



INTERNAL RULES OF PROCEDURE

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Introduction

The document entitled “Internal Rules of Procedure” is intended to provide detailed information on the functioning of the European Clinical Research Infrastructure Network-European Research Infrastructure Consortium (hereinafter referred to as “ECRIN-ERIC”) and must be read in conjunction with the ECRIN-ERIC Statutes. However in order to make the document self-understandable, a short summary of the statutes is provided at the beginning of the paragraph when necessary.

This first version of the Internal Rules of Procedure is drafted to start the ECRIN-ERIC activities and will be reviewed, and updated if required, in six months in order to take into account the first months of functioning and the adaptations and specifications needed.

The Internal Rules of Procedure are prepared by the ECRIN-ERIC Director General and are adopted by the Assembly of Members as defined in ECRIN-ERIC Statutes Article 17 and Article 7-2 (c)-iv.

Section I: The organization of the work (between the Members, Observers, Bodies and Partners)

Article 1

Members and Observers

1. Application

Members States, Associate Countries, Third Countries other than Associate Countries, Intergovernmental Organisations wishing to become Members or Observers of ECRIN-ERIC shall apply in writing to the Director General providing the following information:

- background information regarding Membership, the contribution, the National Representative
- statement accepting the ECRIN-ERIC statutes and the current version of the Internal Rules of Procedure
 - the Scientific Partner proposed including the following:
 - a statement regarding the compliance with the criteria (see appendix A)
 - the description of the national network and the national hub, including relevant administrative information
 - the representative at the network committee (ECRIN-ERIC Statutes Article 6-2e)
 - the European Correspondent position
 - statement approving the template Framework Agreement with Scientific Partners
 - for associated countries, third countries and international organisations, declaration on recognition of the ECRIN-ERIC legal personality and on tax exemption.

There shall be one single Scientific Partner per country.

The applications can be submitted at any time during the year.

When the application is sent after July 1st, half of the contribution shall be paid for the first year.

2. Decision

The Assembly of Members shall decide on the acceptance of the candidate Member or Observer as well as of the Scientific Partner proposed during a regular or extraordinary meeting. For the Scientific Partner, the Assembly of Members will take into account the recommendation of the Network Committee.

The Director General will communicate to the applicant, in writing, the Decision of the Assembly of Members within five (5) working days.

3. Rights and obligations governing the scientific partnership

Each Scientific Partner, by signing the Framework Agreement, agrees to cooperate and provide services to the clinical research projects approved by the Director General upon recommendation of the Network Committee, following the assessment performed by the Scientific Board and the logistical assessment and feasibility performed by the Partners.

The information, advice and services which may be provided by the Scientific Partner are defined in the Framework Agreement and, for specific projects, are detailed in the study specific agreements. The activities necessary to coordinate the national provision of services are performed by the European Correspondents and supervised by the ECRIN-ERIC Management Office.

Each Scientific Partner is represented within the ECRIN-ERIC by its representative/proxy at the Network Committee (ECRIN-ERIC Statutes Article 6-2e).

4. Procedure for negotiation of an extended Observer status: As mentioned in Article 5(2) of the Statutes, a country may, under exceptional circumstances, request a temporary time extension of the Observer status. This request shall be sent to the Director General at least six months before the planned end of its participation as an Observer State. The Assembly of Members shall recognize the exceptional circumstances, then agree to the duration of the extended Observer Status, the contribution (full local contribution as set out in Annex III(3a), and partial core financial contribution based on Annex III(3b) description), and the nature of the support provided by ECRIN-ERIC during the extended duration of its participation as an Observer.

Article 2

Partners

1. Scientific Partner

a. Application

For the countries who are neither Member nor Observer, a National Clinical Research Network wishing to become a Scientific Partner of ECRIN-ERIC shall apply in writing to the Director General providing the following information:

- a statement regarding the compliance with the criteria (see appendix A)
- the background information regarding Partnership including
 - o the description of the national network and the national hub, including relevant administrative information

- the contribution to the ECRIN-ERIC tasks and activities (ECRIN-ERIC Statutes Article 3) (including the commitment to cover the salary and operation costs of the European Correspondent)
- the European Correspondent position and
- the representative at the network committee (ECRIN-ERIC Statutes Article 6-2e)

The applications can be submitted at any time during the year.

b. Decision

The Assembly of Members shall decide, upon recommendation of the Network Committee, on the acceptance of the candidate Scientific Partner during a regular or extraordinary meeting.

