

NIH Extramural Nexus

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

January 2006

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INTRODUCING THE NIH EXTRAMURAL NEXUS

The National Institutes of Health Office of Extramural Research (OER) welcomes you to your first update on NIH extramural issues via the *NIH Extramural Nexus*. The OER is the [hub](#) for grants policy and operations, grants administration, and the coordination of NIH's extramural programs and activities. Through the *Nexus*, the OER will provide the external scientific community with updates on NIH policies and activities as well as an opportunity to gain a better understanding of the operation of extramural programs. We intend the *Nexus* to be a two-way communications portal — we will be listening to you and plan to modify the content of the *Nexus* accordingly.

The *Nexus* appears at a time of considerable change at the NIH. Among other things, the President has signed the FY 2006 budget and we have developed financial operations policies; we are moving quickly to electronic submission of applications; we are considering new policies to facilitate the careers of new investigators; and, we are redesigning our grant programs to recognize the contribution of multiple members of research teams.



Click on graphic to expand (opens in new window)

Each bimonthly issue of the *NIH Extramural Nexus* will acquaint readers with topical information about extramural policies and initiatives as well as the various programs that comprise the OER. In the articles below, identified by the [Nexus Symbol](#) you will be

» Guide Notices

[NIH Office of Extramural Research Announces the NIH Extramural Nexus Bimonthly Update](#)

[March IACUC 101 and PRIMR/ARENA Annual IACUC Meeting in Boston](#)

[Ruth L. Kirschstein National Research Service Award \(NRSA\) Stipend and Other Budgetary Levels Effective for Fiscal Year 2006](#)

[NIH Financial Policy for Grant Awards - FY 2006](#)

[Extension of Expiration Date for NIH National Research Service Award Institutional Research Training Grants \(T32\) Program Announcement](#)

[Special Emphasis Notice: Research Priorities for the Agency for Healthcare Research and Quality](#)

[Announcing Availability of Pre-registration for the NIH Regional Seminars on Program Funding and Grants Administration](#)

[Important Clarification for Academic Research Enhancement Award \(R15\) Application Submissions](#)

[Registration Open for](#)

introduced to [NIH FY 2006 financial operations policies](#), the [status of Electronic Submission](#), the [Division of Extramural Inventions & Technology Resources](#), the [Multiple Principal Investigator](#) and [New Investigator](#) initiatives, and [NIH's Public Access Policy](#) — all important extramural issues and components integral to the NIH mission. In future months, in conjunction with providing information about policy, the *Nexus* will highlight many other aspects of the NIH's extramural program.

— *Norka Ruiz Bravo, PhD* - Director, OER and NIH Deputy Director for Extramural Research

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NIH FISCAL OPERATIONS PLAN FOR FY 2006

As many of you know, the President signed the Department of Health and Human Services appropriations bill on December 30, 2005. The NIH appropriation included a 1 percent across-the-board cut for all non-emergency discretionary programs; the NIH share is \$286 million. This has forced NIH to make some very tough choices. Paramount in making these choices is two principles: we must continue to support the very best biomedical research in the world; and we must ensure that the next generation of scientists continues to have the opportunity to compete successfully for grants and transition to independent investigator status.

Guided by these principles, NIH will reduce all non-competing research project grant (RPG) awards by 2.35 percent ([see definition of RPGs](#)); restore funds to all previously issued FY 2006 awards to 97.65 percent of the amount indicated in the FY 2005 Notice of Grant Award; and maintain the average cost of competing RPGs at FY 2005 levels. By undertaking these difficult measures, we expect to achieve an overall success rate of approximately 19.5 percent compared to 22.3 percent in FY 2005. We also expect to fund more than 38,300 competing and non-competing RPGs. When compared to FY 2005, this represents a decrease of about 570 RPGs or 1.5 percent (see the [NIH Fiscal Operations Plan](#)).

