Enhancing Peer Review

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NIH Peer Review

- Cornerstone of the NIH extramural mission
- Standard of excellence worldwide
- Collaboration between NIH extramural staff and scientific community
Enhancing Peer Review at NIH

Enhancing Peer Review

- Facilitates changing nature of science
  - Interdisciplinary and team science
  - Recognizes and utilizes new sources of information
- Encourages New and Early Stage Investigators
- Eases burden on research enterprise
- Streamlines time to award
Enhancing Peer Review at NIH

Key Recommendations

• Engage the best reviewers
• Improve the quality & transparency of review
• Ensure balanced & fair reviews across scientific fields & career stages
• Continuous review of peer review
Enhancing Peer Review at NIH

Timeline

**SO FAR**
- Phase out of A2 applications
- Identification of Early Stage Inv. (ESI) applications

**NOW**
- Enhanced review criteria
- New scoring system
- Criterion scoring
- Structured critiques
- Clustering of New Inv. Applications
- Score order review

**LATER**
- Alignment of applications & review criteria
- Shorter Research Plans

January 2009

May/June 2009

January 2010 Submissions
Phase Out of A2 Applications

PURPOSE:
• ensure largest number of high-quality meritorious applications receive funding earlier
• improve system efficiency
• enhance success rates of new and resubmitted applications
Changes So Far: Limited Resubmission of Applications

• Applications submitted for 1/25/09 and beyond allowed a single resubmission

• Applications submitted for due dates prior to 1/25/09 are allowed two amendments. Last date NIH will accept the second amendment is 1/7/2011

• All activity codes, and new, renewal (competing continuation) and revision (competing supplement) applications
Changes So Far: Limited Resubmission of Applications

Criteria for a New Application

- Substantially different in content and scope
- Fundamental changes in questions being asked and/or outcomes examined
- Rewording of the Title and Specific Aims or incorporating minor changes in response to reviewer comments does not constitute substantial change
- Request for review by a different committee or funding consideration by a different IC are not sufficient reasons to consider an application new
Changes So Far:
Limited Resubmission of Applications

New Submissions

• Applications changing activity codes are new submissions
• Applications to RFAs are new submissions (unless specified otherwise for reissued RFAs)
• If resubmitted, unsuccessful ARRA applications will be new applications
Changes So Far: 
Limited Resubmission of Applications

Information Sources

- NOT-OD-09-100 (5/15/2009) - Reminder and Clarification of NIH Policies on Similar, Identical, or Essentially Identical Applications, Submission of Applications Following RFA Review, and Submission of Applications with a Changed Activity Code

  – Includes references to: NOT OD- 03-019 (1-16-03) - Resubmission of Unpaid RFA Applications and Resubmission of Applications with Changed Mechanism

- NOT-OD-07-015 (11-13-06) – Limits on Resubmission of an Application (clarification of “new” application)
Identification of ESI Applicants

PURPOSE:
• Encourage earlier transition to research independence
• Counter trend of increasing time spent in training phase of career
• Strongly encourage New Investigators, particularly ESIs, to apply for R01 grants when seeking first-time NIH funding
New and Early Stage Investigator Policies

- Identify applications from ESIs and New Investigators for reviewers
- Apprise NIH staff of ESI and New Investigator status
- Support New Investigators (majority expected to be ESIs) at success rates equivalent to that of established investigators submitting new applications
Definition of New Investigator

- New Investigator (NI) is a PD/PI who has not yet competed successfully for a substantial NIH research grant.
- Receipt of the following awards does not remove new investigator status: R00, R03, R15, R21, R34, R36, R41, R42, R55, R56, SC2, SC3, all Fs, most Ks, all Loan Repayment contracts, G07, G08, G11, G13, G20, S10, S15, S21, S22.
- For multiple PD/PIs: all PD/PIs must meet definition of NI.

Definition of Early Stage Investigator

- A New Investigator who is within 10 years of completing the terminal research degree or is within 10 years of completing medical residency (or equivalent)
- For multiple PD/PIs, all PD/PIs must meet requirements for ESI status
- ESIs are also eligible for the Shortened Review Cycle option available to NIs

Definition of Early Stage Investigator

- Status applies only to R01s
- Does not apply to Recovery Act RFAs for mechanisms that are not R01s, such as:
  - Challenge grants (RC1s)
  - Grand Opportunities grants (RC2s)
  - Faculty Recruitment grants (P01s)
- But an investigator who receives a Recovery Act award loses NI/ESI status
Changes So Far: New/Early Stage Investigators

NI/ESI Designation in eRA Commons

• Enter dates of degrees and medical residency in eRA Commons Personal Profile (as of 1-17-09)
• Potentially eligible ESIs should promptly provide this information (individual must update)
• Investigators then notified of ESI status by email
• ESI designation in effect for applications due 2/5/09 and later
• Enter data before application submission (call NIH if not entered prior to submission)

NIH systems will identify NIs using NIH data
Changes So Far: New/Early Stage Investigators

Extension of ESI Status

• ESI eligibility period may be extended due to active duty military service, medical concerns, disability, family care responsibilities, natural disasters, extended periods of clinical training, or other reasons

• Circumstance or event must occur within the ten year period after degree or end of residency.

