Policy (POL)

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Lead author(s)	**Reviewer(s)**	**Approver**
Name: Sabine Klager	Name: Christine Kubiak	Name: Jacques Demotes
Function: Head of Clinical Operations Unit	Function: Operations Director	Function: Director General
Signature:	Signature:	Signature:
Date: 19/02/2020	Date: 20/2/2020	Date: 20-2-2020
	Name: Christine Toneatti	
	Function Head of Quality and IS Unit	
	Date: 19/04/2020 .	
	Signature:	

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1 INTRODUCTION

1.1 Objective

This policy describes the consideration and procedures set in place by ECRIN for deciding on a collaboration with Sponsors and Investigators of multi-national European clinical trials or studies, thereby seeking access to ECRIN clinical project services.

1.2 Scope

This policy applies to any multinational European clinical trial or clinical study requesting access to ECRIN clinical project services. This policy applies to ECRIN-ERIC Director General, ECRIN Core Team based in the Paris head quarter office, the ***European Correspondent***s (EuCos) based in the ECRIN member countries, the members of the ***Scientific Board (SB)***, its sub-committees and its secretariat, the methodological and medical experts.

This policy does **not** apply for any request to ECRIN for the collaboration in infrastructure, capacity building or projects (please refer to PART-SOP-015-1) or to any application for ECRIN quality services (please refer to QA-SOP-011-1).

1.3 Roles and Responsibilities

The access to ERIC research infrastructures must be based on scientific excellence. Hence, the ECRIN Scientific Board was set-up upon the decision of the ECRIN Assembly of Members. It is responsible for granting access to ECRIN clinical project services following the ECRIN Statutes and internal rules of procedures [1;2]. Access is granted based on the evaluation of the projects submitted to ECRIN through defined eligibility criteria, as listed in PRO-FOR- 093 and [3;4].

The **Scientific Board** is composed of 11 members, 5 ECRIN staff and 6 external experts. It has an **independent chair (SB-chair)**, is built of two sub-committees and is managed by the **Scientific Board Secretariat** (see Fig. 1)

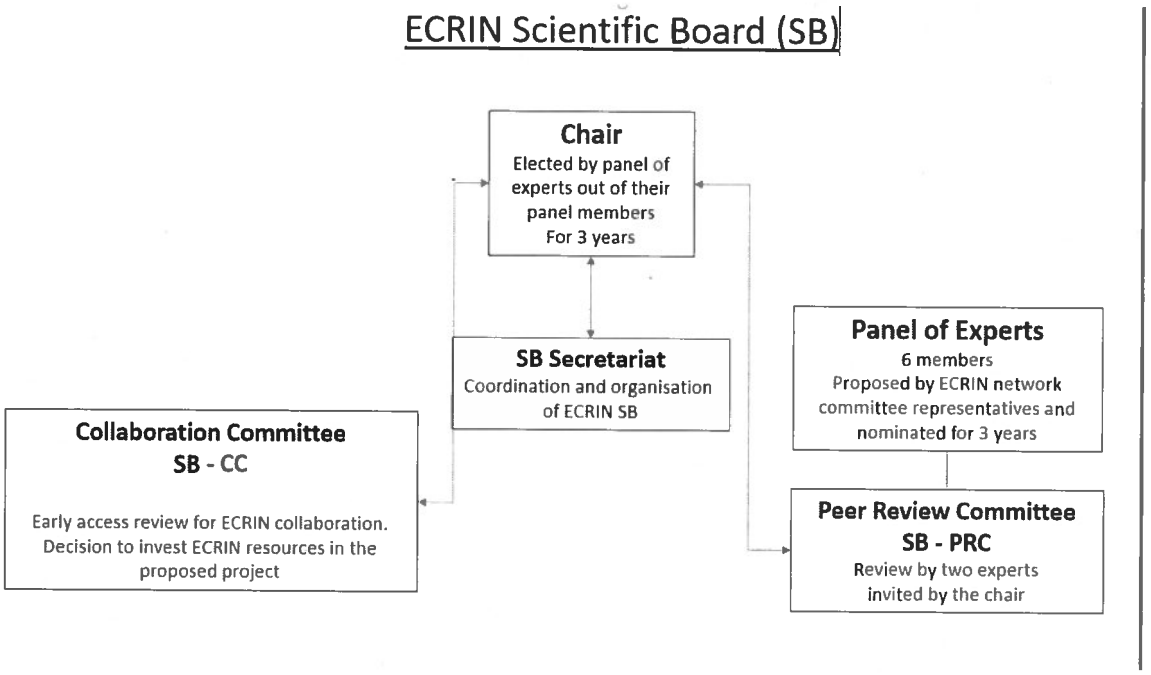
The two sub-committees are:

a) The **Collaboration Committee (CC)** for providing quick answers to requests for support and collaboration in the planning, design and funding application. This is composed of five ECRIN senior staff members. The independent SB-chair oversees the CC activities and decisions.

