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

May 2006

In This Issue

News From the Director of OER: NIH Communication Plan Launched

Dr. Zerhouni Testifies Before House and Senate: $28.4 Billion FY 2007 Budget Requested

Review of F32 Grant Applications to be Streamlined

Genome-Wide Association Studies

Request for Public Comment: *Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease*

Continuing Series on Programs in the OER Extramural Nexus: The Office of Extramural Programs

Frequently Asked Questions About NIH/Agency for Healthcare Research and Quality Electronic Submission Verification Process Change

Additional Frequently Asked Questions

Percent Effort to Person Months FAQs and Calculator Now Available

Who is a New Investigator?

Science in the News

Institute and Center News Links

Announcements

Electronic Submission Web Site Gets New Look and Feel

Enrichment for Nonhuman Primates Resource: Six-Booklet

NEWS FROM THE DIRECTOR OF OER: NIH Communication Plan Launched

Dear Extramural Community:

IIn an effort to demystify, provide insight, answer questions, and clear up common misconceptions about the NIH and its role in biomedical discovery, the NIH is launching a new communication plan. It is designed to increase awareness of the role that research will play in transforming medicine in the 21st century and of the tremendous benefit received by every American from the Nation's investment in biomedical research. Communications will emphasize scientific discovery, facts about biomedical research funding, and the role of NIH in fighting disease, saving and improving lives, and transforming 21st century medicine to be more predictive, personalized, and preemptive.

Coordinated by the NIH Office of Communication and Public Liaison, information will be conveyed to the extramural scientific community and other NIH stakeholders through a variety of communication channels—the Web (posting of downloadable fact sheets and data snapshots), television, radio, podcasts, professional meetings, and regular communiqués from NIH Director, Dr. Zerhouni.

Expected to be fully operational in the next few weeks, the Research Results for the Public Web page is already displaying several of the fact sheets that are part of the communication plan. Some of the available fact sheets address specific medical conditions, such as heart, kidney and Parkinson's disease while others describe medical concepts and research accomplishments, such as Amazing Research, Amazing Help and Driving the Transformation to Predictive, Personalized and Preemptive Medicine. Stay tuned for fact sheets containing data describing NIH's investments in extramural grants programs.

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

Back to top

DR. ZERHOUNI TESTIFIES BEFORE HOUSE AND SENATE: $28.4 Billion FY 2007 Budget Requested

On April 6, 2006, NIH Director Dr. Elias Zerhouni testified before the House Subcommittee on Labor-HHS-Education Appropriations. On May 19, Dr. Zerhouni also

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Communicate With the *NIH Extramural Nexus*

Back to top

presented testimony before the United States Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies. Dr. Zerhouni focused his testimony on the return on the public's investment in NIH, providing specific examples of dollars invested per American over the years for studying a number of diseases. He also discussed how discoveries fueled by this investment are transforming the practice of medicine, and the importance of maintaining the momentum developed over the past several years to reach our goals. Dr. Zerhouni laid out his vision of a future where medicine will be predictive, personalized, and preemptive. Predictive in that we will be able to predict better who is at risk for disease; develop personalized interventions for individuals rather than a "one size fits all" approach; and preemptive, stopping the disease before it develops in the first place.

For both the House and Senate, in requesting an FY 2007 budget of $28.4 billion, the same as the FY 2006, Dr. Zerhouni highlighted a number of NIH accomplishments and their impact on public health, as follows:

- Advances in Cardiovascular Disease and Stroke
- Advances in Cancer
- Advances in HIV/AIDS
- Advances Against the Threat of Pandemic Influenza
- Development of Biodefense Research
- Advances in Diabetes and Related Illnesses
- Advances in Image-Guided Microsurgery
- Advances in Health Information for Scientists and the Public
- New Research Tools
- New Diagnostic and Therapeutic Technologies
- The Changing Landscape of Disease
- Strategic Vision for NIH: from Curative to Preemptive Care
- Rapid Advances in the Genomic Era
- Translating Discoveries into Better Medical Treatment
- Training a New Generation of Scientists

Additional information, presentation materials, and testimony transcripts are available at the NIH Budget Requests Web page.

