



Horizon Europe

Project: 101079789

D5.3 – Legal Framework Proposal
WP5 – Governance & Legal Framework

WP Leader:	MU
Date:	September 2024
Nature:	DEC
Dissemination level:	Public

Document Information

Grant Agreement Number	101079789	Acronym	EIRENE PPP
Full title	EIRENE PPP		
Project URL	https://www.eirene.eu/		
Project Officer	Andreas Holtel, Andreas.HOLTEL@ec.europa.eu		

Delivery date	Contractual	30/09/2024	Actual	30/09/2024
Status	Draft/Final			
Nature	DEC			
Dissemination level	Confidential/Public			

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Document History

Institution	Date	Version
MU	30/09/2024	v.01

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Glossary of Terms

<i>ERIC</i>	<i>European Research Infrastructure Consortium</i>
<i>ELI</i>	<i>Extreme Light Infrastructure</i>
<i>ICOS</i>	<i>Integrated Carbon Observation System ERIC</i>
<i>BBMRI</i>	<i>Biobanking & Biomolecular Resources Research Infrastructure</i>
<i>ACTRIS</i>	<i>Aerosol, Clouds & Trace Gases Research Infrastructure</i>
<i>ESFRI</i>	<i>European Strategic Forum on Research Infrastructures</i>
<i>SHARE</i>	<i>Survey of Health, Ageing & Retirement in Europe</i>
<i>ECRIN</i>	<i>European Clinical Research Infrastructure Network</i>
<i>IHEN</i>	<i>International Human Exposome Network</i>
<i>DARIAH</i>	<i>Digital Research Infrastructure for the Arts & Humanities</i>
<i>EATRIS</i>	<i>European Research Infrastructure for Translational Medicine</i>
<i>EMBRIC</i>	<i>European Marine Biological Resources Centre</i>
<i>ECCSEL</i>	<i>European Research Infrastructure for CO₂ Capture, Utilisation, Transport & Storage</i>
<i>CERIC</i>	<i>Central European Research Infrastructure Consortium</i>
<i>AnaEE</i>	<i>Analysis and Experimentation on Ecosystems</i>

Introduction

EIRENE is a distributed research infrastructure whose structure models existing ESFRI Research Infrastructure Projects and Landmarks, such as ICOS, BBMRI, and ACTRIS. This model, developed over many years, has proven very efficient for coordinating and managing large pan-European distributed research infrastructures. The development of EIRENE follows the Design, Preparation, Implementation, and Operation ESFRI lifecycle phases. EIRENE is in the Preparation phase, currently funded by the Horizon Europe EIRENE PPP project, and plans to establish itself as a **European Research Infrastructure Consortium (ERIC)** during the subsequent Implementation phase. "An ERIC is a legal entity set up by a decision of the European Commission. It has a legal personality and full legal capacity recognized in all EU Member States. The basic internal structure of an ERIC is flexible and defined by its members in the statutes." The ERIC Regulation was adopted in 2009 under Council Regulation (EC) No 723/2009. In 2013, the Regulation was amended to better reflect the contribution of associated countries to the ERIC. This deliverable describes the steps EIRENE will take towards becoming an ERIC. **Figure 1 below illustrates the timeline for establishing EIRENE-ERIC** in the context of the ESFRI lifecycle phases, as well as the dedicated Horizon Europe projects that will facilitate achieving this goal. In the upcoming Horizon Europe Calls, EIRENE will submit an INFRA-DEV proposal for a project (EIRENE IMP) that will support the Implementation phase, in which EIRENE will submit an application for becoming an ERIC.

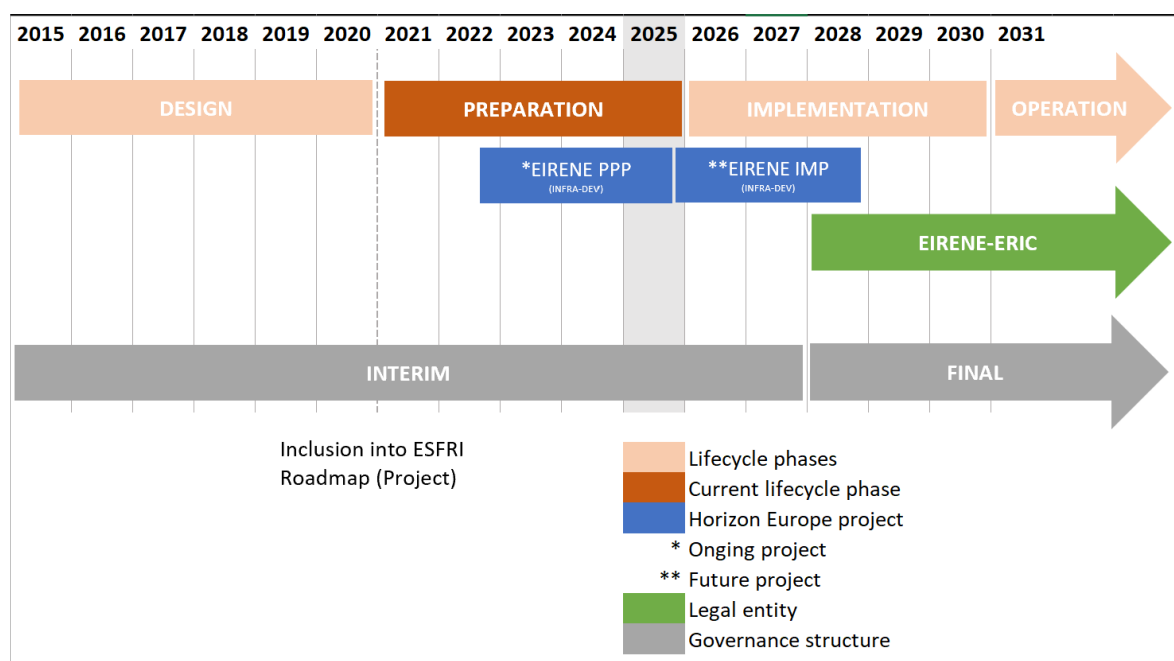


Figure 1 - Timeline for the establishment of EIRENE-ERIC

The legal framework encompasses both European and national levels. On the European level, it consists of the ERIC legal entity, i.e., EIRENE-ERIC, while on the national level, it consists of the National Nodes, comprising one or more research-performing organizations. National Nodes may establish a legal entity to represent them or form a consortium without the legal entity, in which case the leading institution will act as their legal

representative. In EIRENE, this is currently the case in France (<https://www.france-exposome.org/en>), Austria (<https://exposome.at/>), and the Netherlands (<https://exposome.nl/>). As National Nodes can elect an established legal entity, such as a university or research institution, to represent them forming a national legal entity is not obligatory. While the national legal framework is important to the overall functioning of EIRENE as an organization, it does not have direct implications on the European-level, EIRENE-ERIC legal framework. Therefore, this deliverable will focus mainly on establishing the European-level legal framework.

Steps and actions for preparing EIRENE for applying to become an ERIC

The EIRENE consortium has made significant progress in the last few years in preparing EIRENE for implementation, primarily through the current EIRENE PPP project. EIRENE members offer comprehensive and diverse services described in *D2.1 - List of EIRENE RI core services according to the pillar structure*; nonetheless, the level of development across the members and between institutions in member countries differ significantly. While several National Nodes offer services, others are only beginning to develop their capacities. There are also considerable differences in political and financial support and how research infrastructures are handled in individual countries. Some countries have national roadmaps, while others do not; some national roadmaps include funding, while others do not. In some countries, financial support is coupled with inclusion in national research infrastructure roadmaps. Since national roadmaps are updated only every several years, the inclusion process is lengthy, and thus newer members of EIRENE have not had a chance to submit applications to join.

As with other research infrastructures, **EIRENE-ERIC will initially include only a few of the current 21 national nodes**, i.e., those who have secured political and financial support from their governments. Once EIRENE-ERIC is established, the number of members is expected to increase as more national nodes obtain governmental support. There are obvious advantages and disadvantages to forming EIRENE-ERIC with an initially limited number of members. On the one hand, reaching agreements on significant, complex matters, such as organizational structure, statutes, financial aspects such as membership fee calculation and levels, cash and in-kind contributions, voting rights, etc., might be easier and faster to achieve. On the other hand, it will require a higher financial commitment from the members in the form of membership fees, as the overall burden of financing the ERIC will fall on fewer members.

At least three members are required to establish an ERIC. They must include at least one Member State and two other countries that are either EU Member States or associated countries. Nonetheless, third countries other than associated countries and intergovernmental organizations may also become members. Currently, a sufficient number of members have gained political and financial support from their respective governments, including the Czech Republic, the future statutory seat of EIRENE-ERIC. To that end, the

support of the Czech Republic is crucial. The Czech Republic has been heavily involved in European research infrastructures for many years and is currently a member of 18 of 26 ERIC consortia. One ERIC, ELI, has its statutory seat in the Czech Republic. The Ministry of Education, Youth, and Sports of the Czech Republic is the national authority responsible for large research infrastructures. One of its important activities is the development of the national roadmap for large Research Infrastructures, which is periodically updated. RECETOX RI – Masaryk University, which acts as EIRENE coordinator, was first included in the National Roadmap in 2010. RECETOX RI has also been involved in the activities of other ESFRI RIs, such as ELIXIR, as with the Czech national nodes of ACTRIS and BBMRI. The extensive experience of RECETOX RI in operating a large research infrastructure, coupled with experience at the national level with large research infrastructures in general, and ERICs in particular, will be instrumental in facilitating a smooth process towards becoming an ERIC, at least from the perspective of the host of the statutory seat of EIRENE-ERIC. Masaryk University participates in twelve ESFRI RIs, some of which are ERICs (e.g. EATRIS, ECRIN, BBMRI, ACTRIS, INSTRUCT).

EIRENE is involved in many complementary activities, notably in the ERIC Forum, particularly the Horizon Europe [ERIC Forum Implementation Project II](#). The ERIC Forum is a forum of all the established ERICs. The Forum's "aim is to advance operations of ERICs and to contribute to the development of ERIC-related policies strategically." The know-how of existing ERICs is invaluable for EIRENE's development. The ERIC Forum also discusses challenges in implementing the ERIC Regulation with the European Commission. Issues such as human resources management, procurement, VAT and excise taxes, in-kind contributions, the socioeconomic impacts of ERICs, and sustainability are of particular concern for the future operations of ERICs, including EIRENE.

Establishing communication with the ESFRI delegates in the future EIRENE-ERIC member countries, as well as with the respective ministries, is essential for moving the process forward. In October 2024, EIRENE will jointly meet with the [International Human Exposome Network](#) (IHEN) project in Utrecht. IHEN "aims to build a worldwide network to collaborate and improve human exposome research. The network will bring together researchers, policymakers, and independent experts to enhance the impact of future studies in this field." An important objective of the meeting is consultation with the stakeholders, including ESFRI delegates and ministries, regarding the realization of a future vision and the development of a comprehensive roadmap for future research.

Statutes are an essential legal document for submitting a proposal to establish an ERIC. A first draft of EIRENE-ERIC Statutes was developed during the project, and is presented in Annex A. Reaching the final version of the statutes will certainly require many more iterations, as it will necessitate extensive consultations with all EIRENE members and legal experts, and the final agreement of all the founding members of EIRENE-ERIC. However, since the format and content of the ERIC statutes are, to a large extent, mandated under the ERIC Regulation, and the statutes of the existing ERICs are, for the most part, very similar, the process should be relatively straightforward. In the following section, we provide a detailed comparison of the statutes of the existing ERICs.

The financial model was developed within the EIRENE PPP project and delivered toward the end of the project in 2025. It depends to a large degree on the final architecture of EIRENE, e.g., the number of “founding” members and Central Coordination Units.

The ERIC application (detailed below) contains five sections. **Section 2 (statutes)** and **section 3 (technical and scientific description, risk assessment, and key performance indicators)** are covered extensively in the EIRENE PPP project, which was specifically designed to prepare EIRENE for submitting the ERIC application. The relevance of EIRENE PPP deliverables to the content of the ERIC application is highlighted in Table 2.

