



Fondazione
Regionale
per la
Ricerca
Biomedica



Regione
Lombardia

FONDAZIONE REGIONALE
PER LA RICERCA BIOMEDICA

EARLY CAREER AWARD

II EDITION

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1. INTRODUCTION AND BACKGROUND

Fondazione Regionale per la Ricerca Biomedica (or hereinafter "FRRB") is a non-for-profit organization founded by Lombardy Region in October 2011 to implement the research priorities identified by the General Directorate for Healthcare.

The mission of FRRB is to promote research and innovation in the biomedical field, allowing the Lombardy regional healthcare system to be at the forefront of the human health sector, whose development requires significant investments. As such, FRRB invests in innovative basic and translational research projects that can be transferred, in the medium term, to the regional healthcare system and to the citizens of Lombardy.

FRRB, in line with the strategy developed by Lombardy Region, also aims to develop and implement Personalized Medicine approaches.

FRRB acknowledges that the new generations of researchers are key to the growth and reinforcement of innovative biomedical research in Lombardy. Considering the lack of support and the career barriers that early-stage researchers might encounter to develop independency, FRRB aims to support the most promising young researchers and sustain their scientific career through its "Early Career Award" calls for proposals.

After the success of the first edition, FRRB intends to keep investing resources in order to reinforce the human capital in Lombardy dedicated to research, by supporting the career of young researchers and promoting their independence.

In this context, the "Early Career Award – II Edition" call will fund biomedical research projects, led by early career researchers (Principal Investigators or PIs), aiming at understanding the pathological processes underlying urgent medical needs and analysing the impact of diagnostics and therapies in context of the research areas mentioned below and of Personalized Medicine. The research projects may contain basic research elements and must highlight the transferability of the obtained results to the regional healthcare system, considering any ethical and social implications.

The research project shall cover one of the following **research areas**:

1. Cardiovascular
2. Oncological
3. Neurological
4. Rare diseases

Projects addressing specific **topics within the research areas** will receive an additional bonus, as detailed in paragraph 3. The so called "reward topics" are the following:

1. Cardiovascular area

Reward topics:

- Out-of-hospital cardiac arrest (OHCA): identification of cardiovascular genetic-molecular causes.

- Coronary Artery Disease: morpho-functional basis of acute plaque instability. *In vivo* identification of new risk factors and/or markers.

2. Oncological area

Reward topics:

- Development of cell therapies for oncological and onco-hematological diseases.
- Development of therapies and diagnostic approaches based on nuclear medicine.

Projects focusing on rare tumors are not fundable under this call. Rare tumors are defined as cancers with an incidence rate of less than 6 per 100.000 persons per year.

3. Neurological area

Reward topics:

- Diagnostic and therapeutic innovation in the treatment of neuromuscular diseases.
- Free radicals, oxidative stress and neurological damage: diagnostic and therapeutic innovation for neurodegenerative diseases.

4. Rare diseases area

Reward topics:

- Early diagnosis, cell therapies, new therapeutic approaches, new molecules and surgical innovations for the treatment of pediatric and/or adult rare genetic diseases.
- Neonatal screening.

Projects focusing on C3 glomerulopathy/immune complex membranoproliferative glomerulonephritis are not fundable under this call.

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.

2. APPLICATION REQUIREMENTS

2.1. HOST INSTITUTION

The Early Career Award is granted to the institution hosting the PI.

The Host Institution **must** belong to one of the following categories:

- Public or private I.R.C.C.S. (*Scientific Institutes for Health Research and Health Care*);
- Public Healthcare Providers (*Azienda Socio-Sanitarie Territoriali, ASST*);
- Health Protection Agency (*Agenzia di Tutela della Salute, ATS*);
- Regional Emergency Service Company (*Azienda Regionale Emergenza Urgenza, AREU*).

PIs affiliated to Universities or Research Organisations¹ might apply to the Call provided that they will demonstrate to have an on-going collaboration agreement with one of the

¹ For the purpose of this call, a "research organization" is defined as any organization that has all of the following characteristics:
a) its Statute includes research and dissemination of scientific knowledge among its main corporate purposes;
b) it mainly and continuously carries out independent research and dissemination of scientific knowledge;

organizations listed above. In such case, the Host Institution must always be a public or private I.R.C.C.S., an ASST, an ATS or an AREU and the PI **must** declare that he/she will perform the project-related activities for a minimum of 16 hours per week in one the Host Institutions listed above.

To be eligible, the Host Institution where the research project will be developed **must be in Lombardy**.

The eligible Host Institution must confirm its commitment to support the PI through a binding statement (“Attachment 1” or “*Allegato 1 - Dichiarazione di impegno da parte del Soggetto beneficiario*”).

Host Institutions must provide their PI with appropriate work, office and laboratory space, access to equipment, qualified support staff (e.g., lab technicians), as well as with any other resources needed to carry out the research project adequately and independently.

Each Host Institution can submit **a maximum of 5 applications in response to this Call**.

