Programma di Ricerca Regione - Università 2010-2012

Area 1 "Ricerca Innovativa"

Bando "Giovani ricercatori"

Guide for Applicants

This document is intended as an aid to walk Principal Investigators (PIs) through the assembly of the Project by explaining in details how to appropriately fill in the Application Form.

Introduction

Eligibility Check

All Proposals received within the Deadline (February 29th 2012, 12pm – noon -) as published in the Call, will be checked by the *Segreteria Scientifico-organizzativa Programma di Ricerca Regione-Università* against the presence of eligibility criteria:

- presence of the appropriately filled parts and Forms, also respecting the given characters limits;
- validity of the requested Declarations:
    1. Declaration of PI engagement by the Legal Representative of the hosting Institution (*Institutional Statement*)[1]. As part of the application, the hosting Institution must: i) confirm the affiliation of the PI; ii) declare its willingness to support the PI by providing her/him the conditions ideal to carry out the Project;
    2. PI Declaration of not having received any grant from the Emilia-Romagna Region Health Care Service in the past 5 (five) years[2];
    3. PI Declaration that the research proposal, and/or research activities related to it, have never been funded before by the Emilia-Romagna Region Health Care System[3];
    4. PI Declaration of co-funding, if applicable, together with a declaration of the relevant Granting Institution stating the name of the recipient, the title of the project, and the amount of money awarded[4].

[1] Supplementary Declaration Form 1
[2] Supplementary Declaration Form 2
[3] Supplementary Declaration Form 3
[4] Supplementary Declaration Form 4

All the attached Forms have to be personalized by appropriately changing the voices in blue italics.

Proposals are submitted by the Principal Investigator who has scientific responsibility for the Project, on behalf of the hosting Institution, which is the applicant legal entity.

The specific conditions of engagement, as declared in the "Supplementary Declaration Form 1", will be subject to clarification by the *Segreteria Scientifico-organizzativa Programma di Ricerca Regione-Università* before the peer reviewing process (and during the granting procedure as well).

Proposals must fulfil all eligibility criteria if they are to be retained for peer review evaluation.

The peer review process

Three Referees (*i.e.* independent Experts), unrelated to the Emilia-Romagna Region, will remotely perform individual assessments and marking of Proposals, following the guidelines that will be provided,

The names of the enrolled independent Experts will not made public until completion of the review process.

Any direct or indirect contact about the peer review evaluation of this specific Call between the PI (or the PI hosting Institution) and any independent Expert involved in the relevant peer review evaluation is strictly forbidden. Any such contact may result in the decision of the Emilia-Romagna Region to exclude the proposal concerned from the Call in question.

Should the judgment of reviewers be discordant with regard to one or more specific Proposal(s), a previously identified independent Committee will be gathered to reach an agreement.

Based on the outcome of the peer review evaluation, a rank order list (ROL) of Proposals for possible funding will be prepared by the *Segreteria scientifico-organizzativa Programma di Ricerca Regione-Università*, establishing the priority for funding within the limits of the budget available for the Call. The ROL will be evaluated by the Comitato di Indirizzo Programma di Ricerca Regione-Università, which is endowed with decision-making power.

Language

Please note that the **working language** of the submission and peer review evaluation is **English**. An effort should be done in writing the proposal in the most clear and effective way in order to facilitate the overall reviewing process.

General Rules

Any document or information not strictly indicated in the Form, yet deemed helpful for the reviewing process, can be attached to the official application.

Acronyms should be explicitly clarified the first time they are used, even when widely recognized (*eg* "Glasgow Coma Score, hereafter GCS"). In case the text contains a discrete number of acronyms, in addition to the aforementioned acronym explanation, it is advisable to add a "list of acronyms", either at the beginning or at the end of the Project.

For optimal reproduction, **Figures** should be submitted in b/w, avoiding grey shades and/or colours as much as possible.

References formatting: when citing articles with up to 6 authors, all authors should be listed; for articles with more than 6 authors, the name of the first 6 authors should be listed instead, followed by *et al.* The suggested format is: "Authors (Surname, Initials); title. Journal, year of publication; Volume: pages." Articles in press, or submitted and accepted for publication, may be listed among the references, provided a journal name and the DOI (or a tentative year of publication) can be verified.

Full Project Form

The Full Project Form is composed of 4 Parts:

Part 1. General information about the Project

Part 2. Description of the Project

Part 3. Detailed description of the contribution of each Research Unit

Part 4. Budget

Part 1. General information about the Project

- **Project Title** (max 200 characters[5]): Title should be as short and clear as possible to precisely identify the context, type and general aim of the Project.
- **Short title** (max 50 characters): The Short Title should allow catching the core of the Project at a glance.
- **Type of research ("biomedical research" or "clinical research")**

  "biomedical research" (*theory enhancing*) also see Italian version of Call for Proposal

  "clinical research" (*change promoting*) also see Italian version of Call for Proposal

[5] The indicated number of characters always includes spaces.