Table 1 - Relevance of EIRENE PPP Deliverables to the ERIC application

Deliverable Name	Relevance to ERIC application	
	Section 2	Section 3
D1.1 - National Hubs Report	✓	✓
D1.2 - EIRENE RI Architecture		✓
D1.3 - EIRENE RI technical implementation plan		✓
D2.1 - List of EIRENE RI core services according to the pillar structure		✓
D2.2 - Roadmap for the development of EIRENE RI services		✓
D2.3 - EIRENE RI service access rules & procedures		✓
D3.1 - Data policy and DMP of EIRENE		✓
D3.2 - ELSA guidelines		✓
D3.3 - Report on data collection and generation		✓
D3.4 - Report on data access and sharing		✓
D4.1 - EIRENE RI Access procedures to be tested		✓
D4.2 - EIRENE RI facilities to be used in the Pilot		✓
D4.3 - EIRENE RI pilot design and tools		✓
D5.1 - Updated Governance and management structure and implementation report	✓	
D5.2 - Risk assessment and management plan		✓
D5.3 - Legal framework proposal	✓	
D5.4 - Updated business plan		✓
D6.1 - HR development strategy		✓
D6.2 - Education and training strategy		✓
D6.3 - User-support strategy		✓
D7.1 - EIRENE Cost Book		✓
D7.2 - Financial model		✓
D8.1 - Model socioeconomic analysis		✓
D8.2 - Stakeholder engagement report	✓	
D8.3 - Evaluation methodology, preliminary KPIs set		✓
D9.1 - Dissemination and Communication Plan		
D9.2 - Data Management Plan		✓
D9.3 - Webpage		
D9.4 - Policy Brief No. 1		
D9.5 - Policy Brief No. 2		

Section 2 - Proposed statutes

Section 3 - Technical and scientific description of the research infrastructure, including key

performance indicators and a risk assessment associated with implementing the research infrastructure.

Sections 4 and 5 involve Members' declarations recognizing the ERIC's legal status. While the political and financial support already granted to several EIRENE members does not necessarily guarantee support for becoming an ERIC, as in many cases, the support was granted before selecting the ERIC as the legal structure, and it will likely be accepted since the ERIC legal entity was created by the EC specifically for this purpose and has already been applied successfully in the past.

In March 2015, the European Commission published the "ERIC Practical Guidelines." Among other things, the guidelines explain the steps involved in applying to become an ERIC. The steps include:

Step 1: *Verification of compliance with the requirements laid down in the ERIC Regulation (duration: 3 months)*

Step 2: *Formal request to the Commission to set up the ERIC (duration: 6 months)*

The content of the application must contain:

1. *A request to the Commission to set up the ERIC*
2. *Proposed statutes*
3. *A technical and scientific description of the research infrastructure, including key performance indicators and a risk assessment associated with implementation of the research infrastructure.*
4. *A declaration by the host Member State recognising the ERIC as an international body and international organisation within the meaning of the of the directive on VAT and excise duties*
5. *Each Member who is an Associated countries, third countries or intergovernmental organisations must sign a declaration recognising the legal personality and capacity of the ERIC, agreeing that it will be subject to rules and jurisdiction as defined in the ERIC regulation and providing equivalent treatment as an international body or international organisation with respect to VAT and excise duties exemption and to procurement rules.*

Comparing the statutes of existing ERICS

Currently, there are 26 ERICs, with the first ERIC, SHARE, being established in 2011. For this deliverable, the statutes of all 26 ERICS were compared. Overall, except for minor variations, the statutes are very similar. This similarity is not surprising as it is dictated by the ERIC Regulation, which clearly defines the structure and content of the statutes. Specifically, Article 10 of the Regulation (shown below) specifies what the statutes should contain. Because of the similarity in the statutes and the generally strict adherence to the language of the ERIC Regulation, we only highlight the differences between the statutes as well as information not mentioned in the Regulation.

The ERIC Regulation, i.e., Council Regulation (EU) No 723/2009 stipulating the legal framework for a European Research Infrastructure Consortium (ERIC), was passed in 2009 and amended in 2013. In the 2013 amendment, the EC recognized the crucial role of associated countries in European research infrastructures and thus amended the Regulation to allow associated countries to "participate in ERICs on the same footing as Member States" so their contributions "can be fully reflected in terms of membership and voting rights." The original requirement that "an ERIC shall have at least three Member States as members" was changed to **"membership of an ERIC must include a Member State and two other countries that are either Member States or associated countries."** Furthermore, the amendment states, "Member States or associated countries shall hold jointly the majority of the voting rights in the assembly of members."

According to Article 10 of the ERIC Regulation, the statutes of an ERIC shall contain at least the following:

- a list of members, observers, and, where applicable, entities representing members and the conditions of and the procedure for changes in Membership and representation
- task and activities of the ERIC
- statutory seat
- name of the ERIC
- duration, and the procedure for the winding up
- liability regime
- The basic principles covering:
 - access policy for users
 - scientific evaluation policy
 - dissemination policy
 - intellectual property rights policy
 - employment policy, including equal opportunities
 - procurement policy respecting the principles of transparency, non-discrimination, and competition
 - a decommissioning, if relevant
 - data policy

- rights and obligations of the members, including the obligation to make contributions to a balanced budget and voting rights
- bodies of the ERIC, their roles and responsibilities and the manner in which they are constituted and in which they decide, including upon the amendment of the Statutes.
- identification of the working language(s)
- references to rules implementing the Statutes.

The Statutes (based on the ERIC Regulation) shall provide for at least the following bodies having the following competencies:

- An **assembly of members** as the body having full decision-making powers, including the adoption of the budget
- A **director** or **board of directors** appointed by the assembly of members as the executive body and legal representative of the ERIC
- The Statutes shall specify the manner in which the members of the board of directors legally represent the ERIC.

The ERIC Regulation stipulates that all ERICS must have an *Assembly of Members*. Some ERICS use alternative names such as *General Assembly* or *Board of Governors*. While not stipulated in the regulation, all ERICS the General Assemblies have an elected Chair and Vice-chair. In terms of the voting rights of the Chair, CESSDA, ECCSEL, and ELI stipulate in their statutes that "When elected, the *Chair (of the General Assembly)* shall no longer be part of the Member's delegation." (i.e., they cannot vote). Other ERICS take a less drastic approach, allowing the Chair to vote in some instances.

Regarding voting, Observers do not have voting rights under the ERIC regulation (Article 9(2)). The majority of ERICS allow one vote per Member. Exceptionally, in ELI, "The votes of the Members shall be weighted according to the proportion of their respective due contributions to the total annual due contributions of the Members." ACTRIS allows one vote per Member, an additional vote for members hosting at least one Central Facility, and an additional two votes for those hosting at least three Central Facilities. There is certainly merit to allowing additional votes and, thereby, higher decision power to Members hosting central facilities, such as in ACTRIS, as those members shoulder higher costs and associated risks. The additional votes compensate and motivate them to take on the added responsibility.

While the number of representatives in the Assembly or Members varies, in most cases, they include at least one scientific and one administrative from each Member and Observer. In most cases, withdrawal of Membership (and in many cases, observership) is forbidden in the first five years of establishing the ERIC unless there is a prior agreement. This rule is crucial for guaranteeing a steady cash flow during the first years of the newly established ERIC.

All ERICS retain the right to terminate Membership or Observership under certain conditions. Observers are admitted for a defined period, usually three to five years, with the

possibility to extend or become Members. Observers have similar rights and obligations as Members but without voting rights. In most cases, a simple majority is applied to voting of the Assembly of Members. Nonetheless, in major decisions (e.g., termination of Membership or winding up), a higher majority (e.g., 2/3, 3/4) or even unanimity is required.

Most ERICs have a *Director-General/Executive Director*, while a few have a *Board of Directors* (DARIAH)/*Executive Board* (EATRIS). Nonetheless, the roles are similar. They are the legal representative of the ERIC and are responsible for preparing the annual budget, strategies, and policies to be adopted by the General Assembly. The Director-General is responsible for implementing the decisions of the General Assembly and for the day-to-day management of the ERIC. Usually, the Director-General is elected for five years and may be reappointed once.

While not stipulated in the Regulation, all ERICs have a main office at their statutory seat. They are given many names, including *Coordination & Support Office*, *Head Office*, *Operations Centre*, *Management Office*, and *Headquarters*. Nonetheless, they all have similar functions, such as operational management and supporting all the ERIC functions (e.g., financial, human resources, training, and communication). They are also responsible for providing organizational support to Members and Observers and the user community, preparing annual work plans, budgets, reports, financial statements, audits, and contract management, ensuring the long-term financial sustainability of the ERICs through strategic planning, evaluating the performance of the National Nodes, development of standard operating procedures and operational documents.

An interesting approach is taken by ECRIN. ECRIN-ERIC employs *European Correspondents*, who "work under the ECRIN Director-General, with a functional link to the national node, and acts as a relay to the national clinical research network and node for the various ECRIN-ERIC activities such as structuring activities and provision of coordinated services."

The heads of the National Nodes in each ERIC form a management body responsible for coordinating the operations of the National Nodes and supporting the Director-General. This body is called the *Board of National Directors* (EATRIS) or *Committee of Nodes* (EMBRC).

All ERICs have advisory bodies consisting of independent and internationally recognized scientists in their respective fields. Several examples are the *Scientific Advisory Board* (EATRIS, ECCSEL), *Ethical Board*, *Ethical Advisory Committee*, and *Scientific and Ethical Advisory Board*.

Regarding the statutory seat, the ERIC Regulation (Article 8 (1)) states that "An ERIC shall have a statutory seat, which shall be located on the territory of a member which shall be a Member State or an associated country." Selection of the statutory seat has legal implications, as the law and jurisdiction of the State where the ERIC has its statutory seat are applicable in the case of matters not, or only partially, regulated by Community Law (Article 15). To this end, only one ERIC, CERIC, allows changing the seat, stating in its statutes that "The General Assembly shall consider every five years whether the Statutory Seat shall remain in the same country or be transferred to the territory of another country."

According to Article 9, Requirements for Members, Member States of the European Union, associated countries, third countries other than associated countries, and intergovernmental organizations may become Members or Observers of an ERIC. Several ERICS (e.g., ACTRIS, ECCSEL) have opted for an additional category, Permanent Observer. This category is used for entities that foresee long-term participation in the ERIC but, for national reasons, cannot become Members. The amendment to the ERIC Regulation in 2013 changed the type of entities that can form the ERIC from "at least three Member States as Members" to "at least one Member State and two other Members that are either Member States or associated countries." This change is reflected in the types of entities forming ERICs who submitted applications after the amendment.

The duration and winding up of ERICs (Article 10(e) and 16) vary from 20 years (ELI) to indefinite/indeterminate (EATRIS, ECCSEL, ECRIN).

The methods and principles of calculating Member and Observer contributions vary, but in all cases, they include a combination of cash and in-kind contributions. Usually, the operation of the ERIC Head Office, including the salaries of the Head Office staff and Director-General, is paid in cash. A combination of cash and in-kind pay for the operations of the scientific facilities.

The remaining items, such as access policy, scientific evaluation policy, intellectual property rights, and others, are not discussed since they are clearly defined in the Regulation and, therefore, are the same across the ERICs.

It is important to mention that while the comparison of the 26 ERICs offers essential insights into the differences among the ERICs, it does not allow evaluation of how the language of the statutes correlates with the real-life operation of the ERICs. Some ERICs, such as AnaEE, supplement the Statutes with Rules of Operations (see [Anaee Rules of Operations](#)). The Rules of Operations are instrumental in providing very detailed information, thereby allowing the scope of the Statutes to remain relatively broad. This simplifies the process in case changes need to be made, as changes to the Rules of Operations can be done internally within the ERIC, requiring only the approval of the Assembly of Members, as statute amendments are more complex, requiring approval at the European Commission level. Other ERICs likely take a similar approach, but since they are not always shared, it is impossible to ascertain how common of a practice it is.

The ERIC Forum mentioned earlier, is vital for discussing issues related to the ERIC Regulation and communicating them with the EC. "The ERIC Forum organizes the ERICs and ERICs-to-be in a network with the objective to ensure a joint representation and to support integrating and coordination activities, thus developing a systems approach." Specifically, the ERIC Forum II project, which just started, will deal extensively with implementing the ERIC Regulation. Finally, in the Commission's Third Report on the Application of the ERIC to the Council and European Parliament on August 2023, the Commission highlighted that several topics in Regulation, such as Human resources, Tax and procurement, Economic activities, and Operational synergies "need further consideration in order to ensure the operational sustainability" of the ERICs.

