

Writing effective critiques for NIH research applications

This document provides information for reviewers on preparing critiques that best support informed funding decisions by institutes and give clear feedback to investigators. It includes fictitious examples of weak and strong comments for each major section in the critique template; points highlighted in red around the periphery elaborate on why comments made in the critique are considered effective or not.

General guidance for all sections of the critique:

- Avoid general comments and provide specific details.
- Provide sufficient context to orient comments (e.g. does the comment refer to a specific aim?)
- Make sure bullets have evaluative statements that indicate your assessment of a particular aspect of the application.
- Make sure that the text within each section is consistent with the [score](#).
 - Scores of 1-3 should be supported by clearly articulated strengths.
 - Scores of 4-6 may have a balance of strengths and weaknesses.
 - Scores of 7-9 should be supported by clearly articulated weaknesses (or lack of strengths).
- Address all relevant review criteria and critique sections (e.g. many applications require evaluation of issues in addition to Overall Impact, Significance, Investigators, Innovation, Approach, and Environment).
- Include attention to Rigor and Transparency in research (rigor of prior research, scientific rigor, consideration of biological variables including sex, and biological/chemical resource authentication), as appropriate for the research questions.

Overall Impact

Overall Impact: *What is the likelihood of the research to exert a sustained, powerful influence on the research field?*

Write a paragraph supporting the overall impact score that should contain the following:

- Introduce the general objective of the project in one sentence to orient reader.
- State the level of impact the application is likely to have and why (what is the major contribution/advance to be gained?).
- Identify what the **major** score-driving factors were for you.
- Explain how you balanced/combined/weighted the various criteria in the overall impact score.

This is the MOST important part of your review. It comes first but is based upon all the individual pieces in your completed critique template. The impact level should be clear after reading just this paragraph!

Overall Impact: *Write a paragraph summarizing the factors that informed your Overall Impact score*

LESS EFFECTIVE

The proposal is overly ambitious. There are design flaws. Significance is questionable. The PI's productivity is low.

In Aim 1, the PI plans to generate XX reagents and test them in the YY system. In Aim 2, XX will be used to explore the ZZ pathway. Then Aim 3 will examine XX as potential treatments for ABC disease. If successful, this research could significantly impact the field.

Only moderate enthusiasm was generated for this application. Strengths noted were the PI and team, excellent environment, state-of-the-art methodologies, and potential importance of the work to understanding XX. Weaknesses were the over ambitious nature, lack of experimental details, some confusing preliminary data, and concern about the choice of YY to be used. Altogether, this project will have a moderate impact on the field.

EFFECTIVE

This proposal addresses a very significant issue in the field of XX and overall impact is high because the research is likely to provide the link between two seemingly contradictory outcomes that have stymied recent advancements in this area. The project is not technically innovative, but this is not considered a weakness because the focus on XX is important and the methods are appropriate and rigorous. The approach has some very strong aspects such as X and Y. Most of the weaknesses were minor. However, one weakness created some concern. The weakness was XX. The problem with this is that they make an assumption about ZZ that does not seem to be supported by adequate data. The investigator is well-trained in X, Y, and Z and the collaboration with Drs. A and B, who will bring strengths of C and D, increases the likelihood of a successful outcome. In conclusion, despite the weakness in the approach, the potential overall impact of this project remains high because it will advance understanding of the mechanisms underlying the relationship between XX and YY and test new methods that will be useful in both basic and clinical research areas.

Explains how the strengths and weaknesses were balanced to arrive at the final score.

Lacks detail. Hard to interpret. →

Uses clear and specific language to explain points.

Just a rehash of the aims. → No evaluation of the impact and what the score-driving issues were.

Highlights only the main score-drivers. Any minor points are left in the criterion sections.

Just a listing of strengths-weaknesses without context. Only the major score-driving concerns should be listed in the Overall Impact along with the reasons why they are major and how they drove the final score. →

Indicates importance of strengths and seriousness of weaknesses when appropriate.

Significance

If all the specific aims are achieved, what would the project contribute to this field and how significant/important is this contribution?

