Changes in NIH proposal submission guidelines and the transition to electronic submission through Grants.gov.
Non-Competing Grant Awards Under the Current Continuing Resolution

Notice Number: NOT-OD-07-004

Key Dates
Release Date: October 6, 2006

Issued by
National Institutes of Health (NIH), (http://www.nih.gov)

The Department of Health and Human Services (HHS) continues to operate on a continuing resolution (CR) that currently extends through November 17, 2006. The CR applies the terms of the FY 2006 appropriations for the period covered by the CR. Until the final FY 2007 appropriation is enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 80% of the previously committed level). This is consistent with our practice during the FY 2006 Continuing Resolution (CR). NIH will consider upward adjustments to these levels after the final appropriation is enacted, but expects institutions to monitor their expenditures carefully during this period.

Inquiries

Questions regarding adjustments applied to individual grant awards may be directed to the Grants Management Specialist identified on the Notice of Award.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Department of Health and Human Services
National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892
Change in Standing Receipt Dates for NIH/AHRQ/NIOSH Beginning in January 2007

**Notice Number:** NOT-OD-07-001 (See Notice NOT-HS-07-026 Standing Receipt Dates for AHRQ Small Conference Grant (R13) Applications.

**Key Dates**
- Release Date: October 5, 2006
- Effective Date: January 1, 2007

**Issued by**
- National Institutes of Health (NIH) (http://www.nih.gov)
- Agency for Healthcare Research and Quality (AHRQ) (http://www.ahrq.gov)
- National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (NIOSH/CDC) (http://www.cdc.gov/niosh/oep)

The purpose of this Notice is to inform the research community of a change in standard receipt dates for grant applications submitted to NIH, AHRQ and NIOSH. The new receipt dates will be effective as of January 2007 and will apply to both paper and electronic applications.

The transition to electronic application submission has heightened our awareness of challenges posed by having very large numbers of incoming grant applications on any single day. We currently spread the workload involved with receiving incoming grant applications across three annual council rounds that include multiple submission dates for each round. However, some of our standing receipt dates allow for six to eight thousand applications to be submitted for a single date. This volume has the potential to cause bottlenecks in a number of critical places: the research administration offices at the applicant institution, which must now submit all applications; Grants.gov and eRA systems, where response time may slow under heavy volume; the Grants.gov and NIH help desks, which have to handle large spikes in call volume; and the CSR Division of Receipt and Referral, which is responsible for referral of incoming applications in a timely way. Spreading receipt dates to have a steady flow of applications rather than "boom and bust" cycles will allow many different groups to have a realistic approach to this complex process and maximize electronic system responsiveness.

The new receipt dates are based on many factors including:

- The heaviest receipt dates from all agencies on Grants.gov are the first of the month, the 15th of the month, the first Friday, and last day of the month. The proposed NIH receipt dates have been intentionally offset from these dates to improve Grants.gov response times for NIH applicants.
- An effort was made to use recurring days of the month for simplicity (i.e. new R01s would come in on February 5 and renewals on March 5).
- The R01s, NIH’s most frequently used mechanism, were kept early in the receipt window to allow time for processing. The receipt date of the 5th of the month was chosen to be sure the boxes of submissions that come in on the receipt date and the few days prior missed Grants.gov’s heaviest volume days.
- The proposed dates provide additional time for proposal development for application mechanisms often used by new investigators - R03s, R21s, and Ks.
- The AREA date was already changed in the fall of 2005 so it was not moved.
- The New Investigator R01 date was not changed to avoid affecting the pilot. At present this involves only new investigator R01 applications reviewed in forty study sections in CSR (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-060.html)

NIH has revised its **standard** receipt dates as follows. Applications for Request for Applications (RFAs) and Program Announcements (PAs, PARs, PASs) with **special** receipt dates continue to be due on the specified dates listed in the FOA. For an application to be considered on time it must be received by Grants.gov by 5 p.m. local time for the applicant institution.


11/8/2006
<table>
<thead>
<tr>
<th>Program Project Grants and Center Grants – all P Series</th>
<th>Receipt Cycle I</th>
<th>Receipt Cycle II</th>
<th>Receipt Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>new, renewal, resubmission, revision*</td>
<td>January 25 (old date Feb. 1)</td>
<td>May 25 (old date June 1)</td>
<td>September 25 (old date Oct. 1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Grants – R10, R18, R24, R25</th>
<th>Receipt Cycle I</th>
<th>Receipt Cycle II</th>
<th>Receipt Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>new, renewal, resubmission, revision*</td>
<td>January 25 (old date Feb. 1)</td>
<td>May 25 (old date June 1)</td>
<td>September 25 (old date Oct. 1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research-Related and Other Programs – all S and G Series, C06, M01</th>
<th>Receipt Cycle I</th>
<th>Receipt Cycle II</th>
<th>Receipt Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>new, renewal, resubmission, revision*</td>
<td>January 25 (old date Feb. 1)</td>
<td>May 25 (old date June 1)</td>
<td>September 25 (old date Oct. 1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Institutional Ruth L. Kirschstein National Research Service Awards - T Series (Training)**</th>
<th>Receipt Cycle I</th>
<th>Receipt Cycle II</th>
<th>Receipt Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>new, renewal, resubmission, revision*</td>
<td>January 25 (old date Jan. 10)</td>
<td>May 25 (old date May 10)</td>
<td>September 25 (old date Sept. 10)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Grants - R01</th>
<th>Receipt Cycle I</th>
<th>Receipt Cycle II</th>
<th>Receipt Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>new</td>
<td>February 5 (old date Feb. 1)</td>
<td>June 5 (old date June 1)</td>
<td>October 5 (old date Oct. 1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Career Development – all K series</th>
<th>Receipt Cycle I</th>
<th>Receipt Cycle II</th>
<th>Receipt Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>new</td>
<td>Feb 12 (old date Feb. 1)</td>
<td>June 12 (old date June 1)</td>
<td>October 12 (old date Oct. 1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Grants - R03, R21, R33, R21/R33, R34, R36</th>
<th>Receipt Cycle I</th>
<th>Receipt Cycle II</th>
<th>Receipt Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>new</td>
<td>February 16 (old date Feb. 1)</td>
<td>June 16 (old date June 1)</td>
<td>October 16 (old date Oct. 1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Academic Research Enhancement Award (AREA) - R15</th>
<th>Receipt Cycle I</th>
<th>Receipt Cycle II</th>
<th>Receipt Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>new, renewal, resubmission, revision*</td>
<td>February 25 (no change)</td>
<td>June 25 (no change)</td>
<td>October 25 (no change)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Grants - R01</th>
<th>Receipt Cycle I</th>
<th>Receipt Cycle II</th>
<th>Receipt Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>renewal, resubmission, revision*</td>
<td>March 5 (old date March 1)</td>
<td>July 5 (old date July 1)</td>
<td>November 5 (old date Nov. 1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Career Development – all K series</th>
<th>Receipt Cycle I</th>
<th>Receipt Cycle II</th>
<th>Receipt Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>renewal, resubmission, revision*</td>
<td>March 12 (old date March 1)</td>
<td>July 12 (old date July 1)</td>
<td>November 12 (old date Nov. 1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Research Grants - R03, R21, R33, R21/R33, R34, R36</th>
<th>Receipt Cycle I</th>
<th>Receipt Cycle II</th>
<th>Receipt Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>new</td>
<td>March 16</td>
<td>July 16</td>
<td>November 16</td>
</tr>
<tr>
<td>Type of Grant</td>
<td>Old Date 1</td>
<td>Old Date 2</td>
<td>Old Date 3</td>
</tr>
<tr>
<td>--------------</td>
<td>------------</td>
<td>------------</td>
<td>------------</td>
</tr>
<tr>
<td>New Investigator - R01</td>
<td>March 20 (no change)</td>
<td>July 20 (no change)</td>
<td>November 20 (no change)</td>
</tr>
<tr>
<td>Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Grants - R43, R44, R41 and R42</td>
<td>April 5 (old date April 1)</td>
<td>August 5 (old date Aug. 1)</td>
<td>December 5 (old date Dec. 1)</td>
</tr>
<tr>
<td>Individual Ruth L. Kirshstein National Research Service Awards (Standard) - all F series Fellowships.</td>
<td>April 8 (old date April 5)</td>
<td>August 8 (old date Aug. 5)</td>
<td>December 8 (old date Dec. 5)</td>
</tr>
<tr>
<td>Conference Grants and Conference Cooperative Agreements - R13, U13</td>
<td>April 12 (old date April 15)</td>
<td>August 12 (old date Aug. 15)</td>
<td>December 12 (old date Dec. 15)</td>
</tr>
<tr>
<td>AIDS and AIDS-Related Grants</td>
<td>May 1 (no change)</td>
<td>September 1 (no change)</td>
<td>January 2 (no change)</td>
</tr>
</tbody>
</table>

* The move to electronic applications also has brought a change in terminology. The new Grants.gov terminology (included in the table above) corresponds to traditional NIH terms as follows:
  - New = new
  - Resubmission = a revised or amended application
  - Renewal = Competing Continuation
  - Continuation = Noncompeting Progress Report
  - Revision = Competing Supplement

** Institutional Research Training Grants (T32) ** are accepted by many NIH Institutes and Centers (IC) for only one or two of the dates. Applicants should contact the relevant IC for specific dates.

At present NIH receives and processes applications for NIOSH and also for components of CDC that participate in the Omnibus Solicitation for Small Business Innovation Research grant applications. This notice applies only to these two groups of applications and not to other CDC submissions.

The following resources continue to be available for assistance in the electronic submission of grant applications to NIH/AHRQ/NIOSH through Grants.gov:

** General Information:**
- http://www.ahrq.gov/path/egrant.htm

** Inquiry**

Inquiries regarding this Notice should be directed to:

Grants Info
Office of Extramural Research
National Institutes of Health
Report all PIs in CRISP and on Notice of Grant Award

PIs - via footnote
Includes informal budget appropriation associated with individual involved
Some pilots permit linked awards when more than one institution is relationship
Include leadership plan to describe roles, responsibilities,
All PIs have access to electronic application information in status
Use contact PI for communication
No upper limit on number of PIs allowed.
No upper limit on number of PIs allowed.