The Director General will communicate to the applicant, in writing, the Decision of the Assembly of Members within five (5) working days.

c. Rights and obligations governing the scientific partnership

Each Scientific Partner, by signing the Framework Agreement, agrees to cooperate and provide services to the clinical research projects approved by the Director General upon recommendation of the Network Committee following the assessment performed by the Scientific Board and the logistical assessment and feasibility performed by the Partners.

The information, advice and services which may be provided by the Scientific Partner are defined in the Framework Agreement and, for specific projects, are detailed in the study specific agreements. The activities necessary to coordinate the national provision of services are performed by the European Correspondents and supervised by the ECRIN-ERIC Management Office.

Each Scientific Partner is represented within the ECRIN-ERIC by its representative/proxy in the Extended Network Committee (ECRIN-ERIC Statutes Article 6-2e).

2. Affiliate Partners

a. Application

Organisations (as defined in ECRIN-ERIC Statutes Article 6-3b) wishing to become Affiliate Partner of ECRIN-ERIC shall apply in writing to the Director General providing the following information:

- a statement regarding the compliance with the criteria (see appendix A)
- the background information regarding Partnership including the description of the partner, including relevant administrative information and contribution to the ECRIN-ERIC tasks and activities
- the objective of the collaboration and provisions for a Memorandum of Understanding or Collaboration Agreement

The applications can be submitted at any time during the year.

b. Decision

The Assembly of Members shall decide, upon recommendation of the Network Committee, on the acceptance of the candidate Affiliate Partner during a regular or extraordinary meeting.

The Director General will communicate in writing the Decision of the Assembly of Members within five (5) working days to the applicant.

c. Rights and obligations governing the affiliate partnership

The ECRIN-ERIC Director General shall set up a contract (Memorandum of Understanding or collaboration agreement) with the affiliate partner describing the activities performed and the rights and obligations of the Parties.

Article 3

Bodies

1. The Assembly of Members

Cf. ECRIN-ERIC Statutes Article 7-2

a. Representation

- All Members and Observers should be present or represented at any meeting of the Assembly of Members. A quorum of two thirds of Members shall be required for having a valid Assembly of Members meeting (cf. ECRIN-ERIC Statutes Article 7-4d)
- Members and Observers should communicate to the ECRIN-ERIC management office, the names of the participants (either representative or proxy) to the Assembly of Members. It is recommended to provide to the ECRIN-ERIC management office the name of the participants at least fifteen (15) days before any ordinary meeting. However, this can be done until the beginning of the meeting. Each representative or proxy should have the mandate to participate in the Assembly of Members.
- Members can have more than one representative at the meetings, but each Member shall have one vote

b. Chair and Vice Chair

Cf. ECRIN-ERIC Statutes Article 7- 3

c. Operational procedures

With the exception of the constitutional meeting of the Assembly of Members, the following rules (table 1) shall apply to the meetings of the Assembly of Members.

d. Working Committees

Whenever needed, the Assembly of Member can decide to set-up, for a limited period of time, a Working Committee to address a specific issue that requires cooperation or specific competences.

The composition of the Working Committee will be defined by the Assembly of Members according to the topic and needs, and may involve external experts.

The Assembly of Members will design a chair who will be responsible for the organisation of the work and in particular to convene meetings (face-to-face, or remotely using teleconference or videoconference systems), organise the tasks, write minutes and reports and report to the Assembly of Members.