Members of Collaboration Committee are:
ECRIN Head of Clinical Operations Unit
ECRIN Operations Director
ECRIN Director General
ECRIN Senior European Correspondent
ECRIN Medical Expert

b) The **Peer-Review Committee (PRC)** for making recommendations based on a peer review of the full protocol before operational services are provided. The PRC is composed of six external members, selected from nominations provided by the National Partners. The independent SB-chair is allocating peer review requests to two members for each protocol, and oversees the PRC activities, reviews and recommendations.

Figure 1



The SB-chair: The independent external members of the PRC elect a SB-chair out of its midst who will serve a period of 3 years, which is renewable. The SB-chairs provides independent oversight to all decision making processes of both, the CC and the PRC.

SB-Secretariat: provides organisational support to the chair, and the two sub-committees, and is located at the ECRIN head office in Paris.

Coordinating EuCo:

- Is the contact point on the national ECRIN member country level between the ***Applicant*** (Sponsor/Investigator) from that country and ECRIN;
- Provides information to the Applicant on the ECRIN evaluation criteria and procedure;
- Submits the project to the Scientific Board -Collaboration Committee (SB-CC), and if applicable at a later point the protocol to the SB-Peer review committee (SB-PRC).
- Is invited to participate in the relevant SB-CC meeting for the introduction of the project to the SB-CC, and informs Applicant on the out-come
- Ensures that the timelines for CC and PRC are met.

ECRIN Head of Clinical Operations Unit:

- Acts as chair of the SB-CC; providing agenda, submission documentation, and minutes to the CC
- Allocates necessary resources if CC has approved collaboration with ECRIN.
- Assigns new projects to a ***Coordinating EuCo*** in the Applicant's country, and in case no EuCo is available to another member of ECRIN staff.
- Supports the EuCos in the risk assessment for ECRIN;

ECRIN DIRECTOR GENERAL:

- Sits on the SB-CC
- Takes the final decision to provide or not access to the ECRIN services for the clinical trial based on the SB-PRC assessment, the logistical assessment, the discussion with the head of Clinical Operations Unit, ECRIN Medical Expert and Operations Director,
- Informs the Applicant of the final decision of providing or not access to the ECRIN services

***Participating EuCos*:**

- On request from the Coordinating EuCo are responsible for providing all the information relevant in their given country and communicating this to the Coordinating EuCo in a timely manner
- On request are responsible for collecting the national information required for the logistical assessment in a timely manner

2 REQUIREMENT

2.1 Collaboration Committee

For ECRIN it is necessary to optimize its resources for engaging in timely support during the planning phase of a grant application period in view of tide deadlines. An early decision process on the requests for collaboration and access to services is needed. Hence the Collaboration Committee was set-up. The decision to reject or accept a request for collaboration is understandably based on limited information - the study synopsis - and is made within one week by the Collaboration Committee based on the eligibility criteria (PRO-FOR-093-1). The review is based on limited preliminary information given and considers suitability of funding call, number of countries, participating sites and recruitment target; methodology and study design, timelines, stated scientific rational issues, realistic operational and budget proposal (ECRIN PRO-FOR-048-3). The application is submitted by the coordinating, national EuCo from the Investigator/Sponsor's country to the chair of the Collaboration Committee. The decision to collaborate determines the commitment of ECRIN to provide free support to the planning and design phase. It is the green light for all ECRIN staff to invest resources.

At times, investigator approach ECRIN with a collaboration request with a final proposal, or even when funding has already been secured. These collaboration request will also be reviewed and assessed in the same way.

2.2 Peer-Review Committee

The Peer Review Committee (PRC) is composed of five independent methodology experts plus the ECRIN Medical Expert. The members of the PRC evaluate the protocols submitted according to the adopted ECRIN SB-PRC evaluation criteria (PRO-FOR-094) which are following international guidelines to design the protocol [5;6] and report the trial or observational study [7;8] as well as ethical principles applying to research involving Human Subjects [9]; agree by majority an opinion with a list of recommendations for improving the protocol.

The Scientific Board secretariat is the contact point of the Peer Review Committee and is in charge of the peer-review submission management, the follow-up of the procedure until completion. Protocols will be submitted for full peer-review to the Scientific Board Secretariat by the coordinating EuCo in charge of the project.

