

## **Writing Effective Critiques for Research Applications**

This document provides guidance for reviewers on preparing critiques that best support informed funding decisions by institutes and give clear feedback to investigators.

## **General Guidance for all Sections of the Critique**

- Avoid general comments and provide specific details.
- Provide sufficient context to orient your 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 scored 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 include sex, and biological/chemical resource authentication), as appropriate for the research questions.

## **Overall Impact**

Ask yourself: 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.** 

#### **Scored Review Criteria**

## 1. Significance

Ask yourself: 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 objective 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.

## 2. Investigators

Ask yourself: 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 (MPI) 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.

#### 3. Innovation

Ask yourself: 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.

## 4. Approach

Ask yourself: 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).



#### 5. Environment

# Ask yourself: 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.

## **Additional Review Criteria**

Reviewers are asked to evaluate other elements that will apply to some applications, but not all. These factors do not receive a separate score **but can affect your overall impact score**.

If **Human Subjects, Vertebrate Animals, or Biohazards** are involved in the project then this part of the critique **MUST be completed**.

Click on "Click here to select" for each and select, as appropriate:

- Not applicable (no comments needed)
- Acceptable/Justified scientifically/Yes (comments optional)
- Unacceptable/Not justified scientifically/No (add brief explanation in comments section)

#### **Study Timeline** (MUST be filled in if a Clinical Trial is part of the application)

 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 Protections**

- If the research involves human subjects (but does not qualify for Exemptions), you must provide comments on whether the following four points are appropriately addressed: (1) the risk to subjects; (2) the adequacy of protections against risk; (3) potential benefits of the research to subjects and others; and (4) the importance of the knowledge to be gained.
- If the application proposes a clinical trial, also comment on whether the applicants provided an acceptable Data and Safety Monitoring Plan and/or Data Safety Monitoring Board, as applicable.
- For additional guidance see <u>Guidance for Review of Protections for Human Subjects</u>

#### Inclusion of Women, Minorities, and Age Across the Lifespan

- Evaluate the proposed plans for the inclusion of individuals on the basis of their sex or gender, race, ethnicity, and age.
- Additionally for NIH-defined Phase III clinical trials, you must comment on whether the study can be expected to identify potential differences by sex or gender, race, and/or ethnicity and whether the plans for the valid design and analysis of potential group differences are adequate for the scientific goals of the study.
- For additional guidance see Guidance for Review of Inclusion in Clinical Research



#### **Vertebrate Animals**

- If the research involves the use of live vertebrate animals, provide comments on whether the following four points are appropriately addressed: (1) description of procedures; (2) justification for choice of species; (3) minimization of pain and distress; and (4) justification for euthanasia method (only if not consistent with AVMA guidelines).
- For additional guidance see <u>Reviewer Training Module for the Vertebrate Animals Section</u> and VAS Reviewer Cheat Sheet

#### **Biohazards**

- Applications do not contain a separate section on Biohazards; they can be addressed throughout the application, including the Facilities section.
- Provide comments on the plans for proper handling procedures and that adequate protections are addressed (personnel training, safety protocols, containment facilities, waste disposal).
- For additional guidance see <u>Guidance for Review of Biohazards including Select Agents</u>

## ADD COMMENTS in the appropriate box if the application is a resubmission, renewal, or revision.

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

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

Revisions (rarely seen; fill out if the grant number starts with a '3')

#### **Additional Review Considerations**

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

#### **Applications from Foreign Organizations**

- Did the application appropriately explain/justify how the project that will be conducted in the foreign organization presents special opportunities or resources that are not readily available in the United States?
- Note that this review criterion does not apply to applications from U.S. organizations containing a foreign component.

#### Select Agent Research

• See Guidance for Review of Biohazards including Select Agents

#### **Resource Sharing Plans**

• See Guidance for Review of Resource Sharing Plans

#### **Authentication of Key Biological and/or Chemical Resources**

 Did the applicant provide an appropriate plan for identifying and regularly validating key biological and/or chemical resources?

## **Budget and Period of Support**

See Guidance for Review of Budget