- Significance assumes success of the specific aims.
- **Rigor of Prior Research** pertains to the strength of the prior research supporting the objectives of the study, or Clinical Trial. Is the prior research that provides the justification for the research objectives rigorous?
- Focus on the importance of the proposed work in the field, NOT the importance of the disease or condition (e.g., child obesity, probe development) being studied.
- Direct relevance to human health is not required. Significance can be related to the basic/ fundamental, mechanistic, technological, translational, clinical and public health contributions.

1. <u>Significance</u>	
LESS EFFECTIVE	EFFECTIVE
<p>Strengths</p> <ul style="list-style-type: none"> • The proposal will seek to explore the role of XX in the YY pathway. • The treatment of XX disease would be very significant for YY. • ZZ is a significant problem. • The rigor of the prior research is excellent because the applicants cite all the relevant work in the field. <p>Weaknesses</p> <ul style="list-style-type: none"> ☐ The proposal is unlikely to impact the field of XX. ☐ The study design is flawed. 	<p>Strengths</p> <ul style="list-style-type: none"> • The study is poised to resolve a long-standing controversy in the field about XYZ. • Prior research supporting this application includes robust preliminary results that suggest the role of YY as a mediator in the relationship between xx and ZYY that will advance understanding of ABC. • This application seeks to develop XX and advance current knowledge of YY. If successful, such understanding of YY would further allow ZZ to be accomplished, which would have a high impact on the field of ABC. • The role of XX in YY is clearly important, but key knowledge regarding XX is lacking. These studies may provide insights that could lead to novel treatments (or approaches) and develop methods that can be applied to YY and other related diseases (or techniques). <p>Weaknesses</p> <ul style="list-style-type: none"> • The proposed studies of XX do not offer a notable advantage over studies already done, and relevance to the YY pathway is questionable. Even if successful, it is unclear that these results would move the field of ZZ forward. • The application lacks justification that use of the ZZ system could yield results to advance the field in therapeutic directions to address YY. • While the studies will develop an additional method with which to examine XX, this technology won't substantially improve upon YY methods available for XX analysis.

Just restates an aim. State the value added. →

Only speaks to significance of topic, not how THESE studies are significant

This does not address the quality of the previous work. ↗

Why not? →

Not → significance. Belongs in approach.

Detailed and clear statements that highlight features of a study's significance.

Clearly articulates why study lacks significance

Investigator(s)

Does the investigative team have the collective expertise to lead the project, do the work and interpret the results?

- Assess evidence of appropriate expertise for the proposed project.
- Assess evidence of or potential for successful project management and execution.
- Investigator independence should not be considered.
- For Multi-PI applications, you should address each Principal Investigator and the leadership plan.
- For Multi-Center Clinical trials, you should address the organizational structure and investigators for the coordinating center.

2. Investigator(s)	
LESS EFFECTIVE	EFFECTIVE
<p>Strengths</p> <ul style="list-style-type: none"> • She has published 5 papers in the last 3 years. • The PI is outstanding • The team is very strong. <p>Weaknesses</p> <ul style="list-style-type: none"> • Since establishing his own laboratory, the PI has not been very productive. • The PI is quite junior. • The degree of independence of the PI is unclear. • The team has not worked together before. • The investigator has not published in top tier journals. 	<p>Strengths</p> <ul style="list-style-type: none"> • Over the past 3 years, the PI has published multiple key papers on the proposed activity, important to this field. • The PI has demonstrated expertise in XX and she has assembled a strong team of experts representing other key disciplines important for the successful completion of this proposal; these disciplines include YY and ZZ. • Multi-PI Dr. X is highly accomplished in the field of YY. • Co-investigator Dr. Y is a leader in the field of ZZ. <p>Weaknesses</p> <ul style="list-style-type: none"> • The experience of the PI for conducting these complicated studies is not extensive. He does not appear to have significant expertise to provide guidance for critical aspects such as XX. • The team appears to lack expertise in MM, particularly important for completing Aims 2 and 3. • The investigators have not worked together as a team. Though the PI and Dr. X are at the same institution, Dr. Y is at different location; it is unclear how well they will coordinate the YY aspects of the project.

How does this speak to the → quality or strength?

By what measure? Too general.

Not a relevant criticism. Can they do the work?

How will this → affect the project?

Detailed and specific measures / qualities

Detailed and specific concerns

Focus on outcomes/consequences of work, not journal.