All PIs jointly responsible for the scientific and technical direction
Multi-PI model optional - based on the research proposal
Logged-in more than 40 Multi-PI applications

Institutional approval changes in administrative database and data
Responsive to a select group of funding opportunity announcements.
The multi-PI option is only available for applications submitted in
Pilot: May - December 2006 to test systems

Site:  http://grants.nih.gov/grants/multi_pi/index.htm

Multi-PI Pilot Program
Establishment of Multiple Principal Investigator Awards for the Support of Team Science Projects

Notice Number: NOT-OD-07-017

Key Dates
Release Date: November 20, 2006

Issued by
National Institutes of Health (NIH), (http://www.nih.gov)

Implementing the Multiple Principal Investigator Policy: Beginning with research grant applications submitted for February 2007 receipt dates, the NIH will allow applicants and their institutions to identify more than one Principal Investigator (PI). The Multiple PI option will be extended to most research grant applications submitted electronically through Grants.gov (http://www.grants.gov/) using the SF424 R&R application package. Grant applications that will accommodate more than one PI beginning in February include: R01, R03, R13/U13, R15, R18/U18, R21, R21/R33, R25, R33, R34, R41, R42, R43, R44, and C06/UC6 (see http://era.nih.gov/ElectronicReceipt/strategy_timeline.htm). Some types of applications including individual career awards (K08, K23, etc.), individual fellowships (F31, F32, etc.), Dissertation Grants (R36), Director's Pioneer Awards (DP1), and Shared Instrumentation Grants (S10) will not accommodate more than a single PI. The restriction to a single PI will be described in announcements for those programs.

The NIH will extend the multiple PI option to most research grant applications when they transition to an electronic format. Some paper applications submitted on PHS 398 application forms also will allow inclusion of more than one PI, but only when the multiple PI option is clearly specified in the soliciting Request for Applications (RFA) or Program Announcement (PA). Other paper applications listing more than one PI may be delayed in the review process or returned to the applicant.

The decision to apply for a single PI or a multiple PI grant will be the responsibility of the investigators and the applicant organization. Those decisions should be consistent with and justified by the scientific goals of the project. As described in the Background section below and on the Multiple Principal Investigator website at http://grants.nih.gov/grants/multi_pi/index.htm, the NIH expects the availability of the Multiple PI option to encourage interdisciplinary and other team approaches to biomedical research.

Features of the Multiple PI Option: The Multiple PI option will include the following features beginning in February 2007:

- Applications
  - NIH Grant Application Forms including the PHS 398 and SF424 R&R will accommodate more than one PI (see application forms at http://grants1.nih.gov/grants/forms.htm)
  - Applications that involve more than one PI must include a Leadership Plan that describes the roles, the responsibilities, and the working relationship of the identified PIs (see application instructions below)
- Principal Investigators
  - All PIs are designated by the applicant institution (see definition of PI below)
  - All PIs share the responsibility and authority for leading and directing the project (see definition of PI below)
  - All listed PIs must be registered in eRA Commons with a PI role type.
  - All listed PIs will have access to Status on the eRA Commons at https://commons.era.nih.gov/commons/
  - The first PI listed must be affiliated with the institution submitting the application and will serve as the contact PI.
  - The contact PI will be responsible for communication between the NIH and the rest of the leadership team.
  - Being named contact PI does not imply any particular role within the leadership team.
  - When requested by the grantee institution at the time of a non-competing application, another member


11/21/06
of the leadership team may assume the role of contact PI.

- All PIs will be listed on summary statements
- All PIs will be listed on the Notice of Grant Award (NOGA)
- All PIs will be listed in CRISP (see http://crisp.cit.nih.gov/)
- Any requested allocation of funds to components of the project or the associated PIs must be included in the Leadership Plan (see below). If an award is made, the requested allocation will be acknowledged in the NOGA. Unless limited by a specific term of award, the acknowledgment of the requested allocation will not limit institutional authority to manage the funds nor will it impose additional prior approval requirements.
- The role type, “Co-PI” will not be used by the NIH

- New Investigator Policies
  - NIH policies related to New Investigators will be applied to applications only when all PIs involved are classified as New Investigators (see http://grants.nih.gov/grants/new_investigators/resources.htm).
  - The New Investigator Box on the application may be checked only when all PIs involved are classified as New Investigators (see instructions for Section 5.3 of the SF 424 R&R application at http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.doc).
  - For the purpose of classification as a New Investigator, serving as a PI on a multiple PI grant will be equivalent to serving as a PI on a single PI grant.

- Review Criteria
  - Standard NIH review criteria have been modified to accommodate both single PI and multiple PI applications (see below)

- Awards Involving More Than One Institution
  - Awards involving PIs at different institutions will be managed using subcontracts until options involving linked awards have been developed.

Features of the Multiple PI Option Still Under Development: The following Multiple PI options are still being developed or assessed:

- The ability to manage research projects using linked awards involving PIs located at more than one institution is being developed.
- The ability to recognize non-PI key contributors to the project is being developed.
- The desirability of formally apportioning funds under a grant to various components of a project or the PIs associated with those components will be assessed.

Background and Purpose: The NIH announced a pilot initiative involving applications that permitted more than one PI on February 7, 2006 (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-036.html). As indicated in that announcement, it is believed that the multiple PI option will offer a new and important opportunity for investigators seeking support for projects or activities that require a “team science” approach. The multiple-PI model is intended to supplement, and not to replace, the traditional single PI model. The goal is to encourage collaboration among equals when that is the most appropriate way to address a scientific problem. Although the number of applications submitted with more than one PI is expected to be relatively small compared with those that continue to use the traditional single-PI format, the ability to submit applications with more than one PI should encourage multidisciplinary efforts. This effort was undertaken in response to recommendations from the 2003 NIH Bioengineering Consortium (BECON) Symposium, “Catalyzing Team Science” (see http://www.bec.on.nih.gov/symposium2003.htm); as a 2005 Roadmap initiative to stimulate interdisciplinary science (see http://nihroadmap.nih.gov/interdisciplinary/); and the Office of Science and Technology Policy (OSTP) issued to all federal research agencies in January 2005 (see http://rbm.nih.gov/PI_memo_050104.pdf). The policies have been shaped by responses to a Request for Information (RFI) issued by OSTP (see http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gov/2005/pdf/05-14015.pdf) and a second RFI issued by the NIH (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-055.html). The NIH also conducted a pilot, receiving more than 60 applications that included multiple PIs in response to nine different Requests for Applications (RFAs) and Program Announcements (PAs). In addition, the NIH has held detailed discussions with the Council on Governmental Relations, the National Council of University Research Administrators, the Association of American Medical Colleges, the Federation of American Societies for Experimental Biology and other organizations to
discuss the features and the policies associated with the multiple PI option.

**Findings from the Pilot**  During the period of the pilot a number of applicants and peer reviewers were interviewed. Nearly everyone expressed support for the concept and offered constructive comments that have been incorporated into the instructions and review criteria shown below. During the Pilot, peer reviewers expressed the following reservations about applications that included teams of scientists:

- In some cases, applications described projects that included PIs that did not have an identified function within the leadership team based on their expertise and the nature of the project.
- In some cases applications identified PIs who seemed too junior to function in a leadership role and in other cases it appeared that senior PIs were included in what might be a considered a “courtesy role”.
- In other cases, it appeared that the leadership team had been expanded only to justify additional salary support for involved personnel.

In each of these cases, reviewers felt that the multiple PI approach detracted from the perceived merit of the application. Reviewers expressed hope that NIH would provide sufficient guidance to future applicants so that the decision to use a team approach was driven by the nature of the project and carefully justified in the Leadership Plan section of the application. Although the multiple PI option can facilitate interdisciplinary and other types of team research, PIs should take care to explain how the members of the leadership team will function on the project and how their inclusion will facilitate the accomplishment of the identified aims of the project.

Based on information received, the NIH developed the following definitions and instructions for the initial roll-out of the multiple PI option. It is expected that the NIH will continue to learn about collaborative approaches. Future input will lead to additional refinement of instructions and policies. The following information has been incorporated into the templates for RFAs and PARs as well as the instructions for completing the PHS 398 and the SF424 R&R application forms. In addition, the standard five NIH review criteria have been modified to accommodate both single-PI and multiple-PI applications and are shown below. To adjust to electronic applications and the SF424 R&R, the PI is referred to as the Program Director/Principal Investigator (PD/PI) in these instructions to accommodate a broader range of application types. Additional information including Frequently Asked Questions (FAQs) has been updated on the NIH Multiple PI website at http://grants.nih.gov/grants/multi_pi/index.htm

**NIH Definition of a Principal Investigator:** The individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant. The applicant organization may designate multiple individuals as PD/Pis who share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the applicant organization, or, as appropriate, to a collaborating organization, for the proper conduct of the project or program including the submission of all required reports. The presence of more than one identified PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI.

**Deciding to Use the Multiple PI Option:** The decision to apply for a single PD/PI or multiple PD/PI grant is the responsibility of the investigators and the applicant organization and should be determined by the scientific goals of the project. Applications for multiple PD/PI grants will require additional information, as outlined in the instructions. The NIH review criteria for approach, investigators, and environment have been modified to accommodate applications involving either a single PD/PI or multiple PD/Pis. When considering multiple PD/Pis, please be aware that the organizational structure and governance of the PD/PI leadership team as well as the knowledge, skills and experience of the individual PD/Pis will be factored into the assessment of the overall scientific merit of the application. Multiple PDs/Pis on a project share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the grantee organization, or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of required reports. For further information on multiple PD/Pis, please see http://grants.nih.gov/grants/multi_pi.

**Multiple PD/PI Leadership Plan:** For applications designating multiple PD/Pis, a new section of the research plan, entitled “Multiple PD/PI Leadership Plan” (section 14 of the Research Plan Component in the SF424 R&R or Section I of the
Research Plan in the PHS 398), must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators. If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs must be delineated in the Leadership Plan. In the event of an award, the requested allocation may be reflected in a footnote on the NOGA.

**Standard Review Criteria Modified to Accommodate Applications with and without Multiple PIs:**

**Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? For applications designating multiple PD/PIs, is the leadership approach, including the designated roles and responsibilities, governance and organizational structure consistent with and justified by the aims of the project and the expertise of each of the PD/PIs?

**Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

**Investigators:** Are the PD/PI(s) and other key personnel appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI(s) and other researchers? Do the PD/PI(s) and the investigative team bring complementary and integrated expertise to the project (if applicable).

**Environment:** Does the scientific environment(s) in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment(s), or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

**Inquiry**

For additional information please visit the Multiple Principal Investigator website at [http://grants.nih.gov/grants/multi_pi/](http://grants.nih.gov/grants/multi_pi/) and feel free to send email to multi_Pi@mail.nih.gov.