As difficult as these decreases will be to absorb, by tightening our belts in this fashion, we will be able to continue to fund the very best biomedical research in the world. We remain concerned, however, about the impact of falling success rates on the next generation of investigators. Therefore, we expect to announce programs targeting new investigators soon — look for these in the [NIH Guide to Grants and Contracts](#).

We fully recognize that the difficult budget situation will make the competition for funds even tougher than in the past, and we stand ready to assist you in any way that we can. I encourage you to contact your program director or grants management specialist if you have questions specific to your grant. In addition, please feel free to [contact me](#) with questions or comments about NIH's fiscal operation plan or other issues that you may wish to discuss.

— *Norka Ruiz Bravo, PhD* - Director, OER and NIH Deputy Director for Extramural

[January 11 Training Sessions on NIH's New Electronic Grant Application Process and the SF424 \(R&R\)](#)

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Research

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NIH SUCCESSFULLY RECEIVES GRANT APPLICATIONS ELECTRONICALLY THROUGH GRANTS.GOV

The first round of electronic grant submissions through the [Grants.gov](#) Federal Web portal involved applications for the Small Business Innovative Technology (SBIR) and Small Business Technology Transfer (STTR) grant program and was followed by applications for the R13 Grant Program (Support for Conference and Scientific Meetings) for the December 15, 2005, submission deadline.



The change to electronic applications is very complex. It involves not only a change from paper to electronic submission, it also involves a new application form (from the PHS 398 to the new SF424 Research and Related (R&R) form). As expected with any change of this magnitude, we have encountered a number of hurdles. Many applicants for the initial submission dates were not fully aware of the registration requirements or the business validations associated with the new electronic process. The use of automated validations caught many application errors that might not have been noticed in the paper process. Ultimately, these validations will lead to improved accuracy and fairness in the process, but requires careful adherence to instructions. Many applicants had to submit multiple corrected applications in order to pass NIH validations. Despite a doubling of the size of the NIH Help Desk, applicants found it difficult to reach support staff during peak times. Educating applicants about registration requirements and explaining the NIH validation process were among the main issues that NIH encountered. Clearly, educating applicants and addressing the related issue of Help Desk support will be high priorities as we move ahead with electronic submissions.

"We are very pleased with the results of our first electronic submissions through Grants.gov and feel that we have a solid foundation from which to build upon for future submissions," Dr. Norka Ruiz Bravo, NIH deputy director for Extramural Research, said. "We've learned a great deal from our initial submissions and we are already developing an action plan to address identified issues."

Working hand-in-hand with Grants.gov through this initial round, NIH has cemented a strong working relationship with its Federal partner. Grants.gov and the NIH worked together to lay the groundwork for this initiative in advance, ensuring sufficient capacity to handle the additional load of NIH grant applications, making sure that the NIH retrieval of applications from Grants.gov went smoothly.

NIH is now rolling up its sleeves to prepare for the October 1, 2006 transition of its largest grant program, the R01 or Research Project Grant Program, which has been



FREQUENTLY ASKED QUESTIONS FROM GRANTSINFO

Q: If an application receipt date falls on a weekend or a holiday, when is the application due?

A: When a standard postmark/submission date falls on a weekend or Federal holiday, the submission deadline will be extended to the next business day.

Q: How can I get a copy of the NIH Guide for Grants and Contracts?

A: You may subscribe to the NIH Guide LISTSERV by sending an email to: listserv@list.nih.gov with the following text in the message body (not the Subject line): subscribe NIHTOC-L your name (Example: subscribe

NIHTOC-L Joe Smith). Your e-mail address will be automatically obtained from the e-mail message and add you to the LISTSERV.

Q: How can I find grants awards by state?

A: You will find awards by state and foreign site under the heading, "Award Trends" at the [Award Data Web site](#).

Q: What do extramural and intramural mean?

A: Extramural refers to research conducted at universities and institutions outside of NIH; intramural refers to research conducted at the NIH.

Q: What is the definition of key personnel?

