

Guidelines for Reviewers



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For more information, please go to the EDCTP website: www.edctp.org

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1 Introduction

This document aims to provide comprehensive guidelines for the selection procedure of grant applications submitted to EDCTP either in response to an open *Call for Proposals* or a *Brokering Initiative* or through other means.

These guidelines provide a description of the selection procedure from publication of the *Call for Proposals* until the final decision of funding by the General Assembly (GA). They also describe how External Reviewers (ERs) and the Scientific Review Committee (SRC) members are identified and what their role is in peer-review. These guidelines are applicable to a one-stage submission, i.e. applicants directly submit a full proposal in response to an open *Call for Proposals*, as well as to a two-stage procedure, i.e. to proposals resulting from a *Brokering Meeting* (see scheme of Figure 1).

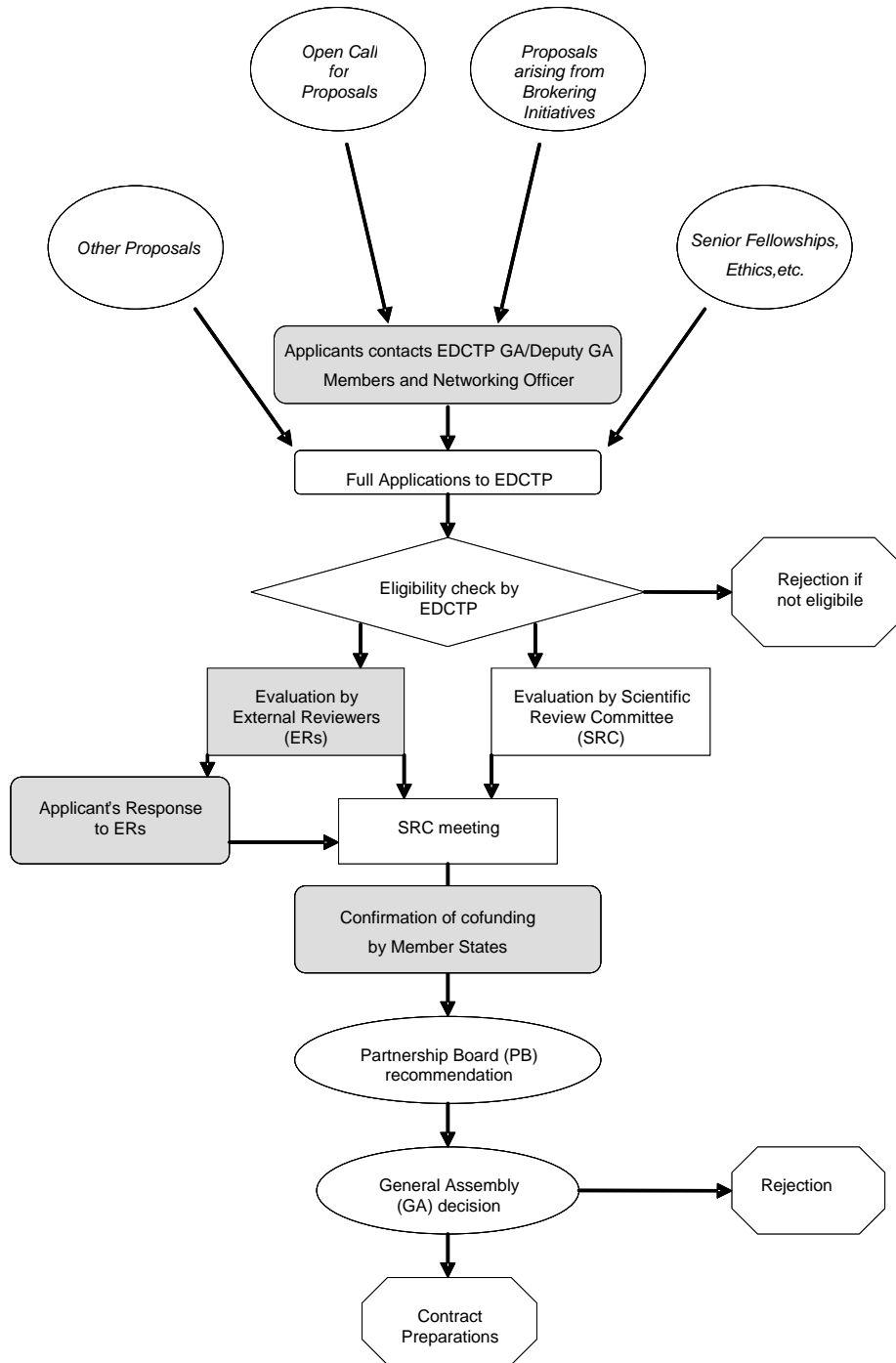
In order to ensure the highest transparency across the grant's selection procedure, these guidelines are made public and the EDCTP Secretariat (SEC) is responsible for ensuring that implementation of the procedures is correctly applied.

