NIH Extramural Nexus

WHERE GRANTS POLICY, PROGRAM COORDINATION, COMPLIANCE AND ELECTRONIC RESEARCH ADMINISTRATION CONVERGE

July 2007

NEWS FROM THE DIRECTOR OF OER:
NIH Seeks Input on its Support of Biomedical and Behavioral Research and Peer Review

The March 2007 *NIH Extramural Nexus* featured the Center for Scientific Review's (CSR) pilot offering shortened review cycles that started in February 2006. In a complementary effort, the NIH director is establishing both an ad hoc working group of the NIH Steering Committee and a working group of the Advisory Committee to the NIH Director (ACD) on peer review. These working groups will act in concert to gather internal and external input to guide NIH as it develops policy to reshape the peer review process. NIH strongly believes that continued analysis of the entire system employed by NIH to support biomedical and behavioral research, including the two-tiered review system, is required to ensure that we continue to meet the needs of the biomedical and behavioral research community and the public at large.

A critical component of this outreach effort, a Request for Information (RFI): NIH System to Support Biomedical and Behavioral Research and Peer Review, was published in the *NIH Guide for Grants and Contracts* on July 6, 2007. The RFI is seeking input from applicants, reviewers and other members of the research community regarding NIH's support of biomedical and behavioral research, including peer review, with the goal of examining the current system to optimize its efficiency and effectiveness. **Due to the level of interest in this effort, NIH just extended the closing date of this RFI to September 7**.

NIH and the working group of the Advisory Committee to the NIH Director would particularly like your opinion on how to enhance the system employed by NIH to support biomedical and behavioral research, including the peer review process. You are strongly encouraged to offer creative ideas, even if they involve radical changes to the current

approach.

We are especially interested in innovative, concrete suggestions for strengthening, over the long term, any and all aspects of our system for identifying the most meritorious and innovative research for support, in the following areas:

- ◆ Challenges of NIH system of research support
- ◆ Challenges of NIH peer review process
- ◆ Solutions to challenges
- ◆ Core values of NIH peer review process
- ◆ Peer review criteria and scoring
- ◆ Career pathways

We will accept responses until September 7, 2007 through the RFI comment Web site.

A summary of the results obtained from the responses to this RFI will be available to the public on the NIH Peer Review Web site.

If you have comments or questions please write to me at DDER@NIH. gov.

— *Norka Ruiz Bravo, Ph.D.,* Director, Office of Extramural Research and NIH Deputy Director for Extramural Research

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ELECTRONIC GRANT APPLICATION SUBMISSION

eSubmission—Now Business as Usual

» Science in the News

Faster-Acting Antidepressants Closer to Becoming a Reality

Framingham Observational Study Notes Greater Incidence of Metabolic Syndrome Among Adults Consuming Soft Drinks

First Genome-Wide Study of Infectious Disease Opens New Avenues for HIV Treatment, Vaccines

Ability to Listen to Two Things at Once Is Largely Inherited

With 80 percent of NIH competing grant applications arriving electronically and over 56,000 electronic applications received, electronic submission has become "business as usual." That isn't to say it didn't take a tremendous effort at NIH and within the applicant community to get here, but it is amazing how far we've come.

July 5 marked the fourth major electronic R01 submission deadline, and the numbers continue to be impressive. Ninety two percent of the applications were successfully submitted within two submission attempts and many applicants were able to address their errors/warnings without calling for support. Despite receiving 20 percent more applications as compared to the first R01 electronic submission date, the eRA Commons helpdesk received 30 percent fewer calls. The process improvements made, based on your feedback, are paying off and are helping us to move closer to our customer service goals.

More and more organizations are creating their own system-to-system solutions or using commercial service providers to send application data directly to Grants.gov as an alternative to using Grants.gov's downloadable forms. For the July 5 submission deadline, nearly 18 percent of applications were submitted using a system-to-system solution (up from 10 percent for the February 5 submission deadline). To date, over 100 organizations have submitted applications to NIH using system-to-system solutions.

We continue to post new resources and information about future developments to our Electronic Submission of Grant Applications Web site and in the *NIH Extramural Nexus*. Check out our tip sheets for Principal Investigators, small business and international applicants.

If you have suggestions for additional resources or want to provide general feedback on the electronic submission program, please email us.

Grants.gov is moving from PureEdge™ to Adobe® forms. NIH expects to begin posting Adobe forms packages later this year. For now just keep doing what you are doing…we will keep you posted.

Electronic Application Submission and Windows Vista

New computers are shipping with the Microsoft Windows Vista™ operating system and NIH is now receiving inquiries about the effects of the new software on electronic grant application submission.

