Overview of NIH Peer Review and Grant Application Changes

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NIH Peer Review Process

NIH policy requires:

• Peer review be carried out in a manner that ensures objectivity, fairness, and scientific and technical competence.

• All applications accepted for review are subjected to the same review process.

• Both levels of NIH peer review must be conducted in accordance with applicable laws, regulations, and policies.

Overview of NIH Peer Review - grants

• Mandated by law: The Public Health Service Act
  o Two-tiered system
  o Initial peer review (study section, SRG, etc.)
  o National Advisory Council or Board

• Defined in regulation: 42 CFR 52h

• Further defined by NIH policy on Peer Review and NIH Guide Notices
**NIH Peer Review Process**

- Conducted according to the Federal Advisory Committee Act (FACA)
  - Meetings are closed to the public
  - All materials and discussions – strictly confidential

**Initial Peer Review**

- Scientific Review Groups (SRGs) make recommendations:
  - Scientific and technical merit
  - Protections for human subjects, women, minorities, children inclusion plans, animal welfare, biohazards
  - Budget amount and project duration
  - Resource sharing plans
  - Other administrative considerations

**Per year:**
- Nearly 80,000 applications
- Over 18,000 reviewers

**Second Level of Review**

- Advisory Councils or Boards
  - Make recommendations to the IC Director
  - Applications to consider for funding
  - Emerging areas of sciences
  - Program priorities
  - Appeals of initial peer review

- COUNCILS DO NOT MAKE FUNDING DECISIONS
NIH Peer Review Process

- IC Director
  - Recommendations from Advisory Council
  - Recommendations from NIH IC staff
  - NIH or IC policy

- FINAL FUNDING DECISIONS

NIH Peer Review Process

Application received
NIH Center for Scientific Review (CSR)
Assignments made

Initial peer review
Scientific Review Group (SRG)
IC or CSR study section
Scientific Review Officer (SRO)

Second level of review
National Advisory Council or Board (IC)
Recommendations to IC

Award!

Re-apply

Funding decisions
IC Director

Funding considerations
Institutes or Centers (ICs)
Duals possible (more than one IC)
Program Officer, IC staff

Review Cycle

<table>
<thead>
<tr>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
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<tbody>
<tr>
<td>Scientific Merit Review</td>
<td>June - July</td>
<td>October - November</td>
</tr>
<tr>
<td>Advisory Council Review</td>
<td>October</td>
<td>January</td>
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</tbody>
</table>

Standard Receipt Dates for Competing Applications
http://grants.nih.gov/grants/funding/submissionschedule.htm
Continuous Submission

Modified receipt for eligible investigators, applicable to R01, R21 and R34 applications normally submitted for standard due dates.

Eligibility:
Appointed members of:
- chartered standing NIH Study Sections
- NIH Boards of Scientific Counselors,
- NIH Advisory Boards or Councils,
- NIH Program Advisory Committees, and
Peer reviewers who have served as regular or temporary members of peer review committees six times in 18 months.

Where will my application be reviewed?

Referral to an SRG

CSR Review
- Most R01s, fellowships, small business applications, AREA
- Some Program Announcements (PAs)
- Some Requests for Applications (RFAs)

Institute/Center Review
- IC-specific features
- Program Projects
- Training grants
- Career Development Awards
- Clinical Trials
- RFAs

The review locus is stated in the Funding Opportunity Announcement (FOA)

Types of Scientific Review Groups (SRGs)

- "Chartered" SRGs
  - Multyear terms (4-6 years) NEW 6-year terms, since 7/2009
  - Formal appointment process
  - May include temporary members (per meeting) for additional or special expertise

- Special Emphasis Panels (SEP)
  - Meet on ad hoc basis, often only once
  - Temporary membership
Scientific Review Officer (SRO)

- First level of peer review
  - Designated Federal Official
  - Identifies and recruits reviewers
    - Expertise, stature in field, impartiality, availability
    - Committee diversity with respect to the geographic distribution, gender, race and ethnicity
  - Manages Conflicts of Interest (COI) between a reviewer and an application
    - Examples: financial, personal, professional, SRG membership
  - Oversees arrangements for review meetings
  - Presides at review committee meetings
  - Prepares and releases summary statements

Reviewer Assignments

Assignments are confidential!

- For each application:
  - ≥ Three qualified reviewers are assigned
  - Assignments are made by the SRO
    - Based on the scientific content of application
    - Expertise of the reviewer
    - Suggestions from the PI on required expertise—no names!
    - Suggestions from Program staff, SRB members
  - Additional considerations for assignments
    - Managing conflicts of interest
    - Balancing workload

Enhancing Peer Review

- Phase out of A2 applications
- Identification of Early Stage Investigator (ESI) R01 applications
- Clustering of New Investigator Applications
- Enhanced review criteria
- New scoring system
- Criterion scoring
- Structured critiques
- Restructured Applications
- Shorter Page Limits and New Instructions
Phase out of A2 applications

Resubmissions (Amended) Applications

• The NIH will accept only a single amendment (resubmission, A1) to the original application (A0)

• An A2 (second re-submission) application is allowed until January 7, 2011 if the A0 (original) application was submitted before the new policy began (January 25, 2009)

NOT-OD-09-003 October 8, 2008

NI/ESI Goals

Background:

• Concern about the number of New Investigators (NI) and the increasing age at first award.

