



Scientific Research Area

Scientific Research on Major Depressive Disorder and Anxiety Syndrome: prevention, early diagnosys and personalized therapy

Projects' submission deadline June 27<sup>th</sup>, 2019

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#### 1. INTRODUCTION

Scientific Research on Major Depressive Disorder and Anxiety Syndrome: prevention, early diagnosys and personalized therapy is a Call of the Scientific Research Area with deadline June the 27<sup>th</sup>.

#### 2. BACKGROUND

A survey conducted by the World Health Organization -WHO-, entitled 'Anxiety and other mental health desorders<sup>1</sup>, demonstrates that approximately 300 mlns people around the globe are affected by Major Depressive Diseases and Anxiety Disease. The survey states also an increase of these two syndromes beyond 18% over the decade 2005-2015. These pathologies, from the points of view of epidemiology, onset and social burden, are paradigmatic as diseases and the WHO classifies them to be the first cause of disability worldwide. Moreover, evidence exists of interaction between depression and non-contagious diseases such as substances abuse (including different therapeutic drugs), diabetes and cardiovascular diseases, all of which are basically the results of wrong lifestyle - wrong habits. Depression is a deceptive condition, often hidden by affected people and their families. In this setting the worst epilogue is represented by suicide, which is many times covered up by subjects' entourage and by the media. Between the three years 2011-2013 the Italian Institute of Statistics -ISTAT- estimates that 1 out of 5 italian suicidal cases, namely 2401/12877, may be ascribed to MDD<sup>2</sup>.

Considering these data, it looks mandatory that a social wellbeing devoted charity such as Fondazione Cariplo should focus its effort on further clarifying the causes of a plague increasingly affecting both world's as well as local population, by means of scientific 'target oriented' research.

#### 3. AIMS

Fondazione Cariplo will fund research programs aimed at the understanding of biological and physiopathological mechanisms underlying early and/or late manifestation and development of anxiety-depressive disorders' symptoms. Viceversa, projects will have the possibility to identify and collect clinical and psychological issues of the syndrome then look for their genetic, molecular, biological, environmental (...) aetiologies.

More properly will be considered eligible projects that will be able to define both:

- cellular, molecular, chemical, genetic and epigenetic mechanisms underlying depression neurologic features. In this setting are also included anatomic anomalies i.e. those regarding neural pathways and dendritic or synaptic arborization;
- different risk factors and patterns of the diseases through appropriate psychologic/psychiatric clinical evaluations.

Projects must be built on effective collaboration between basic and clinical research units. It is important to explain how the merge of different expertise is likely to allow the development of a global approach to AD-MDD. Applicants must demonstrate the successful combination of mechanistic studies in preclinical models (cellular lines and/or animal models) and clinical studies in well-defined cohorts. Data must be suitable to be analized by computational approach to enhance the long-medium term understandings of all the phases of the disease. Research project's rationale must be developed upon solid preliminary data (state of the art and/or applicants' original results) and properly discussed in relation to the ongoing academic debate. The methodological approach must be clearly motivated in order to understand its adequacy to reach project's expected results.

In addition, projects must represent training and professional opportunities for young researchers.

<sup>&</sup>lt;sup>1</sup> World Health Organization - Depression and Other Common Mental Disorders: Global Health Estim World Hates (2017) WHO/MSD/MER/2017.2

<sup>&</sup>lt;sup>2</sup> https://www.istat.it/it/archivio/suicidi

Finally, embracing the principles of Responsible Research and Innovation<sup>3</sup>, Fondazione Cariplo aims to promote initiatives fostering communication and interaction between researchers and civil society. In particular, researchers must propose a communication plan inclusive and open to all stakeholders differently implicated in the research. Planned activities are meant to facilitate the activation of a dual exchange between science and society. The communication plan is considered an integral part of the research proposal.

#### 4. GUIDELINES

## 4.1 ELIGIBLE APPLICANTS

It is mandatory for the leading host institution, and more specifically the operational headquarters of the project, to be located within the geographical area of interest of Cariplo Foundation (Lombardia plus Novara and Verbania districts). This requirement does not pertain partners.

Host institutions must provide PIs with appropriate workspaces, laboratories, equipment, qualified staff (e.g. lab technicians), as well as any other resources needed to adequately carry out the project.

By participating to this Call, organizations accept the "portability of the grant". Any change involving the host institutions depends on Fondazione Cariplo approval according to the guidelines of the Call.

