


 National Institute of Dental and Craniofacial Research

Overview of NIH Peer Review and Grant Application Changes





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 National Institute of Dental and Craniofacial Research

Overview of NIH Peer Review - grants

- Mandated by law: The Public Health Service Act
 - Two-tiered system
 - Initial peer review (study section, SRG, etc.)
 - National Advisory Council or Board
- Defined in regulation: 42 CFR 52h
- Further defined by NIH policy on Peer Review and NIH Guide Notices




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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.



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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



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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

SRGS DO NOT MAKE FUNDING DECISIONS

• Per year:
– Nearly 80,000 applications
– Over 18,000 reviewers

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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**

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NIH Peer Review Process

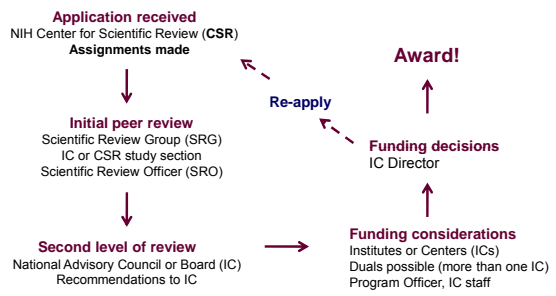
- **IC Director**
 - Recommendations from Advisory Council
 - Recommendations from NIH IC staff
 - NIH or IC policy
- **FINAL FUNDING DECISIONS**



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NIH Peer Review Process




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Review Cycle

	Cycle I	Cycle II	Cycle III
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Review	October	January	May

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



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 **Continuous Submission** National Institute of Dental and Craniofacial Research

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

See NIH Notices:
[NOT-OD-08-026](#)
[NOT-OD-09-114](#)
[NOT-OD-09-155](#)
[NOT-OD-10-090](#)

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.

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Where will my application be reviewed?

Referral to an SRG

<p>CSR Review</p> <ul style="list-style-type: none"> • Most R01s, fellowships, small business applications, AREA • Some Program Announcements (PAs) • Some Requests for Applications (RFAs) 	<p>Institute/Center Review</p> <ul style="list-style-type: none"> • IC-specific features • Program Projects • Training grants • Career Development Awards • Clinical Trials • RFAs
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The review locus is stated in the Funding Opportunity Announcement (FOA)


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Types of Scientific Review Groups (SRGs)

- **“Chartered” SRGs**
 - Multiyear 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


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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


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 **Reviewer Assignments** National Institute of Dental and Craniofacial Research

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

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 **Enhancing Peer Review** National Institute of Dental and Craniofacial Research

January 2009


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


May/June 2009 Reviews

January 25, 2010 Submissions

- Clustering of New Investigator Applications
- Enhanced review criteria
- New scoring system
- Criterion scoring
- Structured critiques

- Restructured Applications
- Shorter Page Limits and New Instructions


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 **Phase out of A2 applications** National Institute of Dental and Craniofacial Research

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

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 **NI/ESI Goals** National Institute of Dental and Craniofacial Research


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




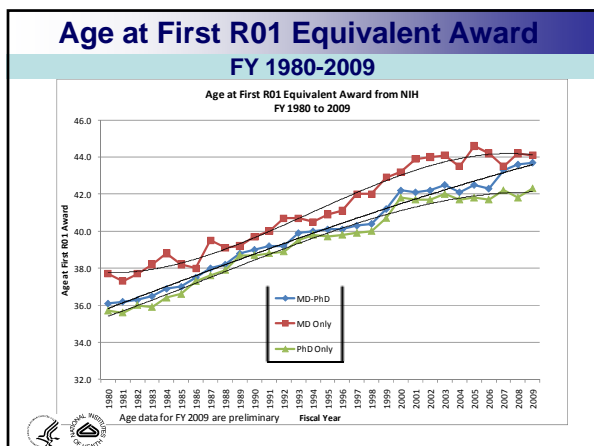
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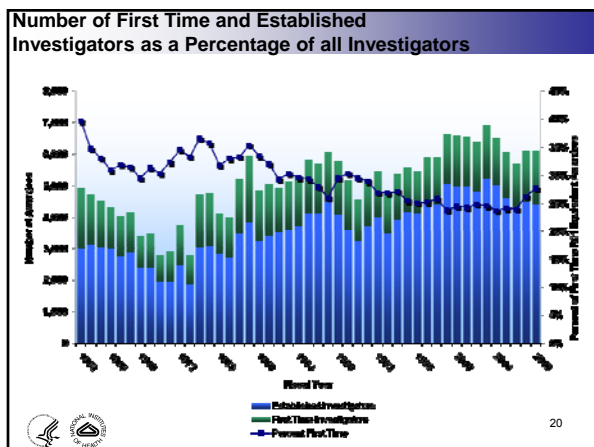
 **NI/ESI Definitions** National Institute of Dental and Craniofacial Research

- **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).