A: Individuals who contribute in a substantive way to the scientific development or execution of a project, whether or not they receive compensation from the grant supporting that project.

Q: Where can I find information about the current salary cap?

A: Visit the [Salary Cap Summary Web site](#).

[GrantsInfo](#) is a communication service of the NIH Office of Extramural Research. It provides general information to the biomedical research community about NIH extramural research and research training programs, grant application procedures and process, how to obtain the [NIH Guide](#) and

known to receive 10,000 applications for a single receipt cycle.

NIH will continue to transition grant programs to electronic submission using the new form set through the end of May 2007. For additional details, see [NIH's electronic submission timeline](#).

Having received a great deal of feedback from applicants that took part in the initial submissions, NIH offers the following advice to applicants:

- ◆ **Be informed.** For up-to-date, general information on electronic submission, the SF424 (R&R), and Service Providers, visit the [NIH Electronic Submission of Grant Applications Web site](#).
- ◆ **Be prepared, register early.** One-time registrations for both [Grants.gov](#) and [eRA Commons](#) systems must be completed before application submission. These are two distinct systems with separate registration requirements.

Registration Tips:

- ▶ The registration process can take several weeks, especially when close to submission dates when registration volume peaks. Start early to avoid delays! NIH recommends starting the registration process now, or at a minimum two-four weeks ahead of your target submission date. New organizations may need to start the Grants.gov registration process even earlier to obtain the necessary DUNS numbers and CCR registrations required for Grants.gov registration.
- ▶ Applicant organizations must register both in Grants.gov and eRA Commons, but Principal Investigators (PIs) need only register in eRA Commons.
- ▶ The PI must hold a PI account and be affiliated with the applicant organization in the eRA Commons.
- ▶ Both the Principal Investigator (PI) and Signing Official (SO) need separate accounts in eRA Commons since both need to verify the application. If you are the SO for your organization as well as a PI of the grant, you will need two separate accounts with different user names - one with SO authority and one with PI authority.
- ▶ Organizations must include the DUNS number in their eRA Commons profile that matches the DUNS number to be used on the submitted applications.

resources available on the [NIH Web site](#). In addition, [GrantsInfo](#) is the contact point for organizations to request application kits and forms.

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- ▶ Grants.gov and eRA Commons registration processes may be done concurrently.

- ◆ **Follow all instructions carefully.** Information found in the funding opportunity announcement and the application guide that accompanies each application package is critical to submitting a complete and accurate application to NIH. Many applicants spent a great deal of time correcting errors and resubmitting applications. Much of this effort can be avoided by reading and following the instructions up-front. [Sample versions of the application guide and packages are available](#), as are the [most common application errors](#).

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

[Feedback \(to the Editor\)](#)

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

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(Adobe Acrobat Reader Required)

ECONOMIC IMPACT OF FEDERAL HEALTH CARE REGULATIONS: REQUEST FOR PUBLIC COMMENT AND SCHEDULE OF PUBLIC MEETINGS IN CALENDAR YEAR 2006

The NIH is helping the Department of Health and Human Services (HHS) disseminate information about an opportunity to provide input on reducing regulatory burden. HHS requests public comments estimating the economic impact of health care regulations, guidance documents, or paperwork requirements, and on methods they use to calculate the economic impact of the regulations. This activity is being driven by House Report language requesting government review of federal regulations governing the health care industry in order to reduce costs and to improve translation of biomedical research into medical practice.

The government is holding several public meetings to allow the public to provide their input on the economic impact of federal regulations. Those who are unable to attend the public meetings [may submit written comments](#), including a description of their proposed methods for quantifying the economic impact of health care

NIH ELECTRONIC APPLICATION SUBMISSION TRAINING FOR POTENTIAL APPLICANTS AVAILABLE VIA VIDEOCAST

All research grant applications for the NIH will have to be submitted electronically through Grants.gov using the SF424 (R&R) form set by May 2007. The transition began in December 2005, with SBIR/STTR and R13 Conference applications and will continue on a grant program by program basis ([see timeline](#)). Potential NIH grant applicants learned about NIH's transition to electronic submission of grants during two repeat training sessions held on January 11, 2006.



