

Title Slide: The NIH Peer Review System

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Slide 2: Learning Objectives

1. Describe what happens to a submitted grant.
2. Understand the new NIH grant review criteria.
3. Describe what happens at an NIH study section meeting.
4. Understand how to interpret a summary statement and prepare a revised application.

Slide 3: No title

[image]

A scientist reviews another scientist's work on the chalk board. The second step of the work says "Then a miracle occurs". The reviewing scientist says :I think you should be more explicit here in step two".

[end image]

Slide 4: No Title

[image]

Snoopy thinking "Here's the famous scientist mailing in his latest application".

The mailbox reject his envelope.

A dejected Snoopy is thinking "I have a hard time believing they read it very carefully" [end image]

Slide 5: After Submission....

- Use your NIH (eRA) Commons account to follow the progress of your application.
- Retrieve your score and summary statement through your Commons account, too!

[image]

Earlier age scientist looking through a microscope and looking at bunson burner.

National Institutes of Health

e R A Commons

[end image]

Slide 6: NIH Grant Applications

- NIH receives over 80,000 grant applications each year; $\leq 20\%$ receive funding.
- NIH's Center for Scientific Review (CSR) facilitates the peer review process for all NIH R01 applications and most other application types (mechanisms).

Slide 7: CSR Study Sections

- Approximately 220 study sections and regularly recurring special emphasis panels.
- Clustered by science into 4 Divisions and then Integrated Review Groups (IRGs).
- Have 12-24 members who are leaders in their academic fields.
- Managed by Scientific Review Officer (SROs) with scientific backgrounds relevant to each study section/panel.
- Meet regularly to consider 60-120 applications per meeting.
- Individual institutes provide review for specific application types based on individual agreements (e.g., NCI and R03).

Slide 8: What *Really* Happens?

[image]

Group of international people seated around a conference area.

[end image]

[image]

Cartoon figure of crazy mad scientist

[end image]

[image]

Muppet characters: muppet scientist pointing a device at Beaker

[end image]

Slide 9: The Tasks of Reviewers

- Receive review materials 6 weeks before meeting.
- Check assignments for potential conflicts.
- Read, note, and ponder your application.
- Write critiques, post them to the meeting's secure website, provide numeric scores that reflect their respective opinions of your application.
- Read the other assigned reviewers' critiques.
- Ponder the collective thoughts regarding your application before they ever sit down at the table for the study section Meeting.
- Receive a list of unscored applications 2-3 days before they travel.

Slide 10: Before the Review Meeting

- Each of the 2 reviewers and the discussant assigned to an application give a separate score for each of the 5 core review criteria.
- Each assigned reviewer and discussant give a preliminary *impact score* for that application.
- The preliminary impact scores are used to determine which applications will be discussed.
- Each member's impact score reflect his/her evaluation of the overall impact that the project is likely to have on the research field(s) involved, rather than a weighted average applied to the reviewers' scores given to each criterion.

Slide 11: NIH's Review Criteria

- Overall Impact
 - Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

Slide 12: NIH's Review Criteria (cont'd)

- Core Review Criteria
 - Reviewers will consider each of the following five review criteria in the determination of scientific and technical merit, and give a separate score for each.
 - An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Slide 13: NIH's Review Criteria (cont'd)

- **Significance:** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- **Investigator(s):** Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?

Slide 14: NIH's Review Criteria (cont'd)

- **Innovation:** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- **Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented?
- **Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?

Slide 15: NIH's Review Criteria (cont'd)

- **Additional Review Criteria**
 - Reviewers consider additional items, such as protections for human subjects & inclusion of women, minorities & children, in the determination of scientific and technical merit, but will not give separate scores for these items.
- **Additional Review Considerations**
 - Reviewers address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score:
 - Budget and Period Support
 - Applications from Foreign Organizations
 - Resource Sharing Plans

Slide 16: Application Alignment with Review Criteria: Major Examples

| Review Criteria | Application Sections |
|-----------------|--------------------------------------|
| Significance | Research Strategy a. Significance |
| Investigator(s) | Biosketch |
| Innovation | Research Strategy b. Innovation |
| Approach | Research Strategy c. Approach |
| Environment | Resources |

Slide 17: New Scoring Policy for Applications Funded in FY2010

- Reviewers have a new scoring system based on a 9-point scale with “1” for exceptional and “9” for poor.

