



Fondazione
Regionale
per la
Ricerca
Biomedica



Regione
Lombardia

FONDAZIONE REGIONALE
PER LA RICERCA BIOMEDICA



UNMET MEDICAL NEEDS

Guidelines for Reviewers – Remote Evaluation

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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 citizens. 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.

1.2 Personalized 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. "Personalized 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.

1.3 Purpose of this document

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

REMOTE EVALUATION

of the project proposals submitted in response to the UNMET MEDICAL NEEDS 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 define, in detail, the revision process, the responsibilities of the reviewers appointed, the methodology for revision and the management of any conflict of interest.

Before starting the evaluation process, please carefully read the Call Text and these guidelines.

Eligible projects must cover one of the following thematic areas:

1. CARDIOLOGY

Specific objectives:

- identification of the causes and characterization of the pathogenetic mechanisms of cardiogenic shock, both in the strictly cardiological context and in the causes of extra-cardiac shock;
- artificial intelligence applied to non-invasive coronary imaging for the identification of coronary plaques at risk of acute complications and causing acute coronary syndromes.

2. NEUROLOGY

Specific objectives:

- to clarify the role of inflammatory mechanisms in the neurodegeneration processes in diseases of the central and peripheral nervous systems;
- pharmacological and non-pharmacological therapeutic innovation in clinical neuroscience.

3. RARE CANCERS

Specific objective:

- use of new therapeutic approaches for the treatment of rare cancers.

Please note that rare cancers can be defined as those malignancies whose incidence is below 6 out of 100,000 people per year. In addition, the tumor will have to be listed in Orphanet (<https://www.orpha.net/consor/cgi-bin/index.php?lng=EN>).

4. RARE DISEASES (non-oncological ones)

Specific objectives:

- development of disease-specific cell transplant treatments for rare diseases: feasibility, implementation and translation into clinical practice;
- perspectives for the development of innovative therapeutic approaches based on the rapid modelling of the effects of different gene mutations in rare diseases with phenotypic or genetic heterogeneity.

Please note that the criterion to define a rare disease follows the European definition i.e., a disease affecting not more than 5 in 10,000 persons.

5. ANTIMICROBIAL RESISTANCE

Specific objective:

- identification of molecules that enhance the activity of existing antibiotics and that allow to overcome the specific mechanisms of antibiotic resistance.

The UNMET MEDICAL NEEDS Call follows a **one-stage application process**, with the submission of the complete project proposal.

Each project will be evaluated remotely by three reviewers and the 20 best ranking projects will be further evaluated in *Consensus Meeting* by a Scientific Committee.

Scientific revisions must be completed by the deadline set in the Contract between the scientific experts and FRRB.

FRRB Scientific Office will provide a template for the scientific revision, which will be sent to the scientific experts together with the project/s to be evaluated.

All scientific evaluations must be submitted using the evaluation template. Any other template different from the one provided by FRRB will not be considered acceptable.

2. TECHNICAL INFORMATION

2.1 Score table

In assigning the scores, reviewers should take into account the following table:

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

2.2 Evaluation criteria of the project proposal

Three independent scientific experts will evaluate each application submitted in response to the UNMET MEDICAL NEEDS Call.

To perform the evaluation of the proposal, you will receive a proposal application form including the following sections:

1. GENERAL INFORMATION
2. PROJECT DESCRIPTION
3. RESEARCH TEAMS, INFRASTRUCTURES AND PROJECT MANAGEMENT

4. BUDGET

1. General Information. This section includes general information on the project, such as the title, the research area, the keywords, as well as the total number of partners.
2. Project description. This section includes scientific information about the project as well as sections related to RRI (Responsible Research and Innovation), ethics and dissemination of results.
3. Research teams, infrastructures and project management. This section includes information about the partners involved, the infrastructures available and the management of the project.
4. Budget. This section includes details about the requested budget and cost justifications.

Scientific experts are asked to evaluate proposals according to the following table and scores:

CATEGORY: EXCELLENCE	Maximum score 15
Clarity and relevance of the illustrated objectives	(0-5)
Soundness of the hypothesis and of the preliminary data, appropriateness and feasibility of the methodology, ethical aspects included	(0-5)
Quality of the PIs and their research teams	(0-5)
CATEGORY: IMPACT	Maximum score 10
Advancement beyond the state-of-the-art	(0-5)
Quality of the proposal in terms of: <ol style="list-style-type: none"> 1. dissemination and sharing of results to the scientific community 2. dissemination of results to the lay public 3. description of Responsible Research Innovation (RRI) principles 	(0-5)
CATEGORY: QUALITY AND EFFICIENCY	Maximum score 20
Quality and efficiency of the workplan, of the resources allocated to work packages in line with the project objectives	(0-5)
Appropriateness of the technical and management structures	(0-5)
Quality of the research consortium (scientific coordinator and partners)	(0-5)
Appropriateness of the distribution of objectives to partners, including a feasibility analysis of each work package compared to every single partner expertise	(0-5)

For each category, reviewers must provide a written comment for each item, also reporting considerations about adequateness of total requested budget.