The program provided an overview of NIH's transition plans, the submission process and the new SF424 (R&R) form set.

Both sessions have been archived for viewing via [NIH VideoCast](#). A selection of questions submitted during the live sessions were addressed during the training and have been added to the Frequently Asked Questions posted on the [Electronic Submission of Grant Applications Frequently Asked Questions Web site](#).

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regulations. For additional background, more information about submitting public comments, and a schedule of Town Hall meetings, visit the HHS [Action to Reduce Regulatory Burden Web site](#).

Comments will be accepted through February 9, 2006.

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MULTIPLE PRINCIPAL INVESTIGATOR INITIATIVE LAUNCHED

As scientific problems have become more complex, so have the ways that we must address them. Many scientists are moving from reductionist to systems approaches, and biomedical science increasingly involves teams of investigators, who have been trained in different disciplines. NIH recognized the importance of interdisciplinary approaches and team science by launching a comprehensive [Roadmap initiative](#) designed specifically to encourage this kind of research.

There are, however, systemic barriers to team research. These barriers include the fact that NIH recognizes only a single Principal Investigator (PI) on research grants. That means that frequently, major contributors to NIH-funded research projects do not receive appropriate credit for their intellectual contributions, and this serves as a deterrent to team science. To reduce this barrier and encourage and facilitate a broader use of team approaches, the NIH plans to start recognizing more than one PI on research grants and contracts.

Beginning in May 2006, the NIH expects to start receiving applications that name more than one PI. Initially, this capacity will be restricted to a small number of pre-announced Requests for Applications (RFAs) and Program Announcements (PAs). A phased approach will allow us to test this very complex adaptation of our administrative systems in order to ensure that everything is working correctly before we open it up to all applicants. A timeline for the complete roll-out will be announced in the near future.

Applications identifying more than one PI will supplement rather than replace the traditional single-PI model. Each PI listed will be designated as such by the grantee institution and will be expected to share responsibility for directing the grant-supported project or activity. Reviewers will continue to examine qualifications of named PIs as they relate to the proposed project. And if an award is made, each PI will be named on the notice of grant award and will be responsible and accountable to the grantee institution and the NIH for the proper conduct of the project or activity.

The NIH along with the [Office of Science and Technology Policy](#) recently issued Requests for Information (RFIs) in order to gauge the level of support within the

scientific community for the overall multiple-PI concept. The RFI issued by the NIH explored specific issues of interest to the health-related research community, including the desirability of resource allocation to the individual PIs and the use of linked awards when PIs are located at different institutions. Responses revealed overall support for the multiple-PI initiative, as well as for the idea of budget allocation to individual PIs and the development of ways to use linked awards to support projects that span more than one institution. The findings of the RFI can be found on the [Multiple Principal Investigator Web site](#). As implementation plans are approved, they will appear on this website and will be described in future issues of the *Nexus*.

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INTELLECTUAL PROPERTY ISSUES? DEITR IS HERE TO HELP

Increasingly, intellectual property (IP) and issues related to the [Bayh-Dole Act](#) are emerging in NIH funding agreements. OER's Division of Extramural Inventions & Technology Resources (DEITR) within the Office of Policy for Extramural Research Administration supports government agencies, businesses, universities, scientific researchers, and others by providing policy and compliance guidance, technical assistance, and practical advice on extramural inventions and related IP issues. DEITR is well versed in domestic and international patent prosecution and other intellectual property protections, international trade, resource sharing and technology transfer policies, and the development and negotiation of technology transfer agreements.

DEITR also:

- ◆ Supports various other aspects of the Bayh-Dole Act, such as handling of waivers and evaluating Determination of Exceptional Circumstances for which Bayh-Dole patent rights may flow to other parties.