Although Grants.gov is committed to providing support for operating platforms used by the grant applicant community, Windows Vista is not a Grants.gov officially supported platform at this time.

Grants.gov's move to Adobe®-based forms shows promise for Vista-compatibility in the near future since the latest versions of Adobe are Vista compatible. For now, a non-Vista machine is needed for electronic application form preparation and submission.

Remember, the bulk of an application's content (e.g., research plan) is contained in text documents that can be prepared on any computer, converted to Adobe portable document format (PDF) format, and then attached to the application.

» Guide Notices

FDP-NIH ADMINISTRATIVE STREAMLINING INITIATIVE MAKES PROGRESS

NIH is an active member of the Federal Demonstration Partnership (FDP), a cooperative initiative among 10 federal agencies and 98 institutions that receive federal funds. Its purpose is to reduce the administrative burdens associated with research grants and contracts.

An article in the March 2007 *NIH Extramural Nexus* described the launch of the NIH-FDP Administrative Streamlining Initiative and the committee that was formed to collaborate with representatives of grant-making NIH Institutes and Centers (ICs) on

eliminating some of the variations in practice that these funding components present to the research administration community.

The committee conducted a survey of FDP faculty and initially identified a series of concerns. These concerns were then prioritized into high, medium and low categories. The top concerns were the definition of effort and salary on Career Development (K) awards, timing to honor indirect cost rate changes and consistency in expanded authorities on training grants.

Working in partnership with the administrative research community and NIH IC representatives, the committee has made significant progress in addressing the concerns expressed by stakeholders. The streamlining committee provided an update of this progress at the [May 2007 FDP meeting](#).

At the meeting, the committee reported that since its inception, half of the identified concerns have been addressed using a variety of implementation strategies, including (1) clarifying existing guidelines and policies in Funding Opportunity Announcements and IC Web sites, (2) expanding internal NIH staff continuing education programs, and (3) developing and publishing consistent policy statements.

For example, concerns were expressed about grant-related issues such as the definition of effort and salary on K awards, allowable direct cost increases on competitive continuation applications, practices specifying the number of grant awards for individual investigators, applying consistent rules for expanded authorities on training grants, applying consistent rules for honoring changes in indirect cost rates and other, similar grant administration essentials.

Through clarification of existing guidelines and policies described in Funding Opportunity Announcements and NIH Web sites, and by better educating our front-line grants management staff members, routine grants associated matters are now addressed more uniformly across NIH.

Also in response to the NIH-FDP Administrative Streamlining Initiative committee, NIH is currently gathering information technology

requirements necessary for an NIH-wide process for submitting additional materials to study sections. And, we are drafting common processes and policies for letters of intent.

There is, however, more work to be done and I ask for your patience as we focus on your needs. We know the grant community is anxious for consistency, and we continue to address ways to improve.

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OER OFFICE OF EXTRAMURAL PROGRAMS

Personnel and Activities Update
Dr. Peter Preusch has been serving as the acting director, Division of Scientific Programs and NIH research training officer in the Office of Extramural Programs (OEP) over the last year. During his tenure, Peter led the development and implementation of significant policies and programs, including the new NIH tuition and health insurance policy for National Research Service Award (NRSA) programs and permitting applicants to list more than one program director on applications for institutional research training programs. We wish him well as he returns to his important duties at the National Institute of General Medical Sciences.

OEP is initiating a national search process to select a permanent director of Scientific Programs and NIH research training officer, and anticipates advertising for the position by the end of this summer. During the selection process, OEP will utilize a team approach to handle all issues related to the NIH research training and career development programs.

Dr. Henry Khachaturian will assume the role of acting NIH research training officer. He will oversee the implementation of all NIH training policies, coordinate training activities across NIH Institutes and Centers (ICs), serve as the principal research training contact to external organizations and respond to inquiries from the extramural community. He will be assisted by Ms. Jennifer Sutton, NIH training coordinator, who will oversee all activities related to NIH training program surveys and evaluations. In addition, Dr. Nancy Pearson, from the National Center for Complementary and Alternative Medicine, has generously agreed to serve as the chair of the NIH Training Advisory Committee, to facilitate

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>> Feedback

COMMUNICATE WITH THE *NIH EXTRAMURAL NEXUS*—WE WANT TO HEAR FROM YOU

Feedback from recipients and subscribers of the *NIH Extramural Nexus* is vital. Comments, questions, and suggestions for topics will enable *Nexus* editorial staff to deliver appropriate content to the grantee community.

