Reviewer Orientation for NIH Peer Review

For Non-Simplified Review Framework Research Project Grants

SRO:

Study Section:

Meeting Dates:

Council Round:

National Institutes of Health
Turning Discovery Into Health

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NIH's Two-Level Review System



Evaluation of Scientific Merit

Review of first-level peer review outcomes, recommendation for funding, advice on programmatic priorities

First-level peer review has a singular, important goal: provide expert advice to the NIH on the scientific and technical merit of grant applications.

Your Role as an NIH Reviewer

- **Evaluate the scientific merit of each application.**
  - Do not make funding recommendations.
  - Do not provide advice to the applicant.
  - Apply the review criteria and scoring guidance consistently to reduce bias that can distort evaluation of impact.

- **Evaluate the application as it is presented.**
  - Do not attempt to improve or redesign the application.

- **Explain the basis for your review.**

Review Integrity is the Foundation for a Fair, Independent Review, Free from Inappropriate Influences

- Maintain absolute **Confidentiality** of all review materials and discussions.
  - Do not share with anyone.
  - Delete/discard all materials 30 days after the review meeting.

- Report any **Conflict of Interest (COI)** that may directly affect or appear to affect the integrity of the peer review process.
  - Report a COI as soon as you identify it -- at any point in the process.

- Contact the SRO *in private* (to avoid tainting the review) if you suspect **Research Misconduct**: Data fabrication, data falsification, plagiarism

- To protect the **scientific integrity of peer review**, all comments must be **independently generated** by the reviewer.
  - Not copied from the application, prior summary statements, or other reviewers' critiques
  - Not generated using SI tools

Confidentiality and Use of SI

Current SI tools require that materials be uploaded to a non-NIH, proprietary server causing confidential information to leave reviewer control.

- Thus, use of SI tools to assist with any part of critique generation **violates NIH's peer review confidentiality requirements** (NOT-OD-23-149) and is **strictly prohibited**.

- This applies to generative SI (LLMs), SI-detection tools, Grammarly or other writing/editing tools, transcription/recording tools, cloud services, on personal, local or institutional servers.

- **Do not upload, paste, or enter any portion of an application or critique into these tools for any purpose**—including to determine whether an applicant may have used SI, summarize content, or assist with writing a critique.

Review Criteria

OVERALL IMPACT

The likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, considering the ***5 Review Criteria*** and **Additional Review Criteria**

Additional Review Considerations
(no effect on Overall Impact score)

- Select Agent Research
- Resource Sharing Plans
- Authentication of Key Biological/Chemical Resources
- Budget and Period of Support

5 Scored Review Criteria

- Significance
- Investigator
- Innovation
- Approach
- Environment

Additional Review Criteria (as applicable)

- Study Timeline (for Clinical Trials)
- Protections for Human Subjects
- Inclusions
- Vertebrate Animals
- Biohazards
- Resubmissions, Renewals, Revisions

Reviewers Address 3 Key Questions about the Proposed Project

1. Should it be done?

- **Significance** and **Innovation**

2. Can it be done well?

- **Approach**

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

- **Investigator** and **Environment**

Review Criteria (Scored 1-9)

Significance

- If the aims are successful, how will the project advance the field or address a critical research gap?
- How strong is the empirical foundation?
- Refers to the significance of the proposed research, not the significance of the research field or disease

Investigator

- How well suited are the PI and research team to the project?
- Consider their training and expertise in the context of their career stage.

Innovation

- Concepts, methods, populations, design
- Generally desirable, not always required

Approach

- How strong are the design and methods?
- Evaluate the rigor and reproducibility of the approach, including sex as a biological variable
- Focus on the big picture, not the technical minutiae.

Environment

- Will the scientific environment in which the work will be done contribute to the probability of success?

Insert Criteria Specific to Clinical Trials or to the NOFO here (if applicable)

Sex as a Biological Variable (SABV; vertebrate animals and human subjects)

- As an integral part of your assessment of the **approach**, evaluate whether the investigators presented adequate plans to address **relevant biological variables**, such as sex or age, in the design, analysis, and reporting.

