



*Ministero del Lavoro, della Salute
e delle Politiche Sociali*

DEPARTMENT OF INNOVATION
GENERAL OFFICE OF SCIENTIFIC RESEARCH AND TECHNOLOGY

The Italian Ministry of Health, in accordance with the 2007 Budget Law, invites young researchers (who must be under 40 years of age at the submission deadline of this notice) to submit research grant applications for the year 2009. Each project must have a three-year duration.

1. GENERAL AIMS AND CHARACTERISTICS

The projects should aim to produce new knowledge with translational potential to improve the quality and efficiency of the National Health Service. The aim is to create a new generation of researchers whose professional expertise will help to promote the integration of biomedical research and health services.

2. RESEARCH FEATURES

The proposals should comply with the VII EU Framework program and focus on three main kinds of research:

- a. Innovative (progressive) research aimed at the generation of new knowledge and the development of novel technologies;
- b. Translational research aimed at providing knowledge and instruments to improve clinical practice ;
- c. Research into emerging social and health issues.

The available funds will be shared equally between these three research directions.

The research projects must have strong translational potential and be clinically relevant.

Furthermore, researchers will be required to disseminate their findings; in particular, they will be required to publish their results in scientific journals.

3. INSTITUTIONS FUNDED BY THE MINISTRY OF LABOR, HEALTH AND WELFARE

Given that the funds for this program are included in the Ministry's Table C, researchers wishing to apply for funding under this call must be associated with National institutions eligible to receive them, namely: Regions, the Italian National Health Institute (ISS), the Italian National Institute for Occupational Safety and Prevention (ISPESL), Scientific Institutes for Research, Hospitalization and Health Care (IRCCS), Regional Health Service Agencies, and institutes researching animal diseases ("Istituti Zooprofilattici Sperimentali")

4. SUBMISSION REQUIREMENTS

Projects may be submitted by young researchers who have fixed-term and/or permanent contracts with eligible institutions (as specified above), or by young researchers who, despite not being under any contract at the time of the submission, intend to carry out the proposed research at such an institution.

Any individual researcher may submit only one application as principal investigator (PI).

5. AREAS OF RESEARCH PROJECTS.

Projects in the fields of biomedical, basic, translational, clinical, or epidemiological research, social and services organization, disease prevention, and environmental research may be submitted. A broad aim of each research project must be to improve the quality and efficiency of the healthcare delivery through innovations which have translational potential or are relevant to health service practice.

6. ROLE OF THE “PRINCIPAL INVESTIGATOR”

The “Principal Investigator” is the researcher who receives the funding for the project and has the overall responsibility for it.

The Principal Investigator:

1. decides how the allocated funds should be spent;
2. creates and coordinates the research group;
3. publishes the results of the research and chooses the co-authors;
4. is required to acknowledge, in publications and scientific communications, the source of the funding received.

Researchers awarded funds under this competition will also be required to document the management of the relevant human, technological, and financial resources, and to submit annual financial and scientific reports.

7. METHOD AND PROCEDURES FOR SUBMISSION AND EVALUATION OF PROJECTS

7.1 SUBMISSION

The research projects must be edited according to the format described in Appendices 1 and 2, and submitted by the deadline specified in this notice. The applications will receive written critiques, and subsequently will be assessed by an Evaluation Committee.

Applications must be submitted online.

Candidates will register their name, contact information, e-mail address on a web page at www.ministerosalute.it.

Candidates must submit an outline (“letter of intent”) in English – Appendix 1 – summarizing the project’s innovations, aims, expected new knowledge, translational aspects and critical issues. They must also name the national institution where they intend to carry out the research.

The submission and selection process is divided into three phases:

1) During the first phase (lasting one month, from the opening of the website on January 20, 2009 to February 20, 2009), the candidate submits a preliminary draft.

2) During the following 30-day phase, each eligible institution can access the candidate's registration information and preliminary drafts; in the meantime, each researcher finishes writing the final version of the proposal (Appendix 2) in English.