2.2. PRINCIPAL INVESTIGATORS

- o The PI must, at the date of the call deadline (September 29th, 2023):
 - i. have no more than 8 years of experience since the date of his/her PhD or MD (i.e. medical specialty awarded after medical degree). For researchers with a medical degree and a PhD, but not an MD, the date of the PhD degree will be considered; in case the researcher has obtained a medical degree and both qualifications (i.e. PhD and MD), the date of the first eligible qualification will be considered when assessing eligibility. A researcher who has a medical degree but not yet a PhD or MD will not be eligible;
 - ii. be no more than (\leq) 40 years old;
 - iii. have a h-index ≥ 8 according to Scopus²;
 - iv. have published at least 3 original scientific papers (excluding reviews) in peer-reviewed journals as first (or co-first), last (or co-last) or corresponding author (or co-corresponding author);
 - v. declare to dedicate at least 30% of his/her total working time to the project.

Eligibility extensions are admitted for criteria i and ii (see footnote)³.

A PI can submit only one application in response to this call.

c) it is equipped with stable structures, environments, premises and/or laboratories and instruments suitable for carrying out research activities;

d) it employs qualified personnel suitable for the research activity;

e) it does not include, among its activities, the funding of research through competitive call for proposals.

² Source: www.scopus.com/freelookup/form/author.uri

³ Maternity leave: 18-month extension for each child (born before or after the date of obtaining the PhD/MD degree);

Paternity leave: the effective documented time of paternity leave taken (for each child born before or after the date of obtaining the PhD/MD degree);

Long-term illness (over 90 days): the effective elapsed and documented amount of leave taken before or after the date of obtaining the PhD/MD degree.

The funding granted by FRRB under this call is addressed to non-economic activities⁴ and each Host Institution will have to submit, together with the project proposal, a binding statement (see “Attachment 2” or “*Allegato 2 - Dichiarazione di attività non economica o economica meramente ancillare ai sensi delle norme in materia di aiuti di stato*”).

A PI cannot simultaneously hold more than one active FRRB 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 of the “*Early Career Award – II Edition*” call. A project is considered closed when both the final financial and scientific reports have been submitted to FRRB.

2.3. GENERAL PROJECT FEATURES

Project proposals **must**:

- be focused on one of the research areas illustrated in paragraph 1;
- be innovative and foresee a possible transferability to the regional healthcare system;
- have a total maximum budget of **€ 500.000,00**;
- have a duration of **36 months**.

The budget allocated for each year cannot exceed the 40% of the total requested amount.

The total budget of the call “*Early Career Award – II Edition*” call is **€ 11.140.800,00**.

The portability of the funding is NOT admitted. In case, for any reason, the PI will be unable to lead the project, the Host Institution must promptly identify a new PI of similar experience and with the same characteristics. If a new PI cannot be identified, the grant must be returned.

The Early Career Award – II Edition call has a one-stage submission procedure: full proposals must be submitted via “*Bandi online*”, the electronic submission system of Lombardy Region (<http://www.bandiregione.lombardia.it>), no later than **September 29th, 2023 at 5:00 p.m.**

Project proposals must be written in English, strictly adhere to both the template form (Proposal Application Form) in terms of character limits, structure and formatting conditions, and to the instructions reported in the “*Guidelines for applicants*” (or “*Guida alla presentazione del progetto*”).

The Proposal Application form and the call attachments can be downloaded from the FRRB website at the following link: <http://www.frrb.it/en/call-bando-frrb-early-career-award-2>.

Proposals not compliant with the template provided will be automatically declared ineligible.

Communication and Dissemination

Proposals must include a dissemination and communication plan, describing the actions the PI will take to promote the project and share its results. Particular attention must be given to communication and dissemination activities dedicated to the scientific community (papers, poster presentations, workshops, congresses, etc.) and to a non-specialized public

⁴ See for reference art. 2.1.1 (points from 18 to 20) of the Communication from the European Commission “*Framework for State aid for research and development and innovation*” (2014/C 198/01).

(open days with the involvement of patient associations, charity days, brochures, press releases, etc.).

Responsible Research and Innovation (RRI)

A section of the proposal should be dedicated to explaining how the research project will be aligned to the six fundamental principles of Responsible Research and Innovation (RRI)⁵ established by the European Commission: *governance, public engagement, open access, gender, ethics, and science education.*

Sex and Gender

FRRB has been promoting and encouraging the participation of female researchers in funded projects for several years.

Sex and gender differences represent a crucial aspect in the design of a research study but are often overlooked when drafting the proposal, in study implementation, in the research team and during dissemination.

The PI will have to discuss in this section of the proposal the sex and gender analysis integrated in their project.

2.4. ELIGIBLE COSTS

Eligible **direct costs** are:

- Personnel costs: maximum 50% of the total requested budget (the salary of the PI is admitted; for public I.R.C.C.S., ASST, ATS and AREU only staff specifically recruited for the project will be considered eligible for funding);
- Travel costs: maximum 2% of the total requested budget;
- Participation to congresses/training costs: maximum 2% of the total requested budget;
- Consumables: purchase of materials and supplies;
- Equipment: only rental costs or amortisation rates admitted;
- Subcontracting costs: maximum 10% of the total requested budget. FRRB will require the submission of an audit certificate together with the final financial report. This cost to be included under the "Subcontracting cost category" will be eligible up to a maximum of € 8.000,00;
- Other direct costs: publication costs, animal transport and/or purchase costs, shipping costs of samples, and software (admitted 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 refer to the document "*Linee guida per la rendicontazione delle spese ammissibili*" available on the FRRB website (<http://www.frrb.it/en/call-bando-frrb-early-career-award-2>).

