Ministero Salute

call for proposals for applied clinical and biomedical research 2016

Abstract for International Reviewers

PROJECT TYPES

All research proposals must fall under one of the two following project types:

- **Theory-enhancing research**—to develop the knowledge base in biomedicine. Translational research that aims to convert findings in fundamental research into meaningful health outcomes.

- **Change-promoting research**—clinical and applied health research. Research conducted on patients, taking shape in treatments and drugs that directly improve human healthcare.

OBJECTIVES

a) Develop highly innovative procedures and new knowledge that will contribute to enhancing opportunities for prevention, diagnosis, treatment and rehabilitation, also through clinical studies and trials (new knowledge in biomedicine - theory-enhancing research)
b) Evaluate the safety, effectiveness and cost-effectiveness of healthcare treatments/technologies/interventions, also through phase 3 and 4 clinical trials (clinical and applied health research-change-promoting research)
c) Evaluate the professional, organizational and systemic factors that condition the effectiveness and the efficiency of health services and/or that impact the quality of clinical, organizational, management and funding innovations; development and implementation of methods and tools to improve communication with the public and with patients and to foster participation; studies aimed at analyzing the healthcare needs of the socio-economically weaker (clinical and applied health research-change-promoting research)
d) Address topics concerning food safety and animal welfare (change-promoting or theory enhancing)
e) Address topics concerning environmental disease, occupational safety and occupational disease (change-promoting or theory enhancing)

The above-mentioned project types and objectives are common to all **4 call sections** (see below). Each section will have a specific ranking list. All projects must have a duration of 3 years. They can involve multi-centres but must not have more than 3 Operating Units (Work Packages-from now on WP).

This call will be published on the website of the Ministry of Health http://www.salute.gov.it/portale/documentazione/p6_2_4_1.jsp?lingua=italiano&id=135 (Italian language) and on the website of the web based submission and evaluation system named Biomedical Research Workflow Management System (Work Flow della Ricerca-WFR) - http://ricerca.cbim.it/index_en.html.

CALL SECTIONS

1. **Young researcher projects** (first code digits: GR) – researchers under 40 years of age on the closing date of the call
2. **Italian researcher abroad projects** (first code digits: PE) – projects carried out in collaboration with Italian researchers who have been operating abroad for at least 3 years.
3. **Industrial co-financing projects** (first code digits: PC) – projects that are privately co-financed by companies that operate in Italy, with the purpose of developing processes or products that are not yet protected by a private patent, or that have a patent that is held by the NHS researcher or Public Institution
4. **Ordinary applied research projects** (first code digits: RF) – those that do not come under the previous headings.

Grants will be awarded for projects requesting funding from between €150,000.00 and €450,000.00.

THE EVALUATION PROCEDURE

Each Project that meets the call's eligibility requirements will go on to the **Peer Review** phase and will be allocated to reviewers via an automatic classification system in which the key words (IRG/SS Topics defined by the Principal Investigator), that represent the scientific content and topic of the research proposal, will link to reviewers whose expertise matches the Topics. Each project will be assigned to **two separate groups of reviewers**, as described below:

- **Group A** – for the **Scientific Evaluation** of the projects (International reviewers), in accordance with the specific evaluation criteria (see Scientific Evaluation criteria in table below)

- **Group B** – for the **NHS Impact Evaluation** of the projects (Italian reviewers)

Each reviewer is required to write a comment for each criterion and to give a score that is coherent with the comment, as described in detail in the evaluation guidelines.

A scoring system from 1 to 9 will be used to evaluate the proposals with respect to each evaluation criterion. **Please note** that the **Maximum value = 1** and the **Minimum value = 9**. Half marks may be given

Group A - Scientific Evaluation (International reviewers)		
CRITERION	**GROUP**	**SCORE**
Relevance of the research project regarding the topic and the overall objectives of the call. The novelty and originality of the proposal in relation to current knowledge	A	1 – 9
Scientific quality and relevance of the proposed research and the coherence and effectiveness of the methodology in relation to the proposed objectives; practicability of the objectives, taking into account preliminary data and bibliographic references	A	1 – 9
Clarity and appropriateness of the project development strategy (in relation to the 3-year duration of the project)	A	1 – 9
Appropriateness of the allocation of tasks and resources: taking into account the experience of the research partners in the field, the available infrastructures, facilities and equipment	A	1 – 9

For each group of reviewers, once the individual and anonymous evaluation phase has been completed, the two reviewers in each group will carry out a Face-to-Face comparison (F2F) via the electronic evaluation System. During this phase each reviewer will have access to the other reviewer's critique and the two reviewers will try to reach an agreement for the final evaluation of the project in question. Following the F2F all the projects will be assigned to the **Scientific Review Panel** (one for each project section) for the final study session. If an agreement was not reached in the F2F, then a further evaluation will made by the Scientific Review Panel, which will work collectively as "a third referee in arbitration" to give a final evaluation to the project.