Back to top

REVIEW OF F32 GRANT APPLICATIONS TO BE STREAMLINED

Beginning with the grant applications submitted for the August 5, 2006, receipt date, all study sections will use the NIH's streamlined review process for the review of Ruth L. Kirschstein National Research Service Awards (NRSA) Postdoctoral Fellowship

Science in the News

In Drug Design, a Loose Fit May Be Best

Materials Help Youth Evaluate Media Messages, Make Food, Activity Choices

NIH State-of-the-Science Panel Urges More Informed Approach to Multivitamin / Mineral Use for Chronic Disease Prevention, May 17, 2006

Statement of Anthony S. Fauci, M.D. Director, National Institute of Allergy and Infectious Diseases National Institutes of Health on National Asian and Pacific Islander HIV/AIDS Awareness Day May 19, 2006, May 17, 2006

NIEHS Researchers Link Gene Variation to Coronary Heart Disease, May 11, 2006

NIH Launches Clinical Studies Nationwide to Investigate Rare Diseases: $71 Million Effort to Address Neglected Conditions, May 5, 2006

NIH Dedicates the C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases, May 3, 2006

INSTITUTE AND CENTER NEWS LINKS

NIGMS Biomedical Beat

NIDCR Science News In Brief

Back to top

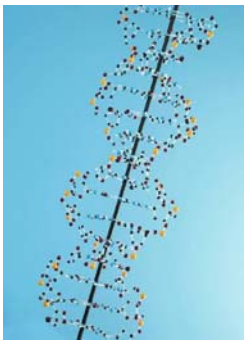
applications (F32). Used at NIH for many years, the streamlined review process allows reviewers more time to discuss applications likely to be supported. Reviewers will be asked to identify and not score the bottom 40 percent of the F32 applications. The bottom 40 percent of applications is generally outside the funding range. This will require unanimous agreement of the study section; if one reviewer disagrees, the application will be discussed by the entire review group. Historically, F32 applications in the top 60 percent represent over 99.5 percent of all funded postdoctoral fellowship applications. The success rate on F32 applications has varied between 30 and 45 percent.

As with nearly all research grant applications, those not scored will be reviewed and will receive summary statements with written critiques prepared by the reviewers as for scored applications. Because applications that are not scored do not receive a full discussion at the study section meeting they will not have a "Resume and Summary of Discussion" paragraph and they will not routinely be taken to the second level of review by NIH Institutes and Centers. The use of the streamlined review process for F32 applications will be assessed after one year.

Although it is unrelated to the plan to streamline Fellowship applications readers should note that fellowship applications are scheduled to transition to an electronic format for submission through Grants.gov beginning August 5, 2007.

Back to top

GENOME-WIDE ASSOCIATION STUDIES



The NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease. The NIH mission is to improve public health through research, and it maintains a longstanding policy to make available to the public the results of the research activities that it supports. Therefore, the NIH has concluded that the maximum public benefit of GWAS can be realized only if the genotype and phenotype datasets derived from GWAS are made available as rapidly as possible to a wide range of scientific investigators.

NIH Guide Notice NOT-OD-06-071, published on May 15, 2006, informs investigators of the NIH plans to (1) update data-sharing policies for research applications involving GWAS data; (2) initiate a public consultation process to inform policy development activities over the next few months; and (3) track GWAS applications and awards at a central level.

Complete information is available in the *Guide* announcement Notice to Applicants for NIH Genome-Wide Association Studies.

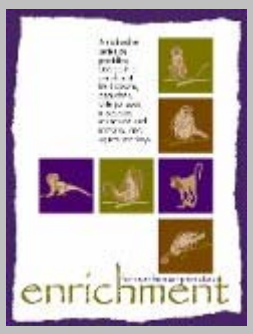
Back to top

Announcements

ELECTRONIC SUBMISSION WEB SITE GETS NEW LOOK AND FEEL

The Electronic Submission Web site has been updated with revised content, easy-to-navigate pages and a

new design. The categories on the main page mimic the electronic application process in logical order, facilitating a better understanding of the process.



ENRICHMENT FOR NONHUMAN PRIMATES RESOURCE: SIX-BOOKLET SERIES NOW AVAILABLE

The Office of Laboratory Animal Welfare announces a new resource on enrichment for nonhuman primates developed in concert with the Association of Primate Veterinarians, American Society of Primatologists, and USDA Animal Care.

