THE NIH PEER REVIEW PROCESS

NIH Regional Seminars 2012

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Your Research Project

• If you have a research interest: a new idea; reason to think the experiments would work and others would care about the results

• If you have time (at least 20%) and some resources (a lab) and drive (to see project through tough times)

• Consider applying to NIH
NIH Peer Review

• Cornerstone of the NIH extramural mission
• Standard of excellence worldwide
• Partnership between NIH and the scientific community

• Per year:
  ~ 80,000 applications
  ~ 18,000 reviewers
Review Process

• Receipt and referral – Center for Scientific Review
• Initial peer review – “Study Sections”
• Second level peer review – Advisory Councils or Boards
NIH Grants Process - Overview

Application received ➔

NIH Center for Scientific Review (CSR)

Assignments made

Initial peer review
- Study section
- IC or CSR
- Scientific Review Officer

Second level of review
- Council or Board (IC)

Funding considerations
- Institutes or Centers (ICs)
- Duals possible
- Program Officer

Funding decisions
- IC Director

Award!
Receipt and Referral

• Key decisions
  – Format compliance
  – Timeliness
  – Assignment to study section for initial peer review
  – Assignment to IC(s) for funding consideration

Study Section
• Initial peer review
• (CSR or IC)

IC(s)
• Council review
• Funding consideration
Locus of Review

• CSR Review
  – Most R01’s, F’s and SBIR’s
  – Some Program Announcements
  – Some Requests for Applications (RFAs)

• Institute/Center Review
  – IC-specific features
  – P’s, T’s, K’s
  – Most RFAs

Study Section
  • Initial peer review
  • (CSR or IC)
Requesting a Study Section

• The locus of review (CSR/IC) is usually stated in the FOA.
• The Study Section assignment is available in the PD/PI’s Commons account.
• Descriptions of study sections in the Center for Scientific Review (CSR) are posted online: http://public.csr.nih.gov/StudySections/IntegratedReviewGroups/Pages/default.aspx
Requesting a Study Section

- Rosters are available on NIH websites

- Permanent membership is available anytime
- Membership for a given meeting is posted 30 days before the meeting
  - Subject to change
  - Some CSR rosters are posted in aggregate
Requesting a Study Section

• Cover letter of application
  – Application title
  – FOA # and title
  – Request:
    ▪ Particular Study Section(s) or Integrated Review Group(s)
    ▪ Particular IC for funding consideration
  – Disciplines involved, if multidisciplinary

• Not all requests can be honored
Conflict of Interest

• Bases for Conflict of Interest (COI)
  – Financial
  – Employment
  – Personal
  - Professional
  - Study Section membership
  - Other interests

• Appearance of COI

• Depending on nature of COI, individual with a COI
  – must be excluded from serving on the Study Section, or
  – must be recused from discussion and scoring of application.
NIH Scoring System

• Reviewers give numerical scores
  – 1 (exceptional) to 9 (poor)
  – Integers

• Used for:
  – Final impact scores
  – Individual criterion scores
## Score Descriptors

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High Impact</strong></td>
<td>1</td>
<td>Exceptional</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
</tr>
<tr>
<td><strong>Moderate Impact</strong></td>
<td>4</td>
<td>Very Good</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
</tr>
<tr>
<td><strong>Low Impact</strong></td>
<td>7</td>
<td>Fair</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
</tr>
</tbody>
</table>
Final Impact Scores

• Voted by all eligible (w/o COI) members
• Voted by private ballot at the meeting
• Calculated by:
  – Averaging all reviewers’ votes
  – Multiplying by 10
• Range from 10 through 90
• Percentiled for some activity codes (R01s)
Criterion Scores

• Minimum of five scored criteria
• Given by assigned reviewers as part of their critiques
• Generally not discussed at the meeting
• Reported on the summary statement

1 – high impact  
9 – low impact
Streamlining

• Allows more in depth discussion of more meritorious applications
  – Less meritorious applications are tabled
  – Designated Not Discussed (ND)
• Requires full concurrence of the entire SRG
• Summary statements contain:
  – Reviewer critiques
  – Criterion scores
  – Overall impact scores (if discussed)
Scientific Review Officer

• Identifies and recruits reviewers
• Assigns reviewers to individual applications
• Manages conflicts of interest
• Arranges and presides over process at review meetings
• Prepares summary statements – official written outcome of initial peer review
Reviewers

• Expertise
• Stature in field
• Mature judgment
• Impartiality
• Ability to work well in a group
• Managed conflicts of interest
• Balanced representation
• Availability
Types of Reviewers

• Regular reviewers
  – Participate in committee discussions
  – Contribute preliminary impact scores, criterion scores, written critiques, final impact scores

• “Mail” reviewers
  – Contribute preliminary impact scores, criterion scores, written critiques
  – Do not participate in committee discussion
  – *Cannot* submit final impact scores
Confidentiality

• All confidential materials, discussions, documents are deleted, retrieved, or destroyed.
• All questions must be referred to the SRO.
• Applicants: *Do not contact reviewers directly!*
Overall Impact

• Overall consideration for all NIH applications
• Defined differently for different types of applications
  – Research grant applications: *Likelihood for the project to exert a sustained, powerful influence on the research field(s) involved*
Scored Review Criteria

• Receive individual, numerical scores from the assigned reviewers.

