

# DECISIONS

## COMMISSION IMPLEMENTING DECISION

of 7 November 2013

on setting up the European Advanced Translational Research Infrastructure in Medicine as a European Research Infrastructure Consortium (EATRIS ERIC)

(2013/640/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 Czech Republic, the Kingdom of Denmark, the Republic of Estonia, the Italian Republic, the Kingdom of the Netherlands and the Republic of Finland requested the Commission to set up the European Advanced Translational Research Infrastructure in Medicine as a European Research Infrastructure Consortium (EATRIS ERIC). The Kingdom of Spain and the Republic of France will participate initially in EATRIS ERIC as an Observer.
- (2) The Kingdom of the Netherlands has been chosen by the Czech Republic, the Kingdom of Denmark, the Republic of Estonia, the Kingdom of Spain, the Republic of France, the Italian Republic and the Republic of Finland as the Host Member State of EATRIS 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 European Advanced Translational Research Infrastructure in Medicine named EATRIS ERIC is hereby established.

2. The statutes of EATRIS ERIC are set out in the Annex. These Statutes shall be kept up to date and made publicly available on the website of EATRIS ERIC and at its statutory seat.

3. The essential elements of the EATRIS 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 1, 2, 18, 20, 21, 22, 23, 24, 25, 28 and 29.

### *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, 7 November 2013.

*For the Commission*

*The President*

José Manuel BARROSO

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

## ANNEX

## STATUTES OF EATRIS ERIC

THE MEMBERS,

while recognising the important role for the national centres and their translational research capacities as organised through the EATRIS ERIC infrastructure;

Having the aim to improve translational biomedical research by developing a European advanced translational research infrastructure consisting of key preclinical and clinical facilities and translational expertise necessary to support the development of new preventive, diagnostic and therapeutic strategies of biomedical research and development for providing people with better healthcare;

Having the aim to provide access to the European advanced translational research infrastructure with the objective to realise a significant impact on healthcare and make a significant contribution to the advancement of the tools and technologies that drive translational science;

Recognising and elaborating on the results of the EATRIS Preparatory Phase project, funded by the European Commission and the progress made during the Transition Phase of EATRIS;

Deciding to request the European Commission to establish the European Advanced Translational Research Infrastructure in Medicine European Research Infrastructure Consortium (EATRIS ERIC) — as an outcome of the Transition Phase of EATRIS;

HAVE THEREFORE AGREED UPON THE FOLLOWING PROVISIONS:

## CHAPTER I

## GENERAL PROVISIONS

*Article 1***Name, seat, and working language**

1. There shall be a distributed European Research Infrastructure called 'European Advanced Translational Research Infrastructure in Medicine', hereinafter referred to as 'EATRIS'.
2. The name of the European Research Infrastructure Consortium (ERIC) — European Advanced Translational Research Infrastructure in Medicine shall be 'EATRIS ERIC'.
3. EATRIS ERIC shall have its statutory seat in Amsterdam, the Netherlands.
4. The working language of EATRIS ERIC shall be English.

*Article 2***Tasks and activities**

1. EATRIS ERIC shall advance research in translational medicine.
2. EATRIS ERIC shall be committed to organising and facilitating the governance and coordination that is required to establish and operate the EATRIS research infrastructure.
3. The EATRIS research infrastructure shall connect leading European research institutes that dedicate part of their research and development capacities to EATRIS ERIC sharing content, tools and knowledge related to research in translational medicine and in particular on the following:
  - (a) biologics and advanced therapies, such as gene and cell therapies and regenerative medicine;
  - (b) biomarkers;
  - (c) small molecules;
  - (d) molecular imaging and tracers;
  - (e) vaccines.

## CHAPTER II

**MEMBERS***Article 3***Membership and representation**

1. EATRIS ERIC shall have at least three Member States as Member, only States and intergovernmental organisations may become Member and have voting rights.
2. Any Member shall appoint one or two representatives in the Board of Governors. Two representatives shall together hold one vote.
3. The Members and their representatives are listed in Appendix 1. The States that submitted the application requesting the setting up of EATRIS ERIC to the European Commission are hereinafter referred to as Founding Members.