Divided into six separate booklets, this resource introduces the basic behavior and environmental enrichment of species commonly used in education, research and entertainment and housed in a diversity of conditions.

The booklets can be downloaded and instructions also are available for requesting

REQUEST FOR PUBLIC COMMENT: *Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease*

The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) requests your input on the Committee's draft report, *Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease*. SACGHS was established by the Department of Health and Human Services (HHS) to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic and genomic technologies and, as warranted, to provide advice on these issues.

In a 2004 priority-setting process, SACGHS determined that opportunities and challenges associated with conducting large population cohort studies aimed at understanding the relationships of genes, the environment, and common, complex diseases warranted in-depth study. NIH Director Elias A. Zerhouni, M.D., specifically requested SACGHS's advice on the scientific, public, and ethical processes and pathways that might help NIH or HHS make decisions about undertaking such an effort. Dr. Zerhouni specified that the Committee could be most helpful to the Secretary by conducting an inquiry that includes the following steps:

- Step 1: Delineate the questions that need to be addressed in order for policymakers to determine whether the U.S. Government should undertake, in any form, a large population project to elucidate the influence of genetic variation and environmental factors on common, complex disease.
- Step 2: Explore the ways in which, or processes by which, the questions that are identified in Step 1 can be addressed, including the need for any intermediate research studies, pilot projects, or policy analysis efforts.
- Step 3: Taking into account the possible ways in which the questions could be addressed, determine which approaches are optimal and feasible and recommends a specific course of action for moving forward.

SACGHS's draft report focuses on preliminary and intermediate questions, steps, and strategies in five areas—research policy, research logistics, regulatory and ethical issues, public health implications of research results, and social implications of research results—that should be addressed before an informed decision can be made about whether the United States should undertake a large population cohort project on the interaction of genes, environment and disease. The report also identifies options for how these issues might be addressed. A central theme of the report is that decisions about such a project must take account of public views and attitudes and that public engagement must be sought in planning for and implementing a large population project.

hard copy (delivery may take 5-6 weeks).

Back to top

SACGHS welcomes your comments on any aspect of the draft report. In particular, the Committee would appreciate your assessment of whether: 1) the policy issues identified in the draft report are appropriately focused; 2) any policy issues have been overlooked; and, 3) the issues are organized in appropriate categories and addressed in such a way as to give policymakers sufficient understanding of why the issue is important. In addition, the Committee would value feedback on the sections of the draft report that discuss the importance of public engagement and the mechanisms that could be employed to achieve such engagement.

Please address comments to Reed V. Tuckson, M.D., SACGHS Chair, and email them to Ms. Amita Mehrotra, FAX to 301-496-9839, or mail to Secretary's Advisory Committee on Genetics, Health, and Society, attn: Amita Mehrotra, NIH Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892 (20817 for non-US Postal Service mail). In order to be considered in the development of the final report, comments should be submitted by close of business Monday, July 31, 2006.

In light of the wide range of public policy issues and questions raised in the draft report, SACGHS hopes to receive input from the wide range of individuals, communities and groups who may have an interest in whether a large population cohort project is undertaken in the U.S. If you have colleagues who may wish to comment on the draft report or know of other individuals, communities, or groups that might be interested in the issue, please forward a copy of this information to them.

Back to top

CONTINUING SERIES ON PROGRAMS IN THE OER EXTRAMURAL NEXUS

Click on graphic to expand (opens in new window)

THE OFFICE OF EXTRAMURAL PROGRAMS

WHAT IS THE MISSION OF THE OFFICE OF EXTRAMURAL PROGRAMS?