Table 1. Operational Procedures for the Meetings of the Assembly of Members

| | Ordinary Meeting | Extraordinary Meeting | Repeated Meeting |
|---|--|--|--|
| Convening | A least once a year by the Chair of the Assembly of Members | When circumstances so demand upon written request of the Chair of the Assembly of Members, the General Director, or of at least one quarter (1/4) of the Members or Observers | When a Ordinary or Extraordinary Meeting is adjourned because the quorum is not met |
| Notice | Two (2) calendar months | One (1) calendar month | Within fifteen (15) calendar days following the adjournment At least seven (7) calendar days before the date of the meeting |
| Sending the Agenda, and the documents to be discussed and approved during the meeting | One (1) calendar month | One (1) calendar month | Seven (7) calendar days. The items on the agenda and documents to be discussed must be the same as for the original meeting |
| Adding agenda item | Each Member is entitled to add item and related documents to the agenda until fifteen (15) calendar days before the meeting Any item which is not on the agenda may not be discussed or decided in the meeting, unless all Members are present and no one objects. | Each Member is entitled to add item and related documents to the agenda until fifteen (15) calendar days before the meeting Any item which is not on the agenda may not be discussed or decided in the meeting, unless all Members are present and no one objects. | No item can be added |
| Quorum | Two thirds of Members present or represented | Two thirds of Members present or represented | The quorum is considered met, if one third of the Members are present or represented |
| Voting procedure and rights | Cf ECRIN-ERIC statutes – Article 7-4-d | Cf ECRIN-ERIC statutes – Article 7-4-d | Cf ECRIN-ERIC statutes – Article 7-4-d |
| Minutes | Fifteen (15) calendar days. Any comments on the draft minutes should be submitted to the Chair of the Assembly of Members within fifteen (15) calendar days following the circulation. If no comments are received, the minutes are automatically approved after fifteen (15) calendar days. The approved minutes are published on the ECRIN-ERIC website. | Fifteen (15) calendar days. Any comments on the draft minutes should be submitted to the Chair of the Assembly of Members within fifteen (15) calendar days following the circulation. If no comments are received, the minutes are automatically approved after fifteen (15) calendar days. The approved minutes are published on the ECRIN-ERIC website. | Fifteen (15) calendar days. Any comments on the draft minutes should be submitted to the Chair of the Assembly of Members within fifteen (15) calendar days following the circulation. If no comments are received, the minutes are automatically approved after fifteen (15) calendar days. The approved minutes are published on the ECRIN-ERIC website. |

2. The Director General

a. Nomination procedure

The Assembly of Members is in charge of appointing, upon recommendation of the Network Committee, the Director General based on the job description as agreed by the Assembly of Members.

The Director General is employed by the ECRIN-ERIC.

The Director General may serve for a term of up to 3 years, renewable.

b. Responsibilities and duties

Cf. ECRIN-ERIC Statutes – Article 7-5 and Article 8-2 and ECRIN-ERIC Director General - Job Description.

The Director General is the legal representative of the ECRIN-ERIC.

The Director General is accountable to the Assembly of Members for the operational management (scientific, technical, financial and administrative) of the ECRIN-ERIC, for the strategic scientific development and for the execution of the decisions of the Assembly of Members.

The Director General is assisted by the staff of the Management Office.

The Director General shall:

- prepare a draft annual work programme and annual budget, and submit it to the Assembly of Members no later than three (3) months before the beginning of each financial year (except for the first year where those document will be prepared for the constitutional meeting)
- prepare a provisional programme and budget for the following two (2) years
- prepare, with the Network Committee, the detailed annual report on the work programme including financial accounts and tasks achieved
- set up the organisation of the Scientific Board
- appoint, upon recommendation of the Network Committee, the members of the External Advisory Board and of the Ethical Advisory Board and convene the meetings of those Boards
- update the list of Members and Observers (annex II of the ECRIN-ERIC statutes)
- maintain an updated list of Scientific and Affiliate Partners
- according to the work plan and budget agreed by the Assembly of Members hire and appoint the staff of the Management Office, including the European Correspondents in link with the scientific partner, and is responsible for the daily management of the staff. For the senior positions, the Assembly of Members mandate the Steering Committee to participate in the selection process, and has the final decision on the suitable candidates to recruit
- discuss, negotiate and sign the Framework Agreements or Memorandum of Understanding with Partners, the specific agreement with Sponsors (if in agreement with Scientific Partners), with Scientific Partners and/or Service Contributors, and any other contract according to the decision of the Assembly of Members.
- prepare and update the Internal Rules of Procedure

3. Steering Committee: members, responsibilities and procedures

The description is provided in Article 7. 6 of the ECRIN-ERIC Statutes.

a. Members

The Steering Committee is composed of 5 members, two from the Assembly of Members (Chair and Vice Chair), two from the Network Committee (Chair and Vice Chair) and the Director General.