2 Principles of the selection procedure

- i. Quality: all grant applications will be objectively evaluated to reflect the highest scientific merit and relevance to EDCTP to fulfil the objectives of the Joint Programme
- ii. Transparency: the decision-making process is described in procedures, and these procedures are available to any interested party upon request
- iii. Equality of treatment: all applications will be evaluated following the same standard procedures, irrespective of their origins and/or the identity of the applicants
- iv. Integrity and impartiality: all applications will be reviewed thoroughly and objectively to avoid any possible circumstances that might interfere or compromise the result of the evaluation
- v. Efficiency and speed: EDCTP aims to ensure that an optimal assessment is achieved in a competent and efficient environment
- vi. Ethical consideration: any proposal that violates the fundamental ethical principles may be excluded from the selection process at any stage.

All proposals that fulfil the eligibility criteria will be selected and evaluated according to the selection criteria as described in the *Call for Proposals*.

Figure 1: Scheme of the evaluation process from publication of *Grant Applications* until a final decision is reached. Grey boxes show steps that are not required for particular grant applications (e.g. Senior Fellowships, Ethics, Joint Programme activities call, etc).



3 Terms of reference

EDCTP appoints independent external experts to assist in the selection of proposals. EDCTP will invite reviewers to become members of a Scientific Review Committee (SRC) or to serve as External Reviewers (ER) with the following terms of reference:

- i. To peer-review (comment, score and rank) the complete grant application for EDCTP and make a recommendation to the Partnership Board (PB)
- ii. To assist EDCTP in identifying priority projects and opportunities for the treatment/prevention and capacity building in the fields of HIV/AIDS, tuberculosis or malaria
- iii. To suggest ways to improve EDCTP review procedures
- iv. To review future progress reports (intermediate and final) of grants that are selected for EDCTP support
- v. The expert will work in a personal capacity and in performing this function will not represent any organisation/institution
- vi. Reviewers will be accountable to the Executive Director of EDCTP.

4 Before the review of applications

Submission of full proposal

In general, applications are submitted either following a *Call for Proposals* that involves a one-stage submission and selection procedure or as a result of a *Brokering Initiative*. Before an applicant submits the full proposal he/she should contact EDCTP General Assembly (GA) and Deputy GA members for possible cofunding or other issues. This can be done directly or via the EDCTP secretariat or website. However, it should be noted that not all calls for proposals (e.g. capacity building projects such as network of excellence, ethics, senior fellowships and *ad hoc* applications) involve all steps shown in the diagram (see Figure 1).

Eligibility check

After the closing date of a given *Call for Proposals*, EDCTP performs a preliminary screening to determine if each submitted application meets the eligibility criteria as described in the *Call for Proposals*. If a proposal does not meet the eligibility criteria, depending on the case, the applicant may be given the opportunity to prove eligibility within a specified time period. If ineligibility becomes apparent in a later stage of the selection process, the application may be withdrawn at any stage of the evaluation process.

5 Identification of reviewers

Selection of reviewers

EDCTP identifies reviewers by an open call for or nomination of scientific experts in the particular programme area on the basis of their expertise and appropriate range of competencies in pre-defined fields. Reviewers are also proactively searched through members of the Partnership Board, other scientists and databases of reviewers from like-minded organisations. After being vetted by the Partnership Board, selected reviewers are added to EDCTP's reviewers' database. Reviewers are commonly individuals from industry and/or research institutions, internationally recognised in a relevant specialist area, and are expected to have the knowledge and expertise within the field in which they are consulted.

Qualities of Reviewers

All independent experts must also have a high level of professional experience in the public or private sector in one or more of the following areas or activities in their particular fields of expertise:

- i. Research in the relevant scientific fields
- ii. Evaluation of projects
- iii. Use of the results of research and technological development projects
- iv. Technology transfer and innovation
- v. International collaboration
- vi. Knowledge of the conduct of clinical trials.

Reviewers are expected to have an excellent command of English. They may be invited from countries other than EDCTP-EEIG Members States or sub-Saharan African countries. Under no circumstances may

reviewers be applicants or collaborators within grant applications submitted in response to the *call for proposals* that they have been selected to review.

Selected reviewers might be requested to serve either as External Reviewers or as SRC members. Possible conflict of interest will be re-assessed each time the SRC members are invited for the peer-review of new grant proposals. EDCTP takes into consideration any arising conflicts while appointing reviewers in compliance with the EDCTP policy on conflict of interest.

