Ministero Salute

The Italian Ministry of Health

REVIEWER GUIDELINES

a comprehensive guide for a SCIENTIFIC EVALUATION OF CLINICAL AND BIOMEDICAL RESEARCH PROPOSALS

The evaluation for the submitted full proposals, refers to rules provided in the calls sections. For of each criterion a scoring system from 1 to 9 will be used. **Please note** the **Maximum value = 1** and the **Minimum value = 9**. **Half marks** may be given

We would ask you to do not mention clearly the name of the researches involved in the proposal in your comments.

GENERAL DESCRIPTION

CALL CRITERION	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	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	1 – 9
Clarity and appropriateness of the project development strategy (in relation to the 3-year duration of the project)	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	1 – 9
Evaluation of the timing to reach a regular use in patient care	1-9

The scores indicate the following with respect to the criterion under examination

1	**Outstanding** -The proposal stands out for one of the following claims: exceptional novelty and or originality, renewal of science at a global level providing a cost-saving approach and/or establishing by references and presentation of material far superior capability. . **PLEASE NOTE THAT TO USE THIS SCORE, NO CRITICAL ISSUES OF ANY KIND (AT ANY LEVEL) ARE REVEALED AND REPORTED IN THE CRITIQUE.**
1.5	**Excellent Plus**
2	**Excellent -** The proposal successfully addresses the criterion, although some minor improvements are still possible.
2.5	**Excellent Minus**
3	**Very Good to Excellent Minus -** The proposal addresses the criterion very well, although some elements could be improved on.
3.5	**Very Good Plus**
4	**Very Good -** The proposal addresses the criterion very well, although some improvements are still possible.
4.5	**Good Plus**
5	**Good -** The proposal addresses the criterion well, although improvements are necessary
5.5	**Good Minus**
6	**Fair to Good -** While the proposal broadly addresses the criterion, there are some shortcomings

6.5	**Fair Plus**
7	**Fair -** The proposal poorly addresses the criterion or there are evident weaknesses
7.5	**Fair Minus**
8	**Weak -** The criterion is addressed in an inadequate manner or there are serious inherent weaknesses
8.5	**Poor to Weak**
9	**Poor -** The proposal fails to address the criterion under examination or cannot be judged due to missing or incomplete information.

SPECIFIC GUIDELINES FOR EACH CRITERION

In each written comment with a matching score of 2 to 4 it is important to clarify which specific aspects of the project require improvement.

CRITERION 1

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

From 1 to 2: this score reflects an excellent application, which fulfils the following criteria:

- The application includes a thorough review of the current scientific literature on the subject, providing an accurate analysis of the existing theories and concepts and demonstrating the importance of the proposed project to fill the gap in current knowledge.
- The project is highly innovative and original, with great potential for the development of new scientific knowledge, new ideas and approaches, new directions for research and for improved understanding of healthcare and illness.
- The project includes the use of novel technologies/methodologies, and/or innovative application of existing methodologies/technologies in new areas.
- The project can be regarded as unconventional and challenges prevalent opinion or practice.
- The project has obvious translational potential; for instance, upon its successful execution, it will provide essential information to unravel physiopathological processes that are important for therapy development, or that will lay the foundation for the development of future therapeutic strategies, new diagnostic tools or equipment to be used in healthcare.
- The project will certainly provide findings that can be translated into health gains where differences in score are only determined by the relevance of the outcomes. For instance, results directly influencing healthcare should be seen more positively.
- An outstanding score indicates for novelty a new approach or methodology while for originality a science that may already be known and with a relevant update respect to others works.

From 3 to 4: the project presents a good level of novelty and originality. There is some potential for translation but it will not be easy to achieve; amendments to the research plan and/or additional experimental evidence will successfully overcome weaknesses.

From 5 to 9: The project lacks novelty and originality. It also shows no or low potential for translation.

CRITERION 2

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

This criterion considers whether the project addresses important issues with feasible outcomes and potentially relevant effects on scientific knowledge and/or methods, technologies, treatments, services or preventative interventions involved in clinical practice.