---

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Department of Health and Human Services

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

---

Parent Announcements are not new to the NIH which are responding to such omnibus or umbrella Parent FOA announcements (formerly known as "unsolicited").

Parent "umbrella" announcements for investigator-initiated applications (for HHS AGENCIES".

The NIH and other HHS AGENCIES plan to develop omnibus Parent "umbrella" announcements (PAR).

Review considerations refer only to special receipt, referral and/or requirements for applications (PAR) and Announcements (PAR). Request for Applications (PAR) and Grant.gov term which NIH refers to as Program Announcements (PAR). Funding Opportunity Announcement (FOA).

All electronic applications must be submitted in response to a Funding Opportunity Announcement (FOA).

What Does It Mean For You?

New "Parent" Announcements...
### Additional Tips for Identifying Opportunities

<table>
<thead>
<tr>
<th>Application Date</th>
<th>Opening Date</th>
<th>Due Date</th>
<th>Announcement Number</th>
<th>Activity Code (Parent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-170</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-171</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-172</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-173</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-174</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-175</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-176</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-177</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-178</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-179</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-180</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-181</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-182</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-183</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-184</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-185</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-186</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-187</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-188</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-189</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-190</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-191</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-192</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-193</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-194</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-195</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-196</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-197</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-198</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-199</td>
<td>PA-03</td>
</tr>
<tr>
<td>01/01/2007</td>
<td>03/01/2007</td>
<td>06/01/2007</td>
<td>PA-06-200</td>
<td>PA-03</td>
</tr>
</tbody>
</table>

Note: The following Parent Announcements are available by activity code:

**Activity Code:** PA-06

About Parent Announcements:

**Parent Announcements** are mandatory for all NIH Funding Opportunity Announcements. They provide a comprehensive overview of the NIH's Funding Opportunity Announcements and are available online. Applications that do not follow the guidelines specified in the Parent Announcements will not be considered for funding. For more information, please visit the NIH website or contact the relevant program officer.
Part I Overview Information

Department of Health and Human Services

Participating Organizations
National Institutes of Health (NIH) (http://www.nih.gov)

Components of Participating Organizations
National Institute on Aging (NIA), (http://www.nia.nih.gov)
National Institute on Alcohol Abuse and Alcoholism (NIAAA), (http://www.niaaa.nih.gov)
National Institute of Allergy and Infectious Diseases (NIAID), (http://www.niaid.nih.gov)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), (http://www.niams.nih.gov)
National Institute of Biomedical Imaging and Bioengineering (NIBIB), (http://www.nibib.nih.gov)
National Cancer Institute (NCI), (http://www.nci.nih.gov)
National Institute of Child Health and Human Development (NICHD), (http://www.nichd.nih.gov)
National Center for Complementary and Alternative Medicine (NCCAM), (http://www.nccam.nih.gov)
National Institute on Deafness and Other Communication Disorders (NIDCD), (http://www.nidcd.nih.gov)
National Institute of Dental and Craniofacial Research (NIDCR), (http://www.nidcr.nih.gov)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), (http://www.niddk.nih.gov)
National Institute on Drug Abuse (NIDA), (http://www.nida.nih.gov)
National Institute of Environmental Health Sciences (NIEHS), (http://www.niehs.nih.gov)
National Eye Institute (NEI), (http://www.nei.nih.gov)
National Institute of General Medical Sciences (NIGMS), (http://www.nigms.nih.gov)
National Heart, Lung, and Blood Institute (NHLBI), (http://www.nhlbi.nih.gov)
National Human Genome Research Institute (NHGRI), (http://www.nhgri.nih.gov)
National Institute of Mental Health (NIMH), (http://www.nimh.nih.gov)
National Institute of Neurological Disorders and Stroke (NINDS), (http://www.ninds.nih.gov)
National Institute of Nursing Research (NINR), (http://www.ninr.nih.gov/ninr)
National Center for Research Resources (NCRR), (http://www.ncrr.nih.gov)

Title: Research Project Grant (Parent R01)

Announcement Type
New

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (http://www.grants.gov) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.

This FOA must be read in conjunction with the application guidelines included with this announcement in Grants.gov/Apply for Grants (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process at least four weeks prior to the grant submission date. See Section IV.

Program Announcement (PA) Number: PA-07-070

Apply for Grant Electronically

For assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at http://grants.gov/CustomerSupport

Catalog of Federal Domestic Assistance Number(s)
93.113, 93.114, 93.115, 93.121, 93.143, 93.172, 93.173, 93.213, 93.233, 93.242, 93.273, 93.279, 93.286, 93.361, 93.389, 93.393, 93.394, 93.395, 93.396, 93.398, 93.837, 93.838, 93.839, 93.846, 93.847, 93.848, 93.849, 93.853, 93.855, 93.856, 93.859, 93.865, 93.866, 93.867, 93.879

Key Dates
Release/Posted Date: November 20, 2006
Opening Date: January 5, 2007 (Earliest date an application may be submitted to Grants.gov)
Letters of Intent Receipt Date(s): Not Applicable
NOTE: On time submission requires that applications be successfully submitted to Grants.gov no later than 5:00 p.m. local time (of the applicant institution/organization).
Application Submission/Receipt Date(s): Standard dates apply, please see http://grants1.nih.gov/grants/funding/submissionschedule.htm
AIDS Application Submission/Receipt Date(s): Standard dates apply, please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS
Peer Review Date(s): Standard dates apply, please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Council Review Date(s): Standard dates apply, please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Earliest Anticipated Start Date(s): Standard dates apply, please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Additional Information To Be Available Date (URL Activation Date): Not Applicable
Expiration/Closing Date: January 3, 2010

Due Dates for E.O. 12372
Not Applicable

Additional Overview Content

Executive Summary

- **Purpose.** The Research Project Grant (R01) is an award made to an institution/organization to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in areas representing the specific interests and competencies of the investigator(s). The R01 research plan proposed by the applicant institution/organization must be related to the stated program interests of one or more of the NIH Institutes and Centers (ICs) based on descriptions of their programs. All research project grant applications described in this announcement will be assigned to NIH ICs according to standard Public Health Service (PHS) referral guidelines and specific program interests. Investigators are encouraged to consult the participating NIH ICs and their Web sites (see http://www.nih.gov/ncid).

- **Mechanism of Support.** This Funding Opportunity Announcement (FOA) will use the NIH Research Project Grant (R01) award mechanism.

- **Funds Available and Anticipated Number of Awards.** Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. The total amount awarded and the number of awards will depend upon the numbers, quality, duration, and costs of the applications selected for award.

- **Eligible Institutions/Organizations.** Public/State Controlled Institution of Higher Education; Private Institution of Higher Education; Nonprofit with 501(c)(3) IRS Status (Other than Institution of Higher Education); Nonprofit without

501(c)(3) IRS Status (Other than Institution of Higher Education); Small Business; For-Profit Organization (Other than Small Business); State Government; U.S. Territory or Possession; Indian/Native American Tribal Government (Federally Recognized); Indian/Native American Tribal Government (Other than Federally Recognized); Indian/Native American Tribally Designated Organization; Non-domestic (non-U.S.) Entity (Foreign Organization); Hispanic-serving Institution; Historically Black Colleges and Universities (HBCUs); Tribally Controlled Colleges and Universities (TCCUs); Alaska Native and Native Hawaiian Serving Institutions; Regional Organization; Other(s): Eligible agencies of the Federal government; Faith-based or community based organizations.

- Eligible Project Directors/Principal Investigators (PDs/PIs). Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

- Number of Applications. Applicants may submit more than one application, provided each application is scientifically distinct.

- Renewals and Resubmissions. Grants can be renewed by competing for additional project periods. Applicants may submit a “resubmission” application, but such application must include an “Introduction” addressing the previous peer review critique (Summary Statement).

- Number of PDs/PIs. More than one PD/PI, or multiple PDs/PIs, may be designated on the application.

- Application Materials. See Section IV.1 for application materials.

- General Information. For general information on SF424 (R&I) Application and Electronic Submission, see these web sites:
  - General Information on Electronic Submission of Grant Applications: http://era.nih.gov/ElectronicReceipt/

- Hearing Impaired. Telecommunications for the hearing impaired is available at: TTY 301-451-0088.

Table of Contents

Part I Overview Information

Part II Full Text of Announcement

Section I. Funding Opportunity Description
  1. Research Objectives

Section II. Award Information
  1. Mechanism of Support
  2. Funds Available

Section III. Eligibility Information
  1. Eligible Applicants
     A. Eligible Institutions
     B. Eligible Individuals
  2. Cost Sharing or Matching
  3. Other - Special Eligibility Criteria

Section IV. Application and Submission Information
  1. Request Application Information
  2. Content and Form of Application Submission
  3. Submission Dates and Times
     A. Submission, Review, and Anticipated Start Dates
        1. Letter of Intent

B. Submitting an Application Electronically to the NIH
   C. Application Processing
4. Intergovernmental Review
5. Funding Restrictions
6. Other Submission Requirements

Section V. Application Review Information
   1. Criteria
   2. Review and Selection Process
      A. Additional Review Criteria
      B. Additional Review Considerations
      C. Sharing Research Data
      D. Sharing Research Resources
   3. Anticipated Announcement and Award Dates

Section VI. Award Administration Information
   1. Award Notices
   2. Administrative and National Policy Requirements
   3. Reporting

Section VII. Agency Contact(s)
   1. Scientific/Research Contact(s)
   2. Peer Review Contact(s)
   3. Financial/Grants Management Contact(s)

Section VIII. Other Information - Required Federal Citations

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

The Research Project Grant (R01) is an award to support a discrete, specified, circumscribed project to be performed by named Project Directors/Principal Investigators (PDs/PIs) in areas representing the investigators’ specific interests and competencies, based on the mission of the NIH. The R01 is the original and historically the oldest grant mechanism used by the NIH to support health-related research and development.

The NIH awards R01 grants to institutions/organizations of all types. This mechanism allows the PDs/PIs to define the scientific focus or objective of the research based on particular areas of interest and competence. Although the PDs/PIs write the grant application and are responsible for conducting and supervising the research, the actual applicant is the research institution/organization.

Research grant applications are assigned to an NIH IC based on receipt and referral guidelines and many applications are assigned to multiple ICs with related research interests.

Each IC maintains a Web site with funding opportunities and areas of interest. Contact with an IC representative may help focus the research plan based on an understanding of the mission of the IC. For specific information about the mission of
each NIH IC, see http://www.nih.gov/icd, which provides a brief summary of the research interests in each IC and access to individual IC home pages.