3) In the third phase, following the decisions reached by the eligible institutions, the Evaluation Committee (E.C.) and the reviewers will be able to access the entire project proposal. Only projects selected by the eligible institutions will be assessed by the E.C.; all the other projects will be kept by the Ministry of Labor, Health and Welfare, which will guarantee their confidentiality.

7.2 PROJECTS PER SINGLE NATIONAL INSTITUTION

No limit is placed on the number of projects per national institution. The available funds will be shared among projects that have requested funding of not less than 300,000 and not more than 600,000 euros, in total, for the entire duration of the project (3 years).

7.3 EVALUATION

The evaluation procedure will be based on the coordinated action of:

- 1) The Evaluation Committee (E.C.)
- 2) International referees (reviewers)
- 3) Two independent experts
- 4) The IV Office of the Directorate General of Scientific and Technological Research of the Ministry of Labor, Health and Welfare
- 5) The National Health Research Committee

The E.C. will make a collective assessment of all proposals.

The reviewers, who will be selected from lists provided by international agencies, are required, on the basis of their specific areas of expertise, to provide initial assessments of the projects.

The two independent experts are appointed to the E.C. by the Undersecretary for Health / Minister of Labor, Health and Welfare. The sole task of these experts is to assign the projects to the best international reviewers (three per project).

The IV Office of the Directorate General of Scientific and Technological Research of the Ministry of Labor, Health and Welfare will support the whole process.

The National Health Research Committee receives documentation from the E.C. and oversees the regularity of the proceedings.

The two independent experts and the IV office of the Directorate General of Scientific and Technological Research of the Ministry of Labor, Health and Welfare will not participate in the evaluation of individual projects.

All procedures are computerized, so there is no movement of paper documents. Only the final list of projects selected by the E.C. is sent, on paper, to the National Health Research Committee.

The administrative procedures will include:

A) The collection of applications, the allocation of projects to reviewers on the basis of the keywords given by the applicants and the directions of the two independent experts, the sending of the reviewers' assessments to the E.C., and the sending of the documentation prepared by E.C. to the National Health

Research Committee. This work will be done by the IV Office of the Directorate General of Scientific and Technological Research of the Ministry of Labor, Health and Welfare.

B) The assignment of projects to best international reviewers (three per project). This work will be performed by two independent experts who have access only to the title and keywords of the project. Their duty is to ensure that each project is submitted to the best reviewers.

C) The preparation of a report of the proceedings, after the work done by both the independent experts and the IV Office of the Directorate General of Scientific and Technological Research of the Ministry of Labor, Health and Welfare is completed.

D) The preparation of a report on the progress of the proceedings and on any issues that have arisen after the work done by both experts and the IV Office of the General Office of Scientific and Technological Research of the Ministry of Labor, Health and Welfare is completed. This report will contain guidelines for improving the review process.

E) The notification of all applicants of the outcomes of the assessments by three reviewers and the E.C., within two months of the end of the review process..

The proposal evaluation stage is the sole responsibility of the E.C. and will include:

A) The final assessment of the research projects during evaluation sessions. Detailed minutes will be taken of each meeting of the E.C. (including those conducted by video conference). First, based on the scores assigned by reviewers, the E.C. will draw up a list of all the projects, in descending order of merit (preliminary ranking); then, after considering for each project, the applicant's training, expertise, list of publications, and other considerations (see Form B below), the order of this list will then be reviewed and possibly adjusted (final ranking).

B) The preparation of the final report by the E.C. For each project, this report will include preliminary and final rankings, the amount of requested funding, and a detailed summary of the minutes of the meetings. All documentation will be forwarded to the National Health Research Committee by the IV Office of the Directorate General of Scientific and Technological Research of the Ministry of Labor, Health and Welfare.

The audit process by the National Health Research Committee will include:

A) Examination of the reports drawn up by E.C., the final report and rankings, and the responsiveness of the projects to the topic areas relevant to this competition.

B) Examination of the report drawn up by the two experts and the IV Office of the Directorate Office of Scientific and Technological Research of the Ministry of Labor, Health and Welfare on procedures, problems, and suggestions.

The National Health Research Committee will then decide, in accordance with the E.C.'s decisions, the allocation of all the available funds.