Interim and final governance structures of EIRENE

The governance structure of a research infrastructure is dictated by the legal framework under which it operates. During the Design and Preparation phases, EIRENE's governance, management structure, and legal framework will be based on Horizon Europe project consortium agreements (such as in the current EIRENE PPP project). During the Implementation phase, when EIRENE-ERIC is established, the governance structure will be dictated by the ERIC legal framework and thus differ significantly.

While the main focus of this deliverable is on the final structure envisioned for when EIRENE becomes fully operational, several components will be developed during the interim phase and thus also described. Developing the components of the future ERIC now, even though they will not yet be legally binding, is essential for ensuring a seamless transition from the interim (project) to the final (ERIC) structure.

EIRENE RI Interim Structure

During the interim period, until EIRENE becomes an ERIC, the governance structure will adhere to the European project structure while developing the necessary elements of the ERIC. Following is a diagram of the governance structure during the interim period and a brief description of each element.

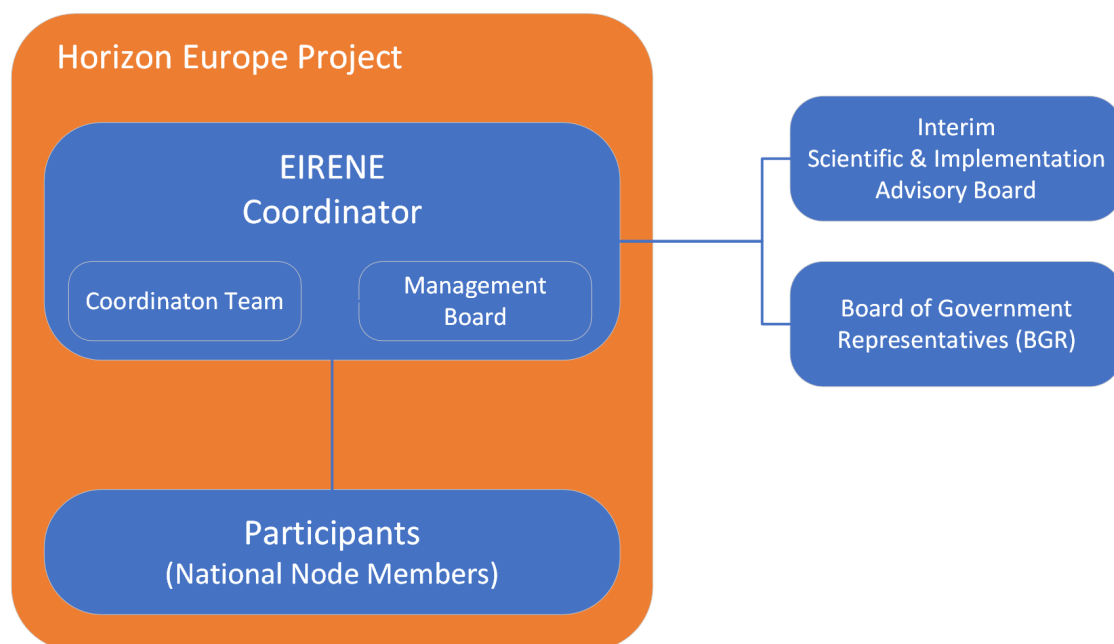


Figure 2 - EIRENE Interim Structure

EIRENE Coordinator

The EIRENE Coordinator is responsible for coordinating all the activities of EIRENE, with the support of the EIRENE Coordination Team and the Management Board. Since EIRENE is not a legal entity, coordination occurs under the Masaryk University (MU) legal entity. This is also true for projects in which EIRENE is a non-coordinating participant.

Interim Scientific & Implementation Advisory Board (ISEIB)

The composition of the Board is similar to that of the future Scientific Advisory Board but focuses primarily on EIRENE's development (implementation). The Management Board will select the ISEIB members. The Board shall meet at least once a year and provide a yearly report to the Management Board.

Board of Government Representatives (BGR)

The BGR consists of country representatives acting on behalf of their respective national authorities responsible for research infrastructures (e.g., ministries of research, science, education, ESFRI country delegates). The BGR is crucial for ensuring that representatives of the future members of EIRENE-ERIC are involved in its development. Once EIRENE becomes an ERIC, the representatives of the countries in the Funders Forum will become members of the EIRENE-ERIC General Assembly. The BGR is currently being established, and will convene for the first time during the first quarter of 2026. The draft Terms of Reference for the establishment and operation of the BGR are presented in Annex B.

EIRENE Coordination Team (CT)

The EIRENE Coordination Team, based at Masaryk University, Czech Republic, coordinates all EIRENE activities during the interim period. The Coordination Team manages development projects such as the current EIRENE PPP, future implementation, and other projects such as INFRASERVs. It will become the EIRENE Head Office when EIRENE-ERIC is established.

Management Board (MB)

The Management Board comprises the EIRENE coordinator and the Work Package leaders of the EIRENE PPP and future projects. The Management Board is responsible for implementing the PPP and future projects for developing EIRENE. The Management Board meets once a month.

Participants (National Nodes)

The development, composition, and function of the National Nodes are detailed elsewhere in this document. In the interim period, members of the National Nodes participate in EIRENE projects as individual institutions.

EIRENE-ERIC Structure

The final structure of EIRENE-ERIC, depicted in Figure 3, is designed to be simple and clear. Notably, the distinction between what is or is not included in the ERIC is distinctly defined (in orange). The governance structure is dictated to a large extent by the ERIC legal framework. EIRENE-ERIC will consist of the elements stipulated in the ERIC Regulation (i.e., General Assembly, Director-General) and a Head Office and Central Coordination Units. Following is a description of all the elements of EIRENE in the Operational phase. While the National Nodes, advisory boards, Stakeholders Forum, and National Nodes Committee are not part of the EIRENE-ERIC legal entity, they are an integral part of EIRENE and thus described.

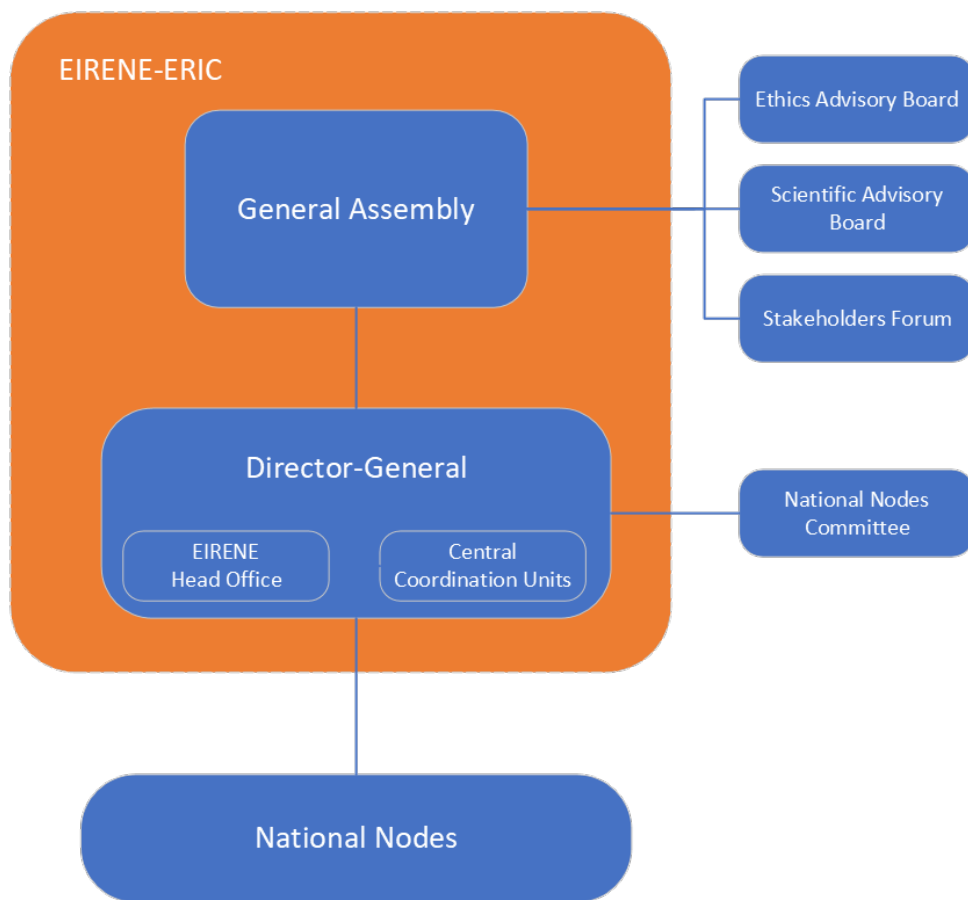


Figure 3 – EIRENE-ERIC Final Structure

General Assembly (GA)

The General Assembly is the highest governing body of EIRENE and the ultimate decision-making body. It comprises delegates of EIRENE members and observers responsible for EIRENE's overall direction and supervision. The General Assembly will consist of the country representatives of the former Funders Forum. As is common in most ERICs, EIRENE will most likely allow one vote per member. To maximize the efficiency of EIRENE's General Assembly, two delegates, an administrator and a scientist, will represent each Member or Observer. This is crucial for ensuring effective GA decision-making, as representatives must

understand the scientific aspects and liaise with their respective countries to ensure continuous political and financial support to the research infrastructure.

The General Assembly is responsible for approving the annual work plan and budget prepared by the Director-General in consultation with the National Nodes Committee. Members of the General Assembly are elected and act on behalf of their respective national authorities responsible for research infrastructures (e.g., ministries of research, science, and education). They can be accompanied by scientific expert advisors. The GA has a Chair and at least one Vice-Chair elected at the first meeting. The GA meets at least once a year. In extraordinary cases, the Director-General can call a special meeting or conference call. While in some ERICs, the GA Chair cannot be part of their country delegation nor vote, in EIRENE, the Chair will remain a delegate during their term and retain voting rights.

Among others, the General Assembly decides on the admission or removal of Members and Observers, approves the strategy, budget, and financial statements, elects the Director-General, and approves changes to the Statutes. General Assembly decisions rely on advice and guidance from the Director-General, the heads of the Central Coordination Units, and advisory bodies such as the Ethics and Scientific Advisory Boards, Stakeholders' Forum, National Nodes Committee, and others.

The ERIC Regulation (Article 12) mandates that all ERICs must have at least a General Assembly and a Director or Board of Directors, and additionally mandates their basic competencies. The Regulation stipulates the General Assembly “as the body having full decision-making powers, including the adoption of the budget.” The role of the GA will be clearly defined in the statutes.

Director-General (DG)

The Director-General, appointed by the General Assembly, is the legal representative of EIRENE-ERIC, responsible for all its activities. The Director-General is accountable for implementing General Assembly decisions and ensuring that EIRENE's scientific and strategic development leads to the expected results on socioeconomic impacts, technological development, and innovation. The DG shall actively contribute to community building by fostering external relations and strategic partnerships and overseeing and coordinating EIRENE activities. The DG shall represent EIRENE-ERIC in any litigation. The term of the DG shall be five years and may be renewed once by the GA. The DG shall be based in the statutory seat of EIRENE-ERIC and shall be responsible for managing the Head Office staff, Central Coordination Units, and other activities of EIRENE-ERIC.

The appointment of a Director-General is mandatory under Article 12 of the ERIC Regulation, which further stipulates "a director or a board of directors, appointed by the assembly of members (i.e., GA) as the executive body and legal representative of the ERIC."

EIRENE will have a Director-General rather than a Board of Directors in the spirit of operating a lean and efficient research infrastructure.

EIRENE Head Office (EHO)

The EIRENE-ERIC Head Office is responsible for the operational management of EIRENE-ERIC and supporting all its functions (e.g., financial, human resources, training, communication). Among others, the Head Office will be responsible for providing organizational support to EIRENE Members and Observers and the user community, preparation of the annual work plan, budget, reports, financial statements, audits, and contract management, ensuring the long-term financial sustainability of EIRENE through strategic planning, evaluation of the performance of the National Nodes, development of standard operating procedures and operational documents based on best practices, and risk management. The EHO will be located at the statutory seat of the EIRENE-ERIC in the Czech Republic. In the interim period, the EIRENE Coordination Team handles tasks that the Head Office until EIRENE-ERIC is established.