Innovation

**Does the application challenge or seek to shift current research or clinical practice paradigms?
Are novel concepts/approaches/methods/instrumentation/interventions employed?**

- Assess the level of “out-of-the-box” thinking. This may involve new directions and/or unique approaches, or for example, the use of existing methods in one field to advance another field.

Don't feel obligated to look for reasons why an application is innovative if you don't think it is. Innovation need not be a driver of impact. High innovation is often related to high significance, but there is important work that will impact the field that is not innovative by nature. You can assign a weak innovation criterion score and still assign a strong Overall Impact score.

3. Innovation	
LESS EFFECTIVE	EFFECTIVE
<p>Strengths</p> <ul style="list-style-type: none"> • The study of XX is innovative. • The use of XX for the treatment of YY is innovative. • Studying XX is a strength. • XX is a nice idea. • The level of innovation is high. <p>Weaknesses</p> <ul style="list-style-type: none"> • The techniques are all standard. • There is no innovation. • XX has been studied previously by other researchers. 	<p>Strengths</p> <ul style="list-style-type: none"> • The combination of XX and YY is distinct from other approaches to study ZZ (could apply to conceptual or technical innovation). • XX is a powerful new method to study YY, and will enable new directions in the ZZ field because it integrates conceptual developments in YZ field and ABC field. • Exploration of the novel XX system is expected to yield numerous advances, including YY and ZZ. • XX has not been explored in past studies of YY. Testing XX in the YY model represents a considerable shift in focus which could have implications for XYZ. <p>Weaknesses</p> <ul style="list-style-type: none"> • Although the project uses new methods such as X and Y, these methods are unlikely to generate different conceptual approaches related to XY than what currently drives YZ field. • The concept of XX is not new to the field. • The research question is a modest extension of the investigator's existing work, and does not move in new directions. • Continued use of the well-established XX technique will yield only incremental additional knowledge.

Why?
Too general.

So what?
Too general.

More a description than evaluation.

Detailed and specific reasons

Approach

Are the strategy, methods, and analyses well-reasoned and appropriate to accomplish the aims?

- Keep your focus on the big picture. Focus more on rationale and study design than on minor details.
- Describe why you think an aspect of the approach is a strength or a weakness. Evaluate if the strategy proposed is likely to produce unbiased and interpretable results. Does the approach address weaknesses in the rigor of the prior research that supports this project? Does the application appropriately account for sex and relevant biological variables? If a Clinical Trial, does the study provide adequate power, use an appropriate study population, address potential ethical issues and include methods to assess effects of intervention and quality control?
- Avoid simply restating the key aims of the application.
- Taking risks in the approach is acceptable.
- Prioritize strengths/weaknesses, i.e. if the comment is major (score-driving) or minor, state this in the critique (otherwise, concerns will be assumed to be of equal weight).

4. [Approach](#)

LESS EFFECTIVE

Strengths

- Approach is strong.
- Using the XX method is a strength.
- Experiments are complex, but the PI is so productive that she will likely be successful.
- These studies will lead to new insights into ZZ disease.

Weaknesses

- The XX model system is too artificial.
- The aims are too diffuse.
- The measures of XX are weak.
- The proposal is overly ambitious.
- Sample includes males only.

EFFECTIVE

Strengths

- Specific Aim 3 was well-designed to test the main hypothesis. The investigators proposed well-controlled, appropriately powered set of rigorous experiments that addresses the impact of XX within this model system.
- The combination of XX and YY studies will establish the role of ZZ in ABC disease progression by developing methods to XYZ.
- The experimental design is comprehensive and cohesively covers all aspects of XX. Alternative strategies are well thought out, with potential problems and limitations associated with YY and ZZ acknowledged.
- The experimental design clearly addresses the limited rigor of the prior research addressing the role of XX by expanding the age range of the study participants.

Weaknesses

- Use of XX in the YY model system will not faithfully mimic ZZ disease, due to A and B.
- The presentation of the experimental strategy in Specific aim 2 is vague and the analytical design lacks rigor. It is unlikely that the investigators can establish utility of XX in a rigorous and unbiased way with insufficient characterization of the proposed test population.
- The proposal is expansive in its scope, which resulted in limited depth to each study component. Experiments in Aims 1 and 2 will only superficially explore the XX pathways without attention to important considerations like X and Y. Major detail necessary to reproduce the study are unaddressed.
- Previous studies of the ZZ disease have demonstrated differences in disease severity between males and females so the proposed study of only males is not scientifically justified.