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Section II. Award Information

1. Mechanism of Support

This Funding Opportunity Announcement (FOA) will use the Research Project Grant (R01) award mechanism.

The applicant will be solely responsible for planning, directing, and executing the proposed project.

This FOA uses “Just-in-Time” information concepts. It also uses the modular as well as the non-modular budget formats (see http://grants.nih.gov/grants/funding/modular/modular.htm).

Specifically, if you are a U.S. organization and are submitting an application with direct costs in each year of $250,000 or less (excluding consortium Facilities and Administrative [F&A] costs), use the PHS398 Modular Budget component provided in the SF424 (R&R) Application Package and SF424 (R&R) Application Guide (see specifically Section 5.4, “Modular Budget Component,” of the Application Guide).

U.S. applicants requesting more than $250,000 in annual direct costs and all foreign applicants must complete and submit detailed budget requests using the Research & Related Budget component found in the application package for this FOA. See NOT-OD-06-096, August 23, 2006.

2. Funds Available

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the Institutes and Centers (ICs) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the submission of a sufficient number of meritorious applications.

NIH grants policies as described in the NIH Grants Policy Statement will apply to the applications submitted and awards made in response to this FOA.

F&A costs requested by consortium participants are not included in the direct cost limitation. See NOT-OD-05-004, November 2, 2004.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit an application(s) if your institution/organization has any of the following characteristics:

- Public/State Controlled Institution of Higher Education
- Private Institution of Higher Education
• Nonprofit with 501(c)(3) IRS Status (Other than Institution of Higher Education)
• Nonprofit without 501(c)(3) IRS Status (Other than Institution of Higher Education)
• Small Business
• For-Profit Organization (Other than Small Business)
• State Government
• U.S. Territory or Possession
• Indian/Native American Tribal Government (Federally Recognized)
• Indian/Native American Tribal Government (Other than Federally Recognized)
• Indian/Native American Tribally Designated Organization
• Non-domestic (non-U.S.) Entity (Foreign Organization)
• Hispanic-serving Institution
• Historically Black Colleges and Universities (HBCUs)
• Tribally Controlled Colleges and Universities (TCCUs)
• Alaska Native and Native Hawaiian Serving Institutions
• Regional Organization
• Other(s): Eligible agencies of the Federal government; Faith-based or community based organizations.

1.B. Eligible Individuals

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the PD/PI is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

More than one PD/PI, or multiple PDs/PIs, may be designated on the application for projects that require a "team science" approach that clearly does not fit the single-PD/PI model. Additional information on the implementation plans and policies and procedures to formally allow more than one PD/PI on individual research projects is available at http://grants.nih.gov/grants/multi_pi. All PDs/PIs must be registered in the NIH eRA Commons prior to the submission of the application (see http://era.nih.gov/ElectronicReceipt/preparing.htm for instructions).

The decision of whether to apply for a single PD/PI or multiple PD/PI grant is the responsibility of the investigators and applicant organizations and should be determined by the scientific goals of the project. Applications for multiple PD/PI grants will require additional information, as outlined in the instructions below. The NIH review criteria for approach, investigators, and environment have been modified to accommodate applications involving either a single PD/PI or multiple PDs/PIs as indicated below. When considering multiple PDs/PIs, please be aware that the structure and governance of the PD/PI leadership team as well as the knowledge, skills and experience of the individual PD/PIs will be factored into the assessment of the overall scientific merit of the application. Multiple PDs/PIs on a project share the authority and responsibility for leading and directing the project, intellectually and logistically. Each PD/PI is responsible and accountable to the grantee organization, or, as appropriate, to a collaborating organization, for the proper conduct of the project or program, including the submission of all required reports. For further information on multiple PDs/PIs, please see http://grants.nih.gov/grants/multi_pi.

2. Cost Sharing or Matching

This program does not require cost sharing as defined in the current NIH Grants Policy Statement.

3. Other-Special Eligibility Criteria

Applicants may submit more than one application, provided each application is scientifically distinct.

Section IV. Application and Submission Information
To download a SF424 (R&R) Application Package and SF424 (R&R) Application Guide for completing the SF424 (R&R) forms for this FOA, link to http://www.grants.gov/applicants/apply_for_grants.jsp and follow the directions provided on that Web site.

A one-time registration is required for institutions/organizations at both:

- Grants.gov (http://www.grants.gov/applicants/get_registered.jsp) and
- eRA Commons (http://era.nih.gov/ElectronicReceipt/preparing.htm)

PDs/PIs should work with their institutions/organizations to make sure they are registered in the eRA Commons.

Several additional separate actions are required before an applicant institution/organization can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov/Get Registered

- Your organization will need to obtain a Data Universal Number System (DUNS) number and register with the Central Contractor Registration (CCR) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- Direct questions regarding Grants.gov registration to:
  Grants.gov Customer Support
  Contact Center Phone: 800-518-4726
  Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time
  Email support@grants.gov

2) Organizational/Institutional Registration in the eRA Commons

- To find out if an organization is already Commons-registered, see the "List of Grantee Organizations Registered in NIH eRA Commons."
- Direct questions regarding the Commons registration to:
  eRA Commons Help Desk
  Phone: 301-402-7469 or 866-504-9552 (Toll Free)
  TTY: 301-451-5939
  Business hours M-F 7:00 a.m. - 8:00 p.m. Eastern Time
  Email commons@od.nih.gov

3) Project Director/Principal Investigator (PD/PI) Registration in the NIH eRA Commons: Refer to the NIH eRA Commons System (COM) Users Guide.

- The individual(s) designated as PDs/PIs on the application must also be registered in the NIH eRA Commons. In the case of multiple PDs/PIs, all PDs/PIs must be registered and be assigned the PI role in the eRA Commons prior to the submission of the application.
- Each PD/PI must hold a PD/PI account in the Commons. Applicants should not share a Commons account for both an Authorized Organization Representative/Signing Official (AOR/SO) role and a PD/PI role; however, if they have both a PD/PI role and an Internet Assisted Review (IAR) role, both roles should exist under one Commons account.
- When multiple PDs/PIs are proposed, all PDs/PIs at the applicant organization must be affiliated with that organization. PDs/PIs located at another institution need not be affiliated with the applicant organization, but must be affiliated with their own organization to be able to access the Commons.
- This registration/affiliation must be done by the AOR/SO or their designee who is already registered in the Commons.

Both the PD/PI(s) and AOR/SO need separate accounts in the NIH eRA Commons since both are authorized to view the application image.

Note that if a PD/PI is also an NIH peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

Several of the steps of the registration process could take four weeks or more. Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered in both Grants.gov and the Commons. The NIH will accept electronic applications only from organizations that have completed all necessary registrations.

1. Request Application Information

Applicants must download the SF424 (R&R) application forms and the SF424 (R&R) Application Guide for this FOA through Grants.gov/Apply.

Note. Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA), although some of the "Attachment" files may be useable for more than one FOA.

For further assistance, contact GrantsInfo: Telephone 301-435-0714, Email. GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Prepare all applications using the SF424 (R & R) application forms and in accordance with the SF424 (R&R) Application Guide for this FOA through Grants.gov/Apply.

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to NIH. There are fields within the SF424 (R&R) application components that, although not marked as mandatory, are required by NIH (e.g., the "Credential" log-in field of the "Research & Related Senior/Key Person Profile" component must contain the PD/PI's assigned eRA Commons User ID). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see "Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications."

The SF424 (R&R) application has several components. Some components are required, others are optional. The forms package associated with this FOA in Grants.gov/APPLY includes all applicable components, required and optional. A completed application in response to this FOA includes the data in the following components:

**Required Components:**
- SF424 (R&R) (Cover component)
- Research & Related Project/Performance Site Locations
- Research & Related Other Project Information
- Research & Related Senior/Key Person
- PHS398 Cover Page Supplement
- PHS398 Research Plan
- PHS398 Checklist
- PHS398 Modular Budget or Research & Related Budget: Use only one, as appropriate. (See Section IV.6., "Special Instructions," regarding appropriate required budget component. Research & Related Budget is required for foreign applications.)
Optional Components:
PHS398 Cover Letter File
Research & Related Subaward Budget Attachment(s) Form

Foreign Organizations (Non-domestic (non-U.S.) Entity)


Applications from foreign organizations must:

- Request budgets in U.S. dollars.
- Prepare detailed budgets for all applications (that is, complete the Research & Related Budget component of the SF424 (R&R) application forms – not the PHS398 Modular Budget component). See NOT-OD-06-095.
- Charge back of customs and import fees is not allowed.
- Format: Every effort should be made to comply with the format specifications, which are based upon a standard U.S. paper size of 8.5" x 11" within each PDF.
- Funds for up to 8% administrative costs (excluding equipment) may be requested. See NOT-OD-01-028, March 29, 2001.
- Organizations must comply with Federal/NIH policies on human subjects, animals, and biohazards.
- Organizations must comply with Federal/NIH biosafety and biosecurity regulations. See Section VI.2., "Administrative and National Policy Requirements."

Proposed research should provide special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources.

SPECIAL INSTRUCTIONS

Applications with Multiple PDs/PIs

When multiple PDs/PIs are proposed, NIH requires one PD/PI to be designated as the “Contact” PI, who will be responsible for all communication between the PDs/PIs and the NIH, for assembling the application materials outlined below, and for coordinating progress reports for the project. The contact PD/PI must meet all eligibility requirements for PDI/PI status in the same way as other PDs/PIs, but has no other special roles or responsibilities within the project team beyond those mentioned above.

Information for the Contact PD/PI should be entered in item 15 of the SF424 (R&R) Cover component. All other PDs/PIs should be listed in the Research & Related Senior/Key Person component and assigned the project role of "PD/PI." Please remember that all PDs/PIs must be registered in the eRA Commons prior to application submission. The Commons ID of each PD/PI must be included in the "Credential" field of the Research & Related Senior/Key Person component. Failure to include this data field will cause the application to be rejected.

All projects proposing Multiple PDs/PIs will be required to include a new section describing the leadership of the project.

Multiple PD/PI Leadership Plan: For applications designating multiple PDs/PIs, a new section of the research plan, entitled “Multiple PD/PI Leadership Plan” (section 14 of the Research Plan Component in the SF424 [R&R]), must be included. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PDs/PIs and other collaborators.
If budget allocation is planned, the distribution of resources to specific components of the project or the individual PDs/PIs should be delineated in the Leadership Plan. In the event of an award, the requested allocations may be reflected in a footnote on the Notice of Award.

