



FONDAZIONE REGIONALE
PER LA RICERCA BIOMEDICA

EARLY CAREER AWARD

Guidelines for Reviewers – CONSENSUS MEETING

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1. GENERAL INFORMATION

1.1 The context

Fondazione Regionale per la Ricerca Biomedica (FRRB) is a non-for-profit organization governed by public law, established in October 2011 by Regione Lombardia, with the aim of promoting and supporting scientific research in Life Sciences in Lombardy. The Foundation represents one of the main funding agencies that promote progress, research, development and innovation within the health sector among the regional academic and industrial life science players. Its *raison d'être* is to serve as support for implementing the regional health care research policy, in order to place the Lombardy regional system in a leading position in Europe. In addition, the Foundation's mission is to support innovative basic and translational research projects, which have a positive impact on the local healthcare eco-system and on citizens through regional and European competitive calls for proposals.

1.2 The Italian National Health Service NHS (*Sistema Sanitario Nazionale – SSN*)

The Italian National Health Service has been established in 1978. The leading principles of the NHS, funded by public funds, are universal coverage and non-discriminatory access to the health care services. It delivers high-quality health care to all citizens and guarantees vast drug coverage paid by the NHS and all hospital and diagnostics services.

Research projects received in response to this Call should provide evidence of their impact on the NHS. The scientific revision should take into account that the final scope of the funded research will be to integrate new findings and approaches into the NHS and have a clear potential impact on patients.

1.3 Precision Medicine

FRRB, in accordance with Lombardy Region and the Italian Ministry of Health, focuses its activities on the development and implementation of a Precision Medicine approach. "*Precision Medicine*" is defined by the Horizon 2020 Advisory group as the "*medical model using characterization of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention*".

To this aim, during scientific evaluation, reviewers should take into account the concept of Personalized Medicine and its potential to move forward to a more personalized approach to prevention, diagnosis and therapy.

1.4 Purpose of this document

This document is a guide to help scientific experts (reviewers) in the revision process of the

CONSENSUS MEETING

the final evaluation step of the projects submitted in response to the EARLY CAREER AWARD Call, and to help them understand the environment where the scientific projects will take place and the main needs of the regional territory.

The selection of proposals that will be funded by FRRB is based on a Peer Review process. The aim of this document is to explain the revision process, the responsibilities of the reviewers appointed, the methodology to adopt for revision and the management of any conflict of interest.

Before joining the Consensus Meeting, please carefully read the Call Text and this guide.

The Call EARLY CAREER AWARD is a two-stage application process:

- Stage 1: pre-proposal
- Stage 2: full proposal followed by a Consensus Meeting.

Scientific experts appointed to participate in the Consensus Meeting are asked to read carefully the scientific revisions of their colleagues who performed the remote evaluation of the full proposal. **The discussions held at the Consensus meeting will lead to the final ranking list of the projects to be funded.**

The Consensus Meeting will be held in person at FRRB headquarter on a date that will be communicated in due time by the Scientific Office.

2. TECHNICAL INFORMATION

2.1 Earlier steps of the revision process

Upon remote evaluation of the submitted pre-proposals, the applicants of the best-ranked projects were invited to submit a full proposal. Full proposals were evaluated by two independent scientific experts who assigned scores and comments according to the following evaluation table:

EXCELLENCE	Maximum score 20
Clarity and relevance of the objectives illustrated	0-10
Soundness of the hypothesis and of the preliminary data, appropriateness and feasibility of the methodology, including ethical aspects	0-10

IMPACT	Maximum score 20
Advancement beyond state-of-the-art	0-10
Quality of the proposal in terms of: <ul style="list-style-type: none"> - Dissemination and sharing of results to the scientific community - Dissemination of results to the lay public - Description of RRI principles¹ 	0-10
QUALITY AND EFFICIENCY	Maximum score 20
Quality and efficiency of the workplan, of the resources allocated to work packages and of the project structure in line with the objectives	0-10
Appropriateness of the technical and management structures	0-10

In assigning the scores, reviewers took into account the following table:

Scores	Description
0	Failure: the proposal does not meet the call requirements. Detailed description of project and PI expertise are missing, incomplete and/or not appropriate.
1-2	Very poor: the proposal poorly meets the requirements of the call and present major shortcomings.
3-4	Poor: the proposal poorly meet the requirements of the call.
5-6	Fair: the proposal meets adequately the call requirements, but shows some shortcomings.
7-8	Good: the proposal responds adequately to the requirements of the call and shows only minor weaknesses.
9-10	Excellent: the proposal effectively meets the requirements of the call, and shows no weaknesses.

In order to be admitted to the Consensus Meeting stage, the average score of each category must have been higher than 15 points (threshold).

Full proposals that did not reach the fixed threshold criteria were not admitted to the Consensus meeting stage.

The Consensus Meeting will discuss all admitted full proposals.

¹ Per ulteriori informazioni: https://ec.europa.eu/research/swafs/pdf/rome_declaration_RRI_final_21_November.pdf

2.2 Evaluation criteria of the Consensus Meeting

A number of Reviewers, among those who performed the pre-proposal evaluation, will be invited to join the Consensus meeting; this number depends on how many proposals will be admitted to this stage. FRRB will appoint a Chair Person who will lead the discussion. Before the meeting, FRRB Scientific Office will send by email to the experts all documents related to the project proposals that will be discussed during the meeting (proposals, remote reviewers' evaluations, score sheet).

