



Fondazione  
Regionale  
per la  
Ricerca  
Biomedica



Regione  
Lombardia

# UNMET MEDICAL NEEDS

Short version of the call text

## Summary

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## 1. INTRODUCTION AND BACKGROUND

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Fondazione Regionale per la Ricerca Biomedica (FRRB) is a non-for-profit organization founded by Lombardy Region in October 2011.

The mission of FRRB is to implement the research priorities identified by the Directorate General for Welfare and Healthcare of Lombardy Region.

Its goal is to promote progress, research, development and innovation in hospitals, universities and research centres focused on biomedical research and located in Lombardy Region.

FRRB aims to invest local and European resources in innovative basic and translational research projects to generate positive impact on the local healthcare eco-system and citizens, by promoting the implementation of Personalized Medicine approaches.

The aim of the call is to fund research projects targeting “*Unmet medical needs*”.

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.

### 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.

## 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 research projects will have to fall into a context of Personalized Medicine, for which public involvement plays a key role. Therefore, the project proposals must include a "*Communication Plan*" addressed not only to the scientific community, but specifically to the lay public, as FRRB strongly wants to raise awareness on this issue.

The "*Communication Plan*" will have to describe the communication measures for promoting the project and its results, through scientific events (workshops, congresses, etc.) and open events addressed to a non-specialized public (open days with the involvement of patient associations, charity days, brochures, press releases, etc.).

This plan will be examined by FRRB, which asks to be actively involved in the planned project events, especially those dedicated to the lay public.

The research projects should explain how they will be aligned with the six fundamental principles of Responsible Research and Innovation (RRI) established by the European Commission: *governance, public engagement, open access, gender, ethics, and science education*.

FRRB is a funding agency that promotes and encourages the participation of female researchers in projects proposals.

For this reason, FRRB pays particular attention to gender aspects, which have to be emphasized by the consortium in the project proposal; each Partner will be asked to answer to specific questions on this issue and to upload their "*Gender Equality Plan (GEP)*" (if present).

## 2. APPLICATION

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### 2.1. HOST INSTITUTIONS

- o The call is open to **consortia** of applicants belonging to one of the following categories:
  - public or private I.R.C.C.S. (Italian Scientific Institutes for Health Research and Health Care)
  - Public health care providers (ASST)
  - Agenzie di Tutela della Salute - Health Protection Agency (ATS)
  - Azienda Regionale Emergenza Urgenza – Regional Emergency Service Company (AREU)
  - Public or private research organizations
  - Universities.
- o The eligible partners of the call must **be located in Lombardy** or declare, at the time of the application, that they will open an operational headquarter within the territory of Lombardy Region.

- The call is addressed to networks from **two to four** organisations belonging to one of the categories listed above.
- The **coordinator** of the consortium MUST be one of the following organisations: public or private I.R.C.C.S., public health care provider (ASST), Agenzie di Tutela della Salute - Health protection agency (ATS) or Azienda Regionale Emergenza Urgenza – Regional Emergency Service Company (AREU).
- Each consortium MUST include **one female Principal Investigator (PI)**. If missing, the consortium will not be considered eligible and will be automatically excluded from the call.
- Each partner MUST declare a budget of **at least 15%** of the total budget cost of the project.
- Each consortium MUST sign a preliminary **agreement** to be drafted according to the template provided by FRRB and which MUST be included in the proposal.
- Each organization (Host Institution) will be allowed to submit **only one application as coordinator**. No limits are foreseen for the participation in multiple applications as project partner.

## 2.2. PRINCIPAL INVESTIGATORS (PIs)

Each consortium MUST include, **at least, one female PI**. This requirement MUST be kept for the whole project duration. In case of female PIs in a percentage higher than 50%, or presence of PIs under 40 years old<sup>1</sup>, the consortium will receive an additional bonus in the evaluation process (see following Paragraph 3.2). Eligibility extensions are admitted (see footnote for details<sup>2</sup>).

## 2.3. NON-ELIGIBLE APPLICANTS

Enterprises and for-profit Organisations are NOT eligible.

The funding from FRRB is of public nature and it is then addressed to non-economic activities<sup>3</sup>.

A PI cannot simultaneously hold more than one FRRB active grant.

The PI of an ongoing project, previously funded by FRRB (in response to a regional or European call), cannot apply to this call unless their project is closed before the deadline for the UNMET MEDICAL NEEDS proposal submission.

A project is considered closed when both the final financial and scientific reports have been sent to FRRB.

This rule applies only to PIs (grant holders), not to their team members.

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<sup>1</sup> This criteria is calculated as follows: the PI must be under 40 years old at the time of the call deadline ie. February 3<sup>rd</sup> 2021.

<sup>2</sup> - Maternity leave: 18 months for each child born;

- Paternity: actual period of paternity leave taken for each child born;

- Long-term illness (over 90 days): the effective amount of leave taken for health reasons.

Any declared extension MUST be documented at the time of the application.

