• Non-Competing Grant Awards Under the Current Continuing Resolution (CR) NOT-OD-09-002.

• Department of Health and Human Services continues to operate on a CR that currently extends through March 6, 2009.

• The CR applies the terms of the FY2008 appropriations for the period covered by the CR.
Encouraging Early Transition to Research Independence: Modifying the NIH New Investigator Policy to Identify Early Stage Investigators

Notice Number : NOT-OD-08-121

Background

For more than three decades the NIH has explicitly encouraged New Investigators to apply for NIH research grant support. The involvement of New Investigators is considered essential to the vitality of health-related research and has been addressed by several important NIH programs and studies which are detailed on the New Investigator Website at http://grants.nih.gov/grants/new_investigators/resources.htm.
New Investigator: An NIH research grant Program Director/Principal Investigator (PD/PI) who has not yet competed successfully for a substantial, competing NIH research grant is considered a New Investigator. For example, a PD/PI who has previously received a competing NIH R01 research grant is no longer considered a New Investigator. However, a PD/PI who has received a Small Grant (R03) or an Exploratory/Developmental Research Grant Award (R21) retains his or her status as a New Investigator. A complete definition of a New Investigator along with a list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator can be found at http://grants1.nih.gov/grants/new_investigators/resources.htm.

For more Information please go to: http://grants.nih.gov/grants/new_investigators/faq.htm

Early Stage Investigator (ESI): An individual who is classified as a New or First-Time Investigator and is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent) is considered an Early Stage Investigator (ESI).

Extension of ESI Eligibility: The 10 year period after completion of the terminal degree or residency may be extended to accommodate special circumstances including various medical concerns, disability, pressing family care responsibilities, or active duty military service. Guidelines for requesting and considering such requests are being developed and will be announced.
Encouraging Early Transition to Research Independence: Modifying the NIH New Investigator Policy to Identify Early Stage Investigators (cont)

Planned Implementation

Beginning with traditional R01 applications received for the February 2009 receipt dates, the NIH will identify applications from ESIs and New Investigators and the career stage of the PD/PI will be considered at the time of review and award. Some of the details are still being worked out and will be announced as they become available. At the current time it is expected that the implementation will include the following features:

- The NIH will modify the data collection related to degree dates and medical residency within the personal profile of the eRA Commons (https://commons.era.nih.gov/commons/). When the revised data collection approach is announced PD/PIs must update their personal profile in the eRA Commons to provide information on degree and residency completion dates in order to be considered for the ESI classification.

- New Investigators within 10 years of their terminal research degree or within 10 years of completing their medical residency will be identified as ESIs using data entered in the eRA Commons.

- Investigators who enter degree and residency completion dates will be notified of their ESI status by email.

- NIH will eliminate the New Investigator Check Box on the face page of PHS 398 and Form 424 R&R application. New Investigators will be identified using data within the NIH administrative database.

- New Investigators as well as ESIs will be eligible for the “Full Implementation to Shorten the Review Cycle for New Investigator R01 Applications Reviewed in Center for Scientific Review (CSR) Recurring Study Sections” (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-083.html).
Encouraging Early Transition to Research Independence: Modifying the NIH New Investigator Policy to Identify Early Stage Investigators (cont)

More complete information on the ESI-related features of the eRA Commons; instructions to reviewers for consideration of ESI applications; grouping of applications from ESIs during peer review; the process and criteria for requesting an extension of the period of eligibility; and a series of Frequently Asked Questions (FAQs) will be developed between the issuance of this announcement and the February R01 receipt dates.
Shortened Review Cycle for New Investigators (NOT-OD-07-083)

• A new investigator is an individual that has not been the principal investigator (PI) on any NIH research project other than R03, R15, R21, R55, R56, K01, K08, K22, K23, K25 or K99/00. *(This applies to all PIs in a Multiple PI proposal.)*

• Recipients of K02, K04, K05, K24 and K26 are not considered new investigators.

• This notice gives the option of submitting a resubmission/amended R01 application for consecutive review cycles cutting four months off of the standard resubmission processing time.

