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Sessions 11 - 13

- Distribution of proposals
- Introduction to the Peer Review Process
- Course Study Section Procedures

Overview of Application Process

- ▶ Send to NIH by grant proposal deadline dates, typically: February 1, June 1, October 1
- ▶ Center for Scientific Review (CSR) receives, logs it in and gives it an ID number
- ▶ CSR assigns it to IRG and to institution. You may request both assignments

- ▶ CSR notifies you within 6 weeks of these assignments
- ▶ CSR mails applications to reviewers and asks to streamline
- ▶ Application undergoes initial peer review
- ▶ You get summary statement (“pink sheets”) 6-8 weeks after review

- ▶ Goes to assigned institution where it goes through 2nd level review by Council
- ▶ Mostly scientific merit is what is used to decide if funded
- ▶ If fundable, Grants Management Branch negotiates award. You receive Notice of Grant Award

The NIH Review Process:

The Players:

Scientific Review Administrator (SRA):

- Assigns grants to reviewers
- Oversees study section
- Prepares summary statements

Chairperson:

- Chairs meeting
- Contributes to discussion
- Voting member

Study Section Members:

- 14-20 PhD/MD level scientists
- “Chartered” sections – same reviewers for years
- Ad hoc as needed
- Diversity

The Process: Grants submitted to the IRG for a particular round is considered in turn according to the score sheet. The SRA or Chairperson asks the primary, secondary and discussant reviewers if they want to score a grant, and if there is consensus that the grant is in the lower half (i.e., the grant would receive a priority score above 250), the grant is streamlined and is not discussed **UNLESS** a member of the IRG wishes to have it discussed, in which case it is reviewed like any other grant. Grants that will be scored are reviewed in turn.

How a Grant gets Reviewed:

- 1. All IRG members who deem themselves to be in conflict of interest must leave the room and cannot vote on that application**
- 2. The primary reviewer begins and gives their initial level of enthusiasm (either as a score or a category corresponding to a range of scores (outstanding, excellent, etc.)).**
- 3. They briefly describe the study according to the applicant's abstract, and highlight the main points of their review according to the 5 criteria (Significance, Approach, Innovation, Investigator, Environment)**

- 4. The secondary reviewer then states whether his/her level of enthusiasm is similar or dissimilar to the primary reviewer, and adds points from their own critique to support their view. To expedite the review process, secondary reviewers are asked not to repeat the points already raised by the primary reviewer.**
- 5. The discussant follows the format of the secondary reviewer, although their review is often not submitted as a written format and their review is usually not as in-depth.**
- 6. The SRA or Chair opens the discussion for the entire IRG. The SRA makes notes for the applicant based on the discussion.**

- 7. Based on the discussion, the SRA or Chair asks the reviewers to come to a consensus on their priority score.**
- 8. All IRG members present are asked to vote around the recommendations of the reviewers.**
- 9. The budget, Human Subjects, Inclusion of Gender/Minorities and Children, and other issues are discussed.**
- 10. Following the review, the grant receives a final score that is the average of all of the scores around the table, to 2 decimal places. The score is multiplied by 100 and is ranked in terms of its percentile relative to all other grants submitted that round.**

11. The SRA prepares a summary statement for all grants and this along with the reviews comprise the “pink sheets” that are sent to the applicant along with their priority score and percentile.

NOTE: The decision of whether or not a grant is funded in NOT made by the IRG, but by the specific NIH council that decides what the “pay line” is, and whether a grant that received a borderline score should be given a higher priority for funding based on its scientific significance.

Guide for Assigned Reviewers' Reviews on Research Grant Applications (R01)

DESCRIPTION: Use the abstract on page 2 of the application unless inappropriate. Summarize the goals of the application. Do not make evaluative statements in this section.

Overall description provided by primary reviewer only.

CRITIQUE: Include as little descriptive information in this section as possible. Address, in five individual sections, each criterion listed below. For each category, consider the strengths and weaknesses of the proposal.