Applications Involving a Single Institution

When all PDs/PIs are within a single institution, follow the instructions contained in the SF424 (R&R) Application Guide.

Applications Involving Multiple Institutions

When multiple institutions are involved, one institution must be designated as the prime institution and funding for the other institution(s) must be requested via a subcontract to be administered by the prime institution. When submitting a detailed budget, the prime institution should submit its budget using the Research & Related Budget component. All other institutions should have their individual budgets attached separately to the Research & Related Subaward Budget Attachment(s) Form. See Section 4.8 of the SF424 (R&R) Application Guide for further instruction regarding the use of the subaward budget form.

When submitting a modular budget, the prime institution completes the PHS398 Modular Budget component only. Information concerning the consortium/subcontract budget is provided in the budget justification. Separate budgets for each consortium/subcontract grantee are not required when using the Modular budget format. See Section 5.4 of the Application Guide for further instruction regarding the use of the PHS398 Modular Budget component.

3. Submission Dates and Times

See Section IV.3.A for details.

3.A. Submission, Review, and Anticipated Start Dates

Opening Date: January 5, 2007 (Earliest date an application may be submitted to Grants.gov)
Application Submission/Receipt Date(s): Standard dates apply, please see http://grants.nih.gov/grants/funding/submissionschedule.htm
AIDS Application Submission/Receipt Date(s): Standard dates apply, please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#AIDS
Peer Review Date(s): Standard dates apply, please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Council Review Date(s): Standard dates apply, please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward
Earliest Anticipated Start Date(s): Standard dates apply, please see http://grants1.nih.gov/grants/funding/submissionschedule.htm#reviewandaward

3.A.1. Letter of Intent

A letter of intent is not required for the funding opportunity.

3.B. Submitting an Application Electronically to the NIH

To submit an application in response to this FOA, applicants should access this FOA via http://www.grants.gov/applicants/apply_for_grants.jsp and follow steps 1-4. Note: Applications must only be submitted electronically. PAPER APPLICATIONS WILL NOT BE ACCEPTED.

3.C. Application Processing

Applications may be submitted on or after the opening date and must be successfully received by Grants.gov no later than

5:00 p.m. local time (of the applicant institution/organization) on the application submission/receipt date(s). (See Section IV.3.A. for all dates.) If an application is not submitted by the receipt date(s) and time, the application may be delayed in the review process or not reviewed.

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two business days to view the application image.

- If everything is acceptable, no further action is necessary. The application will automatically move forward for processing by the Division of Receipt and Referral, Center for Scientific Review, NIH, after two business days.
- Prior to the submission deadline, the AOR/SO can "Reject" the assembled application and submit a changed/corrected application within the two-day viewing window. This option should be used if the AOR/SO determines that warnings should be addressed or if information was lost or compromised during transmission. Reminder: warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two business days if no action is taken. Please remember that some warnings may not be applicable or may need to be addressed after application submission.
- If the two-day window falls after the submission deadline, the AOR/SO will have the option to "Reject" the application if, due to an eRA Commons or Grants.gov system issue, the application does not correctly reflect the submitted application package (e.g., some part of the application was lost or didn’t transfer correctly during the submission process). The AOR/So should first contact the eRA Commons Helpdesk to confirm the system error, document the issue, and determine the best course of action. NIH will not penalize the applicant for an eRA Commons or Grants.gov system issue.
- If the AOR/So chooses to "Reject" the image after the submission deadline for a reason other than an eRA Commons or Grants.gov system failure, a changed/corrected application still can be submitted, but it will be subject to the NIH late policy guidelines and may not be accepted. The reason for this delay should be explained in the cover letter attachment.
- Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two days.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review, NIH. Incomplete applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the Commons. The submitting AOR receives the Grants.gov acknowledgments. The AOR and the PI receive Commons acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

Note: Since email can be unreliable, it is the responsibility of the applicant to check periodically on their application status in the Commons.

The NIH will not accept any application in response to this FOA that is essentially the same as one currently pending initial merit review unless the applicant withdraws the pending application. The NIH will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of an application already reviewed with substantial changes, but such application must include an "introduction" (3 pages maximum) addressing the previous critique. Note such an application is considered a "resubmission" for the SF424 (R&R).

4. Intergovernmental Review

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants
Policy Statement.

Pre-award costs are allowable. A grantee may, at its own risk and without NIH prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new or competing renewal (formerly "competing continuation") award if such costs: are necessary to conduct the project, and would be allowable under the grant, if awarded, without NIH prior approval. If specific expenditures would otherwise require prior approval, the grantee must obtain NIH approval before incurring the cost. NIH prior approval is required for any costs to be incurred more than 90 days before the beginning date of the initial budget period of a new or competing renewal award.

The incurrence of pre-award costs in anticipation of a competing or non-competing award imposes no obligation on NIH to either make the award or to increase the amount of the approved budget if an award is made for less than the amount anticipated and is inadequate to cover the pre-award costs incurred. NIH expects the grantee to be fully aware that pre-award costs result in borrowing against future support and that such borrowing must not impair the grantee’s ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the project. See the NIH Grants Policy Statement.

6. Other Submission Requirements

PD/PI Credential (e.g., Agency Login)

The NIH requires the PD/PI(s) to fill in their Commons User ID in the “PROFILE – Project Director/Principal Investigator” section, “Credential” log-in field of the “Research & Related Senior/Key Person Profile” component.

Organizational DUNS

The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see “Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications.”

PHS398 Research Plan Component Sections

Items 2-5 of the PHS398 Research Plan component are limited to 25 pages. While each section of the Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to better monitor formatting requirements such as page limits. All attachments must be provided to NIH in PDF format, filenames must be included with no spaces or special characters, and a .pdf extension must be used.

All application instructions outlined in the SF424 (R&R) Application Guide are to be followed, incorporating “Just-in-Time” information concepts, and with the following additional requirements:

Special Instructions for Modular Grant applications

R01 applications from U.S. institutions/organizations requesting up to $250,000 per year in direct costs (excluding consortium F&A costs) must be submitted in a modular budget format. Additional information on modular budgets is available at http://grants.nih.gov/grants/funding/modular/modular.htm. When submitting a modular budget, the applicant organization will include only the PHS398 Modular Budget component. See Section 5.4 of the SF424 (R&R) Application Guide for further instructions regarding the use of the PHS398 Modular Budget component. Foreign organizations may not submit modular budgets. See NOT-OD-06-096.

Special Instructions for Applications Requesting $500,000 (direct costs) or More Per Year

Applicants requesting $500,000 or more in direct costs for any year (excluding consortium F&A costs) must carry out the following steps:

1) Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;

2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,

3) Include the PHS398 Cover Letter component with the application to identify the staff member and IC who agreed to accept assignment of the application.

This policy applies to all new applications, competing renewal (formerly "competing continuation") applications, resubmission (formerly "revised/amended") applications, and revision (formerly "competing supplemental") applications. See NOT-OD-02-004, October 16, 2001.

Appendix Materials

IMPORTANT NOTE: NIH has published new limitations on grant application appendix materials to encourage applications to be as concise as possible while containing the information needed for expert scientific review.

Applicants must follow the specific instructions on Appendix materials as described in the SF424 (R&R) Application Guide (See http://grants.nih.gov/grants/funding/424/index.htm).

Do not use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not observe the required page limitations may be delayed in the review process.

Note: While each section of the PHS398 Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to monitor better formatting requirements such as page limits. All attachments must be provided to NIH in PDF format, filenames must be included with no spaces or special characters, and a .pdf extension must be used.

Foreign Applications (Non-domestic (non-U.S.) Entity)

- Indicate how the proposed project has specific relevance to the mission and objectives of the IC and has the potential for significantly advancing the health sciences in the United States.
- Research grant applications from foreign or international organizations may not be funded unless approved by the IC National Advisory Council or Board.

Plan for Sharing Research Data

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal Web site, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.
Applicants requesting more than $500,000 in direct costs in any year of the proposed research must include a plan for sharing research data in their application. The funding organization will be responsible for monitoring the data sharing policy (http://grants.nih.gov/grants/policy/data_sharing).

The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

Sharing Research Resources

NIH policy expects that grant recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (See the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600131). Investigators responding to this funding opportunity should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each Non-Competing Grant Progress Report (PHS 2590). See Section VI.3., "Reporting."

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Applications submitted for this funding opportunity will be assigned to the ICs on the basis of established PHS referral guidelines.

Appropriate scientific review groups convened in accordance with the standard NIH peer review procedures (http://www.csr.nih.gov/refrev.htm) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level of review by the appropriate national advisory council or board.

Applications submitted in response to this funding opportunity will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review.
- Availability of funds.
- Relevance of program priorities.

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of
disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application.

- Significance
- Approach
- Innovation
- Investigator
- Environment

Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

**Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

**Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? For applications designating multiple PDs/Pls, is the leadership approach, including the designated roles and responsibilities, governance, and organizational structure, consistent with and justified by the aims of the project and the expertise of each of the PDs/Pls?

**Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches or methodologies, tools, or technologies for this area?

**Investigators:** Are the PD/Pls and other key personnel appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level(s) of the principal investigator(s) and other researchers? Do the PD/Pls and investigative team bring complementary and integrated expertise to the project (if applicable)?

**Environment:** Do(es) the scientific environment(s) in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment(s), or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

2.A. Additional Review Criteria

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

**Resubmission Applications (formerly “revised/amended” applications):** Are the responses to comments from the previous scientific review group adequate? Are the improvements in the resubmission application appropriate?

**Protection of Human Subjects from Research Risk:** The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. See the “Human Subjects Sections” of the PHS399 Research Plan component of the SF424 (R&R).

**Inclusion of Women, Minorities and Children in Research:** The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated. See the “Human Subjects Sections” of
the PHS398 Research Plan component of the SF424 (R&R).

**Care and Use of Vertebrate Animals in Research:** If vertebrate animals are to be used in the project, the adequacy of the plans for care and use of vertebrate animals to be used in the project will be assessed. See the "Other Research Plan Sections" of the PHS398 Research Plan component of the SF424 (R&R).

**Biohazards:** If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.

### 2.B. Additional Review Considerations

**Budget and Period of Support:** The reasonableness of the proposed budget and the appropriateness of the requested period of support in relation to the proposed research may be assessed by the reviewers. The priority score should not be affected by the evaluation of the budget.

**Applications from Foreign Organizations:** Whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing U.S. resources will be assessed.

