Demystifying the NIH Peer Review Process

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NIH Center for Scientific Review
December 14, 2015
Goals of the Presentation

Familiarization with the NIH Review Process
• The life cycle of a Grant Application
• Receipt and Referral Process
• The Study Section
• The Review Process
• Outcome of Review
• Resources
NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
National Institutes of Health
Your Application Could Be Funded by One of 24 NIH Institutes or Centers
24 NIH Institutes and Centers Fund Grants
Separation of Levels of Review

First Level of Review

Study Section (SRG)
- Scientific Merit
- Budget Recommendations

Second Level of Review

Funding

Institute Councils
- Evaluate Program Priorities/Relevance
- Policy Considerations

Institutes
Program Priorities-generates Program Announcements RFAs
Review Process for a Research Grant

1. **Initiates Research Idea**
2. **Submits Application**
3. **Allocates Funds**
4. **Conducts Research**

- **Research Grant Application**
- **School or Other Research Center**

- **National Institutes of Health**
  - **Center for Scientific Review**
    - Assigns to IC & IRG/Study Section
    - **Study Section**
      - Reviews for Scientific Merit
      - **Institute**
        - Evaluates for Relevance
        - **Advisory Councils and Boards**
          - Recommends Action
          - **Institute Director**
            - Takes Final Action
Electronic Application Process (Overview)

1. **Prepare to Apply & Register**
   - Register with Grants.gov & eRA Commons

2. **Find Opportunity**
   - Submit in response to Funding Opportunity Announcement (FOA)

3. **Prepare Application**
   - Follow Application Guide & Instructions

4. **Submit, Track & View**
   - Submit via your organizational representative
   - Use eRA Commons to view & track

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[NIH Center for Scientific Review]
Who Can Answer Your Questions?

**Before You Submit Your Application**
- A Program Officer at an NIH Institute or Center
- Scientific Review Officer

**After You Submit**
- Your Scientific Review Officer

**After Your Review**
- Your Assigned Program Officer
Your New Application Must Be Written as New

Your new (A0) application should not contain information that might bias the review or provide a competitive advantage:

**You Cannot Refer to a Previous Review**
- No mention of previous score
- No mention of previous reviewer comments
- No mention of how the A0 is responsive to previous review
- No marks in text to indicate changes

**You Cannot Submit Elements of a Renewal**
- No Progress Report
- No Progress Report Publication List
Your Application Goes to the NIH Center for Scientific Review (CSR)

Focal Point for Initial Review at NIH

- Receives all NIH applications
- Refers them to NIH Institutes/Centers and to scientific review groups
- Reviews majority of grant applications for scientific merit
CSR Mission

To see that NIH grant applications receive fair, independent, expert, and timely reviews – free from inappropriate influences – so NIH can fund the most promising research.
CSR Peer Review – Fiscal Year 2014

- 86,000 applications received
- 16,000 reviewers
- 237 Scientific Review Officers
- 1,500 review meetings
What does the Division of Receipt and Referral (DRR) do?

- Determines if application is
  - on time
  - formatted correctly
  - complete
- Makes Institute Assignment for funding consideration
- Makes Study Section Assignment for review
Applications Are Assigned to:

- **Institutes or Centers based on**—
  - Overall mission and guidelines of the Institute or Center
  - Specific programmatic mandates and interests of the Institute or Center
  - Dual assignments are made where applications are appropriate for more than one Institute or Center.