• If option is not taken, use of standard resubmission dates apply:

<table>
<thead>
<tr>
<th>New R01 Proposal Submission Due Date</th>
<th>Resubmission/Amended Proposal Due Date per NOT-OD-07-083</th>
<th>Standard Resubmission Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 5</td>
<td>March 20</td>
<td>July 5</td>
</tr>
<tr>
<td>February 5</td>
<td>July 20</td>
<td>November 5</td>
</tr>
<tr>
<td>June 5</td>
<td>November 20</td>
<td>March 5</td>
</tr>
</tbody>
</table>


• The Summary Statement will explicitly note eligibility for next cycle submission.

• This notice excludes submissions for RFAs and PARs with special dates.
Clarification of NIH Policy on Late Submission of Grant Applications

This notice points out a change in text in Notice OD-08-027 (http://grants1.nih.gov/grants/guide/notice-files/not-od-08-027.html). Previously the notice had the following text:

“Late applications have been accepted for reasons such as: death of an immediate family member of the Principal Investigator, sudden acute severe illness of the Principal Investigator or immediate family member, temporary or ad hoc service on a NIH extramural peer review group, service on a NIH Board of Scientific Counselors or Advisory Board/Council, or large scale natural disasters.”

This has been changed to:

“Late applications have been accepted for reasons such as: death of an immediate family member of the Principal Investigator, sudden acute severe illness of the Principal Investigator or immediate family member, or large scale natural disasters. Recent service by the Principal Investigator only (this does not include other participants in the application) on an NIH extramural review group, NIH Board of Scientific Counselors or Advisory Board/Council that could reasonably be expected to require a time commitment that could have been used to prepare an application is also an allowable reason”

The change emphasizes that this consideration applies only to those with the PD/PI role who have recent service, not past service.
NIH Policy on Submission of Additional Grant Application Materials

NOT-OD-08-082 Released on 7/25/08 states:

The additional materials must be submitted to the NIH SRO with the consent of the applicant organization’s designated AOR/SO. NIH requires that the applicant organization include the AOR in the correspondence; the AOR is not necessarily required to submit the application materials. It is acceptable for the PD/PI or Contact PI for multiple PD/PI applications to send such materials with the concurrence of the AOR (designated institutional signing official). Materials sent without evidence of such concurrence will not be accepted.

G&C suggests the following process for submitting supplemental materials to NIH

1.) If science only is being submitted to NIH, copying G&C (your Grant Analyst) would be sufficient as long as what is submitted to NIH states that “the documentation provided contains only science and by copying Washington University’s institutional official we are showing the AOR’s concurrence”.

2.) If any type of budgetary, compliance, or administrative information, or application form pages are being submitted to NIH, G&C would need to review and sign off on the documentation.
NIH announced a change in the existing policy on resubmission (amended) applications (see http://grants.nih.gov/grants/policy/amendedapps.htm). Beginning with original new applications (i.e., never submitted) and competing renewal applications submitted for the January 25, 2009 due dates and beyond, the NIH will accept only a single amendment to the original application. Failure to receive funding after two submissions (i.e., the original and the single amendment) will mean that the applicant should substantially re-design the project rather than simply change the application in response to previous reviews. It is expected that this policy will lead to funding high quality applications earlier, with fewer resubmissions.

For complete, detailed information, please visit http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html.
Posted Date: 09/30/2008

Content Categories: Policies-Guidelines-Procedures\NIH

Subject: OVC/GGrants and Contracts: NIH Public Access Policy

Please refer to the attached PDF document regarding an update to the NIH Public Access Policy:

http://intramed.wustl.edu/r.nsf/0/C26A3114547C8308862574D3007C7531

This information was authored by John Michnowicz - michnowj@mssnotes.wustl.edu

This message was sent to Research News subscribers in the following Job Function(s): All Faculty, All Research Staff - Administrative
Rnews NIH Public Access Policy


The following is a brief summary of the (3) page notice:

In Federal FY2009 (i.e. October 1, 2008 thru September 30, 2009), NIH will be notifying PDs/PIs via email (cc: for the Institutional Business Official) if citations of papers included in applications, proposals or progress reports appear to fall under subject policy but lack a demonstration of compliance with subject policy. NIH will specifically list the citation(s) of concern.