*Article 4***Admission of new members**

1. Applicants for Membership shall submit a written application to the Chairperson of the Board of Governors describing their financial contribution and other contributions to EATRIS ERIC tasks and activities and how they will fulfill their obligations.
2. The admission of new Members shall be subject to the approval of the Board of Governors.
3. The initial financial commitment of any Member joining EATRIS ERIC for the first time shall be five years;

*Article 5***Withdrawal of a member and termination of membership**

1. No Member may withdraw within the first five years of the establishment of EATRIS ERIC unless the Membership has been entered into for a specified shorter period.
2. After the first five years of the establishment of EATRIS ERIC a Member may withdraw provided a request is submitted to this effect 12 months in advance. A withdrawal shall only become effective at the end of a financial year and after the withdrawing Member has fulfilled its obligations.
3. By derogation from paragraph 1 of this Article, a Member may withdraw during the first five years if the Board of Governors decide to raise the thresholds of the annual financial contribution as specified in points (e) and (f) of Appendix 2. A member wishing to withdraw shall request withdrawal within six months of the adoption of the proposal to raise the annual financial contribution. The withdrawal shall become effective at the end of the financial year on the condition that the withdrawing Member has fulfilled its obligations.
4. The Board of Governors shall have the power to terminate a Membership in the following cases:
  - (a) the Member is in serious breach of one or more of its obligations under these Statutes;
  - (b) the Member has failed to rectify such breach within a period of six months of notification thereof.

The Member shall be invited by the Board of Governors to present its position on the proposed decision of termination before any decision may be adopted.

5. Members that withdraw or have their Membership terminated shall neither have right to restitution or reimbursement of any contributions made, nor the right to lay any claim to the assets of EATRIS ERIC.

*Article 6***Rights and obligations of Members**

1. Rights of Members shall include:
  - (a) the right to attend and vote at the Board of Governors;
  - (b) the right to participate in the development of strategies, policies and decision-making procedures concerning EATRIS ERIC;

- (c) the right of its research community to participate in EATRIS ERIC events;
  - (d) the right of its research community to have access to and to receive support from EATRIS ERIC.
1. Each Member shall:
    - (a) pay an annual financial contribution as decided by the Board of Governors;
    - (b) empower its representatives with the full authority to vote by single vote on all issues raised during a meeting of the Board of Governors;
    - (c) create a national centre or infrastructure consortium for the purpose of fulfilling the obligations arising from these Statutes;
    - (d) appoint one National Director to represent it on the Board of National Directors;
    - (e) provide the necessary technical infrastructure to make access possible;
    - (f) promote the uptake of EATRIS ERIC services among researchers in its own country and gather user feedback and requirements;
    - (g) support centres in its own country that wish to join the national infrastructure of a Member State participating in the EATRIS ERIC infrastructure.
  2. Contributions other than the annual financial contribution may be made by Members individually or jointly in cooperation with other Members, Observers or third parties. Such contributions, in cash or in kind, shall be subject to approval by the Board of Governors.
  3. EATRIS ERIC shall enter into an agreement with the national centres in order to establish the terms and conditions under which the national centres may join the EATRIS ERIC infrastructure and commit to the tasks and activities set out in Article 2. The National Director shall use its best efforts to coordinate the interaction of its national centres with the EATRIS ERIC.

### CHAPTER III

#### **OBSERVERS**

##### *Article 7*

#### **Observer status**

1. States and intergovernmental organisations which are willing to contribute to EATRIS ERIC but are not yet in a position to join as Members may apply for Observer status.
2. Observers shall be admitted for a maximum of three years, unless another term is decided by the Board of Governors.
3. Applications for Observer status shall be made in writing to the Chairperson of the Board of Governors and shall set out how the applicant intends to contribute to EATRIS ERIC tasks and activities.
4. The admission of Observers shall be subject to the approval of the Board of Governors.

##### *Article 8*

#### **Withdrawal of an observer and termination of observer status**

1. Observers may withdraw at the end of a financial year provided they have submitted a request thereto six months in advance.
2. Financial and other obligations must be fulfilled before a withdrawal by an Observer can take effect.
3. The Board of Governors shall have the power to terminate the Observer status of an Observer in the following cases:
  - (a) the Observer is in serious breach of one or more of its obligations under these Statutes;
  - (b) the Observer has failed to rectify such breach within a period of six months of notification thereof.