- Reviewers will focus to a greater extent on the *impact* of the proposed research in assigning priority scores.
- Each assigned reviewer will score applications based on each of five main review criteria, as well as assign a preliminary impact/priority score using the new 1-9 scale.
- “Discussed” applications will receive scores on each of the 5 review criteria as well as an overall impact/priority score.
- Individual scores then will be averaged and then multiplied by 10; possible overall impact scores will range from 10-90.
- “Not discussed” applications do not receive an overall impact/priority score but do receive scores for the 5 individual review criteria.

Slide 18: New Review Procedures & Scoring (cont’d)

The following guidance is used to determine an individual review criterion and overall impact/priority scores:

- Exceptionally strong with essentially no weaknesses (Exceptional)
- Extremely strong with negligible weaknesses (Outstanding)
- Very strong with only some minor weaknesses (Excellent)
- Strong but with numerous minor weaknesses (Very Good)
- Strong but with at least one moderate weakness (Good)
- Some strengths but also some moderate weaknesses (Satisfactory)
- Some strengths but with at least one major weakness (Fair)
- A few strengths and a few major weaknesses (Marginal)
- Very few strengths and numerous major weaknesses (Poor)

Slide 19: “Not Discussed” Applications

- Those applications in approximately the lower half of all applications reviewed during that review meeting.
- Reviewers *MUST* provide a preliminary numeric impact score (i.e., 1.0 – 9.0) for each application to which they’re assigned.
- SRO calculates the median scores and constructs the “not discussed” list from all reviewers’ scores.
- At the meeting, any reviewer (without COI) can object to an nomination.
- Such an application returns to its original place in the meeting’s order of review.
- Throughout the meeting, reviewers can choose to discuss a previously “not discussed” application and/or newly assign another application to be “not discussed.”

Slide 20: At the Review Meeting

- The SRA covers important official information.

- Reviewers, program directors introduce themselves.
- The SRA provides reviewers with the final list of “not discussed” applications.
- Individual reviewers may object to a “not discussed” nomination.
- Reviewers finalize the “not discussed” applications.
- Applications “not discussed” will *not* receive an overall impact/priority score, but will receive both criterion scores and critiques from the assigned reviewers.
- Discussions begin for more meritorious applications.

Slide 21: How an Application is Reviewed

- Chairperson/SRA announces an application; reviewers with conflicts exit.
- Chair asks assigned reviewers for respective numeric scores.
- Each (assigned) reviewer provides numeric score that reflects personal impressions AND those of the other written critiques.
- Primary Reviewer (R1) describes proposed study; perceived strengths, weaknesses.
- Secondary Reviewer (R2) provides other S&W; counters some of R1’s impressions.
- Discussant (R3) does the same as R2.

Slide 22: How an Application is Reviewed (cont)

- Unassigned reviewers contribute, the discussion continues to it’s natural conclusion.
- Chair solicits human subjects issues related to merit scoring.
- Chair solicits final scores from assigned reviewers, announces range.
- All reviewers record numeric scores within range (public objections possible).
- Chair solicits HS and budget issues unrelated to score.

Slide 23: Percentile Ranking of Applications

- The overall impact score or priority score is used to determine an application's rank relative to other applications reviewed by the same SRG. This is referred to as the percentile ranking of an application.
- Scores will be percentile to the appropriate base (e.g. study section base if the number of applications >25; CSR all base, or IC all base if < 25) and reported in whole number percentiles.
- Until a new base has been established from three rounds of reviews, percentiles will be based only on the current round of applications or the prior and current rounds.

Slide 24: Immediately After the Review

- Your priority score and percentile will be posted on your e-commons website about three days after the study section meets.

- You may contact your program person at this time to get a general impression of the reviewers' main points if he/she attended the study section meeting (increasingly less likely).
- Within one or two months of the SRG meeting, a summary statement will be available to the Principal Investigator via his/her NIH Commons account.

Slide 25: Your Summary Statement Contains

- Contact information for the Program Officer
- Overall impact score or priority score (depending on the fiscal year)
- Percentile (if applicable)
- Resume and summary of the discussion (only for applications that are discussed)
- Reviewer critiques and individual criterion
- Committee recommendations concerning the budget
- Human subject and vertebrate animal concerns (if applicable)
- Additional administrative comments (if applicable)
- Official meeting roster

Slide 26: Questions Often Asked by Reviewers

- How meticulous are you? How much care do you give to detail?
- Do you show originality of thought?
- Do you plan ahead – and do so with ingenuity?
- Do you think logically and clearly?
- Do you have good analytical skills?
- Do you recognize limitations and potential pitfalls?
- Do you think about alternative procedures in case your proposed project does not go according to expectation?