### 2.C. Sharing Research Data

**Data Sharing Plan:** The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The funding organization will be responsible for monitoring the data sharing policy. [http://grants.nih.gov/grants/policy/data_sharing](http://grants.nih.gov/grants/policy/data_sharing)

### 2.D. Sharing Research Resources

NIH policy expects that grant recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (See the [NIH Grants Policy Statement](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.html#_Toc54600131)). Investigators responding to this funding opportunity should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.

Program staff will be responsible for the administrative review of the plan for sharing research resources.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each Non-Competing Grant Progress Report (PHS 2590). See Section VI.3., "Reporting."

**Model Organism Sharing Plan:** Reviewers are asked to assess the sharing plan in an administrative note. The sharing plan itself should be discussed after the application is scored. Whether a sharing plan is reasonable can be determined by the reviewers on a case-by-case basis, taking into consideration the organism, the timeline, the applicant’s decision to distribute the resource or deposit it in a repository, and other relevant considerations.

### 3. Anticipated Announcement and Award Dates

Not Applicable.

### Section VI. Award Administration Information

1. Award Notices

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the NIH eRA Commons.

If the application is under consideration for funding, NIH will request “just-in-time” information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the grants management officer is the authorizing document. Once all administrative and programmatic issues have been resolved, the NoA will be generated via email notification from the awarding component to the grantee business official.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See Section IV.5, “Funding Restrictions.”

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities.

3. Reporting

When multiple years are involved, awardees will be required to submit the Non-Competing Grant Progress Report (PHS 2590), annually and financial statements as required in the NIH Grants Policy Statement.

Section VII. Agency Contacts

We encourage scientific/programmatic inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Reminder: Questions concerning electronic submission should be directed to Grants.gov or eRA Commons. See Section IV.

1. Scientific/Research Contacts:

Participating NIH Institutes and Centers are listed on the first page of this announcement (“Components of Participating Organizations”). Scientific/research contact information is listed in the table below.

<table>
<thead>
<tr>
<th>NIH Institute/Center</th>
<th>Scientific/Research Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Cancer Institute</td>
<td><a href="http://www.cancer.gov/researchandfunding/contacts">http://www.cancer.gov/researchandfunding/contacts</a></td>
</tr>
<tr>
<td>National Center for Complementary and Alternative Medicine</td>
<td><a href="http://nccam.nih.gov/research/contact/index.htm">http://nccam.nih.gov/research/contact/index.htm</a></td>
</tr>
<tr>
<td>National Center on Minority Health and Health Disparities</td>
<td><a href="http://ncmhd.nih.gov/">http://ncmhd.nih.gov/</a> 301-402-1366</td>
</tr>
<tr>
<td>---------------------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>National Center for Research Resources</td>
<td><a href="http://www.ncrr.nih.gov/contact_us.asp">http://www.ncrr.nih.gov/contact_us.asp</a> 301-496-6023</td>
</tr>
<tr>
<td>National Eye Institute</td>
<td><a href="http://www.nimh.nih.gov/researchfunding/index.cfm">http://www.nimh.nih.gov/researchfunding/index.cfm</a></td>
</tr>
<tr>
<td>National Heart, Lung, and Blood Institute</td>
<td><a href="http://www.nhlbi.nih.gov/about/staff-expertise.htm">http://www.nhlbi.nih.gov/about/staff-expertise.htm</a></td>
</tr>
<tr>
<td>National Human Genome Research Institute</td>
<td><a href="http://www.genome.gov/10000884">http://www.genome.gov/10000884</a> 301-496-7531</td>
</tr>
<tr>
<td>National Institute on Aging</td>
<td><a href="http://www.nia.nih.gov/ResearchInformation/ExtramuralPrograms/">http://www.nia.nih.gov/ResearchInformation/ExtramuralPrograms/</a></td>
</tr>
<tr>
<td>National Institute on Alcohol Abuse and Alcoholism</td>
<td>301-443-0281</td>
</tr>
<tr>
<td>National Institute of Allergy and Infectious Diseases</td>
<td>AIDS <a href="http://www3.niaid.nih.gov/about/findingpeople/daids.htm">http://www3.niaid.nih.gov/about/findingpeople/daids.htm</a></td>
</tr>
<tr>
<td></td>
<td>Allergy, Immunology, and Transplantation <a href="http://www3.niaid.nih.gov/about/findingpeople/dat.htm">http://www3.niaid.nih.gov/about/findingpeople/dat.htm</a></td>
</tr>
<tr>
<td></td>
<td>Microbiology and Infectious Diseases <a href="http://www3.niaid.nih.gov/about/findingpeople/dmid_staff.htm">http://www3.niaid.nih.gov/about/findingpeople/dmid_staff.htm</a></td>
</tr>
<tr>
<td></td>
<td>General Information on NIAID Extramural Grant Programs <a href="mailto:dart@mail.nih.gov">dart@mail.nih.gov</a></td>
</tr>
<tr>
<td>National Institute of Biomedical Imaging and Bioengineering</td>
<td><a href="http://www.nibib.nih.gov/Research/ProgramAreas">http://www.nibib.nih.gov/Research/ProgramAreas</a></td>
</tr>
<tr>
<td>National Institute of Child Health and Human Development</td>
<td><a href="http://www.nichd.nih.gov/about/org/orgchart/">http://www.nichd.nih.gov/about/org/orgchart/</a></td>
</tr>
<tr>
<td>National Institute on Deafness and Other Communication Disorders</td>
<td>NIDCD Staff Contacts</td>
</tr>
<tr>
<td>National Institute of Dental and Craniofacial Research</td>
<td><a href="http://www.nidcr.nih.gov/AboutNIDCR/Organization/default.htm">http://www.nidcr.nih.gov/AboutNIDCR/Organization/default.htm</a> 301-594-4800</td>
</tr>
<tr>
<td>National Institute of Diabetes and Digestive and Kidney Diseases</td>
<td><a href="http://www2.niddk.nih.gov/Research/ScientificAreas/">http://www2.niddk.nih.gov/Research/ScientificAreas/</a></td>
</tr>
<tr>
<td>National Institute of Environmental Health Sciences</td>
<td><a href="http://www.niehs.nih.gov/dert/pascl.htm">http://www.niehs.nih.gov/dert/pascl.htm</a></td>
</tr>
<tr>
<td>National Institute of General Medical Sciences</td>
<td><a href="http://search.nigms.nih.gov/research/programs.htm">http://search.nigms.nih.gov/research/programs.htm</a> 301-594-4496</td>
</tr>
<tr>
<td>National Institute of Mental Health</td>
<td><a href="http://www.nimh.nih.gov/about/ed_chart.cfm">http://www.nimh.nih.gov/about/ed_chart.cfm</a> 301-443-3367</td>
</tr>
<tr>
<td>National Institute of Neurological Disorders and Stroke</td>
<td><a href="http://www.ninds.nih.gov/funding/areas/index.htm">http://www.ninds.nih.gov/funding/areas/index.htm</a> 301-496-9246</td>
</tr>
</tbody>
</table>
2. Peer Review Contacts:

Not applicable

3. Financial/Grants Management Contact(s):

See participating NIH Institutes and Centers listed on the first page of this announcement ("Components of Participating Organizations").

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:

Human Subjects Protection:
Federal regulations (45 CFR 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Data and Safety Monitoring Plan:
Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (Phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants ("NIH Policy for Data and Safety Monitoring," NIH Guide for Grants and Contracts, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Sharing Research Data:
Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Access to Research Data through the Freedom of Information Act:
The Office of Management and Budget (OMB) Circular A-110 has been revised to provide access to research data through
the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this funding opportunity in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Sharing of Model Organisms:
NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement. Beginning October 1, 2004, all investigators submitting an NIH application or contract proposal are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Inclusion of Women And Minorities in Clinical Research:
It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All Investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the SF424 (R&R) application; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

Required Education on the Protection of Human Subject Participants:
NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

Human Embryonic Stem Cells (hESC):
Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the

NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (http://escr.nih.gov/). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

NIH Public Access Policy:
NIH-funded investigators are requested to submit to the NIH manuscript submission (NIHMS) system (http://www.nihms.nih.gov/) at PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process.

NIH is requesting that authors submit manuscripts resulting from 1) currently funded NIH research projects or 2) previously supported NIH research projects if they are accepted for publication on or after May 2, 2005. The NIH Public Access Policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, institutional and individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies. The Policy applies to peer-reviewed, original research publications that have been supported in whole or in part with direct costs from NIH, but it does not apply to book chapters, editorials, reviews, or conference proceedings. Publications resulting from non-NIH-supported research projects should not be submitted.

For more information about the Policy or the submission process, please visit the NIH Public Access Policy Web site at http://publicaccess.nih.gov/ and view the Policy or other Resources and Tools, including the Authors' Manual.

Standards for Privacy of Individually Identifiable Health Information:
The Department of Health and Human Services (HHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the HHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs in NIH Grant Applications or Appendices:
All applications and proposals for NIH funding must be self-contained within specified page limitations. For publications listed in the appendix and/or Progress report, Internet addresses (URLs) or PubMed Central (PMC) submission identification numbers must be used for publicly accessible on-line journal articles. Publicly accessible on-line journal articles or PMC articles/manuscripts accepted for publication that are directly relevant to the project may be included only as URLs or PMC submission identification numbers accompanying the full reference in either the Bibliography & References Cited section, the Progress Report Publication List section, or the Biographical Sketch section of the NIH grant application. A URL or PMC submission identification number citation may be repeated in each of these sections as appropriate. There is no limit to the number of URLs or PMC submission identification numbers that can be cited.

Healthy People 2010:
The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthyperson.
the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Loan Repayment Programs:
NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see: http://www.lrp.nih.gov.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Department of Health and Human Services

National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892


11/21/06
NIH Announces Requirement for Detailed (Non-Modular) Budget Submissions for All Competing Grant Applications from Foreign (Non-U.S.) Institutions

**Notice Number:** NOT-OD-06-096

**Key Dates**
Release Date: August 23, 2006

**Issued by**
National Institutes of Health (NIH), (http://www.nih.gov/)

The purpose of this Notice is to inform the research community that all competing grant applications (new, competing continuation/renewal applications, amended/resubmission, and competing supplement/revision) from foreign (non-U.S.) institutions must include only detailed (non-modular) budgets. In recent years the number of grantees in foreign sites has expanded significantly. Providing a budget from our foreign applicants will allow the NIH staff to assist this applicant community with applicable regulatory and policy requirements for grant funding expenditure.

