NIH Reviewer Orientation

The peer review of grant applications is at the heart of the NIH grants process. As a reviewer, you play a very important role in NIH's mission of 'making important discoveries that improve health and savelives.' You are tasked with evaluating the scientific merit of NIH grant applications in a fair, independent, expert and timely fashion that is free of inappropriate influence. Your assessment — coupled with that of other esteemed peer reviewers — will determine the most promising basic or applied research that NIH can fund and provide the lifeblood for biomedical research in the US and worldwide.

To orient you to the peer review process, this guide walks you through your pre-meeting responsibilities, activities at the meeting, and post-meeting responsibilities. All eligible Scientific Review Group (SRG) members, who have no conflict of interest, participate in the evaluation of an application. Members are designated as primary, secondary, or tertiary reviewers, and additional reviewers, as needed; mail reviewers; and discussants.

Contents

PRE-MEETING ACTIVITIES

Summary

- Examine your review assignments, review materials [including Funding Opportunity Announcements (FOAs) and applications], and instructions.
- Review all applications pending review in the meeting for conflict of interest or the appearance of conflict of interest. If you perceive a conflict or have questions regarding a conflict, contact the Scientific Review Officer (SRO) immediately.
- Review your application assignments for match with your expertise. If you have questions regarding your assignment to an application, contact the SRO immediately.
- Review the "NIH Conflict of Interest Rules: Information for Reviewers of NIH Applications and R&D Contract Proposals" and complete the NIH pre-review Certification.
- Sign the Confidentiality Certification (usually in the Internet Assisted Review module).
- Read, evaluate and write a critique for each of your assigned applications (discussants may be asked to provide an 'Overall Impact' critique).
- Gain access to and upload critiques, preliminary overall impact scores and individual criterion scores to the Internet Assisted Review (IAR) site for the applications assigned to you; a deadline will be provided by the SRO.
- Read posted critiques for your assigned applications and other applications (you will be denied access to applications where you have a Conflict of Interest).
- Prepare for discussions at the meeting.

Reviewing the Applications

Written Critique

- Use critique templates provided by the SRO. Use bullets to note strengths and weaknesses for each of the scored review criteria and provide context and an explanation for your comments based on the project (e.g., refer to a Specific Aim). While brevity is acceptable, bullets should express complete thoughts and be sufficient to inform the reader.
- Write a paragraph summarizing the factors that informed your Overall Impact score (See Overall Impact below).
- Download the critique templates and enter bulleted comments directly into the document (if you prefer to compose your critique in a separate document, you may wish to "paste special" – as plain text - to retain the bulleted format).
- When finished, upload the document to IAR.
- See the Critique Template Instructions for more information on working with the critique templates.

Scoring

- The NIH scoring system uses a 9-point scale for the overall impact score and individual scores for (at least) five scored criteria.
- For both types of score, ratings are in whole numbers only (no decimal ratings).
- NIH expects that scores of 1 or 9 to be used less frequently than the other scores.
- 5 is considered an average score.
- No formulas used to derive the overall impact score from the individual criterion scores.

Weigh the different criteria as you see fit in deriving your overall scores.
- Ratings are in whole numbers only (no decimal ratings).
- Enter scores into IAR (not on the template).
- See the Scoring System and Procedure for more information on scoring.
- Score an application as presented in its entirety. You may not modify your scores on the assumption that a portion of the work proposed will be deleted or modified according to theSRG's recommendations.

Review Criteria and Considerations

- Each application is evaluated for scientific and technical merit according to the Scored Review Criteria and Additional Review Criteria stated in the FOA.
- The Review Criteria for common award mechanisms are found in Review Criteria at a Glance.

1. Overall Impact
   - In reviewing Research Projects, provide an overall impact score and critique to reflect your assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five (or more) scored review criteria, and additional review criteria (as applicable for the project proposed). For other activity codes (such as fellowships, career awards, training programs, and others), overall impact may be defined differently.
   - Provide a paragraph summarizing the factors that informed your Overall Impact score. This paragraph should be a stand-alone assessment of the strengths and weaknesses outlined for each of the five scored criteria and additional review criteria, not a restatement or summary of the specific aims or the bulleted comments outlined in the critique. Succinctly state the underlying rationale for the Overall Impact score.
   - Basic and applied research are equally relevant to the mission of NIH and you must evaluate overall impact in the context of the application.
   - Unless stated otherwise in the FOA, an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a good impact score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.
   - The Overall Impact score is not necessarily the average of the individual criterion scores.
   - Overall Impact and Significance are different, as described here.

2. Scored Review Criteria
   - Consider each of the scored review criteria in the determination of scientific and technical merit and give a separate score for each.
   - Most FOAs for Research Projects have the following five scored review criteria: Significance, Investigator(s), Innovation, Approach, and Environment.
   - In evaluating the Investigator(s) review criterion, focus on the qualifications and expertise of the members of the research team for the work proposed, including the Personal Statement in each Biosketch. Unless the application is for a fellowship or career development award, remarks about career tracks, titles, or salaries should be reserved forthe Additional Comments to the Applicant box, or the Budget section.

Resources

- See Review Criteria at a Glance.

3. Additional Review Criteria
   - When applicable, consider the additional review criteria in the determination of scientific and technical merit and an overall impact score.
   - Do not give separate scores for these items.