The PDs/PIs will be asked to respond to the email and also cc the Institutional Business Official with a confirmation that citation(s) listed are in compliance. This email confirmation should include:

- The citation for the paper
- Appropriate identifier (i.e. PubMed Central reference number) OR
- NIH manuscript reference number OR
- Indicate “PMC Journal – in Process” (*)

NIH expects citations in an application, proposal or progress report to include the most up-to-date information concerning the status of compliance with the Public Access Policy.

For informational purposes associated specifically with NIH’s Public Access Policy, the following urls are provided:

- http://www.nih.gov/about/publicaccess/
- http://becker.wustl.edu/services/scholarly/faqs.html

(*) = Please refer to the actual Notice for a detailed explanation.
NSF Update

National Science Foundation (NSF) released a revised version of the Proposal & Award Policies & Procedures Guide (PAPPG), NSF 09-1. It is effective for submissions due on or after 1/5/09.

### FY 2008 Submission Data

#### FY08 / FY07 COMPARISON

<table>
<thead>
<tr>
<th>PROPOSALS PROCESSED*</th>
<th>FY08</th>
<th>FY07</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number Processed</td>
<td>% of Total</td>
</tr>
<tr>
<td>Government</td>
<td>1589</td>
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</tr>
<tr>
<td>Non-government</td>
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<tr>
<td><strong>Total Processed</strong></td>
<td><strong>2691</strong></td>
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</tr>
<tr>
<td>Processed Prior to Last 3 Days Before Deadline</td>
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<td>46%</td>
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<tr>
<td>Processed Last Day Before Deadline**</td>
<td>833</td>
<td>31%</td>
</tr>
<tr>
<td>Processed Last 3 Days Before Deadline***</td>
<td>1466</td>
<td>54%</td>
</tr>
</tbody>
</table>

#### Quarter Data

<table>
<thead>
<tr>
<th>Quarter</th>
<th>FY08</th>
<th>% Change From FY07</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st</td>
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<tr>
<td>2nd</td>
<td>631</td>
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</tr>
<tr>
<td>3rd</td>
<td>800</td>
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</tr>
<tr>
<td>4th</td>
<td>757</td>
<td>1.07%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2691</strong></td>
<td></td>
</tr>
</tbody>
</table>
FY 07/08 Award Data

FY08 Award Dollars: $471.9M
FY08 Award Count: 1,647

FY07 Award Dollars: $464.6M
FY07 Award Count: 1,615

Award Dollars: 1.58% increase over FY07
Award Count: 1.98% increase over FY07
• The Medical School Finance Office provides various canned reports to departments as requested by each department

• Reports are accessible to department designees as decided by each department

• Please contact your Grant Analyst for a list of Network Users in your departments
Checks and Balances

• The department should verify the accuracy of any update/maintenance made to fund profiles, as well as any allocations (including cost share accounts) processed, by G&C.

• Departments should notify G&C as soon as possible if any errors are found or a request has not been fulfilled satisfactorily.

• G&C strongly suggests that you check our work.

• Two sets of eyes are better than one!!
Due Dates in PDS

In an effort to be more consistent with the due dates used in PDS, please use the following as a guide:

- **Subawards (e.g. NIH ---> Harvard ---> WU)**: Use the date the application is due to WU's funding source (e.g. Harvard)
- **eSNAP Continuations (submitted via eRA Commons)**: Use the agency due date (16th of the given month)
- **SNAP Continuations (submitted via paper)**: Use the agency due date (1st of the given month)
- **Applications that are being submitted late**: Use the agency due date (the official date, not the extended date). *Utilize PDS comments for additional Information or clarification.*
- **After-the-facts**: Use the original agency due date. If there wasn't a due date, use the date the PI submitted the application.
- **Applications that are being submitted early at the Dept/PI's request**: Use the agency due date
To Copy or not to Copy PDS docs

Please remember to copy the previous year’s PDS doc when creating PDS docs for continuation applications. This will help ensure that the applicable Original FY/Fund number is populated into the PDS doc.