- **Keywords** (max 5): Up to 5 most relevant keywords are allowed to better describe the overall Project.
- **Health Categories:** a maximum of 3 choices are allowed among those in the following list, as defined by the UK Clinical Research Collaboration[6]
    - Blood
    - Cancer (including all Tumours types)
    - Cardiovascular
    - Congenital Disorders
    - Ear
    - Eye
    - Infection
    - Inflammatory and Immune System
    - Injuries & Accidents
    - Mental Health
    - Metabolic & Endocrine
    - Muscoloskeletal
    - Neurological
    - Oral & Gastrointestinal
    - Renal & Urogenital
    - Reproductive Health and Childbirth
    - Respiratory
    - Skin
    - Stroke
    - Genetic Health Relevance
    - Other
- **Provisional Cost of the Project:** full estimation of the total project cost, as reported under the voice "Total (€)" [Part 4 – section 5]
- **Requested Funding**: is the amount of money requested to cover, either totally or partially (in case of a co-funding), the provisional cost of the project.
- **Co-Funding(s)**: to be filled in only if applicable, *i.e.* in case the PI and/or the hosting institution have been granted other Funds to carry out activities related to, integrating/complementing, or overlapping with those foreseen in the presented Project.

[6] http://www.hrcsonline.net/

- **Expected Duration of the Project (in months)**: is the total time, expressed in months (max 36 months), foreseen to carry out all the activities and objectives until their completion.
- **Principal Investigator Contact Details**: Name & Surname; Degree (description and type of the Degree); Affiliation (hosting Institution / Organization); Position in the Organization (short job description); Address (Street, N.; Postal Code; City; State); Phone number; e-mail address.
- **Administrative Coordinator Contact Details:** Name & Surname; Affiliation (hosting Institution / Organization); Position in the Organization (short job description); Address (Street, N.; Postal Code; City; State); Phone number; e-mail address. Should the PI play the role of both scientific and administrative coordinator, only the "Name & Surname" fields have to be filled in.

Part 2. Description of the Project

Description of scientific and technical aspects of the Project, demonstrating the ground-breaking nature of the research, its potential impact, and research methodology.

- **Abstract** (max 2.000 characters): brief description of the Project broken down into: Background; Objectives; Methods; Expected Results.
- **Previous knowledge on the specific topic** (max 3500 characters): up-to-date (international) knowledge on the research topic, including at least three relevant references, possibly in the form of Systematic Reviews.
- **Newly generated expected knowledge** (max 1500 characters): briefly summarize the foreseen generated knowledge and how it is expected to address clinical and/or organizational unmet needs in the medical realm.
- **Detailed description of Primary and Secondary Objectives** (max 2500 characters): List and brief description of aims, divided into Primary Objectives and Secondary Objectives.
- **Research Methodology** (max 9000 characters): a general description of the envisaged research methodology should allow evaluating weather the Project is feasible or not. The presence/participation of a statistical/methodological unit should be clearly stated if involved in both the project set-up and the final data analysis. If applicable do specify:
    - Inclusion/exclusion criteria for individuals/patients to be enrolled in the study
    - Statistical Sample size of the target population needed to carry out the study, how it has been estimated, and time estimated for individuals/patients enrolment
    - Type of planned intervention(s), including a detailed description of technologies, specific interventions, exposure factors…..
    - Health Care/Clinical Setting: inpatient *vs* outpatient setting (inpatient setting – general hospital, (highly) specialized hospital; community hospital; local hospital; long-term health care facility….-; outpatient setting: ambulatory setting, home-based health care setting….)

- Study Design: Treatment Study (*eg* RCT, double blind CT, single blind CT) or Observational Study (*eg* cohort- / prospective- / retrospective- / time-series- / case-control- / cross-sectional-study)
- Data collection (modality and timing) and analysis: a detailed description of methods (*eg* paper/electronic medical records; current literature and/or specific archives; active follow up; evaluation by clinical personnel, patient-reported outcome….) as well as internal data validation methods (comparison between sources, comparison between data collectors…..) have to be specified. Variables and measures foreseen for controlling for confounding and bias should also be clearly stated.
- Expected Outcome(s): a distinction between Primary and Secondary Outcomes is required; mentioning unpredictable, yet possible adverse outcomes along with alternative plans, would be considered a plus.
- Outcome(s) measure system(s): list and description of the optimal system(s) envisaged for outcome(s) appraisal, motivating the choice(s).