- **Integrated Review Groups based on**—
  - Specific review guidelines for each Integrated Review Group (IRG)
Help Your Application Get to the Right Institute

Match your application to NIH:

- Projects: Related research on the same scientific topic
- FOAs: Funding Opportunity Announcements for the topic area
- Institutes: Programs that are funding research in this topic area

http://ProjectRePORTER.NIH.gov
Find a Funding Opportunity (FOA)
Help Your Application Get to the Right Study Section

Find a Study Section

Applications are reviewed in Study Sections (Scientific Review Group, SRG). Integrated Review Groups (IRGs) are clusters of Study Sections based on scientific discipline.

http://www.csr.nih.gov/
Divisions and Integrated Review Groups (IRGs)
Division of AIDS, Behavioral and Population Sciences

<table>
<thead>
<tr>
<th>Integrated Review Groups</th>
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<tbody>
<tr>
<td>Biobehavioral &amp; Behavioral Processes</td>
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<tr>
<td>Risk, Prevention &amp; Health Behavior</td>
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<tr>
<td><strong>Population Sciences and Epidemiology</strong></td>
</tr>
<tr>
<td>Healthcare Delivery &amp; Methodologies</td>
</tr>
<tr>
<td>AIDS and Related Research</td>
</tr>
</tbody>
</table>

- Social Sciences and Population Studies
- Behavioral Genetics and Epidemiology
- Cancer, Heart and Sleep Epidemiology
- Kidney, Nutrition, Obesity, & Diabetes Epidemiology
- Infectious Diseases, Reproductive Health, Asthma and Pulmonary Epidemiology
- Neurological, Aging and Musculoskeletal Epidemiology
- Societal and Ethical Issues in Research
Help Your Application Get to the Right Study Section

Integrated Review Group
Help Your Application Get to the Right Study Section

<table>
<thead>
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NIH Center for Scientific Review
CSR Web Site

- About CSR
- Applicant Resources
- Study Sections
- Rosters and Meetings

http://www.csr.nih.gov
Help Get Your Application to the Right Institute and Study Section

Submit a Cover Letter!
The cover letter should be used for a number of important purposes:

- Suggest Institute/Center assignment
- Suggest review group assignment
- Identify individuals in potential conflict and explain why
- Identify areas of expertise needed to evaluate the application
- Discuss any special situations

It is NOT appropriate to use the cover letter to suggest specific reviewers.

http://www.csr.nih.gov/coverletter
Suggested Cover Letter Format

• Present one request per line
• Separate positive and negative requests
• Separate IC and review requests
• Include name of IC and SRG followed by dash and acronym; do not use parentheses
• Provide explanation in separate paragraph
Sample Cover Letter

Please assign this Phase I SBIR “Drugs for Retinoblastoma Treatment” (RFA-CS-00-000) to the following:

Institutes/Centers
  National Cancer Institute
  National Eye Institute
Scientific Review Group
  Cancer Drug Development & Therapeutics

Please do not assign this application to the following:
  Scientific Review Group
    Biological Chemistry, Biophysics, and Drug Discovery

This study focuses on a new in vitro model for testing drugs for treatment of retinoblastoma, not the synthesis of new chemotherapeutic agents.
Assignment to CSR Study Sections

Within an IRG, applications are assigned to:

Standing Study Sections
- When subject matter of application matches the referral guidelines for the study section or

Special Emphasis Panels (SEPs)
- When the subject matter does not fit into any study section
- When assignment of an application to the most appropriate study section creates a conflict of interest
- When certain types of grants are sought (e.g., fellowships, SBIRs, AREAS)
Applications Are Assigned to:

- **Institutes or Centers based on**—
  - Overall mission and guidelines of the Institute or Center
  - Specific programmatic mandates and interests of the Institute or Center
  - Dual assignments are made where applications are appropriate for more than one Institute or Center.

- **Integrated Review Groups based on**—
  - Specific review guidelines for each Integrated Review Group (IRG)
Your Application Could Be Reviewed Electronically

Electronic reviews are used to facilitate reviewer participation

Electronic Review Platforms
- Telephone Assisted Meetings
- Internet Assisted Meetings
- Video Assisted Meetings
CSR Study Sections: The Meeting

- Each CSR standing Study Section has ~12-22 regular members plus temporary reviewers from the scientific community.
- About 70 applications are usually reviewed by each study section in 1-2 day meetings.
Before the Study Section Meeting

• Each application is assigned to 3 or more reviewers 5-6 weeks in advance

• Reviewers assess each application by providing:
  – A preliminary Overall Impact score
  – Criterion Scores for each of the 5 Core Review Criteria
  – A written critique
How Reviewers Are Selected for Study Section Service

- Demonstrated scientific expertise/research support
- Doctoral degree or equivalent
- Mature judgment
- Work effectively in a group context
- Breadth of perspective
- Impartiality
- Representation of women and minority scientists
- Geographic distribution
Where Do We Find Reviewers?