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coordination of trans-NIH research training policies with members of the NIH research training community. Dr. Sam Shekar, OEP director, will also fill in as the acting director of the Division of Scientific Programs, providing oversight to OEP staff members and programs focused on research training, peer review policy, human subjects protections and other areas.

For inquiries or research training questions, email Dr. Khachaturian or phone him at (301) 443-2613.

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From the MAILBOX

The Director of OER Responds to Your Questions

Question #1: How much does the NIH allocate to funding human embryonic stem cell research? The most up-to-date figures would be appreciated.

Director OER: NIH stem cell funding information is found on the NIH Office of Budget's Web site. Just scroll down the list to see the stem cell funding amounts.

Question #2: I have submitted an R01 proposal twice, which was not funded. In reviewing the NIH guidelines for resubmission of an unfunded proposal, per the guidelines, I am significantly altering the research plan and would like to submit it as a new proposal. Are there any guidelines as to the extent of change in the research plan needed?

Director OER: Grant application resubmission specifics are addressed in *NIH Guide* notice NOT-OD-07-015. The notice explains the distinction between multiple application resubmission and a new application, but also notes "What constitutes "significant" and "substantial" is inevitably a scientific judgment for which no set of universally applicable examples can be provided."

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EYE ON PI

Roadmap Update—Participation of the NIH Intramural Research Program in Roadmap Initiatives

The NIH Roadmap is a series of research programs designed to accelerate fundamental discovery in biomedical science and translate the knowledge gained into effective prevention strategies and new treatments. Two new topic areas have been chosen as major Roadmap initiatives that will be supported by the Common Fund: the Human Microbiome Project and Epigenomics. Two additional areas are being developed for staged implementation: protein capture tools/proteome tools, and phenotyping services and tools.

As these new initiatives move forward, capabilities suitable for the programs may exist within the NIH Intramural Research Program (IRP), and members of the NIH IRP will be allowed to participate in certain Roadmap initiatives when the decision is made by NIH staff that the scientific and programmatic goals of the initiative can be well served by IRP participation.

In cases where the NIH IRP is allowed to participate:

- NIH IRP members may submit requests for allocations of the Common Fund to support projects within the NIH Roadmap, following approval by appropriate NIH IRP officials for the respective Institute or Center (IC). If the request is successful, the project will be supported by allocations of the Common Fund.

◆ In general, requests from the IRP and grant applications from the extramural scientific community that are submitted for the same Roadmap request for application (RFA) will be evaluated together, on a competitive basis, through the NIH peer review system, and the NIH Center for Scientific Review (CSR) will manage these reviews. The evaluation of scientific and technical merit will be based on the review criteria presented in the relevant Roadmap RFA and use the standard scoring system. The Office of Portfolio Analysis and Strategic Initiatives in consultation with relevant IC Director(s) and the Office of Extramural Research may consider different review approaches tailored to the initiative. The review process to be used will be described in the RFA.

Additional updates on the NIH Roadmap, and the participation of the NIH Intramural Research Program in Roadmap activities, will be coming in future editions of the *NIH Extramural Nexus*.

Cover Letter Frequently Asked Questions and Answers

Is a cover letter necessary with all NIH applications?

No. Although it is a good idea to include a cover letter with your application, one is only necessary for the following:

◆ Applications requesting $500,000 or more in direct costs for any one year, excluding consortium facilities and administrative costs require applicants to seek agreement with Institute or Center (IC) program staff at least six weeks prior to application submission. The PD/PI must include a cover letter identifying the approving IC and name of program officer contacted. See related *NIH Guide* notice and applicable application form instructions in the SF424 (R&R) (electronic submission) or the PHS 398 (paper submission).

- Conference grant applications require advance permission to apply from an NIH IC Conference Grant contact at least six weeks prior to application submission. This approval is attached as part of the cover letter component in the electronic submission of an application. See the NIH Support for Conferences and Scientific Meetings (R13 and U13) Web page.

- Late applications are addressed in Standard Due Dates for Competing Applications Web page.

- A changed/corrected electronic application submitted in the five-day window following on-time submission to Grants. gov. See the Electronic Submission of Grant Applications Home Page.

Can I use the cover letter to request a specific study section for the peer review of my application? Can I do the same for a specific IC?

Yes to both questions. Although not a requirement for assignment purposes, a cover letter can help the Division of Receipt and Referral in the Center for Scientific Review (CSR) assign your application to a study section for initial peer review and an IC for possible funding. The National Institute of Allergy and Infectious Diseases offers helpful tips on this topic: Requesting an Institute and Requesting a Study Section.