The Observer shall be invited by the Board of Governors to present its position on the proposed decision of termination before any decision may be adopted.

4. Observers that withdraw or have their Observer status terminated shall have neither the right to restitution or reimbursement of any contribution made, nor the right to lay any claim to the assets of EATRIS ERIC.

*Article 9***Rights and obligations of an Observer**

1. Rights of Observers shall include:
  - (a) the right to attend the meeting of the Board of Governors without a right to vote;
  - (b) the right of their research community to participate in EATRISERIC events;
  - (c) the right of their research community to access EATRIS ERIC infrastructure and to receive support from EATRIS ERIC.
2. Each Observer shall:
  - (a) appoint one or two representatives in the Board of Governors;
  - (b) pay the annual financial contribution as decided by the Board of Governors;
  - (c) set out its contribution to the EATRIS ERIC tasks and activities set out in Article 2.
3. Contributions other than the annual financial contribution to EATRIS ERIC may be provided by Observers individually or jointly in cooperation with other Members, Observers or third parties. Such contributions, in cash or in kind, shall be approved by the Board of Governors.
4. An Observer shall empower its representative(s) to fulfill the obligations referred to in points (b) and (c) of Article 9(2).
5. EATRIS ERIC shall enter into an Observer Agreement with the Observer in order to establish the terms and conditions under which the obligations are to be fulfilled or the contribution is to be made.

## CHAPTER IV

**GOVERNANCE OF EATRIS ERIC***Article 10***Governance and management**

The governance structure of EATRIS ERIC shall comprise the following bodies:

- (a) the Board of Governors;
- (b) the Executive Board.

*Article 11***Board of Governors**

1. The Board of Governors shall be the highest and ultimate governing body of EATRIS ERIC with full decision-making power. The Board of Governors shall meet at least once a year and shall be responsible in accordance with the provisions of these Statutes for the overall direction and supervision of EATRISERIC.
2. Member States shall jointly hold the majority of the votes.
3. The Board of Governors shall elect amongst its members a Chairperson and a deputy for a two-year term. The Chairperson and deputy may be re-elected. Unless decided otherwise, the Chairperson shall chair all meetings of the Board of Governors and shall be assisted by the deputy.
4. The Board of Governors shall use their best efforts to achieve consensus on all decisions. Failing consensus, a simple majority of the votes cast shall suffice to pass a decision, except for decisions referred to in paragraphs 5, 6, 7 and 9.
5. The Board of Governors shall decide with a majority of at least two-thirds of the votes of the Members on decisions to:
  - (a) adopt or change the strategies for the development of EATRIS ERIC;
  - (b) appoint, suspend or dismiss the Finance Director and the Scientific Director after consultation with the Board of National Directors;
  - (c) establish Subsidiary Bodies in addition to the Permanent Bodies;
  - (d) adopt or change Standing Orders which describe the mandate and specify the activities of the Executive Board and of the Subsidiary Bodies;
  - (e) adopt and amend the annual work programme and the annual budget.

6. For decisions regarding financial implications of:
- (a) the long-term strategic plan, (requiring two-thirds majority under Article 11. 5 (a) of the Statutes)
  - (b) adoption and revision of the annual budget, (requiring two-thirds majority under Article 11. 5 (e) of the Statutes)
  - (c) adoption and revision of the quarterly and annual financial reports (requiring simple majority under Article 11.4. of the Statutes), and
  - (d) approval of the consolidated annual accounts (requiring simple majority under Article 11.4 of the Statutes) a double majority vote is required corresponding to the required majorities stipulated in Article 11.6 (a) - (d) above, whereby the required majority is determined both in terms of the number of Members (present and voting), and also in terms of the proportion of Members' annual financial contributions as a share of all Members' annual financial contributions. The double majority voting model may be reviewed by the Board of Governors five years from 1<sup>st</sup> January 2019 or in case the annual financial contribution model as per Appendix 2 is revised;
7. Decisions of the Board of Governors to terminate a Membership or Observer status shall require a majority of at least three quarters of the votes of the Members.
8. A Member whose Membership termination is to be decided upon shall have no vote in that decision.
9. The Board of Governors shall decide with unanimity of the Members, not counting any abstentions, on decisions to:
- (a) amend the statutes, except for Appendix 1;
  - (b) wind up EATRIS ERIC.
- Unless otherwise agreed, Members shall be informed of the exact wording of amendments to the Statutes and to Appendix 2 at least three months before those amendments are put to vote.
10. The Board of Governors shall meet and decide validly only if a quorum of two thirds of all the Members of EATRIS ERIC are present or represented.
11. The Board of Governors shall adopt Rules of Procedure for implementing the provisions of the Statutes.