For each item, reviewers will have to provide a score from 0 to 5 (see paragraph 2.1); 0.5 score points are accepted.

To be admitted to the Consensus Meeting, the proposals must receive a total score at least equal to 33 points (threshold).

Given the high number of applications to the call, only remarkable project proposals submitted by high quality consortia should deserve high scores.

2.3. Scoring and weighting

The maximum score that can be reached is **45 points**, given by the sum of the scores of the individual sub-categories listed in the Table at paragraph 2.1.

The score of each proposal will be given by the average of the evaluations of the three scientific experts.

In order to be admitted to the Consensus meeting, the average of the total scores of the three reviewers must be at least equal to **33 points (threshold)**.

Additional bonuses can be awarded by FRRB during the administrative eligibility check, up to a maximum of **5 points**, according to the following criteria:

BONUSES	Maximum score 5
Number of partners located in different provinces of Lombardy (operational headquarters) (≥ 3 provinces = 1 point)	0-1
At least one Principal Investigator Under 40 in the consortium	0-1
Number of female Principal Investigators in the consortium > 50%	0-1
Consortium including one I.R.C.C.S., one ASST and one University/research organisation	0-1
At least one Principal Investigator inside the consortium who has been awarded an ERC Grant	0-1

At the end of the remote evaluation, a provisional ranking list will be drafted, considering the sum of the average scores of the remote evaluation plus any bonuses.

Only the first 20 best ranking projects will be admitted to the second step of evaluation (Consensus meeting), ideally the 4 best ranked projects per thematic area. In case of absence of projects of adequate quality within a specific area, additional 4 proposals falling in other areas will be admitted to the Consensus meeting, choosing from the projects with higher score.

In case of projects with equal total scores, the projects with the highest score attributed by the reviewers will have priority, net of FRRB bonuses.

In case of projects with equal total scores attributed by the reviewers, these will be ranked according to the scores of each category following this order:

1. Excellence
2. Impact
3. Quality and efficiency

In case of *ex aequo* using the scores of each category, projects will be ranked according to the scores of each sub-category following this order:

1. Clarity and relevance of the illustrated objectives;
2. Soundness of the hypothesis and of the preliminary data, appropriateness and feasibility of the methodology, ethical aspects included;
3. Quality of the PIs and their research teams;
4. Advancement beyond the state-of-the-art;
5. Quality of the proposal in terms of:
 1. Dissemination and sharing of results to the scientific community
 2. Dissemination of results to the lay public
 3. Description of Responsible Research Innovation (RRI) principles;
6. Quality and efficiency of the workplan, of the resources allocated to work packages in line with the project objectives;
7. Appropriateness of the technical and management structures;
8. Quality of the research consortium (scientific coordinator and partners);
9. Appropriateness of the distribution of objectives to partners, including a feasibility analysis of each work package compared to every single partner expertise.

3. REVIEWERS RESPONSIBILITIES

3.1. Conflict of interest

Any possible conflict of interest (according to the definition in the contract between the expert and FRRB) has to be excluded before the assignment of the pre-proposal to the scientific expert.

Should a conflict of interest, for any reason, arise once the reviewer has seen the pre-proposal, s/he must immediately contact FRRB Scientific Office (scientific.office@frrb.it) in order to be replaced.

3.2 The importance of scores and comments

Scores and comments are critical, as they will be taken into account for the initial ranking. Please note that scores and comments will be included in the final evaluation report and, therefore, they will be visible to the applicants.

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:

- Use dispassionate, analytical and unambiguous language.
- Use grammatically correct, complete, clear sentences with no jargon.
- Be constructive.
- Avoid reference to the applicant age, nationality, gender, or personal matters.
- Avoid making reference to scores in the comments.
- 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 Investigators, 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 Scientific Office (scientific.office@frrb.it) in order to be replaced.

IMPORTANT:

Consortia might include 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!**

3.3 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, while gender refers to the socially constructed roles, behaviours, expressions and identities of girls, women, boys, men, and gender diverse people.

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 each research team included in the consortium.

For more information, please rely on:

- <https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-016-0007-6>
- <http://genderedinnovations.stanford.edu/methods/sex.html>
- <https://cihr-irsc.gc.ca/e/50833.html>