Central Coordination Units (CCU)

EIRENE-ERIC will deliver services across six key domains: Chemical Profiling, Toxicological Profiling, Biological Profiling, Environmental Samples & Data, Human Samples & Data, and Tools. Each service domain will be managed at the EIRENE-ERIC level by a Central Coordination Unit and hosted within the EIRENE Head Office or by a Member. This domain-specific coordination is essential for ensuring operational efficiency and delivering high-quality services to users. Since individual institutions or laboratories may specialize in one or more domains, while others within the same country may focus on different or unrelated areas, coordination across domains, in addition to the National Nodes, is crucial for seamless operation. Therefore, while memberships and Observerships are on a national level, operationally, the individual research-performing organizations will work directly with respective CCUs (through service-level agreements). There are several options for hosting the CCUs. Here, they are included as part of the ERIC. While CCUs will legally be part of the ERIC, they can potentially be located in different research-performing organizations based on expertise. In that case, the CCUs will be dispersed across Europe. Inclusion in the ERIC ensures efficient coordination and utilization of the VAT and excise tax benefits given to ERICs. However, it might be complicated by the regulatory differences among the Member States (e.g., in labor laws). Furthermore, locating a CCU in a particular country means funding primarily from the hosting country. This means the host country will be required to pay an additional host premium on top of the regular membership fee.

Other ERICs, such as ICOS and AnaEE, use a similar structure. ICOS, for example, has four Central Facilities (thematic centers), but unlike EIRENE, they are not part of the ERIC. AnaEE has three service centers within the ERIC and four national platforms outside the ERIC.

Scientific Advisory Board (SAB) / Ethics Advisory Board (EAB)

The advisory boards consist of independent, internationally recognized external experts such as Director-Generals of complementary ESFRI RIs (e.g., ICOS, ACTRIS, BBMRI), lawyers, financial experts, etc. They support the decision-making of the General Assembly and the operations of EIRENE by providing input on scientific matters, such as focus, orientation, and future development, on concrete technical or technological issues, and regarding the

commercial markets and international trends. Their activities also promote the strengthening and spreading of excellence within the consortium and across Europe.

The advisory boards and stakeholders forum (Figure 3) are external to the ERIC, ensuring their impartiality. The scientific and ethics advisory boards may be combined into one body, as in some ERICs.

Stakeholders Forum (SF)

The Stakeholders Forum will include a wide range of stakeholders, such as users of EIRENE services, members of the European Commission, policymakers, funding agencies, industry, ESFRI, NGOs, citizens, the media, etc. Additional ad hoc or permanent forums will be established depending on the needs. Members of the Stakeholders Forum will elect a chair from among them. The General Assembly will consult with members of the Stakeholders Forum on topics related to their area of responsibility and expertise.

National Nodes Committee (NNC)

The National Nodes Committee consists of the heads of the National Nodes. The Director-General and the NNC are responsible for developing the annual work plans based on the EIRENE strategy. The General Assembly approves the work plan. The NNC is responsible for developing EIRENE's long-term strategy and coordinating with the national nodes. It is the largest body dealing primarily with EIRENE's scientific, technical, and operational aspects. The Director-General chairs the Committee and has a Vice-chair elected from its members. The Committee has a supportive role without executive power. The National Nodes Committee ensures that the National Nodes implement General Assembly decisions. The NNC Vice-Chair will attend all GA meetings as the representative of the NNC.

The National Nodes Committee is a common body among the ERICS. In most ERICs it consists of at least the heads of the national nodes, but in several ERICs it also includes the heads of central services. ICOS, for example, has an equivalent Research Infrastructure Committee, which consists of one representative from the Head Office, Carbon Portal, each ICOS Central Facility, and each monitoring station assembly, the latter formed by scientific and technical experts from the ICOS National Networks. AnaEE has a Management Board consisting of the Director-General and the Heads of the service centers (which are part of the ERIC) and an Extended Management Board consisting of the Management Board, the National Nodes Heads, and the heads of the National Platform.

National Nodes (NN)

The National Nodes are consortia of national research-performing organizations. In some cases, they have a legal entity, while in other cases, they select a single organization that is a legal entity to represent them. The size, number of institutions or laboratories, areas of expertise, and available services vary considerably among EIRENE National Nodes. While several National Nodes have well-established consortia, political and financial support, are included in their national research infrastructure roadmaps, and provide a wide range of services, others are just beginning to build their networks. On the operational level, the heads of the National Nodes represent their respective NNs in the National Nodes Committee. National Nodes established as legal entities most likely benefit from better

access to national funding (e.g., through national research infrastructure roadmaps). Nonetheless, it is not common practice among established ESFRI RIs to mandate a national legal entity as a prerequisite for becoming a member of the ERIC. They only require one national node member with a legal entity (e.g., a university) to represent the national node.

There are several possible models for financing the development and operation of the NNs. In most cases, the development and operation of the facilities are funded nationally, while the provision of services is funded externally. Many RIs rely extensively on EC project funding (i.e. INFRA calls) to develop and provide services. As mentioned earlier, when RIs have central facilities in several National Nodes, the funding model depends on whether the facilities are part of the ERIC or not.

The table below shows which bodies will be in place during EIRENE's various phases of development.

Table 1 - EIRENE RI Implementation schedule

	Preparatory Phase			Implementation Phase			Operation Phase
	2023	2024	2025	2026	2027	2028	2029 -2050
							EIRENE-ERIC
General Assembly							
Interim Scientific & Implementation Advisory Board							
Ethics Advisory Board							
Scientific Advisory Board							
Funders Forum							
Stakeholders Forum							
EIRENE Coordinator							
EIRENE Director-General							
EIRENE Coordination Team							
Head Office							
Management Board							
National Nodes Committee							
Central Coordination Units							
National Nodes							

Interim body/structure

Final body/structure



Annex A: EIRENE-ERIC Draft Statutes

EIRENE-ERIC Draft Statutes

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PREAMBLE

CONSIDERING that the sustainability of human health and ecosystems is increasingly threatened by complex environmental exposures, and that understanding the human exposome—the totality of environmental exposures from conception onwards—is essential to address the grand societal challenges of our time;

CONSIDERING that the ability to anticipate and mitigate the health impacts of environmental stressors requires integrated, high-resolution data on external and internal exposures, advanced analytical technologies, and harmonised methodologies across disciplines and geographies;

RECOGNISING that EIRENE-ERIC (European Infrastructure for Human Exposome Research) will be a unique, distributed, pan-European research infrastructure designed to support challenge-driven research linking environmental exposures to human health through coordinated access to longitudinal cohorts, experimental platforms, analytical laboratories, and

computational tools;

RECOGNISING that EIRENE-ERIC will integrate services across national nodes and central coordination units, providing open, FAIR-compliant access to physical, remote, and virtual services, and enabling harmonised data collection, processing, and interpretation through advanced platforms including mass spectrometry, omics technologies, and AI-driven analytics;

RECOGNISING that EIRENE-ERIC will contribute to the development of new technologies, standards, and ontologies for exposome science, support training and capacity building, and foster innovation in biomedical research, environmental health, and regulatory science;

RECOGNISING that EIRENE-ERIC will play a strategic role in supporting European and global initiatives such as the European Green Deal, the Chemicals Strategy for Sustainability, the One Health approach, and the Global Exposome Forum, by providing infrastructure for evidence-based policy making and precision public health;

THEREFORE, the Members request the European Commission to set up EIRENE as a European Research Infrastructure Consortium (ERIC) under the Council Regulation (EC) No 723/2009 of 25 June 2009

HAVE AGREED AS FOLLOWS:

CHAPTER 1

ESSENTIAL ELEMENTS

Article 1

Name

A distributed European Research Infrastructure Consortium (ERIC) shall be established called 'Environmental Exposure Assessment Research Infrastructure ERIC' (EIRENE-ERIC). This Consortium shall constitute a European Research Infrastructure Consortium (ERIC) established under the provisions of Regulation (EC) No 723/2009.

Article 2

Statutory seat

EIRENE-ERIC shall have its statutory seat in Brno, Czech Republic.

Article 3

Task and activities

1. The principal task of EIRENE-ERIC shall be to establish and operate a distributed Research Infrastructure devoted to analyzing the human Exposome.

2. For the purposes of paragraph 1, EIRENE-ERIC shall:

- a. facilitate European research programs and projects;*
- b. develop technology, harmonizing methods, building industrial partnerships, and facilitate knowledge transfer;*
- c. contribute to the exchange of knowledge and/or competencies within the European Research Area (ERA) and increase the use of intellectual potential throughout Europe;*
- d. develop data access, sharing, and modeling;*

- e. organize training;*
- f. implement a communication strategy;*
- g. any other related action necessary to achieve its aims.*

3. *EIRENE-ERIC shall pursue its principal task on a non-economic basis. EIRENE-ERIC may carry out limited economic activities provided that they are closely related to the principal tasks set out in Article 3(2) above and they do not jeopardize their achievement thereof.*

Article 4

Duration and procedure for winding up

1. *EIRENE-ERIC shall be established for an initial period of 10 years. The General Assembly can decide to extend the duration by successive periods of 10 years.*
2. *The winding up of EIRENE-ERIC shall be decided by the General Assembly in accordance with Article 18(10) of the Statutes.*
3. *Without undue delay and in any event within 10 days after adoption of the decision to wind up EIRENE-ERIC, EIRENE-ERIC shall notify the European Commission about the decision.*
4. *Assets remaining after payment of EIRENE-ERIC debts shall be apportioned among the Members in proportion to their accumulated annual contribution to EIRENE-ERIC as specified in Article 17 of the Statutes.*
5. *Without undue delay and in any event within 10 days of the closure of the winding up procedure, EIRENE-ERIC shall notify the Commission thereof.*
6. *EIRENE-ERIC shall cease to exist on the day on which the European Commission publishes the appropriate notice in L series of the Official Journal of the European Union.*

Article 5

Liability regime

1. *EIRENE-ERIC shall be liable for its debts.*
2. *The Members' financial liability for the debts of EIRENE-ERIC, of whatever nature, shall be limited to their respective contribution to EIRENE-ERIC in respect to the last full year of operations.*
3. *EIRENE-ERIC shall take appropriate insurance to cover the risks specific to its activities.*

Article 6

Access policy for users

1. *Access to the EIRENE-ERIC facilities and services provided by the Head Office of EIRENE-ERIC shall be provided on the basis of open access principles. EIRENE-ERIC shall implement infrastructure access rules, with a fee policy providing incentives to its Members.*
2. *EIRENE-ERIC shall provide information through its web portal that includes a searchable catalogue of services and cohorts, metadata, and documentation, and a single-point access system for submitting and managing service requests. The portal will offer FAIR-compliant data access, open-source analysis tools, training resources, and guidelines for open science. It will also support stakeholder engagement through a user forum and showcase innovations and impacts relevant to policy and clinical applications.*

3. EIRENE-ERIC shall grant access to the EIRENE facilities and services based on an assessment of the scientific quality of the proposed use, on the basis of the Scientific Advisory Board evaluation and technical feasibility assessed by EIRENE facilities and experts. Possible ethical issues involved in a proposal will be handled by the Ethical Advisory board (see Article 25 of the Statutes).

4. In case research access to the EIRENE-ERIC facilities and services has to be restricted for capacity reasons, a selection shall be made according to the procedure set out in the Rules of Operation of the Statutes, considering selection criteria based on scientific excellence, technical and financial feasibility of the proposals.

5. EIRENE-ERIC shall make available metadata of each project at the start, both for experimental settings in National Platforms and for data produced by service centres.

6. Data shall be made available according to the open access policy of EIRENE-ERIC. Access will be regulated according to the Rules of Operation of the Statutes, in general having a common period of grace, after which the data shall become available to the public. The Access Policy shall take into account the European Data Protection legal framework¹ related to the sharing of personal data of users among the Members.