Guide Notices

Eighth Annual NIH SBIR/STTR Conference, July 13, 2006

Notice to Applicants for NIH Genome-Wide Association Studies

Delays in Grant Application Submission due to Spring Flooding

Multiple PI Implementation Update

Reminder: All R03, R21, R21/R33, R33 and R34 Grant Applications Must Use SF424 (R&R) and Grants.gov for the June 1, 2006, Submission Date and Beyond

NIH Announces Plans to Eliminate Mailing of Paper Assignment and Change of Assignment Letters

Maine IACUC 101 Workshop in July

Solicitation of Comments: Proposed Modifications to Policies Governing Funding of Tuition, Fees, and Health Insurance on Ruth L. Kirschstein

National Research Service Awards

May IACUC 101 Workshop in Austin, Texas

Clarification of Submission Dates for the Pilot Study to Shorten the Review Cycle for New Investigator R01 Applications

NIH Announces Interim Changes to the PHS 2590 Noncompeting Progress Report Forms and Instructions

NIH Announces Changes to the SF424 (R&R) Instructions

NIH Announces Interim Changes to the PHS 398 Application and Instructions

NIH/AHRQ Announce Change in Business Process Concerning eRA Commons Verifications of Electronically Submitted Applications

NIH Announces Change in Business Process: Replacing Principal Investigator Signature on Grant Applications, Progress Reports, and Prior Approval Requests with an Institutional Compliance Requirement

Back to top

The Office of Extramural Programs (OEP) is one of the organizational components within the NIH Office of Extramural Research is a resource, catalyst and facilitator for many of the elements within the NIH Extramural Nexus (see above). The OEP provides overall administration, oversight, guidance and direction, scientific program management, and subject matter expertise to NIH staff across all Institutes and Centers and to the extramural research community regarding extramural programs and policies.

IN WHAT PROGRAMS AND POLICIES IS OEP INVOLVED?

- ***Research Training and Career Development***

  The OEP establishes, implements, coordinates and monitors NIH extramural research training and career development programs and policies across NIH Institutes and Centers; helps determine broad national needs for basic biomedical, behavioral, and clinical research personnel; and oversees and coordinates trans-NIH evaluations of research training and career development programs.

- ***Grants: Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR)*, *Academic Research Enhancement Award (AREA)* and *Conference***

  The OEP coordinates omnibus solicitations for NIH, CDC and FDA SBIR/STTR funding opportunities, addresses eligibility issues, evaluates and makes recommendations on policy issues, and holds regular, informational SBIR/STTR Town Meetings.

- ***Extramural Research Integrity***

  The OEP evaluates and oversees allegations of scientific misconduct including harm to humans and animals, intellectual property theft, violations of confidentiality/conflict of interest in peer review, and misappropriation of funds. The OEP also implements misconduct policies and performs training and outreach.

- ***Human Subjects Research Policy and Protection***

  The OEP identifies, develops, refines and implements policies governing NIH extramural program and review functions for human subjects research protection, resolves human subject concerns, and provides training and outreach.

- ***NIH Loan Repayment***

  The Loan Repayment Programs office recently moved to the OEP and will continue to process and award loan repayments for intramural and extramural researchers.

- ***Program Outreach and Communication including the NIH Guide for Grants and Contracts***

  The OEP provides information about extramural research opportunities, educational outreach to improve institutional awareness of NIH policy guidelines and requirements, subject matter expertise and extramural program guidance. OEP staff members attend conferences to speak about NIH funding opportunities.

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.

Back to top

Printer Friendly Version
(Adobe Acrobat Reader Required)

- ***Review Policy: Development, Interpretation, Guidance and Oversight***
  The OEP assists in guiding review policy, including its development, interpretation and guidance; and oversees issues related to NIH peer review policies.
- ***Extramural Staff Training***
  The OEP develops educational training sessions for NIH extramural staff regarding the operation, regulatory and procedural requirements for extramural programs.
- ***Special Projects***
  Recently, OEP has been involved in the Grants.gov/SF424 (R&R) transition of funding mechanisms and NIH Public Access.

WHO IS THE CONTACT FOR A SPECIFIC OEP PROGRAM OR POLICY?

OEP's general email address, as well as those for key OEP staff members are available by following this link.

Back to top

FREQUENTLY ASKED QUESTIONS: NIH/Agency for Healthcare Research and Quality Electronic Submission Verification Process Change

The April 7 publication of *NIH Guide* Notice NIH/Agency for Healthcare Research and Quality (AHRQ) Announce Change in Business Process Concerning eRA Commons Verifications of Electronically Submitted Applications has brought forth many questions from the grantee community. Provided below are answers to the most frequently asked questions regarding this business process change.