The members have a 3 years mandate as defined by their position in the Assembly of Members and Network Committee, and the name of the appointed members will be published in the ECRIN-ERIC website.

b. Responsibilities

The Steering Committee is in charge of strengthening the link between the Assembly of Members, the Network Committee and the Director General, and preparing the meetings of the Assembly of Members.

In particular, the Steering Committee shall:

- advice the Director General in the preparation of the work plan and budget
- support the Director General in the selection process for senior positions in the ECRIN-ERIC management office and is responsible for the selection of the suitable candidates for the position
- advice the Director General on scientific and technical orientations
- assess the deliverables and ensure that the decisions are implemented
- review and advice on the statements to be endorsed by ECRIN-ERIC
- mediate any disagreement between the Assembly of Members, Network Committee and Director General

c. Procedures

The Steering Committee shall meet in person at least one (1) time a year, but as often as its members deem it necessary (either in person or via electronic means).

The Steering Committee is chaired by the chair of the Assembly of Members.

The meetings are convened by the Chair of the Steering Committee.

Section II: Management

Article 4

Management office and staff policy

1. Employment Policy

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

Subject to the requirements of national legislation, each Member shall, within its jurisdiction, facilitate the movement and residence of nationals of the other Members involved in the tasks of ECRIN-ERIC and of the family members of such nationals.

The ECRIN-ERIC staff is employed by ECRIN-ERIC, or work on the basis of secondment from their home institution and/or hosting institution of the Scientific Partner.

Following the adoption of the pluri-annual work plan, the Director General shall hire the relevant collaborators. The relevant job descriptions will be published on the ECRIN website. The Director General will select the appropriate staff. For the senior positions, the selection is done by the Steering Committee as specified above.

2. Guidelines for the selection of European Correspondents

The selection of the European Correspondents will be based on the Job Description jointly agreed between the Scientific Partner and the ECRIN-ERIC Director General (see Annex III of Statutes).

The recruitment process will follow the procedures described above. The Director General and the Scientific Partner will select the appropriate staff. In case of secondment and in kind contribution, the candidate may be proposed by the Member State but the selection shall necessitate the agreement of both the Director General and the Member, Observer or Scientific Partner.

Article 5
ECRIN-ERIC activities

1. Network Committee
Cf ECRIN-ERIC Statutes Article 9-2

a. Appointment

Each Scientific Partner shall appoint one senior Delegate (senior scientist experienced in the field) in the Network Committee.

The names of the appointed members of the Network Committee will be published on the ECRIN website. A proxy should be nominated.

b. Meetings

All the representatives should be present or represented (by their proxy) at the meetings of the Network Committee.

The following rules (table 2) shall apply to the meetings of the Network Committee (including extended Network Committee).

Table 2. Operational Procedures for the Meetings of the Network Committee

| | Ordinary Meeting /Extraordinary meeting |
|--|---|
| Convening | Ordinary: Face to face meeting at least twice a year by the Chair of the Network Committee Every third month by teleconference Extraordinary: At any time upon written request of the Chair of the Network Committee, the ECRIN-ERIC General Director, or of at least one third (1/3) of the Network Committee |
| Notice | One (1) calendar month |
| Sending the Agenda and related documents | Fifteen (15) calendar days |
| Adding agenda item | Each representative is entitled to add item and related documents to the agenda until seven (7) calendar days before the meeting Any item which is not on the agenda may not be discussed or decided in the meeting, unless all Members are present and no one objects. |
| Quorum | Two thirds of representatives present or represented |
| Voting procedure and rights | Each member of the Network Committee present or represented in the meeting shall have one vote Decisions shall be taken through consensus or following a vote (simple majority) Voting rights are restricted to representatives of Members. |
| Minutes | Seven (7) working days. Any comments on the draft minutes should be submitted to the Chair within seven (7) working days following the circulation. If no comments are received, the minutes are automatically approved after seven (7) working days. The approved minutes are published on the ECRIN-ERIC website. |

Article 6
Access to services and data policy

1. Access

The decision to provide services shall be made by the Director General upon recommendation of the Network Committee (Cf. ECRIN-ERIC Statutes Article 11-2).