• Extensions in whole months only

• Extensions for periods of part-time status will be prorated
Information Sources

- NOT-OD-08-121 (09/26/2008) - Encouraging Early Transition to Independence: Identifying ESIs
  [Link](http://grants1.nih.gov/grants/guide/notice-files/not-od-08-121.html)

- NOT-OD-09-013 (09/31/2008) – Revised New and Early Stage Investigator Policies


- FAQs: [Link](http://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.html)
Enhancing Peer Review at NIH

Changes Happening NOW

- Enhanced review criteria
- New scoring system
- Criterion scoring
- Structured critiques
- Clustering of New Investigator applications
- Score order of review

- Implemented for applications submitted:
  - for Fiscal Year 2010 funding consideration
  - for Recovery Act (ARRA) RFAs
Changes Happening NOW: 
Enhanced Review Criteria

**Overall Impact ➔ Overall Impact/Priority Score**

- Core criteria **order:**
  - Significance*
  - Investigator(s)*
  - Innovation*
  - Approach*
  - Environment*

*Will receive individual criterion scores*

- Additional review criteria & considerations **expanded**

- Side-by-side comparison available
  - [http://grants.nih.gov/grants/peer_review_process.htm](http://grants.nih.gov/grants/peer_review_process.htm)
Overall Impact/Priority Score

Reflects the reviewers’ assessment of the likelihood for the project to *exert a sustained, powerful influence on the research field(s) involved*

In consideration of:
- Core criteria
- Additional review criteria (RFA or PAR)
- Additional review criteria – as applicable
Changes Happening NOW: Enhanced Review Criteria

Scored Review Criteria

• For applications for:
  – Research grants
  – Cooperative agreements
  – Received for:
    ▪ Potential FY2010 funding
    ▪ Recovery Act FOAs

• Will receive individual criterion scores from assigned reviewers & discussants

• Significance
• Investigator(s)
• Innovation
• Approach
• Environment

* Other criteria apply to certain other mechanisms
Changes Happening NOW: Enhanced Review Criteria

**Scored Review Criteria**

**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?

How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
Changes Happening NOW: Enhanced Review Criteria

Scored Review Criteria

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)?

If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? (*Moved from Approach)
Changes Happening NOW:
Enhanced Review Criteria

Scored Review Criteria

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?

Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?

Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
Changes Happening NOW: Enhanced Review Criteria

Scored Review Criteria

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?

If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
Scored Review Criteria

**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?

Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
Changes Happening NOW: Enhanced Review Criteria

Additional Review Criteria

• Protections for Human Subjects

• Inclusion of Women, Minorities, and Children

• Vertebrate Animals

• Resubmission Applications

• Renewal Applications

• Revision Applications

• Biohazards

• As applicable for the project proposed
  • Reviewers will consider in the determination of scientific and technical merit

• Reviewers will not give separate scores for these items.
Changes Happening NOW:
Enhanced Review Criteria

Additional Review Considerations

- **Budget and Period Support**
- **Select Agent Research**
- **Applications from Foreign Organizations**
- **Resource Sharing Plans**

- As applicable for the project proposed
- Reviewers will address each item
- Reviewers *will not* give scores for these items
  *should not* consider them in providing an overall impact score.
9-Point Scale

1 = Exceptional
9 = Poor

• Reduces number of rating discriminations
• Provides rating descriptors
  – To improve reliability
  – To encourage use of the entire range
• Scores rounded to fewer digits
Changes Happening NOW:
New Scoring System

9-Point Scale

• Will be used for:
  – Overall impact/priority scores
  – Individual criterion scores

• Will be implemented for applications submitted for:
  – FY2010 funding consideration
  – Recovery Act funding opportunity announcements
## New Score Descriptors

<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>Moderate 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>
Structured Critiques

- Decrease variability
- Increase quality of information in critiques
- More succinct, better organized
- Encourage evaluative statements
- Ensure that reviewers address all review criteria and considerations
Critique Templates

- Bulleted comments
- Scores for five review criteria
- Required comments:
  - Protections for Human Subjects
  - Inclusion Plans
  - Vertebrate Animal Welfare
  - Biohazards
  - Budget
**Templates for Reviewers**

RPG Review Critique Template

1. **Significance**
   - Please limit text to 1/4 page
   - Strengths
   - Weaknesses

2. **Investigator(s)**
   - Please limit text to 1/4 page
   - Strengths
   - Weaknesses

Links to definitions of review criteria
Clustering of New Investigator Applications

- Where feasible, NI applications will be clustered
- NI and ESI applications will be identified for reviewers
- Expectations for preliminary data or track record should not be the same as for established investigators
Order of Discussion

