



NIH Regional Seminars 2009



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

- **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**



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**



Timeline

Changes
SO FAR

January
2009

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

Changes
NOW

May/June
2009

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

Changes
LATER

January 2010
Submissions

- Alignment of applications & review criteria
- Shorter Research Plans



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





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



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



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
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html>
 - Includes references to: NOT OD- 03-019 (1-16-03) - Resubmission of Unpaid RFA Applications and Resubmission of Applications with Changed Mechanism
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-019.html>
- NOT-OD-07-015 (11-13-06) – Limits on Resubmission of an Application (clarification of “new” application)
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-015.html>



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

http://grants.nih.gov/grants/new_investigators/index.htm



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

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-083.html>



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



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





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
<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
<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html>
- NOT-OD-09-034 (12/31/2008) – ESI Policies: Requesting an Extension of the ESI Period
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-034.html>
- FAQs: http://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.html



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)



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**



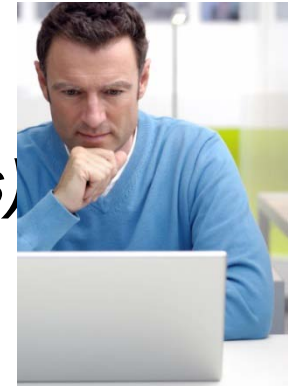


Changes Happening NOW: Enhanced Review Criteria

Scored Review Criteria

- For applications for:
 - Research grants
 - Cooperative agreements
 - Received for:
 - Potential FY2010 funding
 - ecovery 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)?

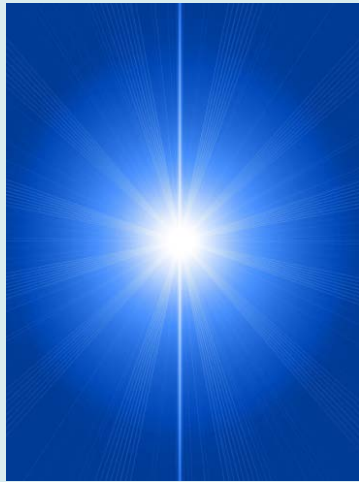
If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project*? (***Moved from Approach**)



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?

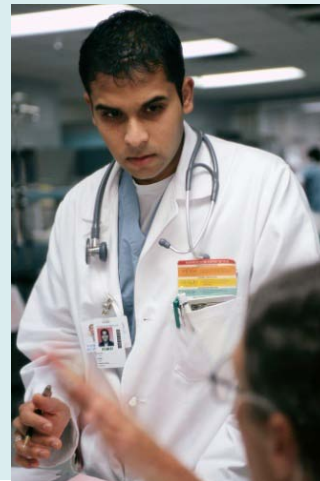
Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?

Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?



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.**



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**



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

Impact	Score	Descriptor
High Impact	1	Exceptional
	2	Outstanding
	3	Excellent
Moderate Impact	4	Very Good
	5	Good
	6	Satisfactory
Low Impact	7	Fair
	8	Marginal
	9	Poor



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

Links to
definitions
of review
criteria

RPG Review Critique Template

1. <u>Significance</u>	Please limit text to 1/4 page
Strengths <ul style="list-style-type: none">••• Weaknesses <ul style="list-style-type: none">•••	

2. <u>Investigator(s)</u>	Please limit text to 1/4 page
Strengths <ul style="list-style-type: none">••• Weaknesses <ul style="list-style-type: none">•••	



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**





Additional Information



- **Enhancing Peer Review Website:**
(<http://enhancing-peer-review.nih.gov/index.html>)
- **NOT-OD-09-025:**
(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-025.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)

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



**Research
Strategy**



Happening LATER: Application Changes

Current Application

New Application

Background and
Significance

Research Design and
Methods

Preliminary
Studies/Progress Report

Research Strategy

a. Significance

b. Innovation

c. Approach

- Preliminary Studies for New Applications
- Progress Report for Renewal/Revision



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.



Happening LATER: Alignment of Application with Review Criteria

Core Review Criteria

Application

Significance

Research Strategy
a. Significance

Investigator(s)

Biosketch
Personal Statement

Innovation

Research Strategy
b. Innovation

Approach

Research Strategy
c. Approach

Environment

Resources
Environment





Shorter Research Plans

Introduction (to Resubmission or Revision)	1 page
Specific Aims	1 page
Research Strategy (R03, 13, 21, 36, 41, 43)	6 pages
Research Strategy (R01 , 10, 15, 18, 21/33, 24, 25, 33, 34, 42, 44)	12 pages
Research Strategy (all other activity codes, including Cs, Ps, Ss, Us,	see FOA



Happening LATER: Page Limit Revisions

Biographical Sketch (per person)	4 pages
Appendix	See FOA
CDA (K) Applicants (combined Candidate Information and Research Strategy)	12 pages
Fellowship (F) Applicants Research Strategy	6 pages
Institutional Rsch Training Applicants (Research Training Program Plan, Ts and K12)	25 pages



Happening LATER

**OMB Approval
May 2009**



Done!

Application Revision Timeline

**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



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