- **Feasibility** (max 2500 characters): list of the infrastructures (*ie* facilities and main equipments), capabilities (relevant skills) and capacities (technical, organizational, ….) needed to carry out the Project, either already available at the participating Institutions, or that can be purchased as services.
- **Expected impact on the Regional Health Care System** (max 2500 characters): describe the foreseen specific beneficial effect(s) of the Proposal and how it is supposed to positively impact the Regional Health Care System in the short/medium/long-term horizon, stressing clinical practice, medical care, organizational features, and economics aspects.
- **List of Indicators to assess and measure the impact of the presented Project** (max 1000 characters): identify the most appropriate qualitative and quantitative indicators to assess and measure the impact described in the above paragraph, while explaining the choice(s).
- **Transferability of results to the Regional Health Care System** (max 2500 characters): describe how the results obtained in the relevant setting of the current study could be transferred to the Regional Health Care System, including possible limitations that might hamper transferability.
- **Outputs of the Project** (max 2000 characters): list all sort of deliverables that will be provided at the conclusion of the Project (*eg* services, clinical pathways, medical procedures, protocols, software,….)
- **Timeline** (max 3500 characters, not including the Gannt chart that has to be attached as a separate file): list of all the activities that will be carried out and the responsible participating Unit(s).
- **Bibliography**: list of max 25 up-to-date references relevant for the presented Project, as suggested in the Introduction.

- **CV of the PI** (max 3000 characters): brief description of the achievements of the PI, unequivocally and unmistakably demonstrating a promising track-record in the relevant research field. Potential for research independence and evidence of maturity should be stressed, as well as scientific leadership potential.
- **List of publications of the PI**: up to 10 significant publications in major international peer reviewed scientific journals following the guidelines in the Introduction. The PI position among the authors (listed in their original order) should be highlighted. If the PI is the 7th (or later) author in the list, please, do report all the authors. The journal Impact Factor should be indicated as well for each publication in the list. The Impact Factor must be that of the year of publication, or as close as possible if not available.

Part 3. Detailed Description of the contribution of each Research Unit (one form should be filled in for each Research Unit)

- **Name / Denomination of the Research Unit**
- **Scientific Coordinator of the Research Unit Contact details**: Name & Surname; Affiliation (hosting Institution / Organization); Position in the Organization (short job description); Address (Street, N.; Postal Code; City; State); Telephone number; e-mail address.
- **Legal Representative of the Institution hosting the Research Unit**: Name & Surname; Affiliation (hosting Institution / Organization); Position in the Organization (short job description); Address (Street, N.; Postal Code; City; State); Telephone number; e-mail address.
- **Short description of the specific and original contribution of the Research Unit to the presented Project** (max 1400 characters): briefly describe how and why the relevant participating Research Unit is essential and unique for the Proposal.
- **Research Methodology** (max 3000 characters): the same as specified in section B applies here.
- **Dedicated personnel**: list of personnel (and motivation) needed to carry out all the foreseen activities, expressed as months *per* person and full time equivalent.
- **Short CV of the Research Unit Scientific Coordinator** (max 3000 characters): including a brief description of experience and expertise in the relevant research area.
- **List of publications of the Research Unit Coordinator**: up to 10 papers relevant for the presented Project. In addition to the fields listed in Introduction, the IF should be reported as well. The Impact Factor must be that of the year of publication, or as close as possible if not available.

Part 4. Budget

This grant can cover up to 100% of the total eligible direct costs of the research plus a contribution towards indirect costs.

All voices in the following Tables have to be filled in.

1. **List of Project Personnel**: only personnel specifically enrolled for participating to the Project have to be reported here. The duration of the contract of employment cannot exceed the foreseen duration of the Project. For each personnel to be enrolled do specify: i) progressive number of the Research Unit as previously reported; ii) Title (Degree) and position (brief job description); iii) contract of employment (examples of this kind are given in the relevant footnote); iv) area of expertise & role (for the latter please, refer to the relevant footnote keeping into account that choices are not mutually exclusive); v) months per person: total time of estimated participation to the Project, as per contract of employment, expressed in months; vi) Full time equivalent: ratio of total number of (to be) paid hours during a period (part-time, full-time, other) by the number of working hours in that period, usually considered Monday to Friday. Administrative personnel can be included, yet should be considered as part-time personnel; vii) the salary foreseen for the entire duration of the Project.
2. **Instrumentation and Materials**: furniture, telephones (including mobiles), fax, and similar items cannot be included.
3. **Services**: services from institutions located outside the E-R Region are considered outsourcing.
4. **Conferences, Meetings, and Workshops**
5. **Summary of Budget breakdown**: costs previously reported have to be broken down into yearly costs.
6. **Budget Breakdown per Research Unit**: costs previously reported have to be broken down into costs ascribable to the single Research Unit(s).