

NIH Simplified Review Framework: Insights from Study Section

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Five regulatory criteria reorganized into three factors

For due dates before Jan
25, 2025

(all considered in overall impact
score)

- **Significance** - scored
- **Investigator(s)** - scored
- **Innovation** - scored
- **Approach** - scored
- **Environment** - scored



For due dates on/after Jan
25, 2025

- **Factor 1 : Importance of the Research**
 - Significance, Innovation
 - Scored 1 - 9
- **Factor 2 : Rigor and Feasibility**
 - Approach (also includes Inclusion and Clinical Trial (CT) Study Timeline)
 - Scored 1 - 9
- **Factor 3 : Expertise and Resources**
 - Investigators, Environment
 - Evaluated as appropriate or gaps identified; gaps require explanation
 - Considered in overall impact; no individual score

Additional Review Criteria (can affect overall score)**Additional Review Criteria Before Jan 25, 2025**

- Human Subject (HS) Protections (for HS and CT)
- Vertebrate Animal Protections
- Biohazards
- Resubmission/Renewal/Revisions
- Study Timeline (for CT only)*
- Inclusion of Women, Minorities, and Individuals across the lifespan (for HS and CT)*

**Revised Additional Review Criteria**

- Human Subject Protections (for HS and CT)
- Vertebrate Animal Protections
- Biohazards
- Resubmission/Renewal/Revisions

*Incorporated into Factor 2

Additional Review Considerations (no effect on overall score)**Additional Review
Considerations Before Jan 25,
2025**

- Applications from Foreign Organization†
- Select Agent Research†
- Resource Sharing Plan†
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period of Support



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- Budget and Period of Support

†Review shifted to NIH staff

From a Reviewer's Perspective

The Simplified Review Framework 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?*

From a Reviewer's Perspective

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

Consider the entire range.

Review Guidance

Factors 1 & 2:

- Scores in the high range should be based on strengths, not merely the absence of weaknesses.
- Scores in the low range should be based on weaknesses.

Factor 3:

Give a binary rating:
Appropriate or Additional expertise and/or resources needed (if gaps are identified).

Overall Impact Guidance:

Logically, a project of moderate or limited importance (Factor 1) cannot be made more impactful by a strong approach (Factor 2) and/or appropriate expertise and resources (Factor 3).

- Your Factor 1 score should set a limit for the best possible overall impact score.
- Your assessment of Factors 2 and 3 can reinforce this score or worsen it.
- Concerns with the Additional Review Criteria can move you towards a worse score.

What this means in practice...

- Importance of the Research (Factor 1) is the score-driving criterion!
 - The Overall Impact Score cannot be better than your Factor 1 score
- Focus on the *Significance* of your research, first and foremost

What this means in practice...

- For *Innovation*, focus on how the research will address a **specific gap** and move the field forward
 - Technical innovation (e.g., state-of-the-art technologies) has been de-emphasized
 - In other words, lacking technical innovation should not be viewed by reviewers as a negative

What this means in practice...

- Rigor and Feasibility (Factor 2) can either reinforce or drive down your Overall Impact Score
 - A strong study design in your *Approach* is still absolutely necessary but cannot rescue an unimportant research question
 - Details from your *Human Subjects and Clinical Trials* forms are now scored – give them the appropriate attention!

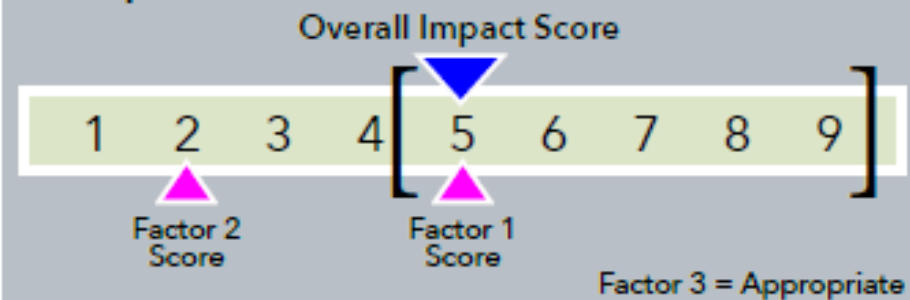
What this means in practice...

- Expertise and Resources (Factor 3) is evaluated as either appropriate for the study or not
 - Since these components are no longer scored, it reduces the bias previously seen in *Investigator* and *Environment* evaluations
 - Reviewers must explain specific gaps if they identify any
 - If gaps are identified, they can drive down your Overall Impact Score

Review Guidance

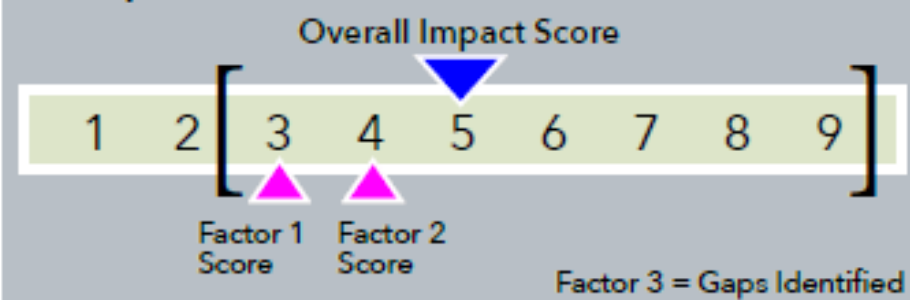
Overall Impact Scoring: Examples

Example 1:



Because the importance of the research (Factor 1) is seen as moderate, a strong approach (Factor 2) and/or appropriate expertise and resources (Factor 3) cannot be expected to improve the overall impact score.

Example 2:



The importance of the research (Factor 1) is seen as strong, yet a moderate approach (Factor 2) and/or gaps in expertise and/or resources (Factor 3) can worsen the overall impact score.

Other Notes

- Most likely that study sections are virtual to increase efficiency
- Overall, study section meetings are shorter and each proposal is getting less discussion time
 - Getting discussed *at all* is so important
 - Your proposal's fate is very much in the hands of your assigned reviewers
- After assigned reviewers give feedback, the rest of the group is most likely to identify additional weaknesses, if there is any commentary

Other Notes

- If your proposal is not discussed due to a lack of *Significance*, you will need to reframe to improve Factor 1 scores
 - Highly suggest getting new eyes on the revised proposal before resubmission
 - This is a good opportunity for a mock review
- In study section review, gaps in Factor 3 are rare among proposals that are discussed
 - Factor 3 generally isn't mentioned at all, unless there are gaps
 - Reviewers are reminded not to mention the investigators' track record unless for a renewal application

My take aways

- Proposal writing 101.
- Write for a general audience.
- Significance is the single most important review criterion.
- Get feedback on your proposal!
- Be thoughtfully responsive when resubmitting.
- Early career investigators: you all are doing some really cool, impactful work!
- Keep submitting proposals.