#### *Article 12*

##### **Executive Board**

1. The Executive Board shall be responsible for the implementation of EATRIS ERIC and for supporting the Board of Governors. The Executive Board shall be accountable solely to the Board of Governors.
2. The Executive Board shall perform its duties as determined by the Board of Governors and shall prepare its own internal procedures of organisation, meetings and the way the Operations and Finance Director and Scientific Director shall work together in the Rules of Procedure, to be submitted for approval by the Board of Governors.
3. The Executive Board shall consist of the Operations and Finance Director and the Scientific Director.
4. The Operations and Finance Director shall be the legal representative of EATRIS ERIC, shall represent EATRIS ERIC in any litigation and shall be responsible for the (day-to-day) operational management of EATRIS ERIC.
5. The Scientific Director of EATRIS ERIC shall be responsible for the strategic scientific development and all operational scientific matters of EATRIS ERIC.
6. The Directors of the Executive Board may serve for a term of up to five years to be decided by the Board of Governors. After the initial term the Board of Governors shall decide on any extension. The procedures for the selection and appointment of Directors shall be laid down in Rules of Procedure adopted by the Board of Governors.

#### *Article 13*

##### **EATRIS ERIC coordination and support office**

1. EATRIS ERIC Coordination and Support Office shall be the central management and daily operations office of EATRIS ERIC and shall assist the Board of Governors. It shall be managed and its staff shall be recruited by the Operations and Finance Director in consultation with the Scientific Director.
2. The EATRIS Coordination and Support Office shall be accommodated at the premises of EATRIS ERIC located at its statutory seat.

## CHAPTER V

**SUBSIDIARY BODIES***Article 14***Subsidiary bodies**

1. EATRIS ERIC shall have the following Subsidiary Bodies:
  - (a) the Board of National Directors;
  - (b) the Scientific Advisory Board.
2. The Board of Governors may establish other Subsidiary Bodies if deemed necessary for the functioning of EATRIS ERIC.

*Article 15***Board of National Directors**

1. The Board of National Directors shall oversee the coordination of the implementation of the strategies approved by the Board of Governors. The Board of National Directors shall be responsible for all national scientific activities related to EATRIS ERIC and shall maintain coherence and consistency across EATRIS ERIC and collaboration between the Members.
2. The Board of National Directors shall consist of the National Directors appointed by the Members.
3. The members of the Board of National Directors shall elect amongst its members a Chairperson and a deputy for a two- year term with the possibility of re-election in conformity with the procedures laid down in Rules of Procedure.
4. The Board of National Directors shall propose the Rules of Procedure and adopt them after approval by the Board of Governors for their internal operational procedures.
5. The Board of National Directors shall perform the activities as determined by the Board of Governors in Standing Orders.
6. The Board of National Directors shall select the members of the Scientific Advisory Board subject to approval by the Board of Governors.

*Article 16***Scientific Advisory Board**

1. The Scientific Advisory Board shall consist of independent and internationally recognised scientists involved in biomedical translational research acting on their personal title and strategic experience.
2. The Scientific Advisory Board shall offer advice on request to the Board of Governors and may be consulted by the Executive Board and the Board of National Directors on all scientifically and technologically relevant matters including questions regarding the EATRIS ERIC research agenda, scientific strategies, ethical issues and the annual work programme.