This policy is effective with applications prepared for submission dates on or after October 1, 2006 and affects all application formats (SF424 (R&R) and PHS 398). This Notice replaces instructions in all active Funding Opportunity Announcements; individual announcements will not be updated.

Applications from foreign (non-U.S.) institutions submitted via Grants.gov using the **SF 424 (R&R)**: Follow the Research & Related Budget Component Instructions. Complete and submit the RESEARCH & RELATED BUDGET forms. Do not complete or submit the PHS 398 Modular Budget component.

Applications from foreign (non-U.S.) institutions submitted using the **PHS 398**: Follow the NON-MODULAR FORMAT instructions and submit Form Page 4 and Form Page 5. Do not complete or submit the Modular Budget Formal Page.

This change does not impact applications from domestic (U.S.) institutions. Domestic institutions submitting applications for grant mechanisms that use the modular budget (R01, R03, R15, R21, and R34) that request $250,000 in direct costs or less for all years must continue to use the modular format even if the application includes a subaward with a foreign (non-U.S.) institution.

**Inquiry**

Inquiries on this NIH Guide Notice may be directed to:

Division of Grants Policy
Office of Policy for Extramural Research Administration
National Institutes of Health
6705 Rockledge Drive, Suite 350
Bethesda, MD 20892
Telephone: (301) 435-0939
Fax: (301) 435-3059
Email: GrantsPolicy@od.nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices
will be easier for both applicants and reviewers.

By encouraging concise applications, we are encouraging

**GOALS**
- And more
- Informed Consent Forms
- Clinical Protocols
- Reprints or preprints of publications
- Photographs

application body.

WHAT CHANGES ARE PROPOSED? The following items will no longer be accepted in the appendix, but may be accepted in designated parts of the application: Purpose Only

For Informational Purposes Only

Deadline for Comments

has expired.

Why?
To evaluate current guidelines for grant application appendices.

Why requested by WHOP, NIH & AHRQ


Grant Appendix Materials

Change in Request for Information (RFI): Proposed
New Limits on Appendix Materials for All NIH/AHRQ/NIOSH Grant Applications Beginning with Receipt Dates On or After January 3, 2007

Notice Number: NOT-OD-07-018

Key Dates
Release Date: November 17, 2006
Effective Date: January 3, 2007

Issued by
National Institutes of Health (NIH), (http://www.nih.gov)
Agency for Healthcare Research and Quality (AHRQ), http://www.ahrq.gov/
National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (NIOSH/CDC; http://www.cdc.gov/niosh/oep)

The purpose of this Notice is to announce a change in policy limiting Appendix materials that may be submitted with grant applications to NIH/AHRQ/NIOSH.

The goal of changing the guidelines for grant application Appendix materials is to encourage applications to be as concise as possible while containing the information needed for expert scientific review. These changes take advantage of electronic access to many publications and should make application preparation and handling easier for both applicants and reviewers.

It is important to note that the Appendix may not be used to circumvent the page limitations of the Research Plan.

The following changes apply to applications in response to any funding opportunity announcement (FOA) with submission/receipt dates on or after January 3, 2007.

Information that May Be Included in the Application

- Published manuscripts and/or abstracts that are publicly available in a free, online format may be referenced in the application. These publications may not be included in the appendix. URLs or NIH PubMed Central (PMC) submission identification numbers may be included along with the full reference in the Bibliography and References Cited section (SF 424RR)/Literature Cited (PHS 398) section, the Progress Report Publication List section and/or the Biographical Sketch section. While there is no limit to the number of URLs or PMC submission identification numbers that can be cited, applicants should be both judicious and concise.

- Applications requiring electronic submission on the SF424 (R&R) may include graphic images of gels, micrographs, photographs, etc. in the Research Plan PDF; however these images may not be included in the Appendix (except when part of a qualifying publication). See the SF 424 (R&R) Application Guide for guidance as to size and resolution of images.

Materials Allowed in the Appendix

Publications:

- Applicants may submit up to 3 of the following types of publications. Any exceptions will be noted in specific FOAs.
  - Manuscripts and/or abstracts accepted for publication but not yet published.
  - Published manuscripts and/or abstracts only when a free, online, publicly available journal link is not available.
  - Patents materials directly relevant to the project.
Other:

- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents may be submitted in the Appendix as necessary.

- Paper PHS398 applications only may include full-sized glossy photographs of material such as electron micrographs or gels in the Appendix; however, an image of each (may be reduced in size but readily legible) must also be included within the page limitations of the Research Plan.

Format of Appendix Materials

- For electronic submission using the SF 424 (R&R) forms and Grants.gov, Appendix materials must be submitted in PDF format.

- For paper submission using the PHS 398, Appendix materials may be submitted in paper format; five collated sets are needed.

- Applicants are encouraged to send Appendix materials submitted with paper PHS 398 applications on a CD in PDF format in lieu of the five collated sets. See application instructions for details on preparing CDs. Only a single CD need be sent.

- For materials that cannot be submitted electronically or materials that cannot be converted to PDF format; e.g., medical devices, prototypes, DVDs, CDs, applicants should contact the Scientific Review Administrator for instructions following notification of assignment of the application to a study section. If the SRA is listed in the FOA, they should be contacted in advance to address acceptability of materials.

Funding Opportunity Announcement (FOA) Details

- Any FOAs that currently disallow publications in the Appendix will continue to do so.

- FOAs currently allowing more than three publications will only allow three for receipt dates on or after January 3.

- FOAs allowing fewer than three publications will now allow three.

- In the case of multi-project applications up to three publications will be allowed for each project.

- FOAs may have additional appendix requirements specified other than publications. In these cases, follow the FOA instructions, which prevail.

Inquiry

Inquiries regarding this Notice should be directed to:

Grants Info  
Office of Extramural Research  
National Institutes of Health  
Phone: 301-435-0714  
TTY: 301-451-0088  
Email: grantsinfo@nih.gov
Clarification of Instructions Regarding Inclusion of Publications as Appendix Materials

**Notice Number:** NOT-OD-06-053

**Key Dates**
Release Date: March 28, 2006

**Issued by**
National Institutes of Health (NIH), (http://www.nih.gov)

The purpose of this Notice is to clarify the recently announced new approach and policy regarding the inclusion of publications as Appendix materials in NIH grant applications (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-051.html). Clarifications have been highlighted in a different color. Applicants should now provide links to the on-line journal article or the NIH PubMed Central (PMC) submission identification number for publications listed in the appendix, whenever possible. This policy applies to all grant mechanisms for which publications are acceptable Appendix material, regardless of which application form is used (e.g., PHS 398, SF424 (R&R), PHS 416-1) or the mode of submission (paper or electronic).

**Note:** Not all grant mechanisms allow the inclusion of publications.

Effective for applications intended for the May 10, 2006 submission date and beyond, the NIH standard policy regarding the inclusion of publications as acceptable Appendix material in grant applications is described below.

The Appendix may include publications, manuscripts (accepted for publication), abstracts, patents, or other printed materials directly relevant to the proposed project. Applicants should refer to instruction guides and specific Funding Opportunity Announcements (FOAs) to determine the appropriate limit on the number of publications that may be submitted for a particular program. Specific FOAs should also be reviewed for any additional program-specific guidance on Appendix material and other application requirements. The Appendix may not include manuscripts submitted for publication.

- **Publications in press:** Include only a publication list with a link to the publicly available on-line journal article or the NIH PubMed Central (PMC) submission identification number. Do not include the entire article.
- **Manuscripts accepted for publication but not yet published:** The entire article may be submitted electronically as a PDF attachment for applications using electronic submission [e.g., the SF424 (R&R)], or as hard copy documents for mechanisms still using paper submission (e.g., the PHS398 or PHS 416-1).
- **Manuscripts published but a publicly available online journal link is not available:** The entire article may be submitted electronically as a PDF attachment for applications using electronic submission [e.g., the SF424 (R&R)], or as hard copy documents for mechanisms still using paper submission (e.g., the PHS398 or PHS 416-1).

Note at this time no changes are being made to the other Appendix components:

- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents.
- No images may be included in the Appendix that are not also represented within Items 2-5 of the Research Plan, or Items a-d of the PHS 398.

Applicants are cautioned not to use the Appendix to circumvent the page limitations of the Research Plan. An application that does not observe the relevant policies and procedures may be delayed in the review process. Applicants are reminded to review specific FOAs for any additional program-specific guidance on Appendix material and other application requirements.

Application instructions for the PHS 398, SF424 (R&R), and PHS 416-1 will be revised to reflect this new policy for inclusion of publications in Appendix

**Inquiries**

11/8/2006

This will continue for each cycle that the pilot is in place.

1. For the July 20 special expedited resubmission date or
   an amended application either:

   & Applications in this pilot reviewed in May/June timeframe may choose to submit
   + NIH Notice (NOT-OD-06-060) clarifies the Resubmission Procedures:

   - The resubmission
   - The principal investigator must agree that the resubmitted application be
   - The application must be reviewed in one of the participating study sections.
   - The February 1 or March 1, 2006 date.

   A new or first resubmission of an R01 application must have been submitted for
   a timetable. Examples include:

   - NIH Notice (NOT-OD-06-13) provides special conditions which must be met and

   - concerns raised and issues identified in the summary statement.
   + Pilot is designed to shorten the time to the next review for some new investigators
   - Spreader NIH Review of Research Applications Planned

   Investigators Begins

   New

   CSRP Pilot Study for New
Questions and Answers

Position.

Support contingent on securing an independent research position.

- This phase will be followed by up to 3 years of independent research.
- For highly promising postdoctoral researchers, the initial phase will provide 1-2 years of mentored support.
- Years of support consisting of two phases.

The Pathway to Independence Award will provide up to five years.

NITH-supported Independent Investigators.

- The primary, long-term goal of the PI Award Program is to increase and maintain a strong cohort of new and talented, independent investigators' research careers.
- Designed to facilitate receiving an RO1 award earlier in an investigators' career.

Pathways to Independence (K99/R00)
Demo Facility
Internet Assisted Review (IAR)
Closeout
Financial Status Reports (FSR)
Request for No-Cost Extensions
Just-In-Time (JIT) Information
Administration

ERA Commons' Functionality
This information for PIs and Individual Fellows to access

This is the only place

View all applications

OGA

Summary Statement

Priority Score

Study Section and IC Assignments

Status

Individual Fellow Access

Important for Investigator and

ERA Commons' Functionality:
Please consult their business office for creating a Commons account. PIs should consult with their business office for creating a Commons account. The Commons and periodically check that all addresses are updated. To avoid delays in the e-notification process, it is vital that grantees and PIs register in the Commons system early and periodically check that all addresses are updated.