Goals:

• Enrich the applicant pool with enough Early Stage Investigator (ESIs) to reduce the average age at first award
• Accelerate the period of training leading to independence

NI/ESI Definitions

• New Investigator (NI): A Program Director or Principal Investigator (PD/PI) is considered a New Investigator if he/she has not previously competed successfully as PD/PI for a “significant independent” NIH research award (R01, R01 equivalent).

• Early Stage Investigator (ESI): A subset of New Investigators who are within 10 years of receiving terminal degree or end of medical residency, whichever occurred most recently (requests for extension will be considered).

NOT-OD-08-121 September 2008
New Investigator/Early Stage Investigator

- New Investigator Policies are limited to R01 applications (traditional research project grant support).
- NIH Director’s New Innovator Award (DP2), Pathway to Independence Award (K99/R00) eligibility: ESI status
- During Peer Review of R01 applications:
  - NI/ESI applications will be clustered during review
  - Consider the career stage of the PD/PI when evaluating elements of the applications, such as the availability of preliminary data
- New and Early Stage Investigator Policies:
Overview and Timeline

- **January 2009**
  - Phase out of A2 applications
  - Identification of Early Stage Investigator (ESI) R01 applications

- **May/June 2009**
  - Clustering of New Inv. Applications
  - Enhanced review criteria
  - New scoring system
  - Criterion scoring
  - Structured critiques

- **January 25, 2010**
  - Restructured Applications
  - Shorter Page Limits and New Instructions

Enhanced Review Criteria

**Overall Impact:** Likelihood for the project to exert a sustained, powerful influence on the research field(s) involved

- In consideration of:
  - At least five scored criteria
    - Receive individual, numerical scores
    - Additional criteria, as applicable for the project proposed
    - Do not receive individual, numerical scores
    - Additional criteria in certain announcements

Overall Impact Score

- **Research Project Grant (RPG):** Likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five core review criteria, and additional review criteria

- **Fellowship (F):** Likelihood that the fellowship will enhance the candidate's potential for, and commitment to, a productive independent scientific research career in a health-related field, in consideration of the scored and additional review criteria

- **Career Development (K):** Likelihood for the candidate to maintain a strong research program, taking into consideration the criteria in determining the overall impact/priority score
Enhanced Review Criteria

Scored Review Criteria

- Applications for:
  - Research grants
  - Cooperative agreements
- Other criteria apply to other mechanisms

- Significance
- Investigator(s)
- Innovation
- Approach
- Environment
- (FOA-specific criteria)


Peer Review Criteria

Additional Review Criteria

As applicable for the project proposed, reviewers:
- Consider in determining scientific and technical merit
- Do not give separate scores for these items.

- FOA-specific criteria
- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Resubmission Applications
- Renewal Applications
- Revision Applications
- Biohazards

NIH Peer Review

Additional Review Considerations

- As applicable for the project proposed, reviewers:
- Address each item
- Do not give scores for these items
- Should not consider them in providing an overall impact/priority score.

- FOA-specific considerations
- Select Agent Research
- Applications from Foreign Organizations
- Resource Sharing Plans
- Budget and Period Support
NIH Scoring System

- **Numerical scores**
  - 1.0 (exceptional) to 9.0 (poor)
  - Final impact/priority score = average of individual scores x 10
  - Individual criterion scores
  - Ranked by percentile for some mechanisms
  - Not Discussed (ND) - streamlining
  - Other designations (NR, DF, AB, NP)

*Final impact/priority scores range from 10 through 90.*

NIH Scoring System

- **Preliminary scores** (before the SRG meeting)
  - Overall Impact and Criterion scores entered by assigned reviewers and discussants in secure website
  - Made available to other SRG members

- **Final overall impact/priority scores** (at the SRG meeting)
  - Voted by private ballot
  - All eligible SRG members vote

*Reviewers are instructed to revise their criterion scores after the meeting.*

NIH Scoring System

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

Score Descriptors
Streamlining

- Allows discussion of more meritorious applications
  - Less meritorious applications tabled at the
  - SRG meeting, designated Not Discussed (ND)
  - Requires concurrence of all SRG members

- Summary statement of ND applications:
  - Reviewer critiques
  - Individual criterion scores
  - No numerical, overall impact/priority score

Structured Critiques

- New summary statement format
  - Bulleted comments from reviewers, less text
  - Criterion scores from assigned reviewers
  - More succinct, better organized
  - Encourages evaluative statements
  - Ensures that reviewers address all review criteria
    and considerations

Critique templates are available at:
http://grants.nih.gov/grants/peer/reviewer_guidelines.htm#general_guidelines