Resources

Here are guidelines for:

- The review of the Vertebrate Animals section (PDF - 43 KB) — March 21, 2016
- The Review of the Human Subjects Section (PDF - 146 KB) —March 21, 2016
- The Review of Inclusion on the Basis of Sex/Gender, Race, Ethnicity, and Age in Clinical Research (PDF - 81 KB) — March 21, 2016
- The review of use of Human Embryonic Stem Cells (PDF-69 KB)— March 21, 2016
- The review of Revision Applications (formerly Competing Supplements) (PDF – 47 KB) — Dec. 18, 2015
- Revised Definition of Clinical Trials and Clinical Trial Decision Tree (from the Office of Science Policy website)
- The Reviewer Guidance on Rigor and Transparency (PDF – 158 KB) – Nov. 18, 2016
- Sex as a Biological Variable (SABV) Decision Tree (PDF – 232 KB) – Aug. 08, 2016

4. Additional Review Considerations
   - When applicable, comment on each of the additional review considerations, but do not assign scores and do not consider these items when determining an overall impact score.
   - Program staff will administratively handle any concerns on these items following the review.

Resources

Here are guidelines for:

- The review of the Budget Information (PDF - 284 KB) — March 5, 2012
- Considering Information on Select Agents

MEETING ACTIVITIES

Summary

- The SRO will begin the meeting by reviewing policies and describing meeting procedures.
- In some SRGs, applications are reviewed based on the preliminary overall impact score (beginning with the best scores).
- Applications will be grouped together when feasible (e.g., same mechanisms, new investigators, or clinical applications).
- In most cases, only the more meritorious applications (based on preliminary scores) will bediscussed at the meeting. All fully participating members of the SRG must concur on therecommendation to not discuss an application.
    - Applications that are discussed at the meeting will receive a final impact score, and a summary statement with individuallyassigned reviewer criterion scores, reviewer critiques, and a resumé and summary of the discussion.
    - Applications that are not discussed will receive summary statements containing written critiques and individual criterion scores from assigned reviewers and in some cases discussants.

Presentation and Discussion

- Applications will be introduced by the Chair of the SRG.
- Assigned reviewers will share their initial overall impact score and should be prepared to explain the significance of the proposed research and the overall impact the research will have on the field.
- Group discussion follows assigned reviewer presentations.
- Open discussion of scientific merit may result in disparate levels of enthusiasm.
    - The reasons for any disparities should be made clear to allow for both an informed vote by all panel members, and a high-quality summary statement.
- Because consideration of human subject protections, inclusion plans, vertebrate animals or biohazards can affect scientific and technical merit, these elements are discussed before final scoring.

Final Score and Voting

Based on the presentation and discussion, and the preliminary critique and overall impact scores from each assigned reviewer, each discussed application is given a score by all reviewers who are eligible to vote on that application. Mail Reviewers do not attend the review meeting and their preliminaryoverall impact scores are not used to calculate the average preliminary or final score. Mail Reviewers' critiques and scores are considered by the review panel.

- Both regularly appointed and temporary members vote on each application for which they do not have a conflict of interest.
- You may use non-numeric impact scores, as appropriate:
    - AB – abstain from voting
    - CF – conflict of interest; did not participate in the discussion and scoring
    - NP – not presentduring discussion
- The following scenarios require a committee decision:

- ND - not discussed
- NR - not recommended for further consideration (may reflect a lack of substantial merit or serious ethical problems in use of human subjects, vertebrate animals, or the environment)
- DF – deferred

- If a particulars core is an outlier, the reviewer must have stated his/her concerns during thediscussion so that they can be reflected in the final summary statement.
- The scores from all eligible reviewers for a given application are averaged (calculated to onedecimal point) and multiplied by 10 to determine the final overall impact score.
- For discussed applications, a final overall impact score and summary of the discussion will be included in thesummary statement.

POST-MEETING ACTIVITIES

- After the meeting, the SRO sets an "Edit Phase" in IAR.
- You should edit your criterion scores and critiques to reflect any changes to their preliminaryassessment.
- You must sign your post-meeting Conflict of Interest (COI) certification.

ETHICAL CONDUCT OF REVIEWERS

Conflict of Interest

- Check for potential conflicts of interest (or appearances of conflicts) and alert the SRO immediately of any conflicts of which you are aware.
- During the meeting, if you have a conflict of interest with any application or proposal, you must leave the room during evaluation and scoring of that application or proposal.
- In signing the post-review certification, you certify that you did not participate in an evaluation of any application or proposal with which you knowingly had a conflict of interest.

Confidentiality

- All applications and related materials are privileged communications that cannot be shown to or discussed with unauthorized individuals. (See Confidentiality in NIH Peer Review.) This means that you are prohibited from:
  - Sharing applications, proposals, or meeting materials with anyone who has not been officially designated to participate in the peer review meeting.
  - Granting access to any NIH secure computer system or advisory committee meeting toanyone who has not been officially designated to participate in the peer review meeting.
  - Disclosing, in any manner, information about the committee deliberations, discussions, evaluations, or documents to anyone who has not been designated to participate in the peer review meeting or who has a declared conflict of interest.
  - Using information contained in an application or proposal for his/her personal benefit or making such information available for the personal benefit of any other individual or organization.
- In signing the confidentiality certification, you certify that you fully understand the confidential

Nature of the review process and agree to confidentiality and non-disclosure.

- You are required to leave all review materials (that are not in the public domain) with the SRO,or destroy them, at the conclusion of the review meeting.

Research Misconduct

- Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results, but not honest error or differences of opinion.
- Do not make allegations of potential misconduct in the critique or during the meeting discussion; instead, bring such concerns to the attention of the SRO in a confidential manner, preferably before the study section meets.