- Reminder: Effective May 10, 2006, all applications must include the ERA Commons User name for all PI and PD/PIs. PIs and PD/PIs must access this information through the ERA Commons.

- Change of Assignment Letters - Effective June 1, 2006
- Assignment Letters - Effective June 1, 2006
- Peer Review Outcome Letters - Effective February 1, 2006
- Summary Statements - Effective October 1, 2005

The NIH will no longer be mailing the following paper notifications:

No more "Paper Chase"!
Announced in the NIH Guide, Aug. 19, 2005:

2. SF424 Discretionary (of limited use for NIH)
   (SF424 [RR])

1. SF424 Research and Research-Related
   SF424 Family of Forms data set.

Transition from the PHS 398 application form to

- Requiring electronic submission through Grants.gov.
- For all NIH grant applications.

By the end of September 2007, NIH plans to:

NIH's Electronic Receipt Goal
Electronic Submission Process

1. Find Opportunity (AOR Submits)
2. Application Package
3. Prepare Application
4. Submit Application to Commons
5. Check Submission Status
6. Review the Application Image
7. Submission Complete

if errors
NIH/AHRQ/NIOSH Confirm R01 Electronic Application Submission Plans for February 5 Receipt Date

**Notice Number:** NOT-OD-07-020

**Key Dates**
Release Date: November 20, 2006

**Issued by**
National Institutes of Health (NIH), (http://www.nih.gov)
Agency for Healthcare Research and Quality (AHRQ), (http://www.ahrq.gov)
National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (NIOSH/CDC; http://www.cdc.gov/niOSH/oep)

The purpose of this Notice is to inform the grantee community that NIH/AHRQ/NIOSH will move forward with the R01 transition to electronic submission of grant applications using the SF424 (R&R) forms for the February 5, 2007 receipt date and beyond. Note that new standard receipt dates take effect in January 2007 (see NOT-OD-07-001); therefore, the R01 transition date has been moved from February 1 to February 5 to match the new standard receipt date. The electronic submission timeline has been updated to reflect the new receipt dates.

Effective for R01 receipt dates on or after February 5, 2007, **ALL applications in response to announcements for the R01 grant program must be submitted electronically (i.e., paper applications will not be accepted).** Applications that were first submitted in paper and are being resubmitted as amended applications must now use electronic submission via Grants.gov using the SF424 (R&R) forms.

Electronic grant applications must be submitted in response to a Funding Opportunity Announcement (FOA) posted on Grants.gov Find and the NIH Guide for Grants and Contracts. The Grants.gov model requires that all applications be submitted in response to a specific Funding Opportunity Announcement. Only the specific application package posted with the FOA can be used for submission. NIH still welcomes unsolicited, investigator-initiated applications. General-use “Parent Announcements” have been created with application packages appropriate for submission of unsolicited research proposals. The R01 parent announcement can be found at: PA-07-070.

Applicants are advised that new options are now available for Mac users. See http://era.nih.gov/ElectronicReceipt/files/mac_options.htm for additional information.

The following resources continue to be available for assistance in the electronic submission of grant applications to NIH/AHRQ/NIOSH through Grants.gov:

**Listserv**
Subscribe to receive Electronic Submission news and updates at http://era.nih.gov/ElectronicReceipt/listserv.htm

**General Information:**
http://era.nih.gov/ElectronicReceipt/
http://grants.nih.gov/grants/oer.htm
http://www.ahrq.gov/path/egrants.htm

**Inquiries**
inquiries regarding this Notice should be directed to:

Grants Info
Office of Extramural Research
National Institutes of Health
Policies Re Electronic Grant Submission in the CHHD Research Office
GRANTS.GOV

Background:

NIH and eventually all Federal Sponsors of Research will be requiring (in a phased-in fashion) electronic submissions for all proposal mechanisms through an organization known as Grants.gov. This process will require new proposal submission procedures and earlier submission from PIs than with the traditional paper proposal submissions. As a general upfront warning, it is our estimation that the new NIH electronic submission procedures will require more attention and effort from PIs than with the traditional paper submissions.

Below we list background considerations and procedures that are necessary for electronic proposal submission together with friendly advice on ways to become effective and efficient in this process.

(Full NIH web addresses for details on electronic submission may be found at the end of this document)

I. Initial Steps PIs Must Take Prior To Submitting Electronically Proposals to Grants.Gov:

A. eRA COMMONS – In order to submit an electronic proposal through Grants.gov each individual faculty person must have an eRA Commons account. Your account will be used by the government to verify that you are a PI and are affiliated with PSU. It will also be the way NIH lists errors that need corrected. Please contact Boe Itzinger immediately if you are not registered with NIH eRA Commons. This is a one time event that all faculty need to complete to use Grants.Gov and should be done well in advance of the grant submission date (if it is not already done). In other words once you have an eRA account it is used for all federal grant submissions (consistent with the specific agency progress in adopting this standard).

B. GRANTS.GOV is the organization the federal government is using for electronic submission of proposals. Please note that Grant.gov is like a clearing house in that they will only receive the initial submission and then pass it on to NIH – NIH will review the proposal and accept if format etc. is OK or post on eRA Commons the errors that need corrected before they will pass on for review. Grants.gov will be using the 424 R&R forms, NIH 398 Forms will no longer be used for electronic submissions. All proposals submitted will be uploaded and submitted from the CHHD Research Office. Once the proposal is uploaded and correct the actual
II. Procedures for Submitting a Proposal:

1. **Identify PA/PAR/RFP and Download the Application** – All proposals submitted to NIH must be submitted in response to an announcement listed on Grants.gov. These are typically posted 2 months before the due date. All proposals submitted to NIH must have an announcement number. The only way to submit is to locate the announcement number on Grants.Gov. Once you select the announcement number, Grants.gov will show you the forms that need to be electronically completed and submitted for that announcement. Each announcement is unique and may require additional or different forms. When you find the announcement you want to respond to on Grants.gov you download the application to see what forms need to be completed. All proposal actions will be done off-line by the CHHD Research Office and also submitted by the CHHD Research Office. You need to notify Boe Ittenger of your intent to submit well in advance (at least 1 month in advance) of the deadline submission date (see later section amplifying on this) and provide the Announcement number at the time you are doing the draft of the budget.

2. **PDF FILES** – All documents except the budget will need to be delivered to the CHHD Research Office as a PDF file on a memory stick or disc. You must save the file as a PDF, then you open up the file and do a file print and select your printer (Adobe PDF) and this will re-create the PDF in an up-loadable format which Grants.gov will accept. Each section of the grant has its own PDF file that you will need to format in advance of bringing the collective of grant files to the research Office for submission. What follows are our requirements for PDF submission.

**PDF Requirements, Creation Process and Naming Standards**

**Adobe minimum requirement:**
Adobe Acrobat 6.0 (Adobe 7.0 Preferred)

**PDF Process:**
Print to a PDF File (This removes editable fields)
File.....Print.....Select Adobe PDF as your printer.
You will be asked where to save your PDF File.

**Naming Standards for Each Section File:**
Research & Related Project/Performance Site Location (s) Additional LocationsPDF
Research & Related Other Project Information
Federal Electronic Grant Proposal Submissions

ResourceSharingPlan.PDF (Data Sharing & Model Organism Sharing)
LettersSupport.PDF
Check List (completed on-line)
Appendix

Not all names will be used on every grant application and additional names may be added if needed.

3. PDF Files and Page Grant Page Length. Separating the proposal sections into separate files may create problem with page length overrun in the final grant submission. This is because the final electronic merging will lead to each file section starting on a new page and so if a section or sections of a grant begin in the middle of a page in your Word (etc) file version they will start on a new page in the PDF submission version and lead to overruns on the final page count. Advice - this means that if one wants to take advantage of all the space available in grant format one needs to have each section of the grant finish fully at the end of a page (even page count so to speak). Recently, NIH has allowed for white space to be included in your overall page limit but this is a fluid issue that needs monitoring and recognition of the possible scenarios.

4. DATE OF SUBMISSION – Because of the additional time is takes to submit proposals through Grants.gov a change in policy will be required from our long standing procedures. We believe that we will need to have all proposals initially submitted at least 2 weeks before the actual due date if we are to assure submission to be completed by the deadline. As the Government, HHD Research Office and investigators become more proficient at this submission process the lead time may be able to be reduced but we anticipate that at least a week will always be necessary to assure appropriate and successful submission. Remember too that NIH requires all grant submission to be completed successfully (with revisions approved) by 5pm of the stated day of submission. Thus, all the corrections and changes need to be made BEFORE the stated deadline – this is, of course, what requires a substantial lead time for the initial submission. Please note that each round of corrections with eRA commons or NIH could take 2-3 days each (and in a worse case scenario even longer).

5. eRA PROPOSAL PROCESSING APPROVAL - The PI and CHHD Research Office MUST log-on to eRA Commons before the due date and review the proposal to make sure the conversion was done correctly. If errors are noted, they must be revised and the entire application must be resubmitted by the Research Office through Grants.gov. Once the proposal is accepted by NIH, it will be sent on to the appropriate review section within 48 hours unless rejected by the CHHD research office.

Note - It will be very important for the PI to be available before and after the initial submission. If errors are detected by NIH after submission, the PI will need to help resolve issues along with
the Research Office. Please be ready to assume your responsibility in the error correction process of the grant submitted.

6. **BUDGETS** – Draft budgets will still need to be completed by the CHHD Research Office (Boe and or Donna) at least 1 month in advance of the grant submission date. Grants.gov uses the 424 budget forms, not the NIH 398 forms. The budget will need to be entered into Grants.gov by the Research Office. If you will have sub-awards in your budget, the process must start even earlier. Boe/Donna will need to enter the sub-award information into Grants.gov and the send via email the appropriate budget to the sub-awardee. They will need to complete the budget form and send back to the Research Office in PDF format so it can be uploaded into Grants.gov. This process may take up to 2 weeks and even longer (given our past experience with all the potential difficulties of subcontracts).

7. **HARDWARE/SOFTWARE** - The Research Office has all the appropriate hardware/software needed to submit proposals through Grants.gov. PI's may need to update their own software concerning the use of PDF’s.

**Websites re Electronic Submission of NIH grant proposals:**

http://era.nih.gov/

http://era.nih.gov/ElectronicReceipt/

http://www.grants.gov/

09/06/06