- **Significance**
- **Approach**
- **Innovation**
- **Investigator**
- **Environment**

1. Significance:

- **Does this study address an important problem?**
- **If the aims of the application are achieved, how will scientific knowledge be advanced?**
- **What will be the effect of these studies on the concepts or methods that drive this field?**

2. Approach:

- **Are the conceptual framework, design (including composition of study population), methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?**
- **Does the applicant acknowledge potential problem areas and consider alternative tactics?**

3. Innovation:

- **Does the project employ novel concepts, approaches or methods?**
- **Are the aims original and innovative?**
- **Does the project challenge existing paradigms or develop new methodologies or technologies?**

4. Investigator:

- **Is the investigator appropriately trained and well suited to carry out this work?**
- **Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)? DO NO INCLUDE descriptive biographical information unless important to the evaluation of merit.**

5. Environment:

- Does the scientific environment in which the work will be done contribute to the probability of success?
- Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?
- Is there evidence of institutional support? **DO NOT INCLUDE** description of available facilities or equipment unless important to the evaluation of merit.

OVERALL EVALUATION: In one paragraph, briefly summarize the most important points of the Critique, addressing the strengths and weaknesses of the application in terms of the five review criteria. Recommend score reflecting overall impact on the field.

PROTECTION OF HUMAN SUBJECTS:

- **Evaluate risk to subjects, adequacy of protection against risks, potential benefits to subjects and others, importance of knowledge to be gained**
- **If all adequately addressed then there are no concerns, write “Acceptable Risks and/or Adequate Protections”**
- **If exemption is noted, determined if justified.**

Gender, Minority and Children Subjects

Examine whether the minority and gender characteristics of the sample are scientifically acceptable and consistent with the aims of the project, using the categories of "1" to "4" as follows. Also examine whether there is appropriate inclusion of children (individuals under the age of 21). Also determine whether the research is a Phase III clinical trial.

Category	Gender (G)	Minority (M)	Children (C)
1	both genders	minority & non-minority	children & adults
2	only women	only minority	only children
3	only men	only non-minority	no children included
4	gender unknown	minority representation unknown	representation of children unknown
5		Only foreign subjects	

Evaluate acceptability as "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness or deficiency in the design of the project and reflect it in the overall score.

If Exemptions are claimed, express any comments or concerns about the appropriateness of the exemption(s) claimed. If No Exemptions are claimed, express any comments or concerns about the appropriateness of the applicant's responses to the required points. Discuss whether the risks to the subjects are reasonable in relation to the anticipated benefits to the subjects and/or in relation to the importance of the knowledge that may reasonably be expected to result from the research.

Animal Welfare

Express any comments or concerns about the appropriateness of the responses to the five required points, especially whether the procedures will be limited to those that are unavoidable in the conduct of scientifically sound research.

Biohazards

Note any materials or procedures that are potentially hazardous to research personnel and indicate whether the protection proposed will be adequate.

Budget

- Evaluate the direct costs only.
- The priority score should not be influenced by the budget.
- Do not focus on detail.
- Determine whether the total budget is appropriate for the project proposed.
- Provide a rationale for suggested modification in amount or duration of support.

Other Considerations

- Note: for competing continuation (renewal) applications, include an evaluation of progress over the past project period.
- For amended applications, address progress, changes, and responses to the critiques in the summary statement from the previous review, indicating whether the application is improved, the same as, or worse than the previous submission.
- Comments on progress and response to the previous review should be provided in a separate paragraph and/or under the appropriate criteria.

- NIH tends to note situations where a new investigator is an applicant, in an effort to support “up and coming” scientists.
- If direct costs > 500K in any year, then data sharing plan is expected. Assess reasonableness of plan or rationale for not sharing.
- Foreign institutions or international organizations, assess:
 - Whether projects presents special opportunities for furthering research programs through use of unusual talent, resources, populations or environmental conditions not readily available in the US.
 - Whether proposed project has special relevance to the mission and objectives of NIH and has potential for significantly advancing health sciences in the US.