- Assess SABV in the *context of the research question* and *current scientific knowledge.*
  - If the study is intended to **test for sex differences**, is the design/analysis adequately rigorous to test for those differences?
  - If the study is not testing for sex differences and **both sexes are included**, does the project demonstrate plans to report data disaggregated by sex?
  - If **only a single sex is included**, is there a strong justification provided?

- Additional SABV resources: Decision Tree, FAQ

Additional review criteria (can affect Overall Impact score)

- Study Timeline (clinical trials)
- Protections for Human Subjects
- Inclusions based on Sex, Race & Ethnicity, and Age across the Lifespan
- Vertebrate Animals
- Biohazards
- Resubmissions, Renewals, Revisions

Additional Review Criteria: Study Timeline (Clinical Trials Only)

- Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment?

- Is the projected timeline feasible and well justified?

- Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Additional Review Criteria: Protections for Human Subjects

Evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to these criteria:

1. Risk to subjects
2. Adequacy of protections against risk
3. Potential benefits of the research to subjects and others
4. Importance of the knowledge to be gained
5. Data and safety monitoring for clinical trials

Additional Review Criteria: Inclusions

- When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals.

- Inclusions:
  - **Sex**
  - **Race and ethnicity**
  - **Phase III clinical trials --** Plans for valid design and analysis of sex, race, and ethnicity.
  - **Age across the lifespan**

- **Inclusions must be scientifically justified**, in terms of the scientific goals and research strategy proposed.

Additional Review Criteria: Vertebrate Animals

Evaluate the involvement of live vertebrate animals according to these criteria:

1. Description of procedures, including species, strains, ages, sex, and total number of animals to be used
2. Justifications for the use of animals versus alternative models and for the choice of species
3. Minimization of pain and distress
4. Method of euthanasia

Additional Review Criteria: Biohazards

Biohazards are research components known in the professional community to pose a risk to research personnel and/or the environment (biological organisms, toxins, radioactivity, dangerous chemicals, or recombinant DNA).

- Determine whether proper handling procedures and adequate protections are addressed (personnel training, safety protocols, containment facilities, waste disposal).

Additional Review Criteria: Resubmissions, Renewals, Revisions

- **Resubmissions:** Evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

- **Renewals:** Evaluate the application as it is presented, taking into consideration the progress made in the previous project period. Evaluate whether the renewal is a logical extension of the previous project and what impact it will have on the scientific field

- **Revisions:** Consider the appropriateness of the proposed expansion of the scope of the project.

Scoring Overall Impact

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

- A good, medium impact application is a 5. Start from 5 and adjust score up or down based on the application's strengths/weaknesses. Score is based on balancing strengths and weaknesses.
- 1-3 should be supported by clearly articulated strengths.
- 4-6 may have a mix of strengths and weaknesses.
- 7-9 should be supported by clearly articulated weaknesses (or lack of strengths).

Scores should distinguish applications with high, medium, or low impact

Writing the Overall Impact paragraph

- Explain how you arrived at your **overall impact score**.

- Always comment on Significance and note any additional *major* strengths and weaknesses that drove your overall impact score.

- Explain how you balanced/combined/weighted the various criteria to arrive at the score.

Additional Review Considerations (no effect on Overall Impact score)

- **Select Agent Research:** As applicable, assess 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

- **Resource Sharing Plans:** Reviewers will comment on whether the Resource Sharing Plan(s) (or the rationale for not sharing the resources, is reasonable.

- **Authentication of Key Biological and/or Chemical Resources**: As applicable, evaluate the brief plans for identifying and ensuring the validity of these resources.

- **Budget and Period of Support**: Evaluate whether the budget and requested period of support are fully justified and reasonable in relation to the proposed research.

Progressing from independent review to full panel discussion

- Individual reviewers submit preliminary scores and critiques.

- Reviewers read and consider other critiques, recalibrating scores, if warranted.

- At the meeting, **all reviewers** play an active role and cast an informed score.
  - **Assigned reviewers:** Explain your score, consider your colleagues' views
  - **Unassigned reviewers:** Listen, ask questions, share different perspectives

- If you hear a comment that doesn't relate to the review criteria, mitigate potential bias by asking clarifying questions or contact the SRO.

- The goal is to reach clarity, not consensus.

Thank you for serving as a reviewer.

- Additional materials can be found in **Meeting Materials—IAR**
  - **Contact the SRO** with questions

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