---On the flip-side---

Please do not copy a PDS doc with an Original FY/Fund number that is unrelated to the application that you are currently submitting. This creates a great deal of confusion in our office and also creates problems with reporting.
Always remember to pull the latest and greatest NIH forms directly from the NIH website.

For latest forms go to: www.nih.gov

In addition, throughout the transition from forms PureEdge to Adobe, please be sure you are working with the latest and greatest FOA.
Reminder

Always forward guidelines for any PDS doc that is sent to Grants and Contracts for review.

Note: If there is more than one program (e.g. A.H.A) please identify the specific program. This will help expedite your review.
Reminder

Please add comments to PDS documents in order to help Grants and Contracts determine what to do with an application (e.g. resubmission of PDS Doc# 86xxx).

Note: Once again this will assist in lowering the turnaround time.
“Non-Human” Means No to Human Subjects

If you receive a HRPO IRB approval that is deemed to be “non-human”, that is the equivalent of the project not involving humans. Therefore you should mark “no” on the face page.

In an instance where the PI checked “YES” to humans or animals and for whatever reason it’s determined that “NO” is appropriate, G&C’s practice will be to ask the PI to e-mail or send a letter to the sponsor with a cc: to G&C (GA) asserting the following:

“My proposal/award entitled, [INSERT TITLE OF PROJECT] at time of submission indicated that IRB/Human was/were pending. Subsequently it has been determined by our [Human Studies Research Protection Office] that [insert reason why protocol is not applicable, e.g., the protocol is non-human]. If you require additional information, please contact [insert department contact]”

If you are not sure if your protocol will be human or non-human, please contact HRPO.
Item 4. Human Subjects Research

No Human Subjects Involved

Check “No” if activities involving human subjects are not planned at any time during the proposed project period. The remaining parts of Item 4 are then not applicable.

Human Subjects Involved

Check “Yes” if activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site or collaborating institution. Check

Item 5. Vertebrate Animals

Check “No” if activities involving vertebrate animals are not planned at any time during the proposed project period, and leave item 5a blank. Note that generation of custom antibodies constitutes an activity involving vertebrate animals.

Check “Yes” if activities involving vertebrate animals are anticipated or planned at any time during the proposed project period, either at the applicant organization or at any other Project/Performance Site or collaborating institution. If animal involvement is anticipated within the period of award but plans are indefinite and it is not possible to describe the use of animals, check “Yes” and in the Research Plan, item 12, provide an explanation and indicate when it is anticipated that animals will be used. Before activities with animals begin, the applicant must provide all of the information required by 5.5, Research Plan, item 12, Vertebrate Animals, with verification of current IACUC approval, to the awarding component for prior approval. IACUC approval must have occurred within the past three years to be considered current.
SPA is now handing the “Administrative Cost Exception Form” for A-21 costs (formerly part of the Prior Approval Form). It is G&C’s practice to look for appropriate justification of A-21 costs in applications. However, we are entering the following into the PDS comments, as an FYI.

You will need to appropriately justify ______________________ in the hard copy application. Note: A-21 items may need to be reviewed and approved by SPA via an Administrative Cost Exception Form (ACE Form) prior to expenditure.

Why?

1. This is an FYI and a heads-up.

2. A-21 justifications can be very subjective and what is determined to be appropriate at one time may later be determined to be inappropriate
Barnes Jewish Hospital Foundation (BJHF)

Please forward all IRB/IACUC/Progress Reports directly to Barnes Jewish Hospital Foundation until further advised.
G&C Website
Updated Items
Grants and Contracts
Most Recent Organization Chart
Go to http://grantsandcontracts.wustl.edu
Under : Contacts
OMB (Humans) instructions have been updated
Go to http://grantsandcontracts.wustl.edu
Under: Forms
Under: External
Reminder: Go to Grants and Contracts website for copies of forms etc.
NCURA Upcoming Meeting

NCURA - 50th Annual Meeting,
November 2-5, 2008,
Hilton Washington, Washington, DC.
For more information visit: http://www.ncura.edu/content/.