Quality Evaluation Process

To ensure that the Peer Review is carried out in compliance with the Evaluation Guidelines and that the reviewers' scores correspond to their written comments, a group of independent reviewers called editors will anonymously access the reviewers' critiques, as well as the details of the project itself (information on the PI and the research group is not accessible). The editors cannot give an opinion on the project and can examine only one evaluation for each single project. The editors will notify the relevant Scientific Review Panel, via the electronic System, of any discrepancies in the evaluation process with respect to the guidelines, which will then be taken into consideration during the final study session.

Duties of the Scientific Review Panels

The role of the Scientific Review Panels is to compensate for any discrepancies with respect to the guidelines in the reviewers' evaluations of a single project and between one project and another, as well as to rank the projects in descending order, following the reviewers' evaluation.

At the end of the evaluation process a Certificate of Attendance will be issued for each reviewer and the names of the members of the Scientific Review Panels, the names of the two independent observers, the list of referees and the list of editors, as well as the final results of the evaluation will be published on the Ministry of Health website (www.ministerosalute.it).

Once the evaluation procedure is complete and the results have been published, the Principal Investigators will be able to access the evaluations made by the reviewers via the electronic submission system. The evaluations will remain anonymous.

ANNEX n. 1

Conflicts of Interest

Reviewers are called to carry out a scientific evaluation of the project proposals in relation to their specific expertise, with the purpose of facilitating the work of the study session in evaluating a potentially high number of projects. Their task is to assess the scientific quality and the feasibility of the project as well as its adherence to the aims of the Call.

Before undertaking the evaluation process, the reviewers must declare:
1. that they have not submitted directly or indirectly any project proposal in the scope of the present call;
2. not to have participated, in any way, in any of the projects that have been submitted;
3. not to be in contact with the Principal Investigator or the Proponent Researcher of any of the project proposals and not to disclose any information about the projects under evaluation.

For the above-mentioned purposes and to ensure the confidentiality of the information, reviewers must confirm, through the electronic system reserved for the evaluation of the projects, the following declaration of confidentiality:
I hereby declare that I will neither disclose any details regarding the evaluation process and its outcomes nor regarding any proposal submitted for evaluation. I understand that I have to maintain the confidentiality of any document or electronic file sent to me and that I will have to return, erase or destroy all confidential documents or files upon completing the evaluation, unless otherwise instructed.

and declaration of no conflicts of interest:
I hereby declare that I have no conflicts of interest regarding any proposal I am asked to evaluate. In particular, I declare to the best of my knowledge that I have neither submitted any proposal currently under evaluation nor am I involved in any proposal currently under evaluation or submitted for evaluation under the afore-mentioned call nor have I collaborated in the last 2 years with any of the researchers who have submitted in this call. I will notify the Ministry of Health immediately if any new situations or actions develop that could be regarded as potential conflicts of interest.

1. Reviewers must recuse themselves from participating in the evaluation of a project proposal if they are currently cooperating with an applicant or if professional dependencies with an applicant exist or if they have published together with an applicant or co-worker within the last three years;
2. Reviewers should refrain from reviewing if they stand to profit professionally, financially or personally;
3. Reviewers should exclude themselves from reviewing if they have had contact with or spoken to an applicant about the call or about any specific project outside the official evaluation procedure.

Violation of the confidentiality clause
Any violation of the confidentiality clause will determine the immediate exclusion from the evaluation procedure. If reviewers should inform third parties of their evaluations or make them public domain, the reviewer will be immediately suspended from the evaluation procedure. The study session will be notified accordingly so as to be able to make a decision with regard to the evaluations already carried out.

ANNEX n. 2

Patent Protection

If the key subject of the project proposal is protected by a patent, the ownership of the patent must be certified by the Beneficiary/Applicant Institution.

Projects with patents will be eligible for evaluation if the patent:

a. belongs to a public body or a Beneficiary/Applicant Institution
b. belongs to an Italian or a foreign university
c. belongs to a public employee
d. belongs to, even in part, to one of the above
e. has expired
f. was issued for software or other equipment used for research purposes but not the object of the research itself

ANNEX n. 3

Eligible Costs

1. Costs for research work agreements must not exceed 50% of the funding requested from the Ministry and must not exceed 38,000.00 euro per researcher per year. Beneficiary/Applicant Institutions can use their own funds to increase this amount.
2. Maximum overheads must not exceed 10% of the funding requested. This limit is to be applied individually to each single WP.
3. Research trip costs must not exceed 2% of the total funding requested. As far as regards Foreign Projects, foreign researchers' travel expenses must not exceed 30% of the total funding.
4. Publication costs cannot exceed 2%. Total funding will be cut by 5% if the Ministry is not mentioned in the publication.
5. Participation in conventions for the diffusion of research results (registration and travel expenses) cannot exceed 1% of the entire amount requested.
6. Personnel paid from funding must not have a permanent employment contract.
7. Only the hiring or leasing of equipment and instrumentation is allowed.
8. The transfer of funds abroad is not permitted.
9. The amount of budget allocated to a WP **outside** the NHS (max one per project) must not exceed 20% of requested funding.
10. A maximum of 10% of the funding allocated to each single WP can be used to subcontract work that cannot be carried out by the WP itself.
11. WP's operating within University hospitals cannot transfer funds from the NHS to the University.