EVALUATION OF HEALTH SCIENCES RESEARCH PROJECTS

The National Evaluation and Foresight Agency's Perspective

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Preface

Victoria Ley Vega de Seoane, Director of ANEP

One of the keys to scientific progress is the correct allocation of resources for research, both public and private. In 2006, aware of its responsibility in this regard, the National Evaluation and Foresight Agency (ANEP) began a series of studies to identify evaluation criteria in scientific fields in which a lack of definition of these criteria were noted or which had characteristics that required refinements to be introduced in the application of evaluation criteria normally used in areas with a long tradition in research. Thus, in September 2006 conclusions regarding the Criteria for Evaluating Technological Merit were presented; in January 2007 the document prepared by the Working Group on Identifying Quality Criteria in Humanities Research was presented; and in 2008 the document relating to the evaluation of Social Sciences. Researchers from public and private institutions were involved in these working groups, including some foreign experts. The documents have been produced from an initial analysis carried out by the group and from suggestions and comments made by other scientists and managers from relevant institutions within each scientific field.

This document contains the evaluation criteria for assessing projects and the scientific production of researchers in the field of Health Sciences. While the areas of Life Sciences can be considered scientific with a long tradition in applying evaluation criteria, in the area of Health Sciences (and particularly with regard to matters that are closest to Clinical Medicine research), these criteria are not as well defined. In this field, the evaluation criteria must correspond to those aspects of scientific activity that lead to progress in knowledge or application of this in pathology diagnosis or therapy, improving health and ultimately, development and social welfare. Similarly, the importance of translational research has been taken into account as well as the involvement of clinical professionals in scientific research work.

These criteria are designed to be used in peer review evaluation processes, which are based on expert evaluation using objective criteria, but bearing in mind that, in certain cases, their providing opinions and experience is essential to modulate the evaluation that would otherwise involve merely applying a mathematical formula. Moreover, these criteria should be fully comparable to the criteria used in the scientific evaluation agencies in developed countries.

Our aim is for anyone conducting research in the field of Health Sciences - including students, PhD students, technicians and clinicians - to be aware of the criteria by which their activity is evaluated. We also hope that this document is of interest and is applicable to managers of medical and scientific institutions, universities, research centres and institutions involved in managing and evaluating scientific activities.

By identifying these criteria, we aim to: make the evaluation process more transparent and objective, facilitate the proper allocation of resources for research and, more importantly, help boost the quality of research in these areas.

Finally, it is important to note that this document is dynamic and its contents must be reviewed when appropriate or otherwise required by changing practices in research, publication and dissemination of scientific advances.

As Director of ANEP, I want to thank everyone who has participated in some way in this work, in particular the working group members, but also all the researchers, clinicians, teachers, managers and scientific policymakers from other agencies who have shown interest in this document and who have provided important ideas, suggestions and criticisms.
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This document has been written from the perspective of the National Evaluation and Foresight Agency (ANEP), driven and supported by the Agency's director. The people involved in drafting this document regularly work with the Agency, (particularly in recent years), and have also had access to the critical analysis of other researchers and managers, who have been kind enough to read and edit the document, adding significant improvements in all cases.

1. THE EVALUATION PROCESS AT ANEP

ANEP evaluates multiple proposals related to research - from research projects to personal or infrastructure applications. At all times, it tries to ensure that evaluations are conducted by experts in a particular field of knowledge, and aim for at least two people to evaluate each proposal. Experts evaluate proposals in isolation and do not have comparative criteria. This means that they may issue different judgements. As part of a second stage, ANEP’s coordination teams analyse the evaluations for a given project, and in turn all the proposals for a particular call for applications, aiming to standardise the evaluation process.

ANEP has defined three areas of evaluation in the field of life and health sciences. This definition is based mainly on the proximity of the research projects that are considered for research into humans. The evaluation process of any of these projects must be superimposed in general terms, but depending on the type of research work to be done, there will be peculiarities that must be taken into account.

2. PURPOSE OF THIS DOCUMENT

The aim of this document is to improve the objectivity and uniformity of evaluations. It should help to minimise any discrepancies that exist in the analysis of a given project by different experts, whilst meeting the quality criteria of the various coordination teams. It is not intended as a rigid element of analysis, but rather a working environment that facilitates the evaluation work, at all times respecting the individual opinion of the experts in their particular area of expertise.

3. ASPECTS TO BE EVALUATED

The definition of this depends on the financing agencies, but the criteria are agreed with ANEP. These criteria include:

- Evaluation of the person or persons involved.
- Evaluation of the quality and feasibility of the proposal.