Article 7

Scientific Evaluation Policy

The activities of EIRENE-ERIC shall be evaluated every 5 years by an ad hoc independent scientific committee. The General Assembly shall initiate such an evaluation and, if appropriate, give specific directions. The Rules of Operation will define the principles and procedures of this evaluation.

Article 8

Dissemination Policy

1. EIRENE-ERIC shall be a facilitator of research and shall as a general rule encourage as free access as possible to research data.

2. EIRENE-ERIC shall request users to make their research results publicly available, and make their results available through EIRENE-ERIC.

3. EIRENE-ERIC shall use several channels to reach its target audiences, including a web portal, newsletter, workshops, presence in conferences, articles in magazines and newspapers, social networks, etc.

Article 9

Intellectual Property Rights Policy

1. All intellectual property rights created, arising from, obtained or developed by EIRENE-ERIC in the course of its activities shall be owned by EIRENE-ERIC.

¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

2. *Subject to the terms of any contracts between EIRENE-ERIC and Members or Observers, all intellectual property rights which are created, arising from, obtained or developed by a Member or Observer shall be owned by that Member or Observer.*

Article 10

Employment policy

1. *EIRENE-ERIC employment conditions shall be governed by the laws of the country in which the staff is employed or by the laws of the country where the activities of EIRENE-ERIC are conducted.*
2. *The selection procedures for EIRENE-ERIC staff positions shall be transparent, non-discriminatory, and respect equal opportunities. Recruitment and employment shall not be discriminatory.*
3. *Recruitment will be carried out with an international publication of a call.*

Article 11

Procurement policy

1. *EIRENE-ERIC shall treat procurement candidates and tenderers equally and without discrimination, regardless of whether or not they are based within the European Union. EIRENE-ERIC Procurement Policy shall respect the principles of transparency, competition, and non-discrimination. Detailed rules on procurement procedures and criteria shall be set out in the Rules of Operation of the Statutes.*
2. *Procurement by Members and Observers concerning EIRENE-ERIC activities shall be done in such a way that due consideration is given to EIRENE-ERIC needs, technical requirements, and specifications issued by the relevant bodies.*

CHAPTER 2

MEMBERSHIP

Article 12

Membership and representing entity

1. *The following entities may become Members of EIRENE-ERIC or may become Observers of EIRENE-ERIC without voting rights:*
 - a) *Member States of the European Union;*
 - b) *associated countries;*
 - c) *third countries other than associated countries;*
 - d) *intergovernmental organizations.*
2. *Conditions for becoming a Member or Observer are set out in Article 13.*
3. *The Membership of EIRENE-ERIC must include at least a Member State and two other countries that are either Member States or associated countries.*
4. *Under any circumstances, Member States of the European Union or associated countries shall hold jointly the majority of the voting rights in the General Assembly. The General Assembly shall determine any modification of voting rights that are necessary to ensure that EIRENE-ERIC complies at all times with that requirement.*

5. *Entities listed in Article 12(1) who are willing to contribute to EIRENE-ERIC, but are not yet in position to join as Members, may apply for Observer status.*

6. *Any Member or Observer referred to in paragraph 1(a) to (c) may be represented by one public entity or one private entity with a public service mission, of its own choosing and appointed in accordance with its own rules and procedures. Each Member or Observer shall inform the General Assembly of any change of its representing entity, of the specific rights and obligations which have been delegated to it, or of any other relevant change.*

7. *The Members and Observers of EIRENE-ERIC and their representing entities are listed in Annex II. Annex II shall be kept up to date by the Chair of the General Assembly.*

Article 13

Admission of a Member or an Observer

1. *The terms for admission of new Members are the following:*

- a) *Applicants shall submit a written application to the Chair of the General Assembly and the EIRENE-ERIC Director-General;*
- b) *The application shall describe how the applicant will contribute to EIRENE-ERIC's objectives and activities described in Article 3 and how it will fulfill the obligations referred to in Article 15;*
- c) *The admission of new Members shall require the approval of the General Assembly, as described in Article 18-(10).*

2. *In particular, an applicant must have shown, to the satisfaction of the General Assembly and verified by adequate means of quality assurance, that it has the means and sustained commitment to do the following:*

- a) *Contribute to the resources and services of EIRENE-ERIC in the fields of exposome research;*
- b) *Adhere to the scientific quality standards and standard operating procedures set by EIRENE-ERIC;*
- c) *Make annual financial contributions to the balanced annual budgets of EIRENE-ERIC;*
- d) *Abide by the present Statutes;*
- e) *Commit to a minimum of five years of Membership to EIRENE-ERIC.*

3. *Entities listed in Article 12(1) who are willing to contribute to EIRENE-ERIC but are not yet in a position to join as Members may apply for Observer status. The terms for admission of Observers are the following:*

- a) *Observers shall be admitted for a 2-year period and two periods at most;*
- b) *Applicants shall submit a written application to the Chair of the General Assembly and the Director-General;*
- c) *The application shall describe how the applicant will contribute to EIRENE-ERIC;*
- d) *The admission or re-admission of Observers shall be subject to the approval of the General Assembly.*

Article 14

Withdrawal of a Member or an Observer/Termination of membership or Observer status

1. *Within the first five calendar years of the establishment of EIRENE-ERIC, no Member may withdraw.*
2. *The first year shall be a shortened year beginning with the date the Commission's decision to set up EIRENE-ERIC takes effect.*
3. *After the first five years of Membership, a Member may withdraw at the end of a financial year, following a request submitted 12 months before the envisaged withdrawal.*
4. *A Member requesting its withdrawal shall have no more voting rights in the General Assembly if the proposed decisions do not directly impact the Member.*
5. *Observers may withdraw at the end of a financial year, following a request submitted 6 months before the envisaged withdrawal.*
6. *All financial and other obligations must be fulfilled before the end of the year of withdrawal. As the circumstances may require, obligations must be fulfilled beyond the effective date of the withdrawal to ensure the fulfillment of legally binding commitments EIRENE-ERIC has already entered into before the request of withdrawal of the Member concerned.*
7. *The General Assembly may terminate Membership or Observer status if all of the following conditions are met:*
 - a) *The Member or Observer is in serious breach of one or more of its obligations under these Statutes;*
 - b) *The Member or Observer has failed to rectify such breach within 6 months after it has received notice of the breach in writing from the General Assembly.*
8. *The Member or Observer referred to in Article 14-(7) shall have to explain its position to the General Assembly of EIRENE-ERIC before it decides on the issue.*
9. *The General Assembly may also decide, in the circumstances set out under Article 14(7), not to terminate a Member's Membership but to suspend a Member's voting right for a certain period of time. The General Assembly may reinstate, by a vote, a Member's voting right at any time if such Member has remedied to the satisfaction of the General Assembly any breach set out under Article 14(7). The representative of the Member mentioned above will be excluded from the said vote.*
10. *A Member's voting right shall be suspended by the General Assembly as long as financial obligations resulting out of Annex III of these Statutes have not been fulfilled in due time.*
11. *Members or Observers that withdraw or have their Membership and observership terminated shall neither have the right to restitution or reimbursement of any contribution made nor the right to lay any claim to the assets of EIRENE-ERIC.*

CHAPTER 3

RIGHTS AND OBLIGATIONS OF THE MEMBERS AND OBSERVERS

Article 15

Members

1. *Rights of Members shall include:*
 - a) *attending and voting at the General Assembly;*
 - b) *participating in the development of strategies and policies of EIRENE-ERIC;*
 - c) *using the EIRENE-ERIC brand;*
 - d) *participating in project proposals where EIRENE-ERIC acts as the submitting consortium;*
 - e) *accessing the services and activities coordinated by EIRENE-ERIC for its research community.*
2. *Each Member shall:*
 - a) *pay the annual financial contribution as specified in the respective annual financial budgets approved by the General Assembly;*
 - b) *empower its representative(s) with full authority to vote on all issues raised during the General Assembly meetings and published in the agenda;*
 - c) *provide access according to the EIRENE-ERIC access policy to National Platform activities complying with EIRENE-ERIC criteria;*
 - d) *promote the adoption and maintenance of the quality standards and standard operating procedures of EIRENE-ERIC in their contributing national research platforms;*
 - e) *promote the use of EIRENE-ERIC resources and services among researchers.*

Article 16

Observers

1. *The rights of Observers shall include:*
 - a) *attending the General Assembly without a vote;*
 - b) *participating in EIRENE-ERIC's events, such as workshops, conferences, training courses, and in any other activities identified by the General Assembly;*
 - c) *accessing support from EIRENE-ERIC in developing relevant systems, processes, and services.*
2. *Each Observer shall:*
 - a) *appoint a representing entity in accordance with Article 18 ;*
 - b) *pay the annual financial contribution as specified in the respective annual financial budgets approved by the General Assembly;*
 - c) *contribute to EIRENE-ERIC's tasks and activities as set out in Article 3;*
 - d) *enter into an Observer agreement with EIRENE-ERIC to establish the terms and conditions under which the obligations are to be fulfilled, and the Observer's rights can be exercised.*

Article 17

Contributions

1. *Members and Observers shall provide annual contributions as described in Annex X.*
2. *Annual Member and Observer contributions must be paid in cash. Principles of contributions are set out in Annex X and further defined in the Rules of Operation.*

CHAPTER 4

GOVERNANCE

Article 18

General Assembly

1. *The General Assembly shall be the highest and ultimate governing body of EIRENE-ERIC, with full decision-making powers, and is responsible for directing and supervising EIRENE-ERIC. It shall be composed of the duly appointed representatives of the Members and Observers of EIRENE-ERIC. Members and Observers shall be represented by a maximum of two persons, one having scientific and one administrative expertise. A Member and Observer is deemed represented if at least one of its representatives is present at the meeting.*
2. *Each Member shall have one vote.*
3. *The General Assembly shall elect a Chair and a Vice-chair from the Member delegations. The Chair and the Vice-chair shall be elected for a 3-year term, renewable once. The Chair shall have no voting rights —the Vice-chair steps in whenever the Chair cannot execute duties. Details of the election and conduct of meetings are laid down in the Rules of Operation adopted by the General Assembly.*
4. *The Chair shall convene the General Assembly with at least eight weeks' notice, and the agenda, including meeting documents, shall be circulated at least two weeks before the meeting. An invitation and agenda are usually provided electronically. Details are laid down in the Rules of Operation adopted by the General Assembly.*
5. *The General Assembly shall meet regularly, at least once a year. The meeting is considered quorate if at least 2/3 (two thirds) of Members are present and duly represented. Meetings through remote participation, including video conferences and any other agreed electronic means, shall be possible; however, their decisions and conclusions must be confirmed through written procedure. An extraordinary meeting of the General Assembly is convened if requested by at least 1/3 (one third) of the Members.*
6. *The Director-General of EIRENE-ERIC shall typically attend the General Assembly meetings.*
7. *The General Assembly may invite experts to participate in its meetings in an advisory capacity. If confidential information is dealt with in the presence of outside persons, they must sign a nondisclosure declaration beforehand.*
8. *The General Assembly shall decide any matters necessary to fulfill the objectives of EIRENE-ERIC and which are not explicitly attributed to another governance body or other body.*
9. *Unless explicitly stated otherwise, all decisions of the General Assembly shall be passed by a simple majority of the votes cast.*
10. *The following decisions shall be taken by a qualified majority of 2/3 of the votes cast:*
 - a) *Appointment and dismissal of the Director-General;*
 - b) *Election of a Chair and a Vice-chair according to Article 18(3) of these Statutes;*
 - c) *Approval of Rules of Operation of these Statutes (bylaws);*
 - d) *Approval of any Rules of Operation of EIRENE-ERIC's bodies;*
 - e) *Approval of the Procurement Rules of EIRENE-ERIC;*
 - f) *Approval of the annual scientific work program;*

- g) Approval of the annual financial statement;*
- h) Modifications to the annual financial budget during the respective financial year which reduce or increase the budget by less than 4 % (four);*
- i) Resolutions on the appropriate level of revenues, including the formation of reserves;*
- j) Decisions concerning data policy principles and access policy principles;*
- k) Decisions concerning Intellectual Property Issues;*
- l) Establishment of the National Nodes Committee;*
- m) Accession of new Members and termination of Membership;*
- n) Accession of a new Observer and termination of the status of Observer;*
- o) Winding up of EIRENE-ERIC.*