Criteria and evaluation tools

The E.C. and the reviewers will apply the following criteria in their evaluation of the research proposals and their compilation of the final list, using the forms provided:

FORM A

Evaluation of applications – compare Appendix 1: Instructions to and Responsibilities of the reviewers

	Evaluation criteria	Scoring Range
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A	Scientific quality and relevance of the research	1-9
B	Innovation and originality of the project (relative to the current international literature)	1-9
C	Approach, including methodology and development strategy, of the project (over its three-year duration), preliminary data and bibliographical references	1-9
D	Translational impact and clinical relevance	1-9
E	Profile of the investigator (general details) and his/her scientific work, based on his/her CV, published scientific papers listed in the application (the best 5, the 5 most relevant to the topic of the application, the most recent 5, including the impact factor of the journals in which they were published, the number of citations from year of publication to time of application for funding, and the H-index (which represents the balance between the number of publications and the number of citations per publication))	1-9
F	Final assessment (half page)	Text
G	Final score	Sum of A-E

A score of 1 is the best and 9 to the worst. Fractions (0.5 points) of scores are admissible.

FORM B

Evaluation of applications – compare Appendix 1: Instructions to and Responsibilities of the E.C.

I	Responsiveness to the objectives of the competition	YES/NO
J	Requested Budget and other financial details (including consideration of possible co-financing)	1-9
K	Facilities and equipment available for research collaborations	1-9
L	Total of the scores of the reviewers + that of the E.C.	From 7 to 63
M	Final score assigned by the E.C.	From 7 to 63
N	Summary of the merits of the project and account of any differences of opinion and score (L vs M) between all those involved in the review process.	Text

A score of 1 is the best and 9 is the worst. Fractions (0.5 points) of scores are admissible.

The members of the E.C. and the reviewers are also invited to make full use of all appropriate tools and databases (PubMed, ISI, etc.) during the evaluation process.

Guarantees on the absence of conflicts of interest.

Appendix 3 of this notice sets out the procedures to ensure that there are no conflicts of interest. However, the members of the E.C. must:

- declare that they have not submitted, directly or indirectly, any proposal for research funding in response to this call

- declare that they are not participating in any way with any of the projects and indicate projects whose principal investigators are researchers with whom they currently have (or have had in the previous two years) scientific collaborations; the E.C. members and reviewers must refrain from assessment of these projects.

The experts and reviewers must declare in advance that they have no conflicts of interest with the review procedures. If conflicts arise, the experts cannot assign the project to the reviewer and the reviewer must refuse to assess it.

8. ADMINISTRATIVE PROCEDURES

The budget of a project can be used, in part, to cover the salary of the principal investigator, other staff, researchers and/or technicians, provided they do not receive any other support for this project. The total cost which may be allocated to salaries must not exceed 50% of total funding. The maximum salary for each eligible researcher must not exceed €35,000 per year.

At the end of the evaluation process, the projects selected by the E.C. will receive funds following agreements reached between the Ministry of Labor, Health and Welfare and the eligible institutions concerned. Therefore, each of these agreements should include a statement by the legal representative of the eligible institution in which the latter:

1. Undertakes measures to ensure that the research activities can be carried out at the site chosen for the entire duration of the project,
2. Waives any rights to the money awarded under this competition, with the exception of overheads of up to 10% of the overall funding (purely for management costs),
3. Declares the formal appointment of the young researcher who is to carry out the research project (a declaration that is duly signed by him/her). This declaration must be accompanied by a photocopy of the identity card of the winning candidate to demonstrate fulfilment of the age requirement.

Should the eligible institution decide that it does not intend to carry out the research project approved and funded by E.C., the researcher may approach other appropriate institutions about the possibility of conducting the research at their facilities. In this case, the legal representative of the eligible institution must provide a formal confirmation, in writing and within 30 days, of its decision not to collaborate with the researcher. The researcher, following such a refusal, can apply to conduct the project in a new location, by submitting a formal application to the IV Office of the Directorate General of Scientific and Technological Research of the Ministry of Labor, Health and Welfare. Once the availability of a new site has been confirmed, the National Health Research Committee will approve the change on the basis of the reasons cited. Should the eligible institution fail to provide the necessary notification either of its refusal or of its intention to take on the researcher, within the said thirty days, a formal decision will be reached by the National Health Research Committee.