These sections can be grouped in a variety of ways, sometimes including additional criteria.
4. THE EVALUATION

4.1 Formal aspects of the evaluation report

There are three general rules to take into account:

- The evaluation should include a description part, containing comments about the characteristics of the project or the research group with reference to a specific section; and an evaluation part, where a reasoned judgement on the quality of that specific aspect of the project is provided. Wherever possible, it is also advisable to highlight the strengths and weaknesses of each section, and in particular the proposal overall.

- Each section must be analysed individually, and should ensure that the criteria issued are not repeated in the different sections to be evaluated. This avoids unnecessarily penalising or overrating a given project.

- There must be consistency between the report that is issued as free text and the quantitative or semi-quantitative scores.

4.2 Evaluation of project participants

All research proposals of all types are assigned to a lead or principal researcher (PR). The majority (though not all) proposals are also supported by a working team. The evaluation of all these people must refer to a limited timeframe, generally set by financing agencies. However, ANEP deems this to be about 10 years, with particular reference to the last six years.

4.2.1 Evaluation of the PR

Evaluation of the PR must be made from a joint analysis of their scientific productivity and their ability to develop research projects. In some calls for applications, the PR's and group's training capacity is also requested. This must be done based on the proven track record in this regard.

4.2.1.1 Scientific productivity

*Comments on publications and transfer of knowledge*

The evaluation should be conducted based on analysis of original research articles published in journals included in standardised international registers. Publications and supplements and reviews should not be considered as original articles, regardless of whether or not they are peer reviewed. Publications of abstracts, conference presentations, case reports and letters to the director should be given a minimum value, except for emerging researchers or in special areas with limited research dissemination activity.

Two very important aspects in the evaluation of publications are the quality and degree of participation in them. The quality should be evaluated based on the bibliometric indicators used (JCR). Special attention should be given to those publications in the first quartile, and even more so those in the first decile,
of their area of expertise. An author's most important publications are those in which he/she appears as the lead or principal author (PA). This is the case where he/she features in first or last position, when he/she is certified as sharing the first or last position or when he/she is the "corresponding author. Showing as being in second position means that he/she should be analysed in terms of the characteristics of the research work and the environment in which the work is carried out. Also important is the number of citations (not self-citations) for a given article.

Evaluation of the transfer of knowledge must be based on patents and products transferred to clinical practice (clinical guidelines). In the case of patents, those that are currently in operation or are newly licensed will be taken into account, with other accredited patents being assigned a much lower value. In the case of "clinical guidelines", an evaluation must be done of their level of dissemination, their practical importance and the quality control to which they have been subjected, when assigning more or less importance to them.

**Quantifying productivity according to publications**

In general, a maximum score (100%) will be awarded to a researcher who publishes regularly in journals included in the JCR, appearing as PA in first-quartile publications (an average of 1-2 publications a year), with some of these within the first decile (an average of 1 publication every 1-2 years). An average score (50%) will be awarded to a researcher who publishes regularly in journals included in the JCR (an average of 1-2 publications a year), appearing as PA in 2 publications in the first quartile.

**These criteria are meant as guidelines** and the experience of the reviewers or other additional criteria (such as the impact on the scientific community) can act as modifiers. Furthermore, in certain areas where there is limited research-dissemination activity - such as nursing or primary care - these criteria must be modulated. In the end, depending on the quality, quantity and authorship of publications, a general score will be assigned for this section on productivity.

**Final quantification of scientific productivity**

The score given to publications should be amended according to the following criteria:

- Researchers who have made very significant contributions in their field of knowledge or who have published articles that have a special impact on the scientific community: maximum rating.
- Researchers who publish in general science magazines, outside their own area of knowledge: improves their rating.
- Researchers with significant activity in the field of knowledge transfer: significantly improves their rating.
- Researchers with a short research career: adapt the assessment to the period assessed.
- Researchers with an extensive research background career, with few publications as PA: reduce the rating.
- Researchers who publish regularly in areas of low scientific impact, not related to their main activity: reduce the rating.
- Researchers who are not accredited as PR on any publication: should not receive a favourable evaluation as PR for projects
- Researchers with care activities who regularly conduct research: improve the rating, provided that the call for applications does not do so specifically.
4.2.1.1 Ability to develop research projects

Comments on the projects

Only projects funded under competitive calls for applications will be considered. The relevance of these will be graduated according to the following scale:

- European and national projects
- Autonomous community projects
- Other projects

Assessment of the ability to develop projects

A maximum score (100%) will be awarded to a researcher who is a regular PR on national or European projects (an average of one project every 3-4 years). An average score (50%) will be awarded to a researcher who has been PR on other projects, including at least one for autonomous communities.