The secretariat checks the completeness of submission documents (PRO-FOR-095) and compliance with the eligibility criteria (PRO-FOR-093); contacts the ***methodological expert***(s) as nominated by the SB-chair; decides in agreement with the SB chair if additional external expertise is required in addition to the competences of the SB methodological experts; and ensures that the timelines are met. On receipt of the peer review reports in accordance with the evaluation criteria (PRO-FOR-094), secretariat drafts a preliminary opinion and

communicates this to the SB-chair, the Coordinating EuCo, the Head of Clinical Operations Unit, and the Director General for a final version to be sent to Applicant (PRO-FOR-097).

A full Peer-Review is not always mandatory. In case of ECRIN being a partner in a grant proposal, whereby a pre-final protocol, including statistical methodology, is evaluated during the funding application, the grant approval and funding decision is considered as evidence for scientific excellence. Hence, access to operational services is given. In this case, a peer review of the trial protocol can be offered as a service for investigators/sponsors willing to get independent methodological assessment, resulting in recommendations to improve the protocol.

However, if the funding for a clinical trial is given through other means (like Industry funding, non-competitive funding, charity funding without peer review) a full peer-review of the trial protocol through the SB is mandatory before access to operational services are given.

2.3 Process Deliverables and Key Performance Indicators

Indicators of performance have been defined to evaluate the process described in the policy and can be found in the ECRIN annual work plan.

3 BIBLIOGRAPHIC REFERENCES

1. Consolidated statutes of the European Clinical Research Infrastructure Network (ECRIN-ERIC) Commission implementing decision of 29 November 2013 on setting up the European Clinical Research Infrastructure Network (ECRIN) as a European Research Infrastructure Consortium (ECRIN-ERIC) (2013/713/EU) amended on 27 February 2017, available at: https://www.ecrin.org/sites/default/files/ecrin%20statutes/consolidated%20ecrin%20statutes_update%20%2023082019.pdf
2. ECRIN Internal rules of procedures last updated on December 11th 2018 available at: https://www.ecrin.org/sites/default/files/ECRIN-ERIC%20IRP%20V4.0_11122018.pdf
3. World Health Organisation, International Clinical Trials Registry Platform (ICTRP), available at: https://www.who.int/ictrp/en/
4. ICMJE recommendations, available at http://www.icmje.org/recommendations/
5. EQUATOR International guidelines available at https://www.equator-network.org/
6. SPIRIT guidelines available at https://www.spirit-statement.org/spirit-statement/
7. CONSORT guidelines available at http://www.consort-statement.org/
8. STROBE guidelines for the reporting of observational studies, available at https://strobe-statement.org/index.php?id=strobe-home

9. World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, available at: https://www.who.int/bulletin/archives/79(4)373.pdf

4 NECESSARY FORMS, REFERENCES, TEMPLATES

Title	Reference	*Status*
SB-Code of Conduct Policy	PRO-FOR-087	Mandatory
SB-CC-meeting charter	PRO-FOR-088	Mandatory
SB- CC form -Submission	PRO-FOR-048	Mandatory
SB-CC- Positive feedback letter template	PRO-FOR-049	Optional
SB-CC- Negative feedback letter template	PRO-FOR-051	Optional
SB eligibility criteria for access to ECRIN clinical services	PRO-FOR-093	Mandatory
SB-PRC- criteria for Peer-Review Committee assessment	PRO-FOR-094	Mandatory
SB-PRC- list of documents to be submitted	PRO-FOR-095	Mandatory
ECRIN Disclosure of Interest Form	LEG-FOR-096	Mandatory
SB- PRC – feedback letter templates	PRO-FOR-097	Optional
SB - PRC working charter	PRO-FOR-098	Mandatory

5 CHANGES FROM PREVIOUS VERSION

This new ECRIN policy has been set up to reflect ECRIN re-organisation of its scientific board and evaluation process for access to ECRIN clinical project services – It replaces SOP-03 v 2.0 dated 1/10/2015.

6 DEFINITIONS AND ABBREVIATIONS

Terms appearing in bold or italics in the main text of this SOP are defined in ECRIN's Glossary (available on the ECRIN intranet).

Applicant:	*Sponsor or coordinating investigator who submits a clinical trial project proposal and/or clinical trial protocol to the ECRIN Scientific Board asking for defined services in defined countries.*
Methodological Experts:	*Panel of external experts in the fields of clinical trials, clinical methodology, and study design selected and appointed to the Scientific Peer Review Committee.*
Scientific Board (SB):	*ECRIN board constituted upon the decision of the ECRIN Assembly of Members responsible for evaluating proposals and protocols submitted to ECRIN, through defined criteria.* *The Scientific Board secretariat is the contact point of the Scientific Board and is in charge of the submission management and follow-up of the procedure. The list of SB members is available on the ECRIN website.*