9 SUBMISSION OF APPLICATIONS

The text of the research project prepared by the applicant in accordance with the criteria specified above and the instructions contained in the appendices, must be electronically transmitted to the Ministry of Labor, Health and Welfare website: www.ministerosalute.it, by the following deadlines:

1. Submission of a preliminary draft by the candidate: **Between 8.00 h on 20 January 2009 and 12.00 h on 20 February 2009**
2. Final selection of researchers by the eligible institutions: by **12 h on 24 March 2009**

10 RESPONSIBILITIES FOR THE IMPLEMENTATION OF THIS NOTICE

The Director of the IV Office of the Directorate-General for Scientific and Technological Research of the Ministry Labor, Health and Welfare is in charge of all procedures related to this competition.

11 EXCLUSION FROM THE COMPETITION

The following candidates will be excluded from participation in the competition for the allocation of funds:

1. Those whose requests were submitted after the deadline stated in this notice,
2. Those whose applications are incomplete (i.e. who submit incomplete forms),
3. Those who do not meet the requirements listed under section 4 of this notice,
4. Those who have applied for funding for more than one project in response to this call,
5. Those who fail to indicate their agreement to processing of their personal data.

Winners unable to produce a declaration signed by the legal representative of the relevant eligible institution certifying the availability of its facilities for conducting the research and its waiver of any rights to the disbursed money will also be denied, temporarily, the allocation of funds under this competition.

12. PROCESSING OF PERSONAL DATA

In accordance with article 13 of Legislative Decree n. 196 of 30 June 2003, the personal data provided by applicants are processed only for purposes of managing the competition and for any subsequent allocation of funding for research. Providing such data and agreement to its processing are necessary requirements for participation.

13. DISBURSEMENT OF FUNDS

A project will be funded when a formal agreement between the Ministry of Labor, Health and Welfare Directorate-General for Scientific and Technological Research and the eligible institution is reached, within the limits of the funds put aside for this competition and within a single fiscal year.

The disbursement of funds will be as follows:

- 40% upon notification of the start of the research project;
- 30% after submission and approval of the interim report (which must be submitted 18 months after the start of the research);
- 30% upon satisfactory completion of the project.

Verification and monitoring of the work will be the responsibility of the Ministry of Labor, Health and Welfare - Directorate General of Scientific Research and Technology, which will be assisted by the National Health Research Committee.

UNDERSECRETARY OF STATE

Legend

N.I. = National Institute

NHRC = National Health Research Committee

E.C. = Evaluation Committee

Reviewer = Anonymous Referee

Appendix 1

		Maximum	Comments
	Funding application form		

		number of characters	
Page 1	Profile of the investigator	2000	1 page
Page 2	Summary and collaborations	2000	1 page
Page 3A	Rationale, aims and impact on the specific topic	4000	2 pages
Page 3B	Up to 5 of the applicant's best scientific papers, including the impact factor of the journals in which they were published, the year of publication, and the number of citations from the year of publication to the current application for funding and H-index	2000	1 page
Page 3C	Up to 5 of the applicant's scientific papers relevant to the topic of the proposed research, including the impact factor of the journals in which they were published, the year of publication, and the number of citations from the year of publication to the current application for funding and H-index	2000	1 page
Page 3D	Up to 5 of the applicant's most recent scientific papers, including the impact factor of the journals in which they were published, the year of publication, and the number of citations from the year of publication to the current application for funding and H-index	2000	1 page

Appendix 2

	Funding application form	Maximum number of characters	Comments
Page 4	Originality of the project	4000	2 pages
Page 5-8	Development strategy of the project, methodology, preliminary data and bibliographical references	4000	2 pages
Page 9	Facilities and equipment available for the research, collaborations	3000	1 page
Page 10	Relevance of the project to the NHS (based on its potential for rapid translation into care)	4000	2 pages
Page 11	Responsiveness to the objectives of the competition (reporting only negative responses)	YES / NO	
Page 12	Detailed financial statement		1 page

Appendix 3

MANAGING CONFLICTS OF INTEREST

The computer services' staff (or anyone who has access to the system for maintenance purposes), who could, voluntarily or involuntarily, become aware of confidential data are required to maintain the strictest confidence.

