Reviewer Orientation

The timeline of the Peer Review process can be divided into pre-meeting responsibilities, activities at the meeting, and post-meeting responsibilities. This guide is intended to serve as an orientation and overview of that process.

PRE-MEETING ACTIVITIES

Overview:

Before the meeting, you will:

- Receive your review assignments, review materials (including applications), and instructions

- Read and evaluate the applications

- Write a critique for each of your assigned applications

- Upload the critiques and preliminary scores into Internet Assisted Review (IAR) in the NIH Commons

- Read posted critiques for your assigned applications and other applications and prepare for discussions

Expectations of Reviewers:

- Each application is assigned to at least three reviewers as primary, secondary, and tertiary or discussant.

- As a primary, secondary or tertiary reviewer, you will be expected to write a complete critique.

- As a discussant, you are not required to provide written comments, although you may choose to do so; a one paragraph "Overall Impact" would be welcomed. The SRO may ask you for written comments if you have a special expertise or if you present views at the meeting not captured in other reviews.

- Although you should prioritize your efforts to evaluate the applications assigned to you, reading other applications is highly encouraged.

Four to Six Weeks before the Meeting:

- You will be given access through IAR to all applications except those with which you have a conflict of interest. You may also receive a compact disk with files of applications and review guidelines.

- You will receive an assignment list indicating those applications to which you have been assigned to review and prepare a written critique.

- Promptly (within a few days) alert the SRO to conflicts or questionable assignments concerning the matching of your expertise.

- Check for potential conflicts of interest on the IAR site. Relationships that often create conflicts of interest are described in the pre-meeting electronic COI (eCOI) documents on the IAR site, where you must certify your COIs.

- Note carefully the SRO's letter that provides information about the study section meeting venue and, if applicable, information about travel.

The Written Critique (Overview):

- Download from the meeting materials site in IAR, or from the CD, template(s) that you will use for the applications assigned to you.

- The template provides space to list bulleted strengths and weaknesses for each of the core review criteria and the overall impact. Reviewers are strongly encouraged to limit their critiques to no more than ¼ page per core criterion or overall impact.

- Enter your comments directly on the template and upload the document to IAR when completed.

- Enter your preliminary impact/priority score and scores for each of the core review criteria (for Research Project Grants: significance, investigators, innovation, approach, and environment) into IAR.

Resubmission, Renewal, and Revision Applications:

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

- ***Renewal Applications:*** Consider the progress made in the last funding period.

- ***Revision Applications (formerly called competing supplement applications):*** Consider the appropriateness of the proposed expansion of the scope of the project. If the Revision application relates to a specific line of investigation presented in the original application that was not recommended for approval by the review committee, please consider whether the responses to comments from the previous scientific review group are adequate and whether substantial changes are clearly evident.

Preliminary Scoring:

- In scoring each of the core criteria and overall impact, reviewers will use a scale of whole numbers, 1-9 (1= exceptional; 9= poor).

- Enter your impact/priority score and scores for each of the core review criteria (for Research Project Grants: significance, investigators, innovation, approach, and environment) into IAR.

Administrative Criteria:

As applicable, reviewers will address each of the following items, but will not give scores for these items and should not consider them in determining an impact/priority score. Reviewer comments on these items will be considered by program staff in making funding decisions and in determining funding levels.

Budget and Period of Support

- *Modular Budgets:* The SRG may recommend either the elimination of specific budget items – not necessarily in $25,000 modules – or elimination of one or more $25,000 modules.

- *Non-Modular Budgets:* The SRG may recommend that positions or other requests be deleted from the budget if they do not appear necessary to conduct the research, or that the percent effort devoted to the project be reduced if judged to be excessive for the needs of the project.

- *Overlap:* Reviewers may identify areas of potential overlap with other supported research; however, it should neither be a reason for altering the budget nor should it affect the impact/priority score.

Select Agent Research: Assess the information provided in this section of the application, including:

- the Select Agent(s) to be used in the proposed research,

- the registration status of all entities where Select Agent(s) will be used,

- the procedures that will be used to monitor possession use and transfer of Select Agent(s), and

- plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans: As appropriate, determine whether:

- *Data Sharing Plan* is present and appropriate (in most cases, for $500k applications)

- *Model Organism Sharing Plan* is present and appropriate (for applications to make new model organisms).

- *Genome Wide Association Studies (GWAS)* applications have appropriate plans for depositing data in the NIH designated data repository.

Foreign Organizations: This is applicable only when the applicant organization is located outside the U.S. Assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

One Week before the Meeting:

All critiques and scores should be posted by the IAR deadline. After that time, reviewers should revisit the site to read and consider the comments of the other reviewers assigned to the same applications in order to be prepared for a focused discussion at the meeting.

Other Important Pre-Meeting Information:

Confidentiality: All materials pertinent to the applications being reviewed are privileged communications that should not be shown to or discussed with other individuals.