- CSR electronic resources
- Successful applicants
- Recommendations from reviewers and NIH staff
- NIH RePORTER
  (http://projectreporter.nih.gov/reporter.cfm)
- Internet
- Scientific conferences
The SRO Assigns at Least Three Reviewers to an Application
Reviewer Conflicts of Interest (COI)

**What Constitutes a Reviewer COI?**

- Institutional
- Family member/close friend
- Collaborator
- Longstanding scientific disagreement
- Personal bias
- Appearance of conflict

Confidentiality

- Review materials and proceedings of review meetings represent privileged information for reviewers and NIH staff.
- At the end of each meeting, reviewers must destroy or return all review-related material.
- Reviewers should not discuss review proceedings with anyone except the SRO.
- Questions concerning review proceedings should be referred to the SRO.
- Applicants should never communicate directly with any members of the study section about an application.
The Study Section Meeting

• Closed Meeting
• Orientation
  – Conflict of Interest
  – Confidentiality
  – Developments of interest to the study section
  – Changes in policy or procedure
  – Roles of the persons present
  – Chair and other Reviewers
  – Program Officers (Observers)
  – SRO
• Application by Application review
Your Scientific Review Officer

During and After the Review Meeting

• Manages the meeting
• Prepares summary statements
• Provides information to NIH Institutes and Centers
Role of Study Section Chair

- Partners with their Scientific Review Officer to conduct the meeting

- Guides and summarizes study section discussion

- Ensures all study section member opinions are given careful consideration

- Manages scientific discussions at the meeting, e.g., timeliness and thoroughness
At The Meeting

Order of Review

- The average of the preliminary Overall Impact score from the assigned reviewers determines the review order
- Discussions start with the application with the best average preliminary Overall Impact score

Clustering of Review

- New Investigator R01 applications are clustered
- Clinical applications & other mechanisms may be clustered (n ≥ 20)

Not Discussed Applications

- About half the applications will be discussed
- Applications unanimously judged by the review committee to be in the lower half are not discussed
New and Early Stage Investigators

• **New Investigator (NI)**
  – PD/PI who has not yet *competed successfully* for an R01 or other substantial NIH research grant

• **Early Stage Investigator (ESI)**
  – PD/PI who qualifies as a New Investigator AND is within 10 years of completing the terminal research degree or is within 10 years of completing medical residency

http://grants.nih.gov/grants/new_investigators/
Review of Each Application

• Reviewers with conflicts leave room
• Assigned reviewers state preliminary scores
• Discussion of scientific and technical merit
  – Based on the 5 review criteria
  – Assigned reviewers first then open discussion to whole committee
• Discussion of Protection of Human Subjects and Inclusion criteria
• Assigned reviewers state final score – range of scores is set
• Every eligible member scores each application
• Budget and Administrative concerns
• Ideal time for each application - 15 to 20 minutes
Additional Criteria Contribute to Overall Impact Scores

- Protections for human subjects
- Inclusions of women, minorities, and children
- Appropriate use of vertebrate animals
- Management of biohazards
Research Involving Children

Children must be considered for inclusion in all human subject research supported by NIH

• Child is defined as an individual under age 18
• If children are included, Investigator must address:
  – age range
  – expertise of investigative team
  – facilities
  – sufficient numbers
• If children are not included, must justify exclusion
Proposed clinical research must include:

• Plans for the inclusion of minorities and members of both genders, as well as the inclusion of children.