According to these guideline criteria, the number of them, the financing agency and whether or not the researcher is PR, an overall score for the projects will be assigned.

Final evaluation of the ability to develop projects

Especially high rating should be awarded to researchers who receive EU funding on a regular basis, acting as leader for the project, and those who obtain private funding that culminate in the accredited transfer of knowledge ( patents, clinical guidelines).

4.2.1.3 Overall evaluation

The overall assessment of the PR will be based on the joint consideration of sections 4.2.1.1 and 4.2.1.2. A weighting of 70% will generally be attributed to the "publications" section and 30% to the "projects" section. However, this will need to be qualified, according to certain peculiarities:

- Researchers demonstrating excellent scientific productivity (according to the criteria set out in paragraph 4.2.1.1) but without funded projects should not be penalised for this. In fact, the final score could be increased.
- Researchers who receive regular funding for their projects but limited scientific results, or results of poor quality, should be penalised, with the final score awarded being reduced.

4.2.2 Evaluation of the research team

This should be done according to the productivity of individual researchers involved in the proposal (50%) and how well suited the team is to the tasks set (50%). The evaluation of individual researchers involved in the project must be based on the criteria set out for PRs, although not as demanding and considering them as a whole. Indeed, in the case of students, residents and PhD students, scientific production should be evaluated in the context of their professional career, and the group must in no way be penalised as a result of including these personnel undergoing training. Suitability should be based on the team's ability to carry out the objectives presented in the project.
4.3 Evaluation of the scientific quality and feasibility of the proposal

4.3.1 General Comments

In the process of evaluating a project, it is normal practice to decouple analysis of the quality from analysis of the feasibility, with more weight being given to quality than feasibility. However, it is difficult to evaluate these two aspects fully independently. For the analyses to be independent, the evaluation of the feasibility should focus on analysing the logistical aspects that may in one way or another determine the development of a proposal.

With regard to the analysis itself, formal and substantive aspects must be considered jointly; however, the latter must prevail over the former.

In addition, the nature of the proposed research should be taken into account, given that evaluating a clinical project is not the same as evaluating a basic research project.

4.3.2 Aspects to consider when evaluating scientific quality

4.3.2.1 Novelty, originality and innovation of the proposal

This is an essential aspect in Fundamental Biology and Biomedicine projects. Indeed, a project in these areas may be formally impeccable but negatively rated due to lack of originality. In the field of Clinical Medicine, projects that tackle confirmatory studies or studies that are similar to those already conducted among other populations or very closely related pathologies may be valid - provided the need for them has been properly justified. The risk in formulating proposals should not be viewed negatively, if it is supported by a research group that has a good scientific background.

4.3.2.2 Relevance, interest and applicability of the proposed

Biomedicine and Clinical Medicine projects should aim to provide specific answers to health problems. Therefore when evaluating them, an important aspect is that they should focus on relevant pathologies - not just on the basis of their frequency but rather their impact in terms of society/health and human. The research proposed should be capable of application, although the period of time for such applicability may not be the same for Biomedicine projects as clinical studies. In this applicability section, and evaluation should be done of the potential of a project to obtain results that can be transferred to the diagnosis/therapeutic area, or its potential to generate patents. The support of a company/business - especially if it is economic in type (budget to cover part of the project, staff, reagents, raw materials) - should be rated very positively. Among the sections to be quantitatively analysed, some financing agencies request a specific assessment of the "applicability." In this case, the analysis discussed here should not be taken into account when evaluating quality.

4.3.2.3 Suitability in formulating objectives

Although this is an apparently formal aspect, clear non-redundant objectives that are free from conceptual and methodological formulations, and are quantifiable where possible, demonstrate a clarity of concepts that will facilitate the development of the proposal. Wherever possible, a categorisation under "Main Objective" and "Secondary Objectives" is recommended, especially in clinical research projects.
4.3.2.4 Conceptual approach

Analysis of the context in which the proposed research is to be carried out must be well established, and enable the proposed hypothesis and objectives to be easily inferred. The bibliography provided must be correct and generally up-to-date. A project should be especially well rated if the applicants provide proof of previous experience in the area - whether this is through articles that have already been published or through preliminary data about the project that is proposed.

4.3.2.5 Methodological approach

In methodological evaluation, there is a radical difference among life sciences projects, based on whether or not studies on humans are included. In general, all projects must demonstrate that a) that the study sample is valid for the proposed objectives, b) the methods to be developed are accessible for the group, c) the project conforms to ethical standards, and d) any possible contingencies and biases that may limit the validity of the results obtained have been considered.