2. Scientific Board

Cf. ECRIN-ERIC Statutes Article 9-3 b

The Members of the Scientific Board shall elect a Chair for a three (3) years period, renewable. The Scientific Board is composed of external and internal members, with two committees:

- the Collaboration Committee providing a quick answer to the requests for support in the planning, design, and funding application
- the Peer-Review Committee in charge of making recommendations based on a peer-review of the full protocol before operational services are provided.

3. Application, assessment procedures and evaluation criteria

Draft application procedure, assessment procedure and evaluation criteria are prepared by the Chair of the Scientific Board with the Director General and the Network Committee and submitted to the Assembly of Members for approval. The approved application procedure, assessment procedure and evaluation criteria are published on the ECRIN website (www.ecrin.org).

4. Data policy

Cf. ECRIN-ERIC Statutes Article 11-5.

The ECRIN-ERIC data policy will be in line with the ESFRI document on data policy.

Article 7

Procurement

1. The objective of this article 7 is to provide the general procurement principles and processes which shall be observed by ECRIN-ERIC in carrying out procurement of services, works and goods for its activities.
2. ECRIN-ERIC treats procurement candidates and tenders equally and in a non-discriminatory way, independent of whether or not they are based in the European Union. All procurement follows the principles of transparency, non-discrimination equal opportunity and competition.
3. Criteria: the award criteria may in particular relate to :
 - a. Quality of services, works and goods
 - b. Interoperability
 - c. Best value for money
4. Procurements methods:
 - a. Competitive bidding: services/works/goods worth €100,000 (for a given project and a given provider) or more must be awarded by means of a tender procedure following publication of a procurement notice. The competitive bidding may be open at national or international level depending on the requirements of the services/works/goods being bid out. The procurement notice will be published in appropriate media (including simap.europa.eu) and in the ECRIN-ERIC website.
 - b. Small purchase procedure: services/works/goods contracts worth less than €100,000 (for a given project and a given provider) must be awarded by means of a negotiated procedure without publication, in which ECRIN-ERIC

consults at least three service providers of its choice and negotiates the terms of the contract with one or more of them. In case of services/works/goods of a value of €5,000 or less (for a given project and a given provider), ECRIN-ERIC may place orders on a basis of a single tender.

5. Sourcing for research activities:
 - a. For the procurement of services/works/goods by ECRIN-ERIC for research projects where the benefit accrues to the entire scientific community, no tender will be performed.
 - b. In addition, distributed services (for instance local monitoring, adverse event reporting, support to ethical and regulatory approvals) may be provided at the national level by ECRIN-ERIC Partners, or members of the national network, selected on their competence, quality and interoperability, upon recommendation by the national hub.
6. Responsibilities: The ECRIN-ERIC Director General is responsible for the procurement process and actions, and in particular the definition of requirements, identification of the vendors if appropriate, evaluation, selection of the vendors, negotiation and contract signature.

Article 8

Intellectual property policy

Cf. ECRIN-ERIC Statutes Article 7.

1. ECRIN-ERIC may claim intellectual property rights (either alone or shared with its service contributors), within applicable national and international jurisdictions over tools, data, products or any other results developed or generated by ECRIN-ERIC (and its Service Contributors in Studies when relevant) while carrying out the work programme.
2. ECRIN-ERIC shall be acknowledged as contributor in each presentation, report and publication related to the Studies.

Article 9

Financial rules

1. Request for funds

The financial year is the calendar year.

The request for funds will be sent to each of the Member and Observer after the approval of the corresponding work plan and annual budget by the Assembly of Members.

The Members or Observers wishing to pay an in-kind local contribution shall apply in writing to the Director General, and must provide evidence that the cost of the salary and operation expenses of the European Correspondent is equivalent to the amount committed. The Assembly of Members shall validate the level of in-kind contribution, or may request changes to be integrated before the contribution is approved.