Before the Consensus Meeting the experts will have to provide a first written evaluation of the projects by filling the score sheet according to the following table:

- 'A': the project fully meets the excellence, impact and quality criteria and is recommended for funding if sufficient funds are available.
- 'B': the project meets most of the criteria and can be recommended for funding.
- 'C': proposal is not of sufficient quality and is not recommended for funding.

Additionally the experts are required to give a numerical score ranging from 45 to 60, according to the evaluation and the score tables reported in paragraph 2.1, the same used by the reviewers involved in the previous step of full-proposal evaluation.

The numerical score will be used only if a common view on project proposals is not reached by the reviewers using the A,B,C score, or in case of *ex equo* results.

The experts have to send the filled score sheet to FRRB Scientific Office before the fixed Consensus Meeting date.

Upon discussion during the meeting, the experts will either confirm or change their initial evaluation by filling a new score sheet.

The evaluation should be comparative and take into account the overall quality, impact and excellence of the projects. The experts are also expected to provide an overall comment on the budget requested.

Projects scored by "C" by the unanimity of the experts will not be funded. Projects scored by "A" by the unanimity of the experts will be granted, depending on the available budget of the call. In the other cases, experts will have to decide their final ranking position. If a consensus is not reached, project proposals will be ranked according to average numerical scores.

The outcome of the Consensus Meeting is a final ranking list, which might differ from the provisional one of the full proposal revision.

3. EXPECTED OUTCOMES OF THE CONSENSUS MEETING

FRRB requires the international experts to perform the evaluation activity with the maximum impartiality, aiming at funding only high-impact projects.

The expected outputs of the Consensus Meeting will be:

1. A final ranking list of proposals to be approved and signed by the international experts before the end of the Consensus Meeting;
2. The minutes of the Meeting to be signed by the experts at the end of the meeting;
3. A draft version of the final evaluation report for each project that will be finalized within one week after the Consensus Meeting.

The final ranking list will be transmitted to the FRRB General Director who will convene the FRRB Board of Directors for its official approval.

The ranking list will be finally published on FRRB institutional website and official communications will be sent to the Young Researchers of all the funded Institutions.

4. REVIEWERS RESPONSIBILITIES

4.1 Conflict of interest

In case one or more scientific experts have a conflict of interest with one or more projects that have to be discussed during the Consensus Meeting, these experts should not participate in the discussion and will be asked to temporarily leave the room.

4.2 The importance of scores and comments

Scores and comments are critical, as they will be taken into account for the initial ranking. Please note: scores and comments will be included in the evaluation report and, therefore, they will be visible to the applicants. Especially in the case of rejection, the final evaluation needs to convey a comprehensive explanation of the fate of the proposal.

Comments should be of good quality, genuine and substantial. They ideally should be an explanation of strengths and weaknesses of the proposal, according to the evaluation criteria.

Reviewers are obliged to observe the following guidelines:

- o Use dispassionate, analytical and unambiguous language.
- o Use grammatically correct, complete, clear sentences with no jargon.
- o Be constructive.
- o Avoid reference to the applicant age, nationality, gender, or personal matters.
- o Avoid making reference to scores in the comments.
- o Avoid any direct comparison with any other proposals.

- Avoid any reference or comparison with previous assessments.
- Avoid comments that give a description or a summary of the proposal.
- Avoid dismissive statements about the Principal Investigator, the proposed science, or the scientific field concerned.

If the reviewer feels that her/his contribution to the revision process is not appropriate for any reason, s/he will have to contact FRRB in order to be replaced.

IMPORTANT:

You are asked to evaluate projects submitted by early career scientists. Many of them might be at the very beginning of their scientific career. Please be aware that your scores and comments might have an impact on their scientific career!

4.3 Gender issues

Sex and gender differences represent a crucial issue in designing a good research study, but are often overlooked in research design, study implementation and scientific reporting, as well as in general science communication. This leads to a limited generalizability of research results and findings, with limited successful application into clinical practice, especially for women, but also for men.

Moreover, reviewers should consider whether the authors are using the words *sex* or *gender* appropriately, as the term *sex* should be used to classify females and males from a biological point of view.

In particular, the reviewers are asked to check:

- In human studies, sex of subjects and how it is assigned should be explained: examination of body characteristics, genetic testing or other means. Principal Investigators should rely on the composition of the biological sample.
- In studies of animals, the term *sex* should be used to distinguish males and females and authors should rely on the composition of the biological sample in terms of sex of the animals.
- In cell biology studies, the origin and sex chromosome constitutions of cells or tissue cultures should be stated. If unknown, the reasons should be stated.

The reviewers should also take into account the gender composition of the research team.

For more information, please rely on:

- <https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-016-0007-6>
- https://ec.europa.eu/research/mariecurieactions/gallery/understanding-gender-dimension-msca-projects_en
- <http://genderedinnovations.stanford.edu/methods/sex.html>