It is especially important in Fundamental Biology and Biomedicine projects that researchers prove their ability to develop technical proposals. This requirement may however be bypassed if a) the group has experienced central support services, b) it is proposed to contract out the implementation of these considerations, c) it is proposed to incorporate experienced researchers, or d) it is proposed to work with expert groups that can verifiably prove their availability for this collaboration work.

In the case of projects where studies are conducted on humans, the characteristics of the sample and certain very specific aspects of experimental design should be taken into account, as shown on the table below, which refers to three types of projects, depending on their quality.

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Optimal</th>
<th>Intermediate</th>
<th>Minimal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection</td>
<td>Cited and correct</td>
<td>Can be reasonably deduced</td>
<td>Not cited and cannot be clearly deduced</td>
</tr>
<tr>
<td>Sample</td>
<td>Cited and correct</td>
<td>Can be reasonably deduced</td>
<td>Not cited and cannot be clearly deduced</td>
</tr>
<tr>
<td>Sample size</td>
<td>Cited and correctly estimated</td>
<td>Cited and based on previous reasonable experience</td>
<td>Not cited</td>
</tr>
<tr>
<td>Design</td>
<td>Cited and correct</td>
<td>Can be reasonably deduced</td>
<td>Not cited and cannot be clearly deduced</td>
</tr>
<tr>
<td>Variables</td>
<td>Cited and explained</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Plan of analysis</td>
<td>Cited, explained, and aligned with the objectives</td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

A special case is that of projects that include studies on humans in a way that is complementary to other studies under different experimental models. In these cases, although the criteria listed in the Table must be taken into account, the analysis should not be as exhaustive and the evaluation should take place in the overall context of the proposal.
ANEP Evaluation of Health Sciences Research Projects

An important consideration in certain research projects is the ability of applicants to establish coherent relationships between the proposed objectives and the proposed methodology. Projects in which the methods consist merely of a list of techniques, without a clear relation with the objectives, can demonstrate a lack of knowledge about the reality of the proposed research.

4.3.3 Aspects to consider in evaluating feasibility

4.3.3.1 Compatibility of objectives and methodology with the characteristics of the group

This is a complex point, because both the group and the methodology have already been evaluated. In this section, we need to consider whether, from a strictly organisational point of view, the group making the proposal is capable of tackling it.

4.3.3.2 Suitability of the distribution of tasks

This aspect is closely related to the previous one, and reflects that there is a plan to organise the implementation of the proposed tasks.

4.3.3.3 Suitability of the work plan

The work plan tends to reflect the clarity of ideas and the group's previous experience. This section should rate positively any mention of anticipated difficulties/problems during the project, along with proposed alternatives to resolve potential problems.

4.3.3.4 Suitability of the work environment and equipment available

Some projects are dependent upon specific types of support (radioactivity service), equipment (instruments) or tools (animal models) to which the group does not have access when writing the proposal. In this case, the availability of such requirements when the research work begins must be stated explicitly and verifiably in the project proposal to avoid financing projects whose objectives may be unachievable. The case of animal models is particularly relevant. The need for these should be calculated (number of animals) and the project proposal should certify that a sufficient supply will be available for the project to be conducted (establishment of the researcher's own colonies or guarantees of supply on the part of the collaborating group).

4.3.3.5 Suitability of the budget

A reasonable budget is essential to evaluating the feasibility. However, analysis of this should be included in this section only where the financing agencies do not request an independent, quantitative or semi-quantitative evaluation of the budget.

4.4 Relative importance of the criteria to evaluate: the balance between the group and the research project

Financing Agencies, in agreement with ANEP, quantify the relative importance of these criteria, such that the final evaluation of a research proposal will be the weighted sum of each of its parts. However, a proposal should not be reported favourably if:

- The quality of the proposal does not exceed 40% of the established standard.
- The feasibility does not exceed 40% of the established standard.
The joint evaluation of the PR and the research group does not exceed 40% of the established standard except in calls for applications for young researchers or emerging groups or when looking for a specific profile of PR.

5. **FINAL CONSIDERATIONS**

The attached chart attempts to summarise the integrated assessment process. In some parts of the chart, a weighting for each item is proposed. In others, those marked with a "1", the importance of each item will be determined by the evaluating agencies in conjunction with ANEP. The quantification of the productivity will be based on publications ("2"), but this score should be modulated according to the transfer activities ("3"). The productivity of the research group must be done in an integrated manner("4").