11. The following decisions shall be taken by a qualified majority of 2/3 of the votes cast, provided that either the contributions of such Members constitute not less than three-quarters of the total contributions to the EIRENE-ERIC budget or that affirmative votes are cast by all but one of the Members present or represented and voting:

- a) Approval of Financial Rules of EIRENE-ERIC;*
- b) Approval of the five-year financial plan;*
- c) Approval of the annual financial budget submitted by the Director-General;*
- d) Modifications to the annual financial budget during the respective financial year which reduce or increase the budget by more than 4 % (four);*
- e) Proposals for amendments to the Statutes of EIRENE-ERIC and the respective notification of the European Commission for approval/objection according to Articles 9 and 11 of Regulation (EC) No 723/2009.*

12. Abstentions shall not be counted as a vote for or against the resolution in question.

Article 19

The Director-General

- 1. The Director-General shall be the chief executive officer and legal representative of EIRENE-ERIC.*
- 2. The Director-General shall be appointed by the General Assembly following an international call. The terms and conditions of the appointment are detailed in the Rules of Operation.*
- 3. The Director-General shall be responsible for*
 - a) The legal representation of EIRENE-ERIC, including concluding contracts and conducting other legal and administrative proceedings as appropriate in accordance with the decisions of the General Assembly;*
 - b) The development of the strategy of EIRENE-ERIC and the delivery of proposals to the General Assembly, drawing on input from direct interaction with the Members, ~~Observers~~, the National Nodes Committee, the advisory boards, the National Nodes, and the EIRENE-ERIC Central Coordination Units;*
 - c) The day-to-day leadership, administration, and management of EIRENE-ERIC, including the implementation of the decisions adopted by the General Assembly, coordinating ongoing projects and initiatives, appointing all employees of the EIRENE-ERIC, and leading the secretariat;*

- d) Chairing the National Nodes Committee and delegating actions to ensure the implementation of EIRENE-ERIC decisions in each Central Coordination Unit or National Node;*
 - e) Ensuring that the National Nodes Committee and the Nodes operate according to the terms of reference set out in the Rules of Operation and in the present document;*
 - f) The organization of the meetings of the General Assembly, including proposing items for the agenda for the meetings and preparing and submitting the annual activity report for approval by the General Assembly as described in Article 28;*
 - g) The organization of the meetings of the EIRENE-ERIC Advisory Boards for the evaluation of the scientific program and the ethical policy according to Articles 24 and 25;*
 - h) Conduct evaluations and interviews with aspiring new Members or Observers to propose admission to EIRENE-ERIC.*
- 4. The Director-General shall provide the General Assembly within six months after the end of the financial year with a statement of account of the previous financial year, audited in accordance with Article 32. The details of such a statement are provided in the Rules of Operation.*
- 5. The Director-General shall provide the General Assembly, by the end of November as further detailed in the Rules of Operation, with:*
- a) a report on the work carried out during the year with a financial statement;*
 - b) the draft Work Program for the following year;*
 - c) the forecast budget for the following financial year.*
- 6. The Director-General shall at any time be entitled to establish working groups to support the activities of EIRENE-ERIC in accordance with the Rules of Operation.*

Article 20

EIRENE Head Office

- 1. The Head Office includes the following support services:*
 - a) Assistance to the Director-General in the implementation of the EIRENE-ERIC Work Program;*
 - b) A central point for communication with stakeholders and interaction with the National Nodes;*
 - c) Coordination of Central Coordination Units activities, including joint development activities and staff exchanges;*
 - d) Organization and training programs;*
 - e) Organization of all governance and management meetings;*
 - f) Administration and management of the web portal;*
 - g) Management of EIRENE-ERIC activities;*
 - h) Promotion, communication, and marketing for EIRENE-ERIC.*
- 2. The Head Office employees shall assist the Director-General in all matters and report to him.*
- 3. The composition of the Head Office and its modus operandi are detailed in the Rules of Operation.*

Article 21

EIRENE-ERIC Central Coordination Units

1. *EIRENE-ERIC Central Coordination Units shall provide expertise, services, and tools relevant to pursuing EIRENE-ERIC's tasks and activities, as set out in the EIRENE-ERIC Work Programmes.*
2. *Five Central Coordination Units shall be established under EIRENE-ERIC and the responsibility of the Director-General: The Analytical Chemistry, Toxicology, Biostatistics/Bioinformatics, Cohorts/Bio-collections, and Data Central Coordination Units.*
3. *Central Coordination Units shall be hosted in countries that are EIRENE-ERIC Members.*
4. *Each Central Coordination Unit shall be managed by a Head, under the authority of the Director-General, and hired according to the Employment Policy.*

Article 22

The National Nodes

1. *The National Node will either have a legal entity or mandate a legal entity to represent it and sign the Service Level Agreement in its name.*
2. *Each National Node is represented by the National Node Contact Point. Members of EIRENE-ERIC will inform the Director-General of the name of their National Node Contact Point. The National Node Contact Points form the National Nodes at the National Nodes Committee.*
3. *Each National Node shall be bound by a Service Level Agreement with EIRENE-ERIC to minimally deliver the services, organize and coordinate the services of the National Node, and organize communications between EIRENE-ERIC and the National Nodes.*
4. *Each National Platform of a Member shall be bound by a Service Level Agreement with EIRENE-ERIC to deliver the services to operate the Research Infrastructure. This Service Level Agreement will include the criteria for National Platforms to be identified as EIRENE-ERIC platforms.*
5. *By derogation from Article 22(4), a Member may also choose to legally bind their National Platforms through the National Node. If no separate Service level agreement is concluded with the National Platforms according to Article 22(4), the National Node will conclude legally binding agreements with the National Platforms to guarantee the services to be delivered for EIRENE-ERIC. In this case, the Service Level Agreement with the National Node will, in addition to Article 22(3), also include the criteria for National Platforms to be identified as EIRENE-ERIC platforms.*
6. *The Node Contact shall provide a report to the EIRENE-ERIC Director-General on the activities of the National Node for EIRENE-ERIC on a regular basis, as defined in the Rules of Operation and the Service Level Agreement.*

Article 23

The National Nodes Committee

1. *The National Nodes Committee shall be comprised of the Director-General and heads of the National Nodes (i.e., the National Nodes Contact Points). The Director-General may invite experts, such as the heads of the Central Coordination Units to National Nodes Committee meetings.*
2. *The National Nodes Committee shall be chaired by the Director-General.*
3. *The National Nodes 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 (year N), together with a preliminary draft Work Programme and a draft budget for the following two years (year N+1 and year N+2);*
- b) *supporting the Director-General in the execution of the Work Programme and for enabling efficient interaction between EIRENE-ERIC and the Members and Observers and the EIRENE-ERIC users and stakeholders.*

Article 24

The Scientific Advisory Board (SAB)

1. *The role of the SAB is to advise the General Assembly on the following items:*
 - a) *Revision of the criteria to accept a service provider in EIRENE-ERIC;*
 - b) *Advise on EIRENE-ERIC strategy regarding services and capacity;*
 - c) *Collaboration with other European or international infrastructures;*
 - d) *Analysis of activity reports of the Central Coordination Units and recommendations for their work programme and long-term strategy;*
 - e) *Occasional review of research projects if requested by the Director-General, potentially including external experts;*
 - f) *Foresight on exposome science and its relevance to human health, focusing on how long-term environmental exposures influence disease risk and public health outcomes.*
2. *The members of the Scientific Advisory Board shall be appointed by the General Assembly. The SAB shall consist of independent experts from the public or private sector with high-level expertise in exposome science, including areas such as environmental health, epidemiology, toxicology, data science, public health, and global change. Members should also have experience in the management of large-scale research infrastructures or programmes. The number of members shall be a minimum of 5 and a maximum of 10.*
3. *The members of the SAB shall be appointed by the General Assembly for a duration of 5 years, with possibility for one renewal. They will elect a Chair and will meet at least once a year. The Chair may be consulted by the Director-General on any occasion.*
4. *The detailed Rules of Operation of the Scientific Advisory Board shall be adopted by the General Assembly.*

Article 25

The Ethical Advisory Board (EAB)

1. *The primary role of the Ethical Advisory Board is to advise the General Assembly.*
2. *The members of the EAB shall be appointed by the General Assembly. The EAB shall consist of independent experts from the public or private sector with high-level expertise in the ethics of environmental and life sciences. The number of members should be a minimum of 3 and a maximum of 10.*
3. *The members of the Ethical Advisory Board shall be appointed by the General Assembly for a duration of 5 years, with the possibility of one renewal. They will elect a Chair and will meet at least once a year. The Chair may be consulted by the Director-General on any occasion.*

4. *The detailed Rules of Operation of the Ethical Advisory Board shall be adopted by the General Assembly.*

Article 26

The Stakeholders Forum

1. *The Stakeholders Forum shall be composed of representatives of the bodies and institutions that have an interest in the services and results delivered by EIRENE-ERIC, such as users of EIRENE-ERIC facilities or data, policy makers, industries, Non-Governmental Organizations, and media. The number of members should be a minimum of 10 and a maximum of 20.*
2. *The role of the Stakeholders Forum is to advise the General Assembly on the following items:*
 - a) *Analysis of activity reports of the Central Coordination Units and recommendations for their work programme and long-term strategy;*
 - b) *Communication plan;*
 - c) *Collaboration with other European or international infrastructures.*
3. *The members of the Stakeholders Forum shall be appointed by the General Assembly for a duration of 5 years, with the possibility for one renewal. They will elect a Chair and will meet at least once a year. The Chair may be consulted by the Director-General on any occasion.*
4. *The detailed Rules of Operation of the Stakeholders Forum shall be adopted by the General Assembly.*

Article 27

The Subsidiary Bodies

1. *The General Assembly may decide to establish any Subsidiary Body, as required by the circumstances, for example to provide recommendations on specific topics.*
2. *The composition and the Rules of Operation of the Subsidiary Bodies shall be approved by the General Assembly, in accordance with Article 18(10).*
3. *Each Subsidiary Body shall meet at least once per year. The General Assembly may request the Chair of the Subsidiary Body to convene meetings to consider and provide recommendations on specific topics.*

CHAPTER 5

REPORTING TO THE EUROPEAN COMMISSION

Article 28

Reporting to the European Commission

1. *EIRENE-ERIC shall produce an annual activity report, containing in particular the scientific, operational and financial aspects of its activities. The report shall be sent for approval to the General Assembly within four months after the end of the corresponding financial year and then transmitted to the Commission and relevant public authorities within six months after the end of the corresponding financial*

year. This report shall be made publicly available.

2. The Director-General of EIRENE-ERIC shall inform the Commission of any circumstances which threaten to seriously jeopardize the achievement of EIRENE-ERIC tasks or hinder EIRENE-ERIC from fulfilling requirements laid down in Regulation (EC) No 723/2009.

CHAPTER 6

FINANCE

Article 29

Financial Year

The financial year of EIRENE-ERIC shall begin on the 1st of January and shall end on 31st of December of each year. The first financial year of the EIRENE-ERIC shall be a shortened financial year beginning with the date the Commission's decision to set up EIRENE-ERIC takes effect.