- **Requesting a Study Section:** Having your application assigned to the correct study section can help you ensure that the right people review your application. CSR provides the referral guidelines for assignment to Integrated Review Groups (IRGs) and study sections on it Review Groups Description Web page. You can request an IRG (the CSR term for a collection of related study sections), a study section, or both in your cover letter. It is also helpful to identify multidisciplinary applications and to make clear the main disciplinary or methodological thrust of the application. The **only** time reviewers should be mentioned by name is if there is a conflict of interest. Do **not** suggest potential reviewers.

◆ **Requesting an IC:** Consider what IC would most likely be interested in the scientific area being studied; if the application or science has been discussed with a specific program director, this information should be included. Applicants may request multiple IC assignments (primary and dual).

Who will see the cover letter?

For paper and electronic applications the cover letter is available only to appropriate referral and review staff. It is not shared with peer reviewers.

What are some additional key tips for inclusion of a cover letter in electronic submissions?

◆ Don't confuse the PHS 398 Cover Letter File with the mandatory PHS 398 Cover Page Supplement form (the latter is used to gather other information including the identification of new investigators). The cover letter is an attachment (in portable document format) to the PHS 398 Cover Letter File component found in the Optional Documents section of the application package. Refer to the SF424 (R&R) Application Guide for specific instructions and appropriate forms.

◆ Remember that if multiple application submissions are necessary to correct errors, only the last cover letter submitted will be retained in the system. A description of all corrections should be included here. Therefore, applicants must ensure that they include all information from previous cover letters in the final cover letter

◆ If the application is late, the cover letter must explain the reasons for the delay. Late applications are evaluated on an individual basis. Be aware of restrictions on late applications. See NIH Policy on Late Submission of Grant Applications and NIH Policy on Late Submission of Grant Applications – Clarification for Multiple PI Applications and New Submission/Receipt Date. *Special Note*: Contacting Division of Receipt and Referral staff, review staff, or Institute program staff in advance will not result in permission to submit an application or influence the acceptance of one.

◆ If applying to a Request for Applications (RFA) or Program Announcement (PA), always check for specific guidelines that may differ from general Funding Opportunity Announcements (FOAs).

Important resources:

◆ Instructions and Form Files for PHS 398 (For those applications that have not transitioned to an electronic submission)

◆ SF424 (R&R) Application and Electronic Submission Information for NIH

◆ NIH Policy on Late Submission of Grant Applications

◆ NIH Policy on Late Submission of Grant Applications – Clarification for Multiple PI Applications and New Submission/Receipt Dates

◆ NIH Forms and Applications

◆ Standard Due Dates for Competing Applications

◆ CSR Submission and Assignment Process

◆ CSR Submission FAQs

◆ Electronic Submission FAQs

◆ Electronic Submission of Grant Applications

◆ Office of Extramural Research Home Page

***Federal Register* Notice: Revising the Definition of Principal Investigator**

The NIH, in late June, published in the *Federal Register* a notice of proposed rulemaking that would amend the existing regulations governing grants for research projects by revising the definition of Principal Investigator. The revision would redefine Principal Investigator such that it does not limit the role to one single individual. Comments on the proposal are due by August 24.

ANNOUNCEMENTS

Countdown to New OER Web Site Begins

It is only a matter of days until the Office of Extramural Research launches a new design of its current Web site, including new search tools, a more comprehensive glossary and acronym list, easy to find resources, updated Web pages and contact information, new content areas that provide an overview of the NIH grants process, and links to a redesigned, user-friendly eRA Web site.

Great effort has been taken to ensure that your saved links will convert to the new sites. These sites will go "live" the beginning of August, just days before NIH also launches a new Web site design. (See the May 2007 *NIH Extramural Nexus* for additional details).

OHRP Posts New FAQs

The Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) has posted a new set of frequently asked questions and answers (FAQs) on informed consent. These FAQs provide guidance on OHRP's current thinking on this topic, and according to OHRP, "should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word 'must' in OHRP guidance means that something is required under HHS regulations at 45 CFR Part 46. The use of the word 'should' in OHRP guidance means that something is recommended or suggested, but not required."

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ORWH to Hold CFS Grantsmanship Workshop

The NIH Office of Research on Women's Health (ORWH) trans-NIH working group for Research on Chronic Fatigue Syndrome (CFS) will conduct a one-day grantsmanship process for CFS initiatives workshop on September 17, 2007.

The workshop will provide researchers with an overview of the diverse funding opportunities available through the NIH, an understanding of the particular research or training needs they meet, and the opportunity to meet with and query program officers from the offices, Institutes and Centers represented on the working group.

Visit the ORWH CFS Web site for workshop information and to download the workshop registration form.

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National Institutes of Health
OFFICE OF EXTRAMURAL RESEARCH

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