- Where feasible, discussion order based on:
  - Clustering of New Investigator applications
  - Clustering of clinical applications
  - Clustering of similar activity codes
  - Preliminary overall impact/priority scores
Changes Happening NOW

Additional Information

• Enhancing Peer Review Website: (http://enhancing-peer-review.nih.gov/index.html)


• Side-by-side comparison of enhanced and former review criteria (http://grants.nih.gov/grants/peer_review_process.htm)

• Guidelines for Reviewers (http://grants.nih.gov/grants/peer/reviewer_guidelines.htm)
Enhancing Peer Review at NIH

Changes Happening LATER
(Beginning with Jan 2010 Submissions*)

- Alignment of applications & review criteria
- Shorter Research Plans

*NIH Plans a Fall Release of new Forms

*Stay Tuned:
Communications Coming Soon
Alignment of Applications and Review Criteria

Changes to three parts of application:
• Biographical sketch
• Research Plan
• Resources
Biographical Sketch

• Personal Statement – why experience and qualifications make the applicant particularly well-suited for role in the project

• Publications limited to 15
  – 5 most recent
  – 5 best
  – 5 most relevant to the application
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
### Happening LATER:
**Application Changes**

<table>
<thead>
<tr>
<th>Current Application</th>
<th>New Application</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Background and Significance</strong></td>
<td><strong>Research Strategy</strong></td>
</tr>
<tr>
<td><strong>Research Design and Methods</strong></td>
<td>a. Significance</td>
</tr>
<tr>
<td><strong>Preliminary Studies/Progress Report</strong></td>
<td>b. Innovation</td>
</tr>
<tr>
<td></td>
<td>c. Approach</td>
</tr>
<tr>
<td></td>
<td>• Preliminary Studies for New Applications</td>
</tr>
<tr>
<td></td>
<td>• Progress Report for Renewal/Revision</td>
</tr>
</tbody>
</table>
Facilities and Other Resources

(in 424 part of the R&R Other Project Information; in 398 the Resources Format Page)

Environment - New instruction to address how scientific environment will contribute to probability of success, unique features of environment, etc. For ESIs, provide description of institutional investment in success of the investigator.
<table>
<thead>
<tr>
<th>Core Review Criteria</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significance</td>
<td>Research Strategy</td>
</tr>
<tr>
<td></td>
<td>a. Significance</td>
</tr>
<tr>
<td>Investigator(s)</td>
<td>Biosketch</td>
</tr>
<tr>
<td></td>
<td>Personal Statement</td>
</tr>
<tr>
<td>Innovation</td>
<td>Research Strategy</td>
</tr>
<tr>
<td></td>
<td>b. Innovation</td>
</tr>
<tr>
<td>Approach</td>
<td>Research Strategy</td>
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<tr>
<td>Environment</td>
<td>Resources</td>
</tr>
<tr>
<td></td>
<td>Environment</td>
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### Shorter Research Plans

<table>
<thead>
<tr>
<th>Section</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction (to Resubmission or Revision)</td>
<td>1 page</td>
</tr>
<tr>
<td>Specific Aims</td>
<td>1 page</td>
</tr>
<tr>
<td>Research Strategy (R03,13, 21, 36, 41, 43)</td>
<td>6 pages</td>
</tr>
<tr>
<td>Research Strategy (R01, 10, 15, 18, 21/33, 24, 25, 33, 34, 42, 44)</td>
<td>12 pages</td>
</tr>
<tr>
<td>Research Strategy (all other activity codes, including Cs, Ps, Ss, Us,)</td>
<td>see FOA</td>
</tr>
<tr>
<td>Biographical Sketch (per person)</td>
<td>4 pages</td>
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<tr>
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</tr>
<tr>
<td>Appendix</td>
<td>See FOA</td>
</tr>
<tr>
<td>CDA (K) Applicants</td>
<td>12 pages</td>
</tr>
<tr>
<td>(combined Candidate Information and Research Strategy)</td>
<td></td>
</tr>
<tr>
<td>Fellowship (F) Applicants</td>
<td>6 pages</td>
</tr>
<tr>
<td>Research Strategy</td>
<td></td>
</tr>
<tr>
<td>Institutional Rsch Training Applicants</td>
<td>25 pages</td>
</tr>
<tr>
<td>(Research Training Program Plan, Ts and K12)</td>
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</tr>
</tbody>
</table>
Application Revision Timeline:

- **OMB Approval**: Done! May 2009
- **Grants.gov forms development**: Summer 2009
- **Post applications**: Fall 2009
- **Require use of new applications**: January 2010
Enhancing Peer Review at NIH Webpages
http://enhancing-peer-review.nih.gov/index.html

Overview of Peer Review Enhancements Video
http://enhancing-peer-review.nih.gov/video_overview.html
Enhancing Peer Review at NIH

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