From 1 to 2: this score reflects an excellent application, which fulfils the following criteria:

- The proposed study has great potential for increasing the opportunity of providing new treatments in the future (in line with the mission of the Italian Ministry of Health) and its consequences on biomedical sciences are clear, as is its potential impact on human health.
- The aim of the research proposal is a relevant issue and it is focused and clearly stated.
- The project is of outstanding scientific quality; it is built on solid experimental evidence and is focused on a highly relevant scientific subject.
- The research plan is well written, realistic and highly feasible.
- The scientific/intellectual merits of the proposed research are clear, convincing and compelling.
- The methodology is appropriate for the project objectives and fully consistent with the skills. The application is realistic and highly feasible within the proposed timeframe (the biostatistical strategy is current).
- The general design, including time schedule, is optimal for implementing the project. In the case of clinical trials, the number of patients to recruit should be coherent with the study design.
- The project is very well written and presented and is fully understandable.
- Risk analysis of possible problems to resolve and the relevant solutions to be found has been thoroughly addressed.
- The project has high translational potential, with a potentially broad impact on healthcare.

With reference to **the young researchers (GR)**, the following criteria should be added:

- The execution of the project is clearly coherent with the candidate's career progression and it lays the foundation for a solid and independent research line and future grant applications. It also has full potential to generate important outcomes in line with the candidate's expertise.

With reference to the projects involving **Italian Researchers operating abroad** (**PE**) the following criteria should be added:

- The team members are appropriately organised and the tasks and responsibilities are well distributed. Their expertise is perfectly complementary.
- The cooperation gives added value to the research and could lead to the transfer of knowledge between applicants.
- The three-year collaboration could lead to the establishment of new research ties.

From 3 to 4: the application is very good, yet fails to fulfil important criteria listed in the previous paragraph. The proposal requires adjustments.

From 5 to 9: the application shows critical flaws.

CRITERION 3

Clarity and appropriateness of the project development strategy (in relation to the 3-year duration of the project)

From 1 to 2: this score reflects an extremely well designed and well laid-out experimental plan, includes an adequate contingency plan.

- Framework, methods, design and analyses are clearly described, adequately developed, thoroughly integrated, well-reasoned and totally appropriate.
- Milestones, timetable and outputs are clearly stated and suitable and are coherent with the study design
- Where applicable, the sampling is appropriate and adequate, with the indication of the approximate values regarding the size of the sample required and the assurance that enough subjects will be studied to provide sufficient information. Correct biostatistical information is mandatory for this evaluation score.
- Participants, events and similar study features are selected to maximize appropriate information.
- The strategy for data collection is clearly stated and suitable. A rationale for methodological choices is provided. The framework is adequate, in view of the aims of the study.
- The project takes into consideration any potential problems that are likely to arise during the risk analysis section. Alternative strategies and benchmarks for success are considered with sufficient flexibility in the study-design and timeline in order to change course should a problem occur.
- A thorough investigation is presented, providing not only the potential findings but also an exhaustive analysis of the existing data**.**
- The project takes advantage of particularly powerful technical resources, for instance particular models, or unique sample repositories, or cutting-edge technologies.
- Involvement of vertebrate animals: the use of animals and the appropriateness of the species and number proposed are justified; the veterinary care is adequate; procedures are taken to limit discomfort, distress, pain and injuries.

From 3 to 4: the section has some flaws, for instance the profile of the applicant might not be fully compatible with the proposed methodology, thus compromising the feasibility of the project. Alternatively the project might rely on sub-optimal models.

From 5 to 9: the project is unrealistic or is based on obsolete techniques and inappropriate models. Overall, the methodology is weak.

CRITERION 4

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

From 1 to 3: The project involves relevant personnel, skills, equipment, facilities/infrastructures and any other necessary resources. The request for the participation of one or more subcontractors in the financial plan should invite the reviewer to reflect on the possible evaluation of 1-3 of the criterion under consideration. Indeed, the necessity for subcontractors indicates the lack, whether partial or total, of adequate resources in the host institution.

- An outstanding score indicates a total autonomy regarding the availability of internal relevant personnel, skills, equipment, facilities/infrastructures, without a necessity for subcontractors and or external facilities.

From 4 to 5: The personnel, skills, equipment, facilities/infrastructures involved in the project are not sufficiently adequate.

From 6 to 7: The proposed infrastructure, equipment and fieldwork are barely sufficient.

From 8 to 9: The proposed infrastructure, equipment and fieldwork are insufficient**.**

CRITERION 5

Evaluation of the timing to reach a regular use in patient care

Score 1 to 1,5: The project result, at the end of it, permit to be transfer immediately to the patient care.

From 2 to 3,5: The project results, at the end of it, need additional clinical trials to transfer them to the patient care

From 4 to 5,5: The project results, at the end of it , need additional knowledge to be obtained by one additional project research proposal to transfer them to the patient care.

From 6 to 7,5: The project results, at the end of it , need additional knowledge to be obtained by more other additional projects step to transfer them to the patient care.

From 8 to 9: the project proposal results are not clear when it's possible to transfer them to the patient care**.**