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## ANNEX I

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

#### 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:

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## 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.

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.

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### *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 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.

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## 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.

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### *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.

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- (1) 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'.

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