Article 30

Resources

The resources of EIRENE-ERIC shall comprise:

- 1. Member and Observer fees according to Articles 17 and 31.*
- 2. The Host Premium contribution, provided by the Members hosting either a Central Coordination Unit or the EIRENE Head Office, as set out in Annex III.*
- 3. Any other contributions, such as grants or income deriving from services or intellectual property rights owned by EIRENE-ERIC, within limits and under terms approved by the General Assembly.*

Article 31

Principles for contributions of Members and Observers

- 1. The Members and Observers shall make annual contributions to EIRENE-ERIC.*
- 2. The level of contribution of the Members shall be established for a budgetary cycle and approved by the General Assembly, according to the procedures set out in Article 18 and Annex III.*
- 3. In-kind contributions shall be considered only when in the form of effective and quantifiable contribution to EIRENE-ERIC, including seconded personnel to EIRENE-ERIC, and agreed by the General Assembly. The General Assembly shall agree on an accounting system, rules for the acceptance of in-kind contributions and the assessment of their value.*
- 4. Financial contributions shall be made in Euro.*
- 5. The value of any in-kind contributions shall be taken into account when calculating the financial contributions provided during the same period of time, in order to calculate (i) the total amount of contributions provided during the year in question and (ii) the specific proportions contributed by each Member to the total amount of contributions.*

Article 32

Budget, budgetary principles, accounts and audit

1. *All items of revenue and expenditure of EIRENE-ERIC shall be included in estimates to be drawn up for each financial year and shall be shown in the budget.*
2. *Revenues and expenditures of EIRENE-ERIC shall be in balance.*
3. *The General Assembly shall ensure that EIRENE-ERIC resources are used in accordance with the principles of sound financial management.*
4. *The budget shall be established and implemented and the accounts presented in compliance with the principle of transparency.*
5. *The accounts of EIRENE-ERIC shall be audited annually and accompanied by a report on the budgetary and financial management of the preceding financial year. The General Assembly shall approve the appointment and duration of an external auditor and shall approve the audited accounts and report on budgetary and financial management for the preceding financial year within six months of the end of the financial year.*
6. *EIRENE-ERIC shall be subject to the requirements of the applicable law as regards preparation, filing, auditing and publication of accounts.*

Article 33

Taxes

1. *VAT exemptions based on Articles 143(1)(g) and 151(1)(b) of Council Directive 2006/112/EC and in accordance with Articles 50 and 51 of Council Implementing Regulation (EU) No 282/2011 shall be applied to purchases of goods and services by EIRENE-ERIC and by a EIRENE-ERIC Member in the meaning of chapters 2 and 3 of the Statutes which are for the official and exclusive use by EIRENE-ERIC, provided that such purchase is made solely for the non-economic activities of EIRENE-ERIC in line with its activities. VAT exemptions shall be limited to purchases exceeding the value of EUR 300.*
2. *Excise duty exemptions based on Article 12 of Council Directive 2020/262 shall be limited to purchases by the EIRENE-ERIC which are for the official and exclusive use by EIRENE-ERIC, provided that such a purchase is made solely for the non-economic activities of EIRENE-ERIC in line with its activities and that the purchase exceeds the value of EUR 300.*
3. *Purchases by staff members are not covered by the exemptions.*

CHAPTER 7

MISCELLANEOUS

Article 34

Applicable law

The internal functioning of EIRENE-ERIC shall be governed:

1. *By Union law, in particular Regulation (EC) No 723/2009, as amended by Regulation (EC) No 1261/2013.*
2. *By the law of the State where EIRENE-ERIC has its statutory seat in the case of matters not, or only partly, regulated by Union law.*
3. *By these Statutes and the Rules of Operations.*

Article 35

Working language

The working language of EIRENE-ERIC shall be English.

Article 36

Disputes

1. *In the event of a dispute or difference between the Members arising out of or in connection with the Statutes, the General Assembly shall meet as soon as reasonably practicable to consult in good faith and seek to solve the dispute amicably.*
2. *The Court of Justice of the European Union shall have jurisdiction over litigation among the Members in relation to EIRENE-ERIC, between Members and EIRENE-ERIC, and over any litigation to which the European Union is a party.*
3. *European Union legislation on jurisdiction shall apply to disputes between EIRENE-ERIC and third parties. In cases not covered by European Union legislation, the law of the State where EIRENE-ERIC has its statutory seat shall determine the competent jurisdiction for the resolution of such disputes.*

Article 37

Amendments to the Statutes, updates and availability

1. *Any amendments of the Statutes shall be subject to the provisions of Article 11 of the Regulation (EC) No 723/2009 as amended by Regulation (EC) No 1261/2013.*
2. *The Statutes shall be kept up to date and be made publicly available on the EIRENE-ERIC website and at the statutory seat.*

Article 38

Setting-up provisions

1. *A first meeting of the General Assembly shall be called by the State where EIRENE-ERIC has its statutory seat as soon as possible after the Commission decision to set up EIRENE-ERIC takes effect.*
2. *Before the first meeting is held and no later than forty-five calendar days after the Commission decision to set up EIRENE-ERIC takes effect, the relevant State shall notify the founding Members and Observers of any specific urgent legal action that needs to be taken on behalf of EIRENE-ERIC. Unless a founding Member objects within five working days after being notified, the legal action shall be carried out by a person duly authorized by the relevant State.*

DEFINITIONS

For the purposes of these Statutes, the following definitions shall apply:

1. **'EIRENE-ERIC'** means: *The legal entity consisting of the EIRENE Head Office and the Central Coordination Units.*
2. **'National Node'** means: *An operational entity that organises the services of a given country to EIRENE-ERIC.*
3. **'National Node Contact Point'** means: *The person appointed by a National Node to interact directly with the Director-General about any question from, or to, a National Node and representing the National Node in the National Nodes Committee.*

ANNEX II

LIST OF MEMBERS, OBSERVERS, AND THEIR REPRESENTING ENTITIES

[illegible]

ANNEX III

BUDGET - CONTRIBUTIONS

FUNDING MODEL OF EIRENE-ERIC

The budget of EIRENE-ERIC shall be decided by the General Assembly. EIRENE-ERIC operational costs shall be covered largely by Member and Observer contributions, as well as by the Host Premium of the EIRENE-ERIC host country.

During the Operational Phase, when EIRENE-ERIC is established, it is expected that a minimum of 30% of expenditures are covered by Host Premium contribution, and 60% by annual Membership fee contributions (hereafter said Membership Fee). Host Premium contributions can be provided as cash and/or partially in-kind, while Membership fee shall be provided in cash to cover expenses related to e.g., consumables, staff travel, meetings, outreach, services (including e.g. legal, accounting, auditing, marketing, recruitment and subcontracting), equipment (software, licenses etc.) and the salary of the Head Office staff, including the Director-General. In-kind contributions in human resources from non-hosting countries shall be considered and decided on a case-by-case basis in the General Assembly.

While it is expected that at least two Central Coordination Units will be established (i.e., a Reference Laboratory and Data Center), the details regarding the associated costs will be available at a later date. Furthermore, it is expected that they will be funded primarily by their host countries nationally.

The membership fees and Host contributions will be determined for the first 5-year period (including the first shortened year). However, the contributions will be revised by the General Assembly as needed . The contribution of new Members will be computed according to the rule proposed by the GA, but, until the end of the first five-year cycle, will not impact the contribution of other Members. At the end of the 5-year cycle, the contribution of Members (i.e. those who become Members after the ERIC has been set up) will be revised according to the rules defined by the General Assembly.

Annex B: EIRENE Board of Government Representatives (BGR) draft Terms of Reference (ToR)

Terms of Reference (ToR)

Board of Governmental Representatives (BGR¹) of EIRENE

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¹ This document draws upon the structure and content of the Terms of Reference developed for the Einstein Telescope Board of Governmental Representatives (ET BGR), version 3, December 2021.

Preamble

EIRENE is the first European research infrastructure dedicated to the human exposome, addressing a critical gap in understanding the complex interplay between environmental exposures and human health. Recognized in the 2021 ESFRI Roadmap, EIRENE responds to the growing need for a coordinated, interdisciplinary approach to assess non-genetic factors influencing chronic diseases and to support evidence-based policy and innovation in environmental health.

EIRENE builds on the achievements of the European Human Exposome Network (EHEN) and other major European and international initiatives. It integrates expertise and infrastructure from over 20 countries, including EU Member States, Associated Countries, and global partners such as the United States, Australia, and Japan. Its mission is to develop high-throughput, harmonized, and open-access services that enable large-scale, longitudinal studies and support regulatory, clinical, and public health applications.

As EIRENE transitions from its preparatory phase (2021–2025) into implementation (2026–2029), establishing a robust governance structure is essential. The Board of Governmental Representatives (BGR)—hereafter referred to as the EIRENE BGR—serves as the interim General Assembly during this phase. It provides a structured forum for national representatives to guide the development of EIRENE’s legal, organizational, and financial framework, ensuring alignment with national priorities and long-term sustainability.

The EIRENE BGR plays a pivotal role in shaping the future EIRENE-ERIC by facilitating consensus on key strategic decisions, including the statutes, host country arrangements, and financial commitments. It ensures building EIRENE on a foundation of shared vision, mutual commitment, and scientific excellence.

This Terms of Reference document outlines the mandate, composition, responsibilities, and operational procedures of the EIRENE BGR. It reflects the collective ambition of EIRENE’s partners to establish a sustainable, high-impact research infrastructure that will advance scientific discovery, foster innovation, and improve public health across Europe and beyond.

Definitions

Member:	<i>A country that has formally joined the BGR with voting rights.</i>
Observer:	<i>A country or organization that participates in the BGR without voting rights.</i>
Delegate:	<i>An individual officially appointed to represent a Member or Observer in the BGR.</i>
Secretariat:	<i>The administrative body supporting the BGR, provided by the EIRENE Coordinators.</i>
Chair/ Vice-Chair:	<i>Elected representatives responsible for leading and coordinating BGR meetings and activities.</i>

Section 1: Purpose and Scope

1. *The BGR is a strategic forum for participating countries to discuss and agree on the progress and process of establishing EIRENE-ERIC in consultation with the EIRENE coordinators. The BGR may invite the coordinators to attend its meetings as appropriate.*
2. *The BGR is responsible for discussing, negotiating, and approving the key documents required to establish the EIRENE-ERIC legal entity.*
3. *In particular, the BGR will aim to reach a consensus on the following:*
 - *Governance structure and statutes*
 - *Financial plan and draft internal financial rules*
 - *Strategic policy papers relevant to the establishment and operation of EIRENE-ERIC*
 - *Any other matters considered essential by the BGR and its members.*
4. *These Terms of Reference shall enter into force upon their formal adoption by the BGR.*
5. *These Terms of Reference shall remain in effect until the formal governance structure of EIRENE-ERIC supersedes them. Upon the establishment of EIRENE-ERIC, the BGR will be dissolved and replaced by the General Assembly, as defined in the EIRENE-ERIC Statutes.*

Section 2: Composition and Membership

1. *All countries participating in the EIRENE project may join the BGR as Members or Observers. Each participating country shall be represented by delegates, as defined in Section 4.*

2. *The initial Members of the BGR are those countries that have signed a letter of political support and confirmed their participation by submitting a written appointment letter to the Secretariat.*
3. *Any country wishing to join the BGR after its establishment—either as a Member or an Observer—shall notify the Chair and the Secretariat in writing, per Section 4, and provide the names of its designated delegates.*
4. *The BGR remains open to new Members and Observers throughout its entire duration.*
5. *Observers may participate fully in BGR discussions, working groups, and activities. They shall receive all relevant documentation and communications and have the same rights and responsibilities as Members, except for voting rights.*

Section 3: Chair and Vice-Chair

1. *The BGR will elect a Chair and Co-Chair at its first meeting.*
2. *The Coordinators will serve as a Secretariat providing administrative support to the BGR.*
3. *The Chair and Vice-Chair of the BGR are elected for two years.*
4. *A Chair and Vice-Chair can serve no more than two terms.*
5. *All provisions applicable to the Chair shall also apply to the Vice-Chair.*
6. *The present Chair is considered elected according to this ToR from the date of its approval.*
7. *The Chair's role is to manage BGR meetings and neutrally moderate the discussion.*
8. *The Chair shall convene BGR meetings on their initiative or a joint request from at least two countries, with a notice of at least three weeks.*
9. *The Chair has the same voting rights as the other Members, meaning that if no other delegate of the country is present, the Chair may vote for their country.*

Section 4: Delegates

1. *Each Member and Observer shall nominate one delegate and one expert to the BGR.*
2. *A Member can appoint the expert as a proxy if the delegate is unavailable.*
3. *Each Member of the respective country's ministry shall send the letter of appointment of its delegate and expert to the Chair and the Secretariat. The composition of delegations shall be maintained and made available by the Secretariat.*
4. *Changes in delegations must be sent by the respective country's ministry to the Chair and the Secretariat by e-mail or letter.*
5. *The Chair may invite guests to attend the BGR as appropriate. At their request, the Coordinators will be allowed to participate in (part of) a BGR meeting.*
6. *BGR meeting participants shall respect the confidentiality of the information provided during the meeting and the content of debates and decisions taken by the BGR.*