<sup>3</sup> See for reference Art. 2.1.1 (from 18 to 19) of the Communication from the European Commission "Framework for State aid for research and development and innovation" (2014/C 198/01).

## 2.4. GENERAL FEATURES OF THE PROJECTS

Each project MUST have the following characteristics:

- develop one of the scientific thematic areas illustrated in paragraph 1;
- be innovative and demonstrate to have characteristics of transferability to the Public Health System;
- a total maximum budget of **€ 1.250.000,00**;
- a fixed total duration of **36 months**.

The total budget of the call "UNMET MEDICAL NEEDS" is of **€ 14.429.465,14**.

The **portability** of the funding is NOT ADMITTED. In case, for any reason, one of the Principal Investigators will be unable to lead the project, the Host Institution MUST promptly identify a new PI with the same characteristics who could carry on the scientific activities.

The UNMET MEDICAL NEEDS is a one-stage call for proposals.

The proposals must be received via "Bandi online", the electronic submission system of Lombardy Region (<http://www.bandiregione.lombardia.it>) no later than **3<sup>rd</sup> February, 2022 at 5:00 p.m.**

The proposals must be written in English, must follow the template form in terms of overall size and section page and character limits, and must strictly adhere to the "Guidelines for project submission" (*Guida alla presentazione del progetto*).

The proposal form and all the official documents compulsory for the submission can be downloaded from the FRRB website at the following link: <https://www.frrb.it/it/bando-unmet-medical-needs>.

Proposals that do not use the respective templates will be automatically declared ineligible.

## 2.5. ELIGIBLE COSTS

According to the call text the eligible **direct costs** are:

- Personnel costs (for public IRCCS and ASST, only staff recruited specifically for the project will be considered eligible for funding)
- Travel costs: max 5% of the total costs requested by every single partner
- Consumables: materials and supplies
- Equipment (on hire or eligible amortisation rate): max 20% of the total costs requested by every single partner
- Subcontracting costs: max 20% of the total costs requested by every single partner. FRRB will require the submission of a financial audit certificate together with the final financial report. This cost MUST be included under the "Subcontracting cost" category and will be eligible up to a maximum of € 8.000,00 per single partner.
- Other direct costs: this cost category will include publication costs, animal purchase, maintenance and breeding, software (eligible only if well justified).

FRRB allows a flat rate of indirect costs (overheads) calculated as 20% of all the direct costs (subcontracting costs excluded).

Only costs generated over the lifetime of the project will be considered eligible

For more information on the cost categories and the related admitted percentages please read the document “*Linee guida per la rendicontazione delle spese ammissibili*” published on FRRB institutional web site (<https://www.frrb.it/it/bando-unmet-medical-needs>).

### 3. PROJECT EVALUATION

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#### 3.1. ADMINISTRATIVE AND TECHNICAL REQUIREMENTS

The staff of FRRB will perform an eligibility formal check of the received proposals from an administrative point of view to ensure that they meet the call's formal criteria.

#### 3.2. SCIENTIFIC EVALUATION

Projects passing the eligibility formal check will proceed with the Scientific Evaluation.

The scientific evaluation will involve two distinct boards:

- An international group of experts, generally defined as “*referees*”, who will perform a scientific evaluation from remote (three experts per project).
- A panel of experts, defined as “*Scientific Committee*”, composed of a minimum of three experts chosen among those who performed the remote evaluation of proposals, who will evaluate projects in a comparative way during a plenary session, called “*Consensus Meeting*”. The meeting will be moderated by a Chair Person with proven expertise in conducting comparative evaluations of projects in different disciplinary areas. The Committee will carry out the final evaluation of the best selected projects.

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 scientific evaluation will take into account both the content of proposals and the financial plan.

The reviewers will perform the assessment of the proposal and complete a written evaluation form with scores and comments for each of the following criteria:

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)

<b>IMPACT</b>	<b>Maximum score 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>QUALITY AND EFFICIENCY</b>	<b>Maximum score 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)

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.

In order to be admitted to the Consensus Meeting (plenary session), the proposals must receive a total score at least equal to **33 (threshold)**.

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

<b>BONUSES</b>	<b>Maximum score 5</b>
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 will be drafted and transmitted to the Scientific Committee for the final evaluation in the Consensus Meeting.

The Scientific Committee will have the possibility to assign up to a maximum of **10 additional points** to each proposal (in addition to the score assigned by the referees and to any



bonuses) according to the relevance of the project proposal with respect to the needs of the regional system in the specific thematic area.

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

At the end of the plenary session, a final ranking list will be provided, and the projects will be funded in order of ranking, up to the available resources.

The entire evaluation procedure shall be completed **within 270 days** starting from the deadline for proposals submission.

#### 4. PLANNED TIME SCHEDULE

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December 13 <sup>th</sup> , 2021, 10 a.m.	Opening of the proposal submission system
February 3 <sup>rd</sup> , 2022, 5 p.m.	Deadline for proposals submission through the online platform
By March 2022	End of administrative and formal eligibility checks
By September 2022	Scientific Peer Review evaluation of proposals and publication of the ranking list