## CHAPTER VI

**FINANCE AND REPORTING***Article 17***Budgetary principles and accounts**

1. The financial year of EATRIS ERIC shall begin on 1 January and shall end on 31 December of each year.
2. EATRIS ERIC funds may be used solely for purposes as laid down in these Statutes.
3. All items of revenue and expenditure of EATRIS ERIC shall be included in estimates to be drawn up for each financial year and shall be recorded in the annual budget.
4. The accounts of EATRIS ERIC shall be accompanied by an audited report on the budgetary and financial management of the financial year. EATRIS ERIC shall produce an annual activity report, describing, in particular, the scientific, operational and financial aspects of its activities. The report shall be approved by the Board of Governors and transmitted to the European Commission and relevant public authorities within six months of the end of the corresponding financial year. This report shall be made publicly available in full or in part.
5. EATRIS ERIC shall be subject to the requirements of the applicable law and regulations as regards preparation, filing, auditing and publication of accounts.
6. EATRIS ERIC shall ensure that all appropriations shall be used in accordance with the principles of sound financial management.

*Article 18***Liability**

1. EATRIS ERIC shall be liable for its debts.
2. The Members' financial liability towards ERIC's debts shall be limited to each individual Member's annual financial contribution.
3. EATRIS ERIC shall take appropriate insurance to cover the risks of liability specific to the construction and operation of EATRIS ERIC.

## CHAPTER VII

**POLICIES***Article 19***Agreements with third parties**

In cases where EATRIS ERIC deems it beneficial, it can enter into agreements with third parties.

*Article 20***Intellectual property rights policy**

1. The term intellectual property shall mean intellectual property as defined in Article 2 of the Convention Establishing the World Intellectual Property Organization signed on 14 July 1967.
2. The Board of National Directors shall provide for common principles and policies for Intellectual Property as laid down in Rules of Procedure. Those common principles and policies shall be approved by the Board of Governors.
3. The Board of National Directors may recommend agreements with the national centres and infrastructure consortia within the EATRIS research infrastructure in order to ensure that these entities as well as third parties have access to the scientific knowledge of the EATRIS research infrastructure.

*Article 21***Access policy**

1. EATRIS ERIC shall ensure as a general rule open access to services and infrastructures supporting and promoting excellence in translational research as well as a culture of 'best practices' through training activities.
2. EATRIS ERIC shall provide guidance for users of EATRIS infrastructure to best ensure that research which has been undertaken using the resources of the EATRIS infrastructure recognises and respects compliance with any property, personal privacy, ethical and data owner's protection rights as well as secrecy and confidentiality obligations as defined in Rules of Procedure, further ensuring that users comply with access terms and conditions, security arrangements for the internal storage and handling of (bio) materials and handling of information of research institutions participating in EATRIS infrastructure.
3. The criteria and procedures that provide or restrict access to EATRIS ERIC infrastructure data and tools shall be defined in Rules of Procedure and decided by the Board of Governors after advice from the Board of National Directors and the Scientific Advisory Board.

*Article 22***Scientific evaluation policy**

1. EATRIS ERIC shall provide access to its translational infrastructure to projects that have the most potential for making a significant impact on health care or a significant contribution to the advancement of the tools and technologies that drive translational science.
2. The scientific evaluation process of projects requesting access to the EATRIS ERIC infrastructure shall consider scientific merit, unmet medical need, eligibility and translational potential, and shall be based on transparency, fairness and impartiality. That process shall be approved by the Board of Governors and laid down in Rules of Procedure.



3. The scientific evaluation of projects within the EATRIS ERIC infrastructure shall consider scientific merit, unmet medical need and translational potential based on transparency, fairness and impartiality and shall be further elaborated by the Board of Governors and laid down in Rules of Procedure.

#### *Article 23*

##### **Dissemination policy**

1. EATRIS ERIC shall take all appropriate action to promote the infrastructure and its use in research and education.
2. EATRIS ERIC shall promote the dissemination and sharing of results obtained by national and international research activities.
3. Without prejudice to any property rights EATRIS ERIC shall request its users to make their research results publicly available and to make results available through EATRIS ERIC.
4. The dissemination policy shall identify the various target groups, and EATRIS ERIC shall use several channels to reach the target audiences, such as web portals, newsletters, workshops, presence at conferences, articles in journals and daily newspapers.