Templates for Reviewers

- Describe major strengths and weaknesses. Provide succinct, meaningful comments.
- Limit text to ¼ page per criterion, although more text may occasionally be needed.
Structured Critiques

**Summary statement**: Table of criterion scores are included at the beginning of each critique.

<table>
<thead>
<tr>
<th>CRITIQUE 1:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Significance</td>
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<tr>
<td>Investigator(s)</td>
<td>1</td>
</tr>
<tr>
<td>Innovation</td>
<td>2</td>
</tr>
<tr>
<td>Approach</td>
<td>3</td>
</tr>
<tr>
<td>Environment</td>
<td>2</td>
</tr>
</tbody>
</table>

Criterion scores are not discussed/revisited during the review meeting.

### Enhancing Peer Review

#### Overview and Timeline

- **January 2009**
  - Phase out of A2 applications
  - Identification of Early Stage Investigator (ESI) R01 applications

- **May/June 2009 Reviews**
  - Clustering of New Inv. Applications
  - Enhanced review criteria
  - New scoring system
  - Criterion scoring
  - Structured critiques

- **January 25, 2010 Submissions**
  - Restructured Applications
  - Shorter Page Limits and New Instructions

### Restructured Applications

**Goals**

- Align the structure and content of the application with review criteria

- To ensure that both reviewer and applicant expectations coincide for a more efficient and transparent application process
### Three Major Changes

1. **Research Plan (Research Project Grants)**
   - Specific Aims
   - Research strategy
     - Significance
     - Innovation
     - Approach

2. **Biographical Sketch**
   - Personal statement
   - 15 publications

3. **Resources**
   - Environment

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### Restructured Applications

1. **Research Plan (Research Project Grants):**
   - **Specific Aims**
     - Separate section Generally **one page**
     - New language about the impact of the proposed research
   - **Research Strategy** (new section, three parts)
     - Significance
     - Innovation
     - Approach
     - Incorporate as appropriate:
       - Preliminary Studies for New Applicants
       - Progress Report for Renewal & Revision Applications

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### Restructured Research Plan

- **Introduction**
- **Specific Aims**
- **Background and Significance**
- **Preliminary Studies/Progress Report**
- **Research Design and Methods**
- **Inclusion Enrollment Report**
- **Progress Report Publication List**
- **Human Subjects Sections**:
  - protections, women/minorities, enrollment, children
- **Other Research Plan Sections**:
  - animals, select agent, MPI, consortium, support, sharing
- **Appendix**
1. Research Plan – Items 2 and 3 of PHS 398 Research Plan form component

2. Resources:
   - Better reflects the Environment criterion
   - Address how scientific environment will contribute to probability of success
   - Address Institutional commitment and support for ESIs

   - Item 10 of SF424 (R&R) Other Project Information form component
   - Item 11 of PHS 398 Research Plan form component, as applicable to applications with Select Agents

3. Biographical Sketch:
   - Personal Statement: Experience and qualifications that make you particularly well-suited for role in the project
   - List up to 15 peer-reviewed publications or manuscripts selected by recency, importance to the field, and/or relevance to the application.
Align Application with Review Criteria

<table>
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<tr>
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<td>Personal Statement</td>
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Shortened Applications

Changes effective for due dates on or after January 25, 2010

- Focus both applicants and reviewers on the essentials of the science rather than the administration of applying
- Enable a larger number of reviewers to read each application and participate in the review in a more informed manner
- Avoid information overload
- Lessen burden on reviewers and applicants

Table of Page Limits:
http://enhancing-peer-review.nih.gov/page_limits.html

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http://enhancing-peer-review.nih.gov/page_limits.html

Enhancing Peer Review at NIH
Enhancing Peer Review at NIH

http://enhancing-peer-review.nih.gov

- Timelines
- Status
- Related Policy Changes
- Frequently Asked Questions
- Training and Communication Resources

SF424 (R&R) Applications

Error Correction Window Elimination

Beginning with due dates on or after January 25, 2011

- NIH will eliminate the error correction window from the application electronic submission process.
- All applications submitted after 5 p.m. local time of the applicant organization on the due date will be subject to the NIH late policy and may not be accepted for review.
- Applicants should submit early to allow time to make any necessary corrections and view the application before the submission deadline.

New Announcements

NOT-OD-10-115 07/23/2010
Enhancing Peer Review: New NIH Policy on Post-Submission Application Materials
Applications submitted to the NIH for the September 25, 2010 due date and thereafter

NOT-OD-10-093 05/07/2010
NIH Expands Provisions of the Streamlined Noncompeting Award Process (eSNAP) and Requires Electronic Submission of SNAPs Beginning August 1, 2010
Resources and Information

**NIH Office of Extramural Research**
http://grants.nih.gov/grants/oer.htm

**Enhancing Peer Review at NIH**
http://enhancing-peer-review.nih.gov/

**NIH Peer Review Policies and Practices**
http://grants.nih.gov/grants/peer/peer.htm

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