SRC Composition

The size and expertise of the final composition of each SRC (and ERs) will be directly correlated with the number of applications submitted and the expertise required to review a specific *call for proposals*. The SEC will appoint a SRC Chair and a SRC Deputy Chair for that particular SRC meeting, and will provide them with all necessary documentation and information on the procedures prior to the SRC meeting.

Typical responsibilities of Chair are:

- Chairing the SRC meetings in compliance with the procedure set by EDCTP
- Leading the discussion at the SRC meeting
- Reaching a consensus following the discussion on the ranking
- Liaising with the responsible officer in the SEC to finalise the agenda, approve the final report and ensure that the consensus reports reflect the individual assessments accurately;
- Representing and communicating the ERs' assessment forms and scores;
- Acting as rapporteur in follow-up meetings of the Partnership Board (PB) or the General Assembly (GA) to discuss and clarify the consensus SRC report (if necessary).

If the Chair of a particular meeting is absent or is removed for any reason (e.g. conflict of interest), the Deputy Chair will take over all duties of the Chair. In the event that both Chair and Deputy Chair are not available for a SRC meeting, the SEC will select a replacement for the Chair from the SRC members within that particular SRC meeting.

6 Documents for reviewers

6.1 Confidentiality and conflict of interest

All reviewers (ERs and SRC members) must sign a declaration of confidentiality and conflict of interest before the review of proposals or reports. Reviewers are required to maintain professional and strict confidentiality of: a) the information contained in the proposals they review; b) the selection process and its outcomes, and c) to act with strict impartiality. Reviewers must declare any arising conflict of interest associated to the applications under review before starting their duties or at a later stage (e.g. upon receipt of the applicants' names for the different grant applications) in compliance with EDCTP Policy on Conflict of Interest.

In case circumstances may lead to unforeseen conflict of interest or be perceived by others as such, the reviewer will be required to reveal sufficient information to EDCTP in order to enable the EDCTP SEC to evaluate the situation and take the most appropriate decision.

Misappropriation of intellectual property, including the unauthorized use of ideas or unique methods obtained from a privilege communication, such as grant or manuscript review, is considered plagiarism and falls under the definition of scientific misconduct.

EDCTP conforms to the legislation of The Netherlands concerning the Personal Data Protection Act.

6.2 Assessment and assessment forms

As experts, reviewers are expected to supply a complete report using the standard assessment forms.

EDCTP uses standardised assessment forms for the review of grant applications. In compliance with EDCTP standard procedures, each grant application must be reviewed by at least two ERs and two SRC members. All ER's and SRC members will be requested to carefully assess each application individually. ER reports will be sent to the applicants to give them the opportunity to respond in writing to the ERs' comments. At this stage, SRC members will not have access to the ERs' assessments, to the applicant's response to the ERs' comments, and to the assessment forms completed by their fellow SRC members.

EDCTP will prepare and organise the SRC meetings. Within these meetings, all assessment forms (from SRC members, ERs and the applicant's response to the ERs' comments) and the preliminary ranking of all applications (based on the SRC and the ERs' assessments) will be discussed. SRC meetings aim to reach a final consensus score and ranking (see section 7.4 of this document) on each application, which may differ from the preliminary ranking.

The assessment forms provided by ERs and SRC members will always be treated with strict confidentiality and will remain anonymous.

7 Overview of selection procedure

7.1 Review and selection criteria

All proposals will be reviewed based on the criteria published on the specific 'call text', which may include some or all of the following:

- i. Project excellence (objectives, feasibility, impact, innovation, quality and record of investigators, quality of the proposed methodology)
- ii. EDCTP relevance (public health relevance for developing countries, adequacy of proposal in context of the call, alignment with the priorities of EDCTP Joint Programme)
- iii. Potential impact (need for strengthening, restructuring existing research capacities, knowledge dissemination, sustainability)
- iv. Compliance with national and international standards of research, Good Clinical Practice, ethics- and safety-related issues (in accordance with EDCTP guidelines, national and EU legislation, international conventions and declaration)
- v. Implementation plan of Capacity Building (research activities, staff and facilities development, networking activities, training activities, consortium management activities, work planning and package of each participant including deliverable list, performance indicators)
- vi. Consortium description (role of participants, achievement of objectives, involvement of private sector participation of public institutions from European EEIG Member States and Africa.
- vii. Project Management (organisational structure, decision-making mechanisms, knowledge management, cofunding arrangements)
- viii. Clinical Trial Management (if applicable – steering committee, sponsorship, daily management for the trial, safety and data management)
- ix. Project resources (mobilisation of resources - personnel, equipment and finances).
- x. Gender issues (promotion of gender equality, gender action plan concerning the staff involved in the project)
- xi. Budget (conformity with the available funds outlined in the EDCTP call for proposals and justification of submitted budget in the proposal).