or

• A clear and compelling justification indicating that inclusion is inappropriate due to the health of the subjects or the purpose of the research.

http://grants.nih.gov/grants/funding/women_min/women_min.htm
Vertebrate Animal Welfare

Important Considerations

• Proposed use of the animals, and species, strains, ages, sex, and numbers to be used
• Justifications for the use of animals and for the appropriateness of the species and numbers proposed
• Adequacy of veterinary care
• Procedures for limiting discomfort, distress, pain and injury
• Euthanasia in accord with American Veterinary Medical Association guidelines
Scoring

9-point score scale is used to provide:
• Criterion Scores for each of the 5 core review criteria
• Overall Impact/Priority Score based on but not a sum of the core criterion scores plus additional criteria

All applications receive scores:
• Not discussed applications will receive only initial criterion scores from the three assigned reviewers.
• Discussed applications also receive an averaged overall impact score from eligible (i.e., without conflicts of interest) panel members.
Scoring

- Score applications on five core criteria using a scale of 1-9
- Preliminary overall impact/priority score using 1-9 scale
- Discussed applications receive an overall score from each eligible (i.e., without conflicts of interest) panel member, and these scores will be averaged to one decimal place, and multiplied by 10. The 81 possible priority scores will thus range from 10-90.
- All applications will receive scores:
  Not discussed applications will receive initial criterion scores from the three assigned reviewers.
Review Criteria

• Overall Impact
  – Assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved

• Core Review Criteria
  – Significance
  – Investigator(s)
  – Innovation
  – Approach
  – Environment

Review criteria each scored from 1-9
## 9-Point Scoring Scale

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Impact</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>Medium Impact</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>Low Impact</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>
Scoring Philosophy

Overall Impact:
The likelihood for a project to exert a sustained, powerful influence on research field(s) involved.

<table>
<thead>
<tr>
<th>Overall Impact</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
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</table>

Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer’s judgment) and other score influences (e.g. human subjects).

- e.g. Applications are addressing a problem of high importance/interest in the field. May have some or no technical weaknesses.
- e.g. Applications may be addressing a problem of high importance in the field, but weaknesses in the criteria bring down the overall impact to medium.
- e.g. Applications may be addressing a problem of moderate importance in the field, with some or no technical weaknesses.
- e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.
- e.g. Applications may be addressing a problem of low or no importance in the field, with some or no technical weaknesses.

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.
Priority Scores

- For each study section, applications in the upper half may be scored from 1-9, with 1 the best score.

- Individual scores are averaged and multiplied by 10 to give the final priority score.
After Your Review

Your SRO

- Prepares summary statements
- Provides information to NIH Institutes and Centers
Your Summary Statement

- Scores for each review criterion
- Critiques from assigned reviewers
- Administrative notes if any

If your application is discussed, you also will receive:

- An overall impact/priority score and percentile ranking
- A summary of review discussion
- Budget recommendations
Summary Statement

Program Officer

Impact/Priority Score 10-90 range

Percentile in whole numbers

Indicator for Early Stage Investigators

NIH Center for Scientific Review
Check the Status of Your Application in NIH Commons
Your Application Was Reviewed
What Do You Do Next?

Visit NIH’s Next Steps Website

http://grants.nih.gov/grants/next_steps.htm
Who Can Answer Your Questions?

Before You Submit Your Application
• A Program Officer at an NIH Institute or Center
• Scientific Review Officer

After You Submit
• Your Scientific Review Officer

After Your Review
• Your Assigned Program Officer
Jumpstart Your Career: CSR Early Career Reviewer Program
Early Career Reviewer Program Goals

• Train and educate qualified scientists to become critical and well-trained reviewers
• Expose investigators to the peer review experience to help make them more competitive as applicants
• Enrich the existing pool of NIH reviewers
Qualifications for the Early Career Reviewer Program