COMMITTEE ADDRESSES ATTRACTING NEW INVESTIGATORS

Entry of new investigators into the ranks of independent, NIH-funded researchers is essential to the health of this country's biomedical research enterprise. In today's challenging budget environment, supporting a healthy cohort of NIH-supported new investigators is the number one priority of NIH Director Elias A. Zerhouni, M.D.

Dr. Zerhouni formed the NIH New Investigator Committee to develop a list of recommended action items that will facilitate an investigator's ability to receive his/her first independent R01 award earlier in their research career. The Committee, chaired by Dr. Norka Ruiz Bravo, Director, OER, and Dr. Story Landis, Director, NINDS, will soon announce a comprehensive, NIH-wide program designed to foster new investigator independence.



The committee's central recommendation is to develop a career transition award program to accelerate the transition to research independence and R01 support. The career transition program will provide five years of support; one to two years of support for postdoctoral fellows, and three years of

- ◆ Is responsible for the [Interagency Edison \(iEdison\) system](#), the lead electronic means of monitoring and adhering to the invention reporting requirements under the Bayh-Dole Act used across the U.S. Government by more than 25 federal agency components.

- ◆ Provides ongoing guidance and educational seminars for NIH funding recipients on a variety of topics, including Bayh-Dole reporting for the research community.

NIH funding recipients who have intellectual property concerns or seek IP guidance on extramural invention/patent matters are encouraged to contact [DEITR](#).

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independent research support, provided the grantee secures a tenure-track or equivalent position. Extramural and NIH intramural postdocs will be eligible for these grants, with the first application deadline expected to be this spring.

Information on current NIH practices cultivating the success of new investigators is available at the [Resources for New Investigators Web page](#).

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NIH PUBLIC ACCESS — WHAT IT MEANS FOR YOU

On May 2, 2005, the NIH's Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research (Public Access Policy) became effective. The Public Access Policy requests that investigators funded by the NIH submit an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication to the NIH National Library of Medicine's PubMed Central (PMC). The Policy has three goals: 1) to create a central archive of NIH-funded research publications; 2) to advance science and enable NIH to better manage its research portfolio; and 3) to provide electronic access to the public to NIH-funded research publications.



PMC is a digital repository of full-text, peer-reviewed biomedical, behavioral, and clinical research journals. It is publicly accessible, permanent and searchable. For authors and investigators, participating in Public Access by submitting manuscripts to PMC provides:

- ◆ Higher Visibility: Investigators will be able to ensure timely public access to their research manuscripts.

- ◆ Time Saving Links: Investigators and institutions can use the manuscript submission process to fulfill the existing requirement to provide publications as part of progress reports.
- ◆ Cutting-edge Tools: Investigators will benefit from the modern information technology tools and services integrated with the PMC system, including PubMed, GenBank (DNA sequences), Complete Genome Maps, Protein Sequences and Structures, Taxonomy, PubChem (Small Molecules), MedlinePlus, and Clinical Trials.

There has been steady growth in the use of PMC as the number of articles it contains increases. From May to December 2005, the contents of the PMC database grew from 371,000 to 515,000 articles overall, and 6.8 million unique users viewed some 32 million copies of these articles. Despite the outstanding visibility of PMC publications, participation with the Public Access Policy is low — less than 4 percent (1,636) of the articles eligible for submission under the Public Access policy have been added to the PMC archive.

NIH has implemented an efficient system for submitting articles. Authors may submit in a variety of electronic formats. The median submission time to PMC is 8.5 minutes; after a few submissions and experience with the process, most authors are able to submit articles faster. NIH is also working to enable publishers to submit articles to PMC on behalf of their authors. Look for further information on the progress of publisher-submitted manuscripts later this year.

For additional information, including Public Access Policy documents, submission instructions, FAQs and statistics, visit the [NIH Public Access Policy Web page](#).

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NATIONAL INSTITUTES OF HEALTH Office of Extramural Research

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