7.2 Assessment and scoring

The ERs and SRC members assess the applications against the above-mentioned selection criteria and score each criterion according to the following category scale:

- Excellent = 5
- Very good = 4
- Good = 3
- Weak = 2
- Poor = 1

On the assessment form the reviewer is required to provide reasons for the selected score category. This explanation should provide clear insight on how the reviewer has come to his/her conclusions.

Exceptions

When assessing the budget, the following scale will be used.

- Low = 1
- Reasonable = 2
- High = 3

The final budget will be agreed with successful applicants, during the negotiation period with EDCTP secretariat. Reviewers are therefore requested to provide detailed comments on the budget and its justification, which can be used for successful projects during contract negotiations by EDCTP.

7.3 Minimum funding threshold

All selection criteria, except the budget, will be scored on a scale of five categories from 'Poor' to 'Excellent' as shown in section 7.3. To ensure that all proposals meet a minimum level of quality before being eligible for funding, the minimum overall consensus score must be 3.0 which is equivalent to 'Good' in the assessment scale. In principle, any proposal with an overall score of less than 3.0 (Good) will not be selected for funding.

7.4 Consensus approach

During the meeting the SRC members will receive:

- The final agenda;
- All proposals and call texts;
- A summary of the ERs' assessment as well as the applicant's response to the ERs' queries for each application; and
- A preliminary ranking of all applications. This preliminary ranking is based on the average overall scores on the assessment forms submitted by ERs and SRC members.

Please note that the identity of ERs will not be revealed to the SRC members at any time. SRC members who reviewed a particular proposal will present or reveal their individual views during the meeting. All other SRC members are encouraged to express their opinion.

Reviewers whose overall average score deviate significantly from their peers (2 or more points) may be asked to justify their score and may have the opportunity to modify their score after hearing all arguments, during the determination of the final average score and ranking.

After discussion the Chairperson will ask whether the preliminary (pre-meeting) average score should be maintained or modified as the final 'consensus' score.

However, if consensus is not reached, individual secret scoring will be necessary. Each SRC member will then reveal their individual overall scores. Thereafter, the average of all individual scores of all reviewers (SRC and ERs) will be calculated to determine the final 'consensus' score.

It is the Chairperson's responsibility to achieve a consensus, to facilitate the voting and to confirm the final ranking.

Please note that the scores given by ERs cannot be changed during SRC meetings.

Based on the scoring and ranking, the SRC recommends to EDCTP projects suitable for funding. All proposals scoring above 3.0 (Good) will be classified as 'suitable for funding' while those scoring below 3.0 are classified as 'not suitable for funding'.

Finally, the SRC will review all the major minor or advice recommendations to the applicants and the SRC chairperson will sign off the final score and ranking sheet before closing the meeting.

The SEC will prepare a summary review report for each proposal. A standard summary review report will contain a project summary, the requested budget, available cofunding (if applicable), the final ranking and comments and recommendations from the SRC and the ERs.

8 Partnership Board (PB) advice

The Partnership Board (PB) is responsible for preparing and maintaining the EDCTP scientific strategy and integrity. They assess whether the proposals recommended for funding by the SRC are in line with EDCTP strategic priorities and the peer review process was conducted properly. The review reports and the minutes from the SRC meeting will be discussed during a PB meeting. In addition, the Chair of the SRC may be requested to act as rapporteur to clarify the consensus discussion during PB meetings or in writing later on. All participants at the PB meeting are asked to declare any conflicts of interest in compliance with EDCTP policy on conflict of interest prior to the PB meeting. The outcome of the PB discussion on the SRC grant selection process is a list of applications recommended for funding that will be presented to the General Assembly for a final funding decision.

9 General Assembly (GA) decision

The SEC compiles the summary review reports, the minutes of the SRC meeting and the recommendation of the PB and sends these to the General Assembly (GA) for their final decision. Again, all participants attending the GA meeting will declare any conflicts of interest in compliance with EDCTP Policy on Conflict of Interest.

Upon final decision from the GA, EDCTP informs the applicants of the results of the selection procedure. The contract negotiations for approved projects will commence immediately after approval by the GA.

10 Reporting and monitoring

During the lifetime of the funded projects, SRC members and ERs may be called upon to review request for changes, intermediate and final progress reports of the projects.