## 4.2 ELIGIBLE PROJECTS

To be eligible, projects must:

- Respect the key priority research areas of this Call;
- Belong to a partnership composed by at least two eligible partners, each one specialized in the field of clinical research and basic research respectively;
- Involve, train and value young researchers<sup>4</sup>;
- Provide a plan of communication activities with the civil society (for more detail see the Communication Guidelines).

Moreover, the PIs of all the involved units (leading and partner) must:

- Be involved as PI (leading or partner unit) in only one project of the Scientific Research Area (except for Calls in partnership with other granting agencies)<sup>5</sup>;
- have concluded any other project previously funded by the Scientific Research Area (except for Calls in partnership with other granting agencies)<sup>6</sup>.

<sup>&</sup>lt;sup>3</sup> The European movement on the theme of Responsible Research and Innovation (RRI) is constantly evolving, as emerges from the debate which has recently led to the so called "Rome declaration on RRI"

<sup>(</sup>https://ec.europa.eu/research/swafs/pdf/rome\_declaration\_RRI\_final\_21\_November.pdf). In light of the available literature, it is possible to describe RRI as a dynamic and iterative process which intends to match research and innovation to values, needs and expectations of the society. Moreover, RRI aims at actively involving all the stakeholders taking part to activities of research and innovation, making them mutually responsible with respect to both the research process and its results.

<sup>&</sup>lt;sup>4</sup> For the matter of this call the term "young researcher" in this Call refers to graduate fellows, PhD students and postdocs not older than 35 years of age at the Call's deadline.

<sup>&</sup>lt;sup>5</sup> It should be noted that in case of multiple submissions as PI (leading or partner unit), only the first one received will be considered.

<sup>&</sup>lt;sup>6</sup> A project is considered ongoing unless the final grant reports – both the scientific and the financial ones - have been uploaded on our website before the deadline of this call.

The total cost of the project should correspond to the requested amount. The latter must be comprehensive of the additional costs<sup>7</sup> related to the realization of the proposal, and the overheads, according to the eligibility criteria and to the thresholds listed below:

## A03 - "Equipment and software"

This entry cannot exceed 20% of sum of all additional cost. It fully covers the costs for newly acquired equipment and software. All costs must be clearly motivated in relation to the specificity of the project. Ranting costs as well as building work expenses for the installation of the new equipment can be included in this category.

#### A04 - "Other amortizable costs"

This entry is fully dedicated to patent costs.

### A06 - "Temporary staff"

This entry is dedicated to research personnel costs. Please note that none costs of administrative staff are allowed.

## A07 - "Sub-contractors and consultants"

This entry is deputed to include audit costs8.

### A08 - "Materials and supplies"

Office supplies and photocopies costs are not included

#### A09 - "Overheads"

This entry cannot exceed 5% of the sum of all additional costs.

## A10 - "Travel, publication and dissemination costs"

This entry cannot exceed 15% of the sum of all additional costs. A10 is dedicated to cover research personnel's travel expenses and conference fees, scientific publications and all communication activities.

The grant will cover 100% of project costs. Requested funding should range from 150,000 to 300,000 euros.

Projects should provide the approval of the Ethical Committee<sup>9</sup>. In case submitted proposals require animal experimentation, Fondazione Cariplo should be informed about the Ministry of Health authorization before the final grant report.

#### 4.3 NOT-ELIGIBLE PROJECTS

Any proposal having the following characteristics will be considered non-eligible:

- failing to meet this Call scientific priorities;
- purely descriptive;
- those projects exclusively meant to develop new diagnostic tools and pharmacologic treatments;
- awareness projects;
- based only on basic or clinical research projects;
- aimed to set up new research centres and/or laboratories and/or animal facilities.

<sup>&</sup>lt;sup>7</sup> Sum of: A03, A04, A06, A07, A08, A10.

<sup>&</sup>lt;sup>8</sup> Exclusively certificated auditors are considered eligible. With the sole aim of ascertaining whether the obligation to perform a financial audit applies or not, the amount which has <to be considered is obtained multiplying the eligible costs detailed in the Budget (sum of entries A06, A07, A08, A09 and A10) by the coefficient 1.25 It is also recommended to refer to chapter 10 of the Grant management and reporting guide and to the Guidelines for audit; both documents are available on the Grant management and reporting page of Cariplo Foundation's website.