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-121.html>
[NOT-OD-08-121](#) September 2008

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

• NOT-OD-08-121, September 26, 2008

Enhancing Peer Review National Institute of Dental and Craniofacial Research

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**
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- January 25, 2010 Submissions**
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Enhanced Review Criteria National Institute of Dental and Craniofacial Research

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

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Overall Impact Score National Institute of Dental and Craniofacial Research

- ✓ **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

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 **Enhanced Review Criteria** National Institute of Dental and Craniofacial Research


Scored Review Criteria

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

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

See **“Review Criteria at a Glance”**
http://grants.nih.gov/grants/peer/reviewer_guidelines.htm

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 **Peer Review Criteria** National Institute of Dental and Craniofacial Research


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*



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 **NIH Peer Review** National Institute of Dental and Craniofacial Research

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*


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 **NIH Scoring System** National Institute of Dental and Craniofacial Research

- **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.


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 **NIH Scoring System** National Institute of Dental and Craniofacial Research

- **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.

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 **NIH Scoring System** National Institute of Dental and Craniofacial Research

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

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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

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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

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Templates for Reviewers

hyperlinks to definitions of review criteria

→ **1. Significance** | Please limit text to 1/4 page

Strengths: Describe major strengths and weaknesses. Provide succinct, meaningful comments.

Weaknesses:


Text boxes expand

→ **2. Investigator(s)** | Please limit text to 1/4 page

Strengths: Limit text to 1/4 page per criterion, although more text may occasionally be needed.

Weaknesses:

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Structured Critiques


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

CRITIQUE 1:

Significance	2
Investigator(s)	1
Innovation	2
Approach	3
Environment	2


Criterion scores are not discussed/revisited during the review meeting


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 **Enhancing Peer Review** National Institute of Dental and Craniofacial Research

Overview and Timeline

- January 2009**
 - Phase out of A2 applications
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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

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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

NEW

Research Strategy

- Significance
- Innovation
- Approach



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Restructured Research Plan National Institute of Dental and Craniofacial Research

1. Research Plan – Items 2 and 3 of PHS 398 Research Plan form component

PHS 398 Research Plan

1. Application Type:
From SF 424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated for your reference, as you attach the appropriate sections of the Research Plan.
*Type of Application:
 New Resubmission Renewal Continuation Revision

2. Research Plan Attachments:
Please attach applicable sections of the research plan, below.

1. Introduction to Application
(or RESUBMISSION or RENEWAL only)

2. Specific Aims ←

3. *Research Strategy ←

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Restructured Application National Institute of Dental and Craniofacial Research

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

10. Facilities & Other Resources ←

- Item 11 of PHS 398 **Research Plan** form component, as applicable to applications with Select Agents

11. Select Agent Research

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Restructured Application National Institute of Dental and Craniofacial Research

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.

Sample

BIOGRAPHICAL SKETCH
Provide the following information for the Senior Key personnel and other significant contributors. Follow the format for each person. **DO NOT EXCEED 1000 CHARACTERS.**

NAME	POSITION/TITLE	DEGREE (if applicable)	YEAR	FIELD OF STUDY
Hunt, Virginia Lively	Associate Professor of Psychology			
EDUCATION/Training (Show with background or other relevant professional education, not in a series, include postdoctoral training and residency training (if applicable))				
University of California, Berkeley		B.S.	05/90	Psychology
University of Vermont		Ph.D.	05/95	Experimental Psychology
University of California, Berkeley		Postdoctoral	08/95	Public Health and Epidemiology


A. Personal Statement ←
The goal of the proposed research is to investigate the interaction between drug abuse and normal aging processes. Specifically, we plan to measure changes in cognitive ability and mental and physical health across a full range of adult ages (from 18 to 80) and to test the hypothesis that the interaction between...


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Align Application with Review Criteria

Scored Review Criteria	Application
Significance	Research Strategy a. Significance
Investigator(s)	Biographical sketch Personal Statement
Innovation	Research Strategy b. Innovation
Approach	Research Strategy c. Approach
Environment	Resources Environment



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 **Shortened Applications** National Institute of Dental and Craniofacial Research

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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 **TABLE OF PAGE LIMITS** National Institute of Dental and Craniofacial Research



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


Enhancing Peer Review at NIH

Peer Review Home
Implementation Goals
Engage the Best Reviewers
Improve the Quality & Transparency of Review
Ensure Balanced and Fair Review
Continuous Review of Peer Review
Policy Announcements
New Scoring System
Shortened/Restructured Applications
Guidance for Reviewers
Training & Communications Resources
Inquiries


Table of Page Limits
Changes effective for due dates on or after January 25, 2010
Most sections that have page limits are listed below. Be sure to check the Funding Opportunity Announcement (FOA) for exceptions.

Section of Application	Activity Codes	Page Limits *
Introduction to Revision Application	For all Activity Codes	1 page
Introduction to Resubmission Application	For all Activity Codes, EXCEPT Training T, D43, D71, K12, and R25 applications	1 page
Introduction to Revision or Resubmission Applications	For institutional Training (T), International Training (D43, D71), Institutional Career Awards (K12), and Research Education Applications (R25)	3 pages
Specific Aims	For each project and core of multi-component applications	1 page
	For all Activity Codes that use an application form with the Specific Aims	1 page

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Enhancing Peer Review at NIH




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

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

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 **SF424 (R&R) Applications** National Institute of Dental and Craniofacial Research


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.

 **NOT-OD-10-123** 47
August 16, 2010

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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

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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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