Conflicts of Interest

- The NIH has guidelines to establish whether a potential reviewer is in conflict of interest.

- According to the NIH:

“An IRG member must leave the room when an application submitted by his/her own organization is being discussed or when the member, his/her immediate family, or close professional associate(s) has a financial or vested interest even if no significant involvement is apparent in the proposal being considered. If the member is available at the principal investigator's institution for discussions; is a provider of services, cell lines, reagents, or other materials, or writer of a letter of reference, the member must be absent from the room during the review. Judgment must be applied on the basis of recency, frequency and strength of the working relationship between the member and the principal investigator as reflected, for example, in publications.”

Examples:

A member should not participate in the deliberations and actions on any application from:

- A recent student, a recent teacher, or a close personal friend;
- A scientist with whom the member has had longstanding differences which could reasonably be viewed as affecting the member's objectivity.

A Note About Language:

- Be professional, polite and to the point.
- Be objective and unemotional.
- Although reviews are confidential, appropriate etiquette will ensure that the applicant knows they received a fair review.

Examples:

What you really think:	How you could say it:
“There is no way these investigators can pull this study off”	“This application is overly ambitious...” or “The investigators lack expertise in the area of X to ensure that the specific aims can be reasonably met.”
“This study is totally unethical”	“The investigators should address the following Human Subjects concerns...”
“This makes no sense”	“Section X is unclear and unfocused.” [Give specific examples of what information is not well explained]
“The budget is too costly”	“The budget appears excessive with respect to the request for X and Y” or “The inclusion of X is not well justified.”
“What is the point of doing this study?”	“The investigators should justify their study design based on the public health significance of disease X.”

Scoring an R01 Application

Scores:

- **100 (best) to 500 (worst)**
- **1.0 to 5.0 (scored by IRG members)**
- **>250 leads to:**
 - **Streamlined or triaged**
 - **Do not receive written reviews**

NOTE: For our course, all will be reviewed and scored

How to score a grant:

Recommend a score reflecting the overall impact of the project on the field, weighting the review criteria, as you feel appropriate for each application.

Use the full range of scores (i.e., 1.0 to 2.5 or beyond).

An application does not need to be strong in all categories to be judged likely to have a major scientific impact and, thus, deserve a high merit rating. 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.

Numerical Rating:	Corresponding Merit Descriptor:
1.0-1.5	Outstanding
1.5-2.0	Excellent
2.0-2.5	Very Good
2.5-3.5	Good
3.5-5.0	Acceptable

Study Section Procedures for Our Course

- All grants will get reviewed by the study section provided the student is registered in the course.
- Each day, the class will break into two study sections. Dr. Celentano will function as the SRA.
- Faculty mentors will participate as discussants who will moderate the discussion for the specific grants they assisted with.
- A student discussant may be picked at random to participate in the discussion of a specific grant. (So you need to read ALL your colleagues' grants in your study section!)
- When your grant is being reviewed, you are requested to remain in the room as an observer but you are NOT permitted to speak! (Remember, in the real world you are not present when the IRG reviews your grant and thus your grant must speak for itself).

- Primary and secondary reviewers must prepare pink sheets for hand-in, in accordance with 4 key areas (Significance, Approach, Innovation, Environment). The discussant need not generate pink sheets for hand-in (this is optional).
- Since only the “science” is being provided to student reviewers, pink sheets should not include the usual discussion of the Investigators or the Budget.
- Pink sheets are due the day the grant in question is being reviewed.
- All students present for the study section on a given day will be asked to score the grants being reviewed that day. Exception: you cannot vote on your own grant!
- Conflicts of Interest: You should not review or score a grant on which you are named as a co-investigator or consultant.