(7); as well as
  - (q) undertake any other functions conferred upon it by the Statutes, including by any annex or modifications hereto.

#### *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:
  - (a) a majority of Members are present, and they represent 75 % of the Members annual mandatory contributions;

- (b) for decisions taken pursuant to paragraph 8, 75 % of Members are present, and they represent 75 % of the Members annual mandatory contributions;
- (c) of the Members present, Member States of the European Union must have the majority of the votes <sup>(1)</sup>.
3. Each Member shall have one vote. Defaulting Members shall have no vote.
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:
- (a) adoption of and changes to the Rules of Procedure, Financial and Internal Rules;
  - (b) acceptance of new Members;
  - (c) acceptance of new Observers;
  - (d) votes regarding Defaulting Members, including but not limited to the exclusion of Members (concerned Members excluded from voting);
  - (e) decision on termination of BBMRI-ERIC.
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:
- (a) decisions on the Work Programme and budget;
  - (b) approval of the annual report and the annual accounts;
  - (c) adjustment of the scale of financial contributions according to Article 5(8);
  - (d) appointment or dismissal of the Director-General;
  - (e) decisions on winding up of BBMRI-ERIC in case of termination of the infrastructure.
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:

<sup>(1)</sup> 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'.

- (a) advise the Assembly of Members and the Director-General on matters relating to the management and preparation of the budget of BBMRI-ERIC, its expenditure and accounts, and its future financial planning;
  - (b) provide the Assembly of Members and the Director-General with advice on the financial implications of the other BBMRI-ERIC bodies' recommendations;
  - (c) upon request, provide advice on other financial matters relating to the management and administration of BBMRI-ERIC;
  - (d) submit a proposal concerning the appointment of external auditors to the Assembly of Members.
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:
  - (a) the efficient administration of BBMRI-ERIC;
  - (b) the finances and the management of the staff of the BBMRI-ERIC;
  - (c) ensuring the execution of the decisions of the Assembly of Members.
3. The Director-General shall:
  - (a) be in charge of the execution of the Work Programme, including establishment of Common Services, and expenditure of the budget;
  - (b) prepare the agenda of the Assembly of Members meetings and prepare the Assembly of Members deliberations;
  - (c) prepare and submit to the Assembly of Members, not later than three months before the beginning of each financial year, a draft annual Work Programme, including a draft budget and staffing plan, together with a preliminary draft Work Programme and a draft budget for the following two years;
  - (d) provide the Assembly of Members with a technically substantive annual report on the Work Programme, including financial accounts, tasks achieved, tasks not achieved and any appropriate explanations;
  - (e) prepare and submit after approval by the Assembly of Members any documentation requested by the European Commission;
  - (f) coordinate the exchange of information among and the activities of the BBMRI-ERIC National/Organisational Nodes and Common Services through the Management Committee and by setting up such committees as deemed necessary for the administration of BBMRI-ERIC;

- (g) organise the selection procedure for the establishment of Common Services and any matter requiring such a procedure according to Annex IV;
- (h) nominate directors of Common Services after consultation with the national delegates of the Member State where Common Services are located;
- (i) organise the Scientific and Ethical Advisory Board for evaluation of research proposals received by the Central Executive Management Office;
- (j) propose the admission and exclusion of Members and Observers to the Assembly of Members;

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 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:
  - (a) contributing to and supporting the Director-General in the development of a draft annual Work Programme and a draft budget, together with a preliminary draft Work Programme and a draft budget for the following two years;
  - (b) supporting the Director-General in the execution of the Work Programme and for enabling efficient interaction between BBMRI-ERIC and the Partner Biobanks of Members.

#### *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.

#### *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.

#### *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.

## 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:
  - (a) European Union Law, in particular the ERIC Regulation and the decisions referred to in Articles 6(1) and 12(1) of afore-mentioned Regulation;
  - (b) the law of the Host Member State in the case of matters not, or partly not, regulated by acts referred in point (a);
  - (c) the Statutes and implementing rules (rules of procedures, financial and internal rules).

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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## ANNEX II

## LIST OF MEMBERS AND OBSERVERS AND THE ENTITIES REPRESENTING THEM

Members	Representing entity (e.g. ministry, research council)
Kingdom of Belgium	Federal Public Planning Service Science Policy (BELSPO)
Czech Republic	Ministry of Education (MŠMT)
Federal Republic of Germany	German Federal Ministry of Education and Research (BMBF)
Republic of Estonia	Ministry of Education and Research of the Republic of Estonia (MER EE)
Hellenic Republic	Biomedical Research Foundation of the Academy of Athens (BRFAA)
French Republic	Institute of Health and Medical Research (INSERM)
Italian Republic	National Institute of Health (ISS)
Republic of Malta	University of Malta (UoM)
Kingdom of the Netherlands	The Netherlands Organisation for Health Research and Development (ZonMW)
Republic of Austria	Austrian Federal Ministry of Science and Research (BMWF)
Republic of Finland	Ministry of Education and Culture of the Republic of Finland (OKM)
Kingdom of Sweden	Swedish Research Council (SRC)
Observers	Representing entity (e.g. ministry, research council)
Norway	Research Council of Norway
Republic of Poland	Ministry of Science and Higher Education of the Republic of Poland (MNiSW)
Switzerland	Swiss National Science Foundation (SNSF)
Turkey	Dokuz Eylul University of Izmir



## ANNEX III

**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 Members that are international organisations, shall pay a fixed contribution according to the lower category; and
    - (b) Members with 3 million or more inhabitants shall pay a fixed contribution according to the higher category.
  4. At the time these Statutes come into effect the fixed contribution shall be:
    - (a) EUR 20 000 for Members of the lower category; and
    - (b) EUR 25 000 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.
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## ANNEX IV

**SELECTION PROCEDURE FOR HOSTING COMMON SERVICES**

The following selection procedure shall be applied to all Common Services where the benefits accrue to the entire scientific community and which are remunerated by the BBMRI-ERIC:

1. The hosts of Common Services shall be selected by an open call procedure. A description of the service to be selected shall be prepared by the Director-General and approved by the Assembly of Members. This will be made publicly available when the open call for a Common Service is launched. Only applicants from BBMRI-ERIC Members are eligible to answer to the call.
  2. The Assembly of Members shall define the composition of an ad hoc committee to evaluate the applications as well as a set of objective and non-discriminatory evaluation criteria that the ad hoc committee shall apply.
  3. The Assembly of Members shall decide on the selection of a Common Service based on the results of the ad hoc committee and after positive recommendation by the Finance Committee.
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