Section 5: Secretariat

1. *The Secretariat shall assist the Chair in organizing and preparing the agenda and related materials for the meetings.*
2. *The Secretariat shall prepare draft minutes of the BGR meetings in agreement with the Chair.*
3. *The Secretariat, provided by the EIRENE Coordinators, shall act in a neutral and administrative capacity. While they may attend BGR meetings to support documentation and coordination, they do not participate in decision-making or voting.*

Section 6: Preparation and Adoption of the Agenda

1. *The Chair shall prepare a draft agenda for BGR meetings in collaboration with the Secretariat and send it to the delegates at least two weeks before the BGR meeting.*
2. *Materials to be considered by the BGR shall be prepared by the Chair in collaboration with the Secretariat and sent to the delegates at least two weeks before the BGR meeting.*
3. *The meetings are open to Members, Observers, and other parties invited to the meeting.*
4. *The draft agenda shall be considered for adoption at the opening of the meeting.*
5. *A Member or Observer may request that a new item be added to the draft agenda by written notification to the Chair and Secretariat at least two weeks before the BGR meeting, including all the material required.*
6. *During a BGR meeting, Members and Observers can request to add a new item to the agenda by a simple majority.*

Section 7: Proxy

1. *A Member may be represented at the meeting by another Member's delegate with a written proxy from the respective country's ministry. The Chair shall be notified preferably before, or at the latest, at the start of the meeting.*

Section 8: Quorum

1. *The quorum is reached if at least 75% of the Members of the BGR are present.*
2. *The Chair shall ensure that the relevant quorum is met.*
3. *If the quorum is not reached, the Chair shall convene, if necessary, a new meeting within a reasonable time with the same agenda. This new meeting shall be quorate regardless of the number of Members represented, but only if this is expressly stated in the invitation to such a new meeting of the BGR.*

Section 9: Voting

1. *The BGR shall always aim to make consensus decisions.*

2. *If consensus cannot be reached and voting is required, each Member represented shall have one vote.*
3. *For all decisions, if requested by at least two Members, voting shall take place by secret ballot. When voting concerns elections or nominations, voting shall always be by secret ballot.*
4. *Decisions of the BGR shall be made by a qualified majority, requiring that at least 75% of the members present and voting at the meeting vote in favour of the proposed decision.*
5. *In case the required majority is not achieved, a written procedure may be used for a second vote using the same 75% majority rule.*
6. *Only delegates of Members may vote, taking into account section 7. Observers may participate in discussions but do not have voting rights.*
7. *The transfer of voting rights should be communicated to the Chair by a written statement (letter or e-mail) prior to the meeting.*
8. *Members who abstain from voting are to be considered as not voting, and such abstention shall not prevent a decision from being taken with the required majority. However, abstentions are to be reported in the minutes in all cases.*

Section 10: Working Groups

1. *If needed, the BGR may establish separate working groups and committees to prepare issues for decision.*

Section 11: Conflict of Interest

1. *At the beginning of each meeting, all participants shall inform the Chair of any conflict of interest with regard to a particular item on the agenda. The opportunity to announce a conflict of interest will always be a standing item on the BGR agenda.*
2. *In the event of such a conflict of interest, the person concerned shall, at the request of the Chair and following a decision of the BGR, withdraw from the meeting whilst the relevant items of the agenda are being discussed.*

Section 12: Minutes

1. *For each meeting, minutes shall be drafted by the Secretariat and the Chair. Decisions taken by the BGR shall be recorded in the minutes.*
2. *The Chair shall send draft minutes to all delegates within three weeks of the meeting.*
3. *No additional point shall be added to the minutes if it has not been raised at the BGR meeting. No member shall modify either their vote or their opinion in the minutes.*
4. *The Chair will then send the accepted draft minutes to all the members.*
5. *The accepted draft minutes will be approved by written procedure or in the next BGR meeting.*

Section 13: Remote Meetings

1. *A meeting may be held remotely if the electronic procedure allows all delegates to attend the meeting.*
2. *Remote meetings are treated as equally valid as physical meetings. A written procedure (e.g., by e-mail) can be applied if necessary.*
3. *The electronic procedure shall be explained before the meeting and before a vote.*
4. *In any case, the BGR procedures shall apply.*

Section 14: Written Procedure

1. *The BGR may, in exceptional cases, make decisions by a written procedure conducted via e-mail.*
2. *The written procedure may be initiated by the Chair, on their initiative, or at the request of a Member or Observer.*
3. *The Chair sends all Members and Observers the relevant material and requests to vote via e-mail on a specific issue.*
4. *No additional items shall be added to this material, and no modifications or amendments can be proposed to the subject of the vote. A decision taken on an additional or modified item shall be considered null and void.*
5. *Usually, Members shall be given three weeks to cast their vote. In case of exceptional urgency, the Chair can shorten the voting period to five working days.*
6. *A written procedure is considered valid if no more than 25% of the Members oppose it.*
7. *The Chair shall collect the votes and abstentions of members after the deadline. The Chair shall immediately notify the Members, Observers, and the Secretariat of the decision, which becomes effective. Decisions made by written procedure shall be announced at the next meeting of the BGR. In any case, the BGR procedures shall apply.*

Section 15: Amendments

1. *These Terms of Reference may be amended by consensus or a qualified majority vote of the Members of the BGR, following a written proposal submitted to the Chair at least three weeks prior to the meeting at which the amendment is to be considered.*

Section 16: Data Handling and Confidentiality

1. *All participants in the EIRENE BGR, including Members, Observers, delegates, experts, and invited guests, shall treat all non-public information shared during or in connection with BGR meetings as confidential, unless explicitly stated otherwise.*
2. *Confidential information includes, but is not limited to, draft documents, internal communications, strategic discussions, financial data, and any other materials designated as confidential by the Chair or Secretariat.*

3. *Participants shall not disclose, distribute, or use confidential information for any purpose other than fulfilling their responsibilities within the BGR, unless prior written consent is obtained from the Chair.*
4. *The Secretariat shall ensure that all meeting materials, minutes, and communications are handled in accordance with applicable data protection regulations, including the General Data Protection Regulation (GDPR), and that appropriate safeguards are in place for storing and transmitting sensitive information.*
5. *Delegates are responsible for ensuring that any data or documents shared by their respective countries comply with national and international data protection laws.*
6. *Breaches of confidentiality or improper handling of data may result in exclusion from specific discussions or, in serious cases, from participation in the BGR, subject to a decision by the Chair in consultation with the Members.*

Supporting documents

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Commission Implementing Decision (EU) [2023/900](#) of 25 April 2023 setting up the Aerosol, Clouds and Trace Gases Research Infrastructure (ACTRIS ERIC) (OJ L 115, 3.5.2023, pp. 15–19).

Commission Implementing Decision (EU) [2022/2297](#) of 19 October 2022 setting up the European Solar Research Infrastructure for Concentrated Solar Power (EU-SOLARIS ERIC) (OJ L 304, 24.11.2022, pp. 78–84).

Commission Implementing Decision (EU) [2022/289](#) of 22 February 2022 setting up the Analysis and Experimentation on Ecosystems ERIC (AnaEE-ERIC) (OJ L 43, 24.2.2022, pp. 73–78).

Commission Implementing Decision (EU) [2022/1204](#) of 16 June 2022 setting up the Microbial Resource Research Infrastructure – European Research Infrastructure Consortium (MIRRI-ERIC) (OJ L 186, 13.7.2022, pp. 14–20).

Commission Implementing Decision (EU) [2021/960](#) of 30 April 2021 setting up the Extreme Light Infrastructure – Extreme Light Infrastructure European Research Infrastructure Consortium (ELI ERIC) (OJ L 212, 15.6.2021, pp. 3–6).

Commission Implementing Decision (EU) [2019/1854](#) of 29 October 2019 setting up the European Research Infrastructure for Imaging Technologies in Biological and Biomedical Sciences – Euro-Biolmaging European Research Infrastructure Consortium (Euro-Biolmaging ERIC) (OJ L 285, 6.11.2019, pp. 9–13).

Commission Implementing Decision (EU) [2018/1732](#) of 30 October 2018 setting up the European Plate Observing System – European Research Infrastructure Consortium (EPOS ERIC) (OJ L 288, 16.11.2018, pp. 10–14).

Report from the Commission to the European Parliament and the Council – Second Report on the Application of Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) ([COM\(2018\) 523 final](#), 6.7.2018).

Commission Implementing Decision (EU) [2018/499](#) of 20 March 2018 setting up the European Infrastructure of Open Screening Platforms for Chemical Biology European Research Infrastructure Consortium (EU-OPENSOURCE ERIC) (OJ L 82, 26.3.2018, pp. 8–12).

Commission Implementing Decision (EU) [2018/272](#) of 20 February 2018 on setting up the European Marine Biological Resource Centre – European Research Infrastructure Consortium (EMBRC-ERIC) (OJ L 51, 23.2.2018, pp. 17–22).

Commission Implementing Decision (EU) [2017/1213](#) of 4 July 2017 on setting up the Integrated Structural Biology – European Research Infrastructure Consortium (Instruct-ERIC) (OJ L 173, 6.7.2017, pp. 47–52).

Commission Implementing Decision (EU) [2017/996](#) of 9 June 2017 setting up the European Carbon Dioxide Capture and Storage Laboratory – European Research Infrastructure Consortium (ECCSEL ERIC) (OJ L 149, 13.6.2017, pp. 91–97).

Commission Implementing Decision (EU) [2017/995](#) of 9 June 2017 setting up the Consortium of European Social Science Data Archives – European Research Infrastructure Consortium (CESSDA ERIC) (OJ L 149, 13.6.2017, pp. 85–90).

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Commission Implementing Decision (EU) [2016/1757](#) of 29 September 2016 on setting up the European Multidisciplinary Seafloor and Water Column Observatory – European Research Infrastructure Consortium (EMSO ERIC) (OJ L 268, 1.10.2016, pp. 113–117).

Commission Implementing Decision (EU) [2015/2097](#) of 26 October 2015 on setting up the Integrated Carbon Observation System European Research Infrastructure Consortium (ICOS ERIC) (OJ L 303, 20.11.2015, pp. 19–34).

Commission Implementing Decision (EU) [2015/1478](#) of 19 August 2015 on setting up the European Spallation Source as a European Research Infrastructure Consortium (European Spallation Source ERIC) (OJ L 225, 28.8.2015, pp. 16–48).

Commission Implementing Decision [2014/923/EU](#) of 12 December 2014 on setting up the Joint Institute for Very Long Baseline Interferometry as a European Research Infrastructure Consortium (JIV-ERIC) (OJ L 363, 18.12.2014, pp. 156–169).

Commission Implementing Decision [2014/526/EU](#) of 6 August 2014 setting up the Digital Research Infrastructure for the Arts and Humanities as a European Research Infrastructure Consortium (DARIAH ERIC) (OJ L 239, 12.8.2014, pp. 64–80).

Commission Implementing Decision [2014/392/EU](#) of 24 June 2014 on setting-up the Central European Research Infrastructure Consortium (CERIC-ERIC) (OJ L 184, 25.6.2014, pp. 49–62).

Commission Implementing Decision [2014/261/EU](#) of 5 May 2014 on setting up Euro-Argo Research Infrastructure as a European Research Infrastructure Consortium (Euro-Argo ERIC) (OJ L 136, 9.5.2014, pp. 35–50).

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Commission Implementing Decision [2013/701/EU](#) of 22 November 2013 on setting up the Biobanks and Biomolecular Resources Research Infrastructure Consortium (BBMRI-ERIC) as a European Research Infrastructure Consortium (OJ L 320, 30.11.2013, pp. 63–80).

Commission Implementing Decision [2013/700/EU](#) of 22 November 2013 on setting up the European Social Survey as a European Research Infrastructure Consortium (ESS ERIC) (OJ L 320, 30.11.2013, pp. 44–62).

Commission Implementing Decision [2013/640/EU](#) of 7 November 2013 on setting up the European Advanced Translational Research Infrastructure in Medicine as a European Research Infrastructure Consortium (EATRIS ERIC) (OJ L 298, 8.11.2013, pp. 38–47).

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Commission Decision [2011/166/EU](#) of 17 March 2011 setting up the SHARE-ERIC (OJ L 71, 18.3.2011, pp. 20–31).