#### *Article 24*

##### **Employment policy**

EATRIS ERIC shall endeavor to select the best candidate on a non-discriminatory basis, regardless of background, nationality, religion or gender, reflecting contributions made by the Members.

#### *Article 25*

##### **Procurement policy**

1. EATRIS ERIC shall treat procurement candidates and tenderers equally and without discrimination, regardless of whether or not they are based within the European Union. The EATRIS ERIC procurement policy shall respect the principles of transparency, non-discrimination and competition. The Board of Governors shall adopt Rules of Procedure establishing detailed rules on procurement procedures and criteria.
2. The Executive Board shall be responsible for all EATRIS ERIC procurement. All tenders shall be published on the EATRIS ERIC website and in the Members' and Observers' territories. EATRIS ERIC shall follow the principles of Directive 2014/24/EU of the European Parliament and of the Council of 26<sup>th</sup> February 2014 on public procurement and repealing Directive 2004/18/EC <sup>(1)</sup>. The decision to award procurement shall be published and include a full justification.

#### *Article 26*

##### **Tax exemption**

1. Tax exemptions based on Articles 143(1)(g) and 151(1)(b) of Council Directive 2006/112/EC <sup>(2)</sup> and in accordance with Articles 50 and 51 of Council Implementing Regulation (EU) No 282/2011 <sup>(3)</sup> shall be limited to the value added tax for such goods and services which are for official use by EATRIS ERIC, exceed the value of EUR 250, and are wholly paid for and procured by EATRIS ERIC. Procurement by individual Members shall not benefit from these exemptions. Without prejudice to paragraphs 2 and 3 no further limits shall apply.
2. Tax exemptions shall apply to non-economic activities, not to economic activities.
3. Tax exemptions shall be applied to goods and services for the scientific, technical and administrative operations undertaken by EATRIS ERIC in line with its principal tasks. This shall also include expenses for conferences, workshops and meetings directly linked to the official activities of EATRIS ERIC. However, travel and accommodation expenses shall not be covered by tax exemptions.

<sup>(1)</sup> OJ L 94, 28.3.2014, p.65

<sup>(2)</sup> OJ L 347, 11.12.2006, p. 1.

<sup>(3)</sup> OJ L 77, 23.3.2011, p. 1.

*Article 27***Data policy**

The Executive Board shall submit to the Board of Governors for approval Rules of Procedure for data policy in relation to users of EATRIS ERIC infrastructure, the national centres and third parties such as universities, research institutes and industry, with due respect for existing licences.

## CHAPTER VIII

**DURATION, WINDING UP, DISPUTES, SET UP PROVISIONS***Article 28***Duration**

The duration of EATRIS ERIC shall be indefinite.

*Article 29***Winding up**

1. The winding up of EATRIS ERIC shall be decided by the Board of Governors.
2. The European Commission shall be notified within 10 calendar days of the decision to wind up EATRIS ERIC.
3. Assets remaining after payment of EATRIS ERIC debts shall be apportioned among the Members in proportion to their accumulated annual contribution to EATRIS ERIC.
4. The European Commission shall be notified within 10 calendar days of the closure of the winding up procedure.

*Article 30***Language and availability of the Statutes**

1. These Statutes shall be kept up to date and made publicly available on the website of the ERIC and at its statutory seat.
2. These Statutes shall be deemed authentic in all official language versions of the Members listed in Appendix 1. These Statutes shall also be deemed authentic in the official language versions of the Members States not listed in Appendix 1. No language version shall prevail.
3. When language versions are not provided for through the Official Journal in case of amendments to these Statutes that do not require a Commission Decision, they shall be provided by EATRIS ERIC Coordination and Support Office.