<sup>&</sup>lt;sup>9</sup> In case the approval is not available by the Call's deadline, the leading organization will be requested to send it together with the preliminary fulfilment.

#### 4.4 SUBMISSION PROCEDURE

Applications must be submitted by 5:00 p.m. on June 27<sup>th</sup>, 2019, under penalty of exclusion from participation in the competition.

The Leading Institution will have the duty to provide the application on behalf of all the research partners, following the instructions of the Guidelines for presentation, available on the informatic platform which is accessible through Fondazione Cariplo's website.

In order to apply for this Call, applicants are required to fill in integrally all the online forms organized as below:

- Project Form<sup>10</sup>, PDF format;
- Budget Form<sup>11</sup> written in Italian and English languages;
- Project Dissemination Form<sup>12</sup>, PDF format;
- Partnership agreement<sup>13</sup>;
- Host institution agreement for both the leading and partner units14;
- Documentation of the applicant organizations.

In any case, any application submitted using forms other than the specific ones provided by the Foundation will not be considered.

#### 4.5 CRITERIA

All proposals submitted before the deadline and according to the formal requirements described above will follow a two-step evaluation process:

# I. Formal Preliminary Control

This step is meant to check that all required documents are correctly submitted and in consistency with the Call's guideline. At this stage, Cariplo Foundation will also check all Organisations' eligibility. This is equally valid for leading organizations as well as for partners. Only applications considered eligible enter the peer review stage. Non-eligible projects will be notified. Organizations will receive a formal letter clearly motivating the exclusion. This information will also be available online on Fondazione Cariplo's website.

## II. Peer Review

Eligible applications will be evaluated by independent experts in a peer review process ensuring scientific expertise and impartiality and the review panel will be built on international experts on circular economy. Reviewer-project matching will be made according to the indications provided by applicants in the keywords selection. Each proposal will be assessed by 3 reviewers.

The final score given to the project reflects the following scores and weight, according to the reviewers' evaluations. In parallel, Cariplo Foundation will evaluate the coherence of the budget and the quality of the dissemination plan.

- 1. DESCRIPTION (weight 10%)
- clarity of the project aims and strategies;
- state of the art analysis;
- preliminary data significance.

<sup>&</sup>lt;sup>10</sup> The detailed project shall be prepared in accordance with the template related to the Call.

The detailed budget form shall be prepared in accordance with the template related to the Call.

<sup>&</sup>lt;sup>12</sup> The project dissemination form shall be prepared in accordance with the template related to the Call.

<sup>&</sup>lt;sup>13</sup> Applicants are advised to carefully read the Guidelines for presentation document available on-line.

<sup>&</sup>lt;sup>14</sup> See footnote 13.

- 2. APPROACH (weight 25%)
- adequacy of the experimental plan;
- adoption of an interdisciplinary approach;
- risk evaluation and presence of adequate back-up plans;
- adequacy of the monitoring plan.
- 3. INNOVATION (weight 15%)
- originality and innovation of the project.
- 4. OUTCOMES (weight 15%)
- expected results and their impact on the scientific community;
- potential benefits for human health.
- 5. PRINCIPAL INVESTIGATOR, TEAM AND ENVIRONMENT (weight 10%)
- Pls' scientific and managerial leadership;
- track record and adequacy of the PI and team competencies (leading organization and partner):
- expected impact of the project in terms of the PI's professional development;
- level of consolidation of the collaborations with research centres and\or the ability to build new partnerships.
- 6. INVOLVEMENT OF YOUNG RESEARCHERS (weight 10%)
- engagement of young researchers in responsibility roles;
- training programmes for young researchers.
- 7. DISSEMINATION (weight 5%)
- consistency with Communication guidelines with Responsible Research and Innovation principles.
- 8. BUDGET AND DURATION (10%)
- budget suitability and coherence and duration of the project.

The final ranking ultimately represents the list of the best projects worth of funding. At the end of the review process, all applicants will receive official communication together with reviewers' feedback.

### **5 AVAILABLE BUDGET**

The budget available for this call for proposals is 3 million euros.

## 6 OTHER USEFUL INFORMATIONS

The Foundation, as a private entity, is not required to comply with public procedures and has the faculty not to allocate the entire budget in whole or in part.

The Call for Proposals and all the mentioned documents can be found on the Foundation website <a href="https://www.fondazionecariplo.it">www.fondazionecariplo.it</a>.