2. Interest rate to a late contributor (annual contribution upon calls)

The penalty interest rate to be applied to a late contributor is the European Central Bank rates in force on the 1st January. The penalty interest due for late payment should be calculated on a daily basis.

A contributor is considered late if the contribution is not paid within 3 months following the reception of the request for funds.

3. Auditing

Cf ECRIN-ERIC Statutes Article 13-2

4. Contributions for year n are calculated based on the rules described in Annex III of the Statutes, using mean values for GDP and GDP per capita provided by EuroStat over years n-2, n-3 and n-4.

5. When a Member withdraws or its core contribution decreases, 50% of the missing contribution is compensated by an increase in the contribution of the other Members (whereas the other 50% results in a decrease in the core budget).

Article 10

Endorsement of statements

1. Procedure

Statements adopted by the ECRIN-ERIC Network Committee will be disseminated, mentioning if needed the divergent opinion of some of the Scientific Partners of Member or Observer countries, after informing the Steering Committee.

Whenever the Steering Committee considers that a statement may have political implications, it will be submitted to the Assembly of Members for information and, if necessary, for endorsement.

Appendices

Appendix A

Criteria for ECRIN-ERIC Scientific Partners and Affiliate Partners

➤ *National ‘Scientific Partners’*

Efficient collaboration with ECRIN typically requires a national ‘scientific partner’, consisting of:

- a network of clinical trials units able to participate in the management of clinical trials through the provision of local services (including ethical and regulatory submissions, adverse event reporting, monitoring)
- in any disease area, for any category of clinical research
- representing the standard and reaching the critical mass in their country
- these national partners should comply with the ECRIN quality policy
- with a single contact point for ECRIN, hosting the national ECRIN European Correspondent
- the national scientific partner should nominate a senior scientist with expertise in clinical trials who will be the national representative in the Network Committee.

- Scientific Partners in ECRIN-ERIC Member or Observer countries should be supported by their government representative

A framework agreement should be established between ECRIN-ERIC and each national scientific partner, defining the nature of the services provided to the management of multinational trials, the quality assurance, the not-for-profit cost model, and the links between the European Correspondent and the national scientific partner.

➤ *‘Affiliate Partners’*

Another way to collaborate with ECRIN is based on the affiliate partner status. This is a looser partnership requiring no specific provisions nor resources. Such partnership can be established, among other, with multinational disease-oriented networks, or with partners in extra-European countries or in countries with whom a limited volume of activity is foreseen.

Appendix B

**Procedure on eligibility and validation of in kind contribution
of Members or Observers of ECRIN-ERIC****a) Purpose**

The purpose of this document is to define basic rules and procedures for the Assembly of Members (AoM) to decide on in-kind contributions of Members or Observers of ECRIN-ERIC.

Such procedure shall be discussed with national hubs / Scientific Partners of ECRIN-ERIC and shall become effective upon approval by the AoM.

Such procedure shall be added as an Annex to the ECRIN-ERIC's Internal Rules of Procedure.

b) Eligibility

The expenses eligible for in kind contribution shall be:

1. salary (with taxes, charges, employers' liability insurance, pension, health insurance according to national law) of the employees fulfilling the mission of the European Correspondent
2. travels of the European Correspondent, training, equipment and consumables in the context of his / her mission
3. meetings involving the European Correspondent organised in the national context (not exceeding 15% of the in-kind contribution)
4. overheads (not exceeding 15% of the in-kind contribution), or detailed presentation of the cost of hosting the European Correspondent.

c) Valuations of in kind contribution

The in-kind contribution shall be paid in local currency for the non-Euro zone countries (as the expenses are made in local currency). This corresponds to the sentence in the Annex III of the Statutes "with an equivalent value of 100k€ or 50k€". To improve the predictability of the in-kind contribution, this equivalence shall be determined for a three-years period based on the currency exchange rate at the onset (January 1st) of the triennial period.

d) Justification of the spending

The justification of expenses shall be based on a financial report, to be included in the annual report and validated by the AoM. A confirmation letter will be sent by the ECRIN-ERIC Director General to the in-kind contributing Member / Observer.

e) Procedure in case of unspent in-kind contribution

In case of under-spending, the unspent contribution shall be transferred to the next year.