*Article 31***Set-up provisions**

1. A constitutional meeting of the Board of Governors shall be called by the host country as soon as possible but no later than within 45 calendar days after the entry into force of the decision of the European Commission setting up EATRIS ERIC. Without prejudice to paragraph 2 no decisions shall be taken by the Board of Governors before at least five Members have joined EATRIS ERIC.
  2. The host country shall notify the Founding Members of any specific urgent legal action that needs to be taken on behalf of EATRIS ERIC before the constitutional meeting is held. Unless a Founding Member objects within five working days of being notified, the legal action shall be carried out by a person duly authorised by the host state.
  3. As of the establishment of EATRIS ERIC, its bodies shall act in accordance with the Standing Orders and Rules of Procedure as approved by the EATRIS Governing Board during the EATRIS Transition Phase.
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*Appendix I***List of members, observers, and the entities representing them**

Members	Representing entity
Republic of Bulgaria	Ministry of Education and Science
Czech Republic	Ministry of Education, Youth and Sports (MEYS)
Republic of Finland	Ministry of Education and Culture (OKM)
French Republic	Commissariat à l'Énergie Atomique et aux Énergies Alternatives (CEA)
Italian Republic	Istituto Superiore di Sanità (ISS)
Kingdom of Luxembourg	Le Gouvernement du grand-Duché de Luxembourg
Kingdom of the Netherlands	ZonMW
Kingdom of Norway	Research Council of Norway
Republic of Portugal	INFARMED-National Authority of Medicines and Health Products
Republic of Slovenia	Ministry of Education, Science and Sport
Kingdom of Spain	Instituto de Salud 'Carlos III' (ISCIII)
Kingdom of Sweden	Vetenskapsrådet
Observers	Representing entity
Republic of Croatia	Ministry of Science and Education
Republic of Latvia	Ministry of Education and Science

*Appendix 2***Annual financial contribution**

As of January 1<sup>st</sup> 2019, the principles for the Financial Commitment shall be as follows:

- (a) the initial financial commitment of any Member joining EATRIS ERIC for the first time shall be five years;
- (b) Members may sign up for less than five years subject to a 25 % increase in the annual contribution; the excess shall be refunded if the Member completes 5-year commitment and financial contribution;
- (c) in the case mentioned in point (b), the 25% extra financial contribution will be held in reserve either until it is refunded to the respective contributing Members upon their satisfying the qualifying conditions specified in point (b), or until the respective contributing Member fails to meet the conditions for refund specified in point (b), in which case that amount will be allocated to operational funds in the following year's budget.
- (d) The Netherlands is host country and will pay an additional host country contribution of EUR 50.000 per annum and in-kind contribution of the host institute which is evaluated every five years by the host country.
- (e) the maximum membership contribution is EUR 140.000 per annum (maximum threshold);
- (f) the minimum membership contribution is EUR 50.000 per annum (minimum threshold);
- (g) as of 2019 the contribution model shall be based on intramural R&D expenditure by all sectors of performance and all sources of funds, and also on the population of the Members, as determined with reference to the latest available figures for each country available on the Eurostat website (<https://ec.europa.eu/eurostat>) as of the 31<sup>st</sup> August 2018,

The contribution model consists of (cumulatively):

- a fixed fee of EUR 90.000, or a reduced fixed fee for countries with a population less than 7.5 million of EUR 60.000, and
- a variable fee of EUR 5.000 in case of less than EUR 4 billion national R&D expenditure per country, EUR 25.000 in case of EUR 4-12 billion national R&D expenditure, or EUR 40.000 in case of more than EUR 12 billion national R&D expenditure.

The annual fees thus calculated on the basis of the annual financial contribution model as per (g) above will remain fixed for each country for a three-year period from January 1<sup>st</sup>, 2019. After the first three year period, the annual fees will be fixed every three years thereafter to reflect the changes in population or national R&D expenditure if such occur.

- (h) in the event that Member withdrawals in a single calendar year will result in a loss of contributions greater than 7% of the combined total annual contributions of Members and Observers, the Members and Observers will make best efforts to compensate for the respective loss of contribution for the following year, in order to ensure operational stability of EATRIS ERIC.
  - (i) where an Observer has institutes, which participate in scientific activities of EATRIS ERIC, including the provision of services and participation in projects, that Observer shall pay the same annual financial contribution as a Member.
  - (j) where an Observer does not have institutes, which participate in scientific activities of EATRIS ERIC, including the provision of services and participation in projects, that Observer shall pay 25% of the annual financial contribution that they would have paid as a Member, subject to a minimum contribution level of EUR 25.000 per year.
-