• For research grant applications:
  – Significance
  – Investigator(s)
  – Innovation
  - Approach
  - Environment
Additional Review Criteria

• Are considered in determining the impact score, as applicable for the project proposed

• For research grant applications:
  – Protections for Human Subjects
  – Inclusion of Women, Minorities, and Children
  – Vertebrate Animals
  – Resubmission, Renewal, and Revision Applications
  – Biohazards
Additional Review Considerations

• Are not considered in determining impact score
• Generate reviewer comments for Program Officials to consider
• For research grant applications:
  – Applications from Foreign Organizations
  – Select Agent Research
  – Resource Sharing Plans
  – Budget and Period of Support
Study Sections

• Make recommendations on:
  – Scientific and technical merit
  – Impact
    ▪ Impact scores
    ▪ Criterion scores
    ▪ Written critiques
  – Other review considerations
Reviewer Assignments

• For each application:
  – ≥ Three qualified reviewers are assigned
  – Assignments are made by the SRO
    ▪ Expertise of the reviewer
    ▪ Suggestions from the PI on expertise – *not names!*
    ▪ Suggestions from Program staff and Study Section members
    ▪ Managing conflicts of interest
    ▪ Balancing workload

• Assignments are confidential
Before the Meeting

• Reviewers
  – Examine assignments (usually six weeks in advance)
  – Often participate in an orientation teleconference with the SRO
  – Submit Conflict of Interest and Confidentiality certifications
  – Read applications, prepare written critiques in templates
  – Enter preliminary scores and critiques into secure website
  – Read and consider critiques and preliminary scores from other Study Section members
Critique Templates

RPG/R01/R03/R15/R21 Review

If you cannot access the hyperlinks below, visit http://grants.nih.gov/grants/peer/critiques/rpg.htm.

Application #:
Principal Investigator(s):

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 scored review criteria, and additional review criteria. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

**Overall Impact** Write a paragraph summarizing the factors that informed your Overall Impact score.

SCORED REVIEW CRITERIA

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each.

1. **Significance**

   Strengths
   *
   Weaknesses
Study Section Agenda

• In some meetings, streamlining done first
• Cluster where feasible:
  – New Investigator (NI) applications
  – Clinical applications
• Discuss each remaining application
  – Assigned reviewers lead off
  – Chairperson summarizes main points
  – Members score after its discussion
  – Members discuss other considerations
Discussion Format

- Members with conflicts excused
- Initial levels of enthusiasm stated (assigned reviewers)
- Primary reviewer - explains project, strengths, weaknesses, likely impact on field
- Other assigned reviewers and discussants follow
- Open discussion (full panel)
- Levels of enthusiasm re-stated (assigned reviewers)
- Chair summarizes main points from discussion
- All Study Section members vote – *private ballot*
- Other review considerations discussed (budget)
After the Review

- eRA Commons (http://era.nih.gov/commons/index.cfm)
  - Final Impact Score is available in 3 days.
  - Summary statement is available in 4 – 8 weeks.

- Available to:
  - PD/PIs
  - NIH officials
  - Advisory Council members

- NIH Program Officer = Point of Contact
Summary Statement

• First page
  – NIH Program Officer (upper left corner)
  – Final Impact Score or other designation
  – Percentile (if applicable)
  – Codes (human subjects, vertebrate animals, inclusion)
  – Budget request

• A favorable score does not guarantee funding!
Summary Statement - continued

• Subsequent Pages
  – Description (provided by applicant)
  – Resumé and Summary of Discussion (if discussed)
  – Reviewer critiques – essentially unedited
  – Administrative Notes
  – Meeting roster
After the Review

• If the outcome is favorable, congratulations!
• If the outcome is unfavorable, consider your options:
  – Revise and resubmit your application
  – Talk to Program Official about appealing the review outcome
Appeals of initial peer review

• Acceptable reasons (**NOT-OD-11-064**)
  – Evidence of bias
  – Conflict of interest, as specified in regulation (**42 CFR 52h.5**)
  – Lack of appropriate expertise
  – Factual error(s) that could have altered the outcome of the review substantially.

• Differences of scientific opinion cannot be appealed
National Advisory Councils

• Broad and diverse membership
  – Basic /research scientists
  – Clinician scientists
  – “Public” members
• Nominated by Institutes; approved by HHS
• Awards cannot be made without Council approval
• Council procedures vary across IC’s
National Advisory Councils

• Advise IC Director about
  – Research priority areas
  – Diverse policy issues
  – Concept Clearance for future initiatives
  – Funding priorities

• Approve applications for funding
  – Expedited awards
  – En bloc concurrence
National Advisory Councils

• Unresolved appeals are presented to Council

• Council options
  – Support the Study Section review
  – Support the appeal, recommend re-review
    • Application could be deferred for next round
    • Application cannot modified or updated
  – Results of re-review cannot be appealed further

• Council cannot overturn the review or impact score
Additional Information

• Office of Extramural Research Peer Review Process
  http://grants.nih.gov/grants/peer_review_process.htm

• Peer Review Policies & Practices
  http://grants.nih.gov/grants/peer/peer.htm

• Center for Scientific Review
  http://cms.csr.nih.gov/AboutCSR/Welcome+to+CSR/