Slide 27: Common Problems in Applications

- Lack of new or original ideas
- Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- Questionable reasoning or detail in experimental approach
- Uncritical approach
- Superficial or unfocused research plan
- Lack of knowledge of relevant published work
- Unrealistically large amount of work proposed
- Uncertainty concerning future directions
- Failure to address human subjects inclusion criteria

Slide 28: Peer Review in CBPR

- Most applications will be assigned to the Community Level Health Promotion study section:
 - <http://cms.csr.nih.gov/PeerReviewMeetings/CSRIRGDescriptionNew/HDMIRG/CLHP.htm>
- Strict review of the science
- Strict review of the community partnerships
- **Must be strong in both to fare well at peer review**
- Some reviewers occasionally have issues with the community's rights to data ownership and review of documents. They are usually over-ruled by colleagues.

Slide 29: What Happens with 'Pink Sheets'?

- **Program officials** (primary audience for summary statements) use summary statements to recommend meritorious applications to division and Institute directors and to mentor investigators on future (amended) applications.
- **Institute directors and advisory councils** rely on scores, abstracts, resumes/summaries, and critiques to make funding decisions.
- **Principal investigators** integrate feedback in summary statements to refine upcoming funded projects or to revise and resubmit applications.

Slide 30: After Receiving the Summary Statement

- Read the summary statement carefully.
- Put it down and walk away.
- Read it a second time after one week, and not before.

Slide 31: After Reading the Reviews

- Don't whine.
- Have the right attitude: "Three very smart people have donated their time to help me improve my study."
- Don't take the criticisms personally.
- Be as persistent as you would with a manuscript.

Slide 32: One Week Later

- Arrange a phone call with the institute staff person listed on the summary statement to discuss your summary statement.
- Go over the summary statement again.
- Ignore the score—focus on the comments.
- Highlight the criticisms, then make a list.
- Preliminarily, determine how you will respond to each criticism.
- Ask yourself if any “fatal flaws” were identified by the reviewers.
- Discuss any human subjects concerns.

Slide 33: Discussions with Institute Staff

- Review each of the main criticisms.
- Discuss how you plan to respond to each criticism.
- Ask for advice, particularly if you don’t want to change the study to respond to a criticism.

Slide 34: After the Discussions

- Think about how to organize the three-page introduction: by topic or by reviewer.
- Write a draft one-page introduction.
- Begin with something like: “We are very thankful for the thoughtful and comprehensive comments by the reviewers. Their reviews have improved the study.”

Slide 35: What if You Receive an Excellent Score?

- Applications in the fundable range are considered for payment.
- Funding is determined by:
 - Scientific merit
 - Program Considerations
 - Availability of funds
- Applications are active for the entire fiscal year (October 1 through September 30).
- Money is sometimes available at the end of the fiscal year for additional applications.

Slide 36: Additional CSR-NIH Links

- <http://www.csr.nih.gov/Committees/rosterindex.asp>
 - *(membership and meeting rosters for all CSR study sections and SEPs)*
- <http://cms.csr.nih.gov/PeerReviewMeetings/CSRIRGDescription>
 - *(Study sections’ referral guidelines)*

- http://www.csr.nih.gov/REVIEW/clin_research_appls.htm
 - *(additional advice on behavioral/clinical applications)*
- <http://www.csr.nih.gov/Video/Video.asp>
 - *CSR's video of a mock study section meeting*
- <http://www.niaid.nih.gov/ncn/grants/default.htm>
 - *(NIAID's "All About Grants" tutorials, but applicable beyond NIAID's focus/mission)*
- <http://www.grants.gov/GetStarted>
 - *Begin the electronic submission process for all Federal grant applications!*

Slide 37: No Title

[image]

Uncle Sam pointing at you saying " I want you"

[end image]

to submit a grant applications to the National Institutes of Health.

Slide 38: Not Title

*"You miss **100%** of the shots you never take."*

Wayne Gretzky

[end presentation]