- Respect for the privacy of the investigators' ideas is also important.

- Misappropriation of intellectual property, including the unauthorized use of ideas or unique methods obtained from a privileged communication, such as a grant or manuscript review, is considered plagiarism and falls under the definition of scientific misconduct.

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.

- It is vital that you not make allegations of potential misconduct in the critique.

- Such concerns must be brought to the attention of the SRO in a confidential manner, preferably before the study section meets.

MEETING ACTIVITIES

At the beginning of the meeting, the SRO reminds the reviewers of review policy and orients the reviewers to review procedures that will be followed at the meeting.

Review Policy:

- ***Conflict of Interest:*** If a reviewer has a real or apparent conflict of interest, the reviewer must be absent from the room during review of that application.
- ***Confidentiality:*** Reviewers are required to leave all review materials that are not in the public domain with the SRO at the conclusion of the review meeting.

Procedural Overview:

- When feasible, applications of the same mechanism will be reviewed in rank order from best (1) to worst (9) mean preliminary "Impact/Priority" scores.
- When feasible, applications from new investigators will be clustered together for review.
- The chair of the scientific review group (SRG) will introduce each application for discussion and call upon individual assigned reviewers for their preliminary "overall impact/priority" scores and evaluations.
- Group discussion follows assigned reviewer presentations. Consensus is not a goal. If open discussion of scientific merit results in disparate levels of enthusiasm by reviewers, the reasons for the disparity should be made clear to allow for informed voting by all panel members and a high quality summary statement.
- A summary of this discussion will be included in the summary statement.
- Further, because deficiencies in human subject protections, inclusion plans, vertebrate animal use or consideration of biohazards can negatively impact the score, these elements are also discussed before a final "impact/priority" score (or score range) is recommended by the assigned reviewers.

- Both regularly appointed and temporary members vote on each application for which they do not have a conflict of interest. Mail reviewers, however, do not vote.
- In most cases, the least meritorious applications will not be discussed at the meeting.

Discussion:

- Each assigned reviewer should:
    - Be prepared to explain the significance of the problem and the overall impact the work will have on the field;
    - Focus his or her presentation on major, score-driving strengths and weaknesses;
    - For Renewal applications, comment on the progress made since the grant was funded;
    - For Resubmission applications, comment on the application as now presented, taking into consideration the responses to comments from the previous SRG and changes made to the project.
    - For Revision (formerly competing supplement) applications, comment on the scientific merit of the new work proposed and the appropriateness of the proposed expansion of the scope of the parent project.

Research Involving Human Subjects: Concerns about Human Subjects Protections may negatively impact the score and will be coded in the summary statement to block funding until protections are adequate. For all application involving human subjects, reviewers must comment on the acceptability of the Inclusion of Women, Minority and Children Plans.

Research Involving Vertebrate Animals: Concerns may negatively impact the score and will be coded in the summary statement to block funding until the concerns have been resolved.

Biohazards: In addition to being an administrative note, egregious concerns relating to biohazards can impact a reviewer's assessment/score under:
- "Investigator" (if the PD/PI seems to lack knowledge about appropriate methods of working with biohazardous agents)
- "Environment" (if appropriate containment is not proposed), or
- "Approach" (if inappropriate plans for use are proposed).

Final Scoring:
- Each discussed application will be scored from 1 (best) to 9 (worst), based on the overall impact/priority score recommended by the assigned reviewers.
- Voting outside the range-indicate to the committee the intention to vote outside the range and the reason why
- In addition to ND for not discussed, applications may be assigned other non-numeric scores by SRG consensus, including

- NR - Not recommended for further consideration, reflecting lack of substantial merit or serious ethical problems in human or animal use;
- DF – deferred
- Individual reviewers may assign the following non-numeric scores
  - AB – abstain from voting
  - CF – conflict of interest; did not participate in the discussion and scoring
  - NP – not present during discussion

Administrative Elements: These do not have an impact on the score except in special cases, as noted in the explanation of the individual review criterion.
- Budget Recommendations (SRG consensus)
- Resource Sharing Plan
  - Data Sharing Plan
  - Model Organism Sharing Plan
  - Genome Wide Association Studies (GWAS)
- Foreign Institution

Note: In most cases, only the more meritorious applications, based on preliminary scores, will be discussed at the meeting and receive a final impact/priority score, individual assigned reviewer criterion scores and a summary statement with critiques and a summary of the discussion. For the remainder of the applications that are not discussed, summary statements that contain the written critiques and individual criterion scores will be provided to the applicant.

POST MEETING ACTIVITIES:

- After the meeting there is an "Edit Phase" in IAR. During this phase the reviewers are asked to revise their critiques and post them in IAR.

- The reviewers are strongly encouraged to edit their critiques (including their criterion scores) based on the discussion(s) at the meeting, particularly if they changed their score(s). The reviewers' written critiques should reflect their final scores.

- Finally, the reviewers must sign their post-meeting eCOI form in IAR.