In what way? Too general.

Confuses approach and investigator; is the approach rigorous?

Not an approach statement. Belongs in significance

In what way? Why? How will this affect feasibility, rigor/transparency

Detailed and clear statements of specific strengths.

Clearly articulates weaknesses in the study design

Environment

Are the resources, facilities and equipment appropriate for the needs of the proposed project?

- This should NOT be an assessment of the quality of the institution.
- Think about what environment and resources are necessary for the project's success and evaluate the institution's ability to provide the necessary conditions and support.
- For Clinical Trials, think about capabilities of all sites/centers for data coordination, enrollment, laboratory testing and conducting the trial.

5. <u>Environment</u>	
LESS EFFECTIVE	EFFECTIVE
<p>Strengths</p> <ul style="list-style-type: none"> • The environment is suitable for the project. • XYZ university is an excellent research environment. • The PI has involved strong collaborators with expertise in XX and YY, which are crucial to the success of the project. <p>Weaknesses</p> <ul style="list-style-type: none"> • Environment is average. • The study site is far from the investigator's university. 	<p>Strengths</p> <ul style="list-style-type: none"> • The environment at XYZ is outstanding because it has all of the XX equipment and instrumentation necessary to conduct the experiments. • The presence of a center for XX research, with full-time staff skilled in XX and YY, and the ZZ department guarantee that expertise will be available to provide appropriate resources for the project. <p>Weaknesses</p> <ul style="list-style-type: none"> • The lack of a XX research department raises concerns about appropriate resources for this XX study. • The YY facilities at XYZ University were not described and it is unclear whether the university can fully support the high demands associated with ZZ studies. • For this large clinical study, the lack of an onsite recruiting center at XX University is likely to compromise the team's ability to achieve sufficient participation.

Why? Too general.

This should be in Investigator.

How will this affect the proposed study?

Detailed and specific reasons/ aspects of the institution that support (or limit) feasibility.

Additional Review Criteria

Reviewers are asked to evaluate other considerations that will apply to some applications but not all.

These factors do not receive a separate score but *can affect your overall impact score*.

Remember:

- Reviewer guidelines for Vertebrate Animals and Human Subjects were updated 2/21/2018. See (https://grants.nih.gov/grants/peer/reviewer_guidelines.htm#general_guidelines for changes.

New! Study Time Line (fill out if electronic cover sheet designates Clinical Trial)

If a Clinical Trial is a part of the application then this part **MUST** be filled in

-Add comments regarding the details, feasibility, and justification of the proposed timeline as well as whether the study incorporates efficiencies, utilizes existing resources and discusses potential challenges and solutions.

Human Subjects and Inclusion of Women, Minorities and Age Across the Lifespan

Vertebrate Animals

Biohazards

If Human subjects, vertebrate animals, or biohazards are involved in the study then this part of the critique **MUST** be filled in. PLEASE fill in all relevant sections following guidelines.

- Click on “Click here to select” for each and select:
 - Not applicable (no comments needed)
 - Acceptable/Justified scientifically/Yes (comments optional)
 - Unacceptable/Not justified scientifically/No (add brief explanation in comments section)

Resubmission (fill out if the grant number ends in **A1**)

Renewal (fill out if the grant number starts with a **2**)

Revision (formerly “supplement”; rarely seen; fill out if the grant number starts with a **3**)

- Add comments in appropriate box if the application is a resubmission, renewal, or revision.

You are not done yet! Keep going.

Additional Review Considerations

These factors do not receive a separate score and *should NOT affect your overall impact score.*

Applications from Foreign

Organizations Select Agents

Resource Sharing Plans

Authentication of Key Biological and/or Chemical Resources Did the applicant provide a plan for identifying and regularly validating key biological and/or chemical resources?

Budget and Period of Support

- Click on “Click here to select” for each and select appropriate response
- Add comments if unacceptable or budget changes are recommended.