- **What changed in the eRA Commons verification process?** The original verification process required that both the Authorized Organization Representative/Signing Official (AOR/SO) and the Project Director/Principal Investigator (PD/PI) access the electronic grant application in the eRA Commons, check it for completeness and verify it by clicking a checkbox to complete the submission. Effective May 10, 2006, and beyond, the verification step was replaced with a two-day period for checking the assembled application in eRA Commons. Unless explicitly rejected by the AOR/SO, the submission process will be complete after two days and the application automatically will move forward to the Division of Receipt and Referral, Center for Scientific Review.
- **When will the application move forward for processing?** After two full days (Monday–Friday, includes holidays), if not explicitly rejected by the AOR/SO, the application will move automatically forward to the

Division of Receipt and Referral for processing. For example, if you submit your application on Monday, you will have all day Tuesday and Wednesday to view the application. The application will move forward at 12:01 a.m. ET on Thursday morning.

- **Will the AOR/SO and PD/PI be notified to check the assembled application?** Yes, both the AOR/SO and the PD/PI will be sent an email notification to check the application for completeness. A notification also is sent if the AOR/SO rejects the application.
- **Can the AOR/SO "Reject" the application if the two-day window falls after the submission deadline?** Yes, the AOR/SO can reject an application after the deadline submission if the assembled application does not correctly reflect the submission due to a Grants.gov or eRA Commons system error. The NIH is allowing the one-week correction window to address errors and warnings.
- **What if the application received warnings, but no errors?** Warnings do not stop further processing. If no action is taken, the application will move automatically forward after two business days.
- **Can the PD/PI "Reject" the application?** No. The PD/PI must work through the AOR/SO to "Reject" an application.
- **Are holidays included in the two-business- day period?** Yes. If a holiday occurs on Monday through Friday, the holiday will be counted as a business day.
- **What can I do if I find a problem after the application moves forward for processing?** The applicant should contact the Scientific Review Administrator assigned to their application for advice and guidance for downstream changes and corrections.
- **Where can I find more information about the verification change?** Complete information is available in the eRA Commons Verification of Electronically Submitted Applications *Guide* notice.

ADDITIONAL FREQUENTLY ASKED QUESTIONS

NIH continues to receive questions regarding the Replacing PI Signature with Institutional Compliance Requirement business process change that recently became effective. The grantee community is advised to visit the respective FAQs, available on the Grants Policy and Guidance Web site.

Back to top

PERCENT EFFORT TO PERSON MONTHS FAQS AND CALCULATOR NOW AVAILABLE

The “person months” unit of measurement collected by the SF424 (R&R) grant application form is a change from the PHS 398 application “percent time and effort” measurement unit. Although person months accounting historically has been the default method used by the majority of grantee institutions, for some institutions and grant applicants, the switch from calculating time and effort to calculating person months presents a new challenge.

The transition from time and effort reporting to person months reporting now will be pain-free, thanks to newly launched Web pages that provide Frequently Asked Questions Regarding the Usage of Person Months and a downloadable Excel®-based interactive conversion calculator.

The FAQ and calculator are also available via the Grants Policy and Guidance Web site.

Back to top

WHO IS A NEW INVESTIGATOR?

For the purpose of review and funding, applicants are considered New Investigators if they have not previously served as the Principal Investigator (PI) on any Public Health Service-supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory/developmental grant (R21), or certain research career awards directed principally to physicians, dentists, or veterinarians at the beginning of their research career (K01, K08, K12, K22, K23, K25 and K99/R00). Current or past recipients of Independent Scientist and other non-mentored career awards (K02, K05, K24, and K26) are not considered New Investigators. Subproject Directors on multi-project grants remain eligible to become New Investigators when they apply for independent funding.

Over the years, special programs to assist New Investigators in obtaining independent research funding have been created. When the Multiple Principal Investigators option is selected for a grant application, all PIs must meet the definition of New Investigator in order for the application to receive special consideration in the review and funding process.

Additional information is available at the New Investigators Program Web site and on the PHS 398 Instructions.

Back to top

The *NIH Extramural Nexus* is a bimonthly update from the NIH Office of Extramural Research. Articles, comments, questions and suggestions may be addressed to the Editor. The *NIH Extramural Nexus* reserves the right to select and edit items submitted for inclusion.

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NIH Extramural Nexus Web site and archives