



FONDAZIONE REGIONALE  
PER LA RICERCA BIOMEDICA

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***UNMET MEDICAL NEEDS***

*Guidelines for Reviewers – CONSENSUS MEETING*

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## 1. GENERAL INFORMATION

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### 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

#### **CONSENSUS MEETING**

the final evaluation step of the projects 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 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 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.

The project has already been evaluated remotely by three reviewers. At this stage, you are requested to read carefully the scientific revisions of the colleagues who performed the remote evaluation of the project proposal and then to provide a collective evaluation in a *Consensus Meeting*, acting as *Scientific Committee*.

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

**Please note that the discussions held inside the Consensus meeting will lead to the final ranking list of the projects to be funded.**

## 2. TECHNICAL INFORMATION

### 2.1 Earlier steps of the revision process

In the remote evaluation, submitted proposals were evaluated by three independent scientific experts who assigned scores and comments according to the following evaluation table:

<b>CATEGORY: EXCELLENCE</b>	<b>Maximum score</b> <b>15</b>
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)
<b>CATEGORY: IMPACT</b>	<b>Maximum score</b> <b>10</b>
Advancement beyond the state-of-the-art	(0-5)
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	(0-5)
<b>CATEGORY: QUALITY AND EFFICIENCY</b>	<b>Maximum score</b> <b>20</b>
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)

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 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 meets 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.

In order to be admitted to the Consensus Meeting, the proposals had to receive an average total score at least equal to **33 points** (threshold).

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

Additional bonuses were 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 headquarter) ( $\geq 3$ provinces = 1 point)	0-1
At least one Principal Investigator Under 40 inside the consortium	0-1
Number of female Principal Investigators in the consortium $> 50\%$	0-1
Consortium including simultaneously 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 was drafted, considering the sum of the average scores of the remote evaluation plus any bonuses.

**Only the first 20 best ranking projects were admitted to the Consensus meeting, ideally the 4 best ranking projects per thematic area.** In case of absence of projects of adequate quality within a specific area, more than 4 proposals falling in other areas were admitted to the Consensus meeting, choosing from the projects with higher score.

## 2.2 Evaluation criteria of the Consensus Meeting

Composition criteria of the Scientific Committee: the number of reviewers, invited to join the Consensus meeting will depend on how many proposals will be admitted at this stage. They will be chosen among those who performed the remote evaluation of proposals. In addition, FRRB will appoint a Chair person who will lead the discussion. Before the meeting, FRRB Scientific Office will provide the experts with all documents related to the project proposals, that will be discussed during the meeting (proposals, remote reviewers' evaluations, score sheets).

Before the Consensus Meeting, the experts will have to fill a score sheet:

- assigning up to a maximum of **10 additional points** to each proposal (in addition to the score assigned by the referees plus any bonuses)
- providing a first written evaluation according to the relevance of the project proposal with respect to the needs of the regional system in the specific thematic area.

The experts must send the filled score sheet by the deadline established by FRRB Scientific Office and, in any case, before the Consensus Meeting date.

The Scientific Committee may also request a revision of the budget of the proposals, cutting, if well justified, up to a maximum of 10% of their total request.

The call aims to fund **the best two projects per thematic area**. In case of absence of projects of adequate quality within a specific area, the residual endowment will be transferred to other areas, choosing from the projects positioned higher in the ranking list.

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 total budget requested.

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

If the Scientific Committee does not reach a common decision on project proposals to be funded, the average of the numerical scores provided by each single expert in the score sheet will be used to produce the final ranking list.

At the end of the plenary session, a final ranking list will be provided, considering the sum of the average scores of the remote evaluation, any bonuses plus the scores attributed in the Consensus Meeting. Projects will be funded in order of ranking, up to the available resources.

**The outcome of the Consensus Meeting is a final ranking list, which might differ from the provisional one provided at the end of the remote evaluation step.**

### 3. EXPECTED OUTCOMES OF THE CONSENSUS MEETING

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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 Chair Person 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 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 coordinating Institutions of the participating consortia.

### 4. REVIEWERS RESPONSIBILITIES

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#### 4.1 *Conflict of interest*

In case one or more scientific experts have a conflict of interest (according to the definition in the contract between the expert and FRRB) with one or more projects that must be discussed during the Consensus Meeting, these experts should not participate in the discussion.

#### 4.2 *The importance of scores and comments*

Scores and comments are critical, as they will be taken into account for the ranking of proposals.

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 set in the Call text.

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 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:

Consortia might include among PIs 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, 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 the research team.

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>