A. Evaluation Committee

The components of the E.C. before the initial session, shall, on penalty of disqualification from the E.C.:

- declare that they have not submitted, directly or indirectly, any proposal for research funding under the this call,
- declare that they are not participating, in any way, with any of the projects

Potential conflicts in evaluation

Should any conflicts of interest arise during the assessment process, the E.C. must immediately report the problem, in order not to invalidate the procedure.

Possible conflicts of interest for E.C. members:

1. Projects whose principal investigators are researchers with whom they currently have (or have had in the previous two years) scientific collaborations
2. Projects whose principal investigators work in institutions with which they currently have (or have had in the previous two years) scientific collaborations

Correct conduct in the first case:

- declare potential conflict
- abstain from assessment of the specific project and any discussion on its evaluation

In the second case:

- declare potential conflict
- determine if the conflict is real
- should a conflict potentially exist, abstain from assessment of the specific project and any discussion during its evaluation

B. Experts

Experts before the initial session must:

- declare that they have not submitted, directly or indirectly, any research proposal under this notice
- declare that they are not involved, in any way, in any of the projects
- declare that they have had no contact with the PI or discussed any aspect of this competition

Possible conflicts of interest for experts:

1. Projects in which, for whatever reason, they and the PI have competing or allied interests
2. Projects in which, for whatever reason, they have interests in the institutions to which the PI belongs
3. When they have had contact with the PI or entered into unofficial discussions relating to this competition
4. When they have been or are in contact with the reviewers

Correct conduct

1. Projects in which experts, for whatever reason, have competing interests with the PI

- declare the potential conflict
- take no part in the assignment of reviewers to the specific project and the meeting's discussion about it, and withdraw from the meeting during such discussion.

2. Projects in which the experts have interests in the institutions to which the PI belongs

- declare the potential conflict
- take no part in the assignment of reviewers to the specific project and the meeting's discussion about it, and withdraw from the meeting during such discussion.

3. When they have had contact with the PI or entered into unofficial discussions relating to this competition

- Such contacts must be described and recorded in detail in the minutes of the meeting. Should there emerge a clear instance of non-casual involvement of an expert, this behavior could lead to his/her removal from the entire review procedure by the National Health Research Committee.
- The expert should take no part in the reviewer assignments to the specific project and the meeting's discussion about it, and withdraw from the meeting during such discussion.

4. When the experts have been or are in contact with the reviewers

- Such contacts must be described and recorded in detail in the minutes of the meeting. Should there emerge a clear instance of non-casual involvement of an expert, this behavior could lead to his/her removal from the entire review procedure by the National Health Research Committee
- Should it emerge that there has been regular contact with a reviewer, the expert should take no part in the reviewers' assignment to the specific project and the meeting's discussion about it.

C. Reviewers

Before making assessments, the reviewers should:

- declare that they have not submitted, directly or indirectly, any research proposal under this notice,
- declare that they are not involved, in any way, in any of the projects
- declare that they have had no contact with the PI or discussed, unofficially, any aspect of this competition

Possible conflicts of interest for reviewers:

1. Projects in which, for whatever reason, they and the PI have competing or allied interests
2. Projects in which, for whatever reason, they have interests in the institutions to which the PI belongs
3. When they have had contact with the PI or entered into unofficial discussions relating to this competition

Correct conduct

1. Projects in which the reviewer, for any reason, has competing or allied interests with the PI

- refuse to evaluate the project

2. Projects in which reviewer, for any reason, has interests in the institutions to which the PI belongs

- the reviewer declares his/her incompatibility and refuses to evaluate the project

3. When reviewers have had contact with the PI or entered into unofficial discussions relating to this competition and to specific projects.

- refuse to evaluate the project