- Demonstrated training and experience in the scientific areas under review as evidenced by:
  - A faculty appointment or equivalent
  - An active independent program of research
  - At least 2 senior authored research publications in peer reviewed journals in the past 2 years
- Has not previously served on a CSR Study Section
- Has not been PI on an R01 award
ECR Service

- Attend study section meeting
- Assigned 2-4 applications as 3rd reviewer
- Write full critiques for assigned application
- Participate in one study section meeting
View the Video

Jumpstart Your Research Career with CSR’s Early Career Reviewer Program

www.csr.nih.gov/video/video.asp
How to Apply for the Early Career Reviewer Program

- Instructions are at [www.csr.nih.gov/ECR](http://www.csr.nih.gov/ECR)
- If eligible, your name will be placed into our ECR database
- You will be invited to serve as an ECR when your expertise is needed for particular applications
CSR and NIH Information Sources
NIH Peer Review Information on the Web

National Institutes of Health: http://www.nih.gov
  • Office of Extramural Research
    http://grants.nih.gov/grants/oer.htm
  • Grants Policy
    http://grants.nih.gov/grants/policy/policy.htm
  • Electronic Submission

Center for Scientific Review: http://www.csr.nih.gov
  • Resources for Applicants
    http://www.csr.nih.gov/ResourcesforApplicants
  • CSR Study Section Descriptions
    http://public.csr.nih.gov/StudySections
  • CSR Rosters and Meeting Dates
    http://public.csr.nih.gov/RosterAndMeetings
CSR Web Site

- About CSR
- Applicant Resources
- Study Sections
- Rosters and Meetings

http://www.csr.nih.gov
Key NIH Review and Grants Web Sites

NIH Center for Scientific Review
http://www.csr.nih.gov

NIH Office of Extramural Research
http://grants.nih.gov/
The NIH Web Site

http://www.nih.gov
Helpful Handouts

Insider’s Guide to Peer Review

What Happens to Your Grant Application

NIH Grant Application Useful Web Links

http://www.csr.nih.gov/publications/
NIH Guide
For Grants and Contracts
U.S. Department of Health and Human Services

• Announces NIH Scientific Initiatives
• Provides NIH Policy and Administrative Information
• Supplies links to application forms
• Available on the NIH Web Site: http://www.nih.gov
A Window to Your Application: eRA Commons

eRA Commons is an online interface where a grant applicant can:

• Check submitted grant application for errors and warnings and view final image
• Track review assignment, view review outcomes (score, summary statements), find contact info
• Update Personal Profile to ensure Early Stage Investigator eligibility is in place
• Submit pre-award information (just in time)
• View Notice of Award and other key documents

And much more!

https://commons.era.nih.gov/commons/
NIH Encourages Applicants to Describe their Research in Terms Easily Understood by Reviewers, Scientists, Congress and the Public

Titles, statements of public health relevance & abstracts should:

- Convey value of research in plain language
- Be understandable by both scientists and the public
- Clearly relay the potential impact of the research on health

The public accesses funded NIH grant info through [http://ProjectRePORTER.NIH.gov](http://ProjectRePORTER.NIH.gov)

Examples and more info: [http://grants.nih.gov/grants/plain_language.htm](http://grants.nih.gov/grants/plain_language.htm)
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NIH’s Resubmission Policy

After an unsuccessful new (A0) application or an unsuccessful resubmission (A1) application, you may submit a new (A0) application with the same idea as long as your summary statement has been issued.

NIH Guide Notices
• NOT-OD-14-074
• NOT-OD-14-082

Resubmission FAQs
View the Videos

- NIH Peer Review Revealed
- Jumpstart Your Research Career with CSR’s Early Career Reviewer Program
- NIH Tips for Applicants
- What Happens to Your NIH Grant Application

Meet the Experts in NIH Peer Review Webinars

For Researchers Seeking:
- R01 Grants
- Fellowship Awards
- AREA/R15 Grants
- Small Business Grants

www.csr.nih.gov/webinar