⁵ For more information, please refer to <http://rri-tools.eu/about-rri>.

3. PROJECT EVALUATION

3.1. ADMINISTRATIVE AND SCIENTIFIC REQUIREMENTS

FRRB will perform a scientific-administrative eligibility check of the proposals, assigning a bonus if a reward topic has been addressed, as detailed in paragraph 3.2.

3.2. SCIENTIFIC EVALUATION

Projects passing the scientific-administrative eligibility check will proceed to the Peer Review process.

The scientific evaluation will take place in two steps:

- 1) An international group of experts, generally referred to as "reviewers", will perform a remote evaluation (3 reviewers per project).
- 2) A panel of experts, referred to as "Technical-Scientific Committee", composed of a minimum of 3 reviewers chosen among those who evaluated the proposals remotely will perform a comparative evaluation during a plenary session, called Consensus Meeting. The discussion will be moderated by a chairperson with proven expertise.

The remote evaluation (step 1) will take into account both the content of the proposals and the financial plan.

Reviewers should evaluate the assigned proposal(s) using the following criteria:

Category: PRINCIPAL INVESTIGATOR (PI) – TRACK RECORD	Maximum score: 20
Ability of the PI in conducting research projects in a creative and independent manner, as demonstrated by previous experiences	0-10
Scientific skills of the PI necessary to successfully implement the proposed project	0-10
Category: EXCELLENCE OF THE PROJECT PROPOSAL	Maximum score: 20
Clarity and relevance of the proposed objectives	0-10
Soundness of the hypothesis and of the preliminary data, credibility of the proposed methodology, ethical aspects included	0-10
Category: IMPACT OF THE PROJECT PROPOSAL	Maximum score: 20
Possibility of the project to contribute to the advancement of scientific knowledge, beyond the state of the art, in the related research area	0-10
Quality of the proposal in terms of: <ul style="list-style-type: none"> - Dissemination to and sharing of results with the scientific community - Dissemination of results to the lay public - Description of Responsible Research Innovation (RRI) principles 	0-10
Category: QUALITY AND EFFICIENCY OF THE PROJECT PROPOSAL	Maximum score: 20

Quality and efficiency of the workplan, adequacy of the budget and of the resources allocated to each work package in line with the project objectives	0-10
Appropriateness of the technical infrastructures and of the management of the project	0-10

When assigning the scores, reviewers should take into account the following score 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.
1-2	Very poor: the proposal poorly meets the requirements of the call and present major shortcomings.
3-4	Poor: the proposal poorly meets 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.

The maximum score an expert can assign to a proposal is **80 points**, given by summing up the scores of the 4 categories, with each individual category being the sum of the scores of the related sub-categories.

Admission of a proposal to the Consensus Meeting is dictated by the final score assigned for each category, calculated as the average of the scores of the 3 experts. In particular, for a proposal to be admitted to the Consensus meeting, each of all 4 categories must have obtained an average score higher than **15 points (threshold)**.

Additional **5 points** (bonus) can be awarded by FRRB during the scientific-administrative eligibility check, according to the following criterion:

BONUS	Maximum score: 5
Consistency of the project proposal with the reward topics identified as priorities within each research area	0 or 5

The consistency of the project with one of the reward topics detailed in section 1 must be confirmed by the reviewers during the evaluation.

At the end of the remote evaluation, a provisional ranking list will be drafted, considering the sum of the average total scores of the remote evaluation and the bonus, if applicable.

The **30 best ranking projects** (i.e. the best 5 projects per research area, if above the threshold, followed by those having a higher score independently of the area) **will be admitted to the Consensus Meeting**.

The Technical-Scientific Committee will have the possibility to assign up to a maximum of **10 additional points** to each proposal according to the expected impact of the project results on prevention and/or diagnosis and/or patient care regarding the pathology of interest, taking into consideration the feasibility of the project itself.

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

A final ranking list will be obtained at the end of the plenary session, based on the sum of the average scores of the remote evaluation, the bonus, and the scores attributed during the Consensus Meeting.

Projects will be funded in order of ranking and consistently with the total financial coverage of the requested budget.

The call aims to fund at least the best 4 projects per research area. If projects within a specific research area are of inadequate quality, the residual endowment will be transferred to other areas, starting from the projects positioned higher in the overall ranking list.

The entire evaluation process has to be completed **within 270 days** starting from the deadline for proposal submission.

4. PLANNED TIME SCHEDULE

August 28 th , 2023, 10 a.m.	Opening of the online proposal submission system
September 29 th , 2023, 5 p.m.	Deadline for proposals submission through the online platform
By December 2023	Scientific-administrative eligibility check
By May 2024	Scientific evaluation of proposals through peer review process
By June 2024	Publication of the final ranking list