Evaluating Applications Under NIH's Simplified Review Framework for Research Project Grants

INTRODUCTION

The goal of peer review is to provide expert advice to NIH on the scientific and technical merit of grant applications to inform their funding decisions. Peer review has two important outputs:

- 1. The written evaluation (for all applications)
- 2. The impact score, and, if applicable, the percentile (for discussed applications only)

Who is the audience for your critique?

The primary audience for your critique is the funding NIH Institute/Center's Advisory Council and staff. An important secondary audience is the other reviewers who will be reading your critique to understand what drove your assessment of overall impact. The applicant will also read your critique, but this should not diminish your candor, nor lead you to make recommendations for improving the application.

General guidance for writing effective critiques:

- Provide a clear and candid write-up of the strengths and weaknesses of the proposed research project.
- Focus on what drove your assessment, not on minor points.
- Explain the basis for your score.
- Evaluate the application as it is presented. Do not attempt to improve or redesign the application.

General scoring guidance:

- Scores are assigned for Factor 1, Factor 2, and Overall Impact.
- NIH uses a 9-point scale (1= exceptional; 5= average; 9= poor).

Factor Strength/Overall Impact	High	Medium	Low
Score	1 2 3	4 5 6	7 8 9

The <u>Simplified Review Framework</u> asks you to address three fundamental questions regarding the proposed scientific research project.

Factor 1: Should it be done?
Factor 2: Can it be done well?

Factor 3: Are the expertise and resources in place to do it?

FACTOR 1: IMPORTANCE OF THE RESEARCH

"Should it be done?"

Evaluate how the proposed project, if successfully completed, would advance the field (Significance). What will be learned and how valuable will that knowledge be?

Evaluate the novelty of the project (Innovation) and the extent to which that novelty influences the importance of the research.

- For some projects, the development of new conceptual models, technologies or methods is precisely what makes the research important. Alternatively, a high degree of innovation can amplify the importance of a significant project.
- For other projects, the importance derives from the application of existing methods to answer a critical question; in this context, the absence of innovation does not detract from the importance of the research.

Note that Importance of the Research refers to the importance of the <u>proposed research</u>, not the importance of the research field or disease.

NIH has a broad scope, including basic and mechanistic research, non-hypothesis driven work, method and technology development, different model systems, rare diseases etc. Do not introduce scientific bias by under- or over-valuing certain types of research.

FACTOR 2: RIGOR AND FEASIBILITY

"Can it be done well?"

Evaluations of Factor 2 should always include comments on both rigor and feasibility. Comments should focus on important issues rather than technical minutia.

When assessing rigor, evaluate whether the proposed approach will produce unbiased, reproducible, and robust data.

Evaluate the strategy for handling potential challenges to feasibility, but don't expect detailed plans to address every possible obstacle. All research has a risk of failure, so it is important that reviewers thoughtfully *evaluate* risk in the context of the potential for major advances rather than seek to eliminate it.

When you evaluate the rigor and feasibility of the study design and methods, avoid assessing personnel effort (this belongs in the Budget) or the qualifications of the investigators/availability of resources (those belong in Factor 3).

• For example, "It does not seem feasible to recruit the targeted number of participants based on the rates of disease" would be an appropriate comment because it evaluates the study design, whereas "This team of investigators lacks experience in recruiting this difficult-to-reach population" would not be appropriate in Factor 2 because it evaluates the expertise.

Scoring Factors 1 & 2:

- Scores in the high range (1-3) should be based on strengths, not merely the absence of weaknesses.
- Scores in the low range (7-9) should be based on weaknesses.

FACTOR 3: EXPERTISE AND RESOURCES

"Are the expertise and resources in place to do it?"

Evaluate the qualifications of the investigative team in the context of the proposed research project.

- If there are any gaps in the expertise or background/training of the investigator/team relevant to the likelihood of the project being successfully completed, choose "additional expertise and/or resources needed" and add specific comments to describe the gaps.
- Your comments provide critical input to the NIH. We rely on your candid assessment of any gap in expertise or training that would impact successful completion of the project.

Examples:

- The investigative team includes expertise in computer simulations, modeling, statistics, informatics, and data analytics, but the absence of a cell biologist as a collaborator could hamper the accomplishment of Aim 3, which relies on an understanding of cell structure and function.
- The multi-disciplinary team includes experts in older adults, memory disorders, and clinical trial design and analysis, but there are concerns about their ability to complete the study given that no one on the team has experience recruiting this challenging population for such a complex, multi-layered clinical trial.

Evaluate the institutional resources available to the investigative team to carry out the proposed research. If there are any gaps in the resources that would affect the successful execution of the proposed research, choose "additional expertise and/or resources needed" and add specific comments to describe the gaps.

Examples:

- The team lacks access to electroencephalography equipment which is crucial for completing the project.
- For this large clinical study, the lack of an onsite recruiting center reduces the likelihood of achieving sufficient patient participation.

If sufficient expertise and resources are in place to do the proposed research, choose "appropriate". No comments are allowed.

The following considerations must not affect your evaluation:

- The investigator's scientific independence, funding status, academic title, or appointment type (e.g., tenure vs. research track)
- The general reputation of the investigator or institution

ADDITIONAL REVIEW CRITERIA

- Protections for Human Subjects, Vertebrate Animals, and Biohazards: Comments are required if there are concerns.
- Resubmissions, Renewals, and Revisions: Describe major strengths/weaknesses, if any.

OVERALL IMPACT

Scoring overall impact:

- Your Factor 1 score should set a limit for the best possible overall impact score. This is because a project of moderate or limited importance (Factor 1) cannot logically be made more impactful by a strong approach (Factor 2) and/or appropriate expertise and resources (Factor 3).
- Factors 2 and 3 should both be thoroughly considered in arriving at the overall impact score and can either reinforce the score set by the Factor 1 limit or worsen it. If there are weaknesses in Factor 2 or gaps in Factor 3, judge how much of a shift towards a worse score is warranted.
- Do not average Factor 1 and 2 scores to arrive at an overall impact score.
- Concerns relating to the Additional Review Criteria can move you towards a worse overall impact score. If there are no concerns, these evaluations should reinforce the overall impact score you arrive at after considering the three factors.

Writing the overall impact paragraph:

- Explain how you arrived at your overall impact score based on the scoring guidance above.
- Always comment on Factors 1 and 2, noting only the major strengths and weaknesses that drove your overall impact score.
- If there are gaps in expertise and/or resources (Factor 3), explain how they affected your overall impact score.
- If Factor 3 is rated as appropriate, a comment such as "The necessary expertise and resources to accomplish the aims are in place" could be noted. Specific comments praising the investigators/environment are not appropriate.

Release date: March 14, 2025