July 2006

NEWS FROM THE DIRECTOR OF OER:
NIH's Partnership with the Extramural Community—Reporting Conflict of Interest

Dear Extramural Community:

NIH's relationship with the extramural community is a partnership in which the NIH, investigators and their academic and research institutions, and private industry each play unique and essential roles in the quest to discover new knowledge to address the biomedical health needs of the nation. Our partnership benefits from the shared and unique perspectives and interests that each of us brings to the table. In this dynamic and complex environment, conflict of interest is inevitable. But, we share the common goal of identifying and managing such conflicts so that they in no way diminish our ability to carry out our missions effectively or endanger the public's trust in us.

I do not mean to imply that an investigator with a conflict of interest, particularly a financial one, cannot engage in NIH-sponsored research. Depending on the circumstances, the conflict may be, as described by Federal regulation, managed, reduced, or eliminated by the institution, allowing the investigator to conduct the research. However, regardless of the outcome, after the identification of a financial conflict, both the existence of the conflict and whether it has been managed, reduced, or eliminated must be reported to the NIH, to ensure integrity and objectivity in research, maintain public trust, and comply with Federal regulation.

NIH and institutions that receive extramural awards are aware of the potential for substantial negative impact that unidentified or unmanaged financial conflicts of interest can have on the integrity of the research they conduct and on their reputation. We also are aware that grantee institutions sometimes face considerable challenges in implementing and complying with the requirements of the Federal regulation. Consequently, last fall NIH began a series of site visits to determine whether grantee institutions have correctly implemented Federal financial conflict of interest regulations and if reporting requirements are being met. We have completed 12 of these site visits and are planning several more before the end of the calendar year.

These site visits have provided NIH with valuable insight into those parts of the regulation that present grantee institutions with the greatest implementation challenges. We are working with institutions to address these problems. In addition, we plan to share our observations publicly so that the entire extramural community can benefit

from the experiences of those site-visited.

Below, you will find a summary of the Financial Conflict of Interest (FCOI) Regulation, which explains the requirements of the regulation as well as the responsibilities of grantee institutions and the NIH. I hope that you will find the information helpful. As always, please feel free to get in touch with me or with OER staff if you have questions or comments.

NIH recognizes that significant resources are invested by institutions to identify, manage, reduce, or eliminate financial conflicts of interest. I can assure you that OER staff will continue its efforts to support institutions by providing clear guidance and consultation. We must ensure that financial conflict of interest is disclosed, reported, and managed in a way that is appropriate for the proposed use of taxpayer funds and preserves the public's trust. NIH truly values its partnership with the extramural community. It has served us all well for many years, and I look forward to our continuing work together to address this and any other difficult challenge that we may encounter.

SUMMARY OF THE FINANCIAL CONFLICT OF INTEREST REGULATION:

- Investigator is broadly defined as the Principal Investigator (PI) and **any other person** who is responsible for the design, conduct, or reporting of research funded by PHS or proposed for such funding. The definition includes the investigator's spouse and dependent children.

- At the time of application, an investigator, which by definition includes any spouse and dependent children, is required to submit to the institution a financial disclosure (a listing of all significant financial interests).

- Financial disclosures must be updated during the period of award, either annually or as new reportable interests are obtained.

- A significant financial interest is defined as anything of monetary value, with exceptions (see 42 CFR Section 50.603 for a full definition of significant financial interests). The minimum threshold established in the regulation for investigator's significant financial interests is $10,000 in value or a five-percent ownership in a single entity.

- Prior to the expenditure of funds under an award, the institution is required to report to the NIH awarding component the existence of a conflict of interest, but not the nature of the interest or other details, and assure that the interest has been managed, reduced, or eliminated. Conflicting interests that are subsequently identified must also be reported within 60 days of identification.

- As necessary, NIH may request additional information about reported conflicts.

- Awardees are required to ensure that subcontractors and subgrantees either comply with the institution's conflict of interest policy, or assure

Researchers Gain Insight Into Why Brain Areas Fail To Work Together in Autism, July 12, 2006

Dopamine Drug Leads to New Neurons and Recovery of Function in Rat Model of Parkinson's Disease, July 4, 2006

Culprit in Grapefruit Juice Drug Interaction Identified, June 23, 2006

Pandemic Flu Information

INSTITUTE AND CENTER NEWS LINKS

NIGMS Feedback Loop

Inside NIDCD

NIH RADIO ARCHIVES AVAILABLE FOR LISTENING AND DOWNLOADING

NIH Radio is a 24-hour audio service designed to provide radio stations with the latest information about NIH research

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that they will enable the collaborating institution to comply.

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

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NIH ROADMAP FOR MEDICAL RESEARCH:
NIH Outlines Process for Idea Solicitation and Initiative Selection

NIH Roadmap FOR MEDICAL RESEARCH

In 2002, NIH Director Dr. Elias Zerhouni conducted a series of discussions with NIH advisors and the scientific community about ways to improve and accelerate biomedical research. These discussions led to the creation of the NIH Roadmap for Medical Research. Roadmap is a process designed to increase synergy across all of NIH, enabling NIH to address proactively emerging scientific needs and opportunities; fund high risk, high impact science; and, incubate and launch pilot efforts that have the potential to transform science. Because Roadmap is intended to evolve constantly and adapt to the realities of science, projects within Roadmap are limited to a maximum of 10 years of support.

Building on the success of the first version of the Roadmap for Medical Research, NIH is beginning a process to identify ideas for a new cohort of Roadmap initiatives to be funded within the existing Roadmap budget in fiscal year 2008. Funds for these new initiatives will become available as current Roadmap initiatives conclude, are adjusted in scale, or their initial funding plans are modified.

In the first part of the process to identify new initiatives, ideas will be solicited through meetings with scientists from around the nation that represent various disciplines and areas of investigation. These meetings will take place during the summer and early fall of this year and will help senior NIH staff identify cross-cutting challenges in biomedical research that meet the Criteria for Roadmap Initiatives shown in the box below.

> The overarching goal of all Roadmap initiatives is to accelerate the discovery and translation of scientific knowledge into public health benefits. Roadmap is conceived of as a five to ten year 'incubator space' for NIH initiatives that meet all of the following criteria:
>
> ◆ Is the proposed initiative truly transforming–could it dramatically affect how biomedical and/or behavioral research is conducted over the next decade?
>
> ◆ Will the outcomes from the proposed initiatives synergistically promote and advance the individual missions of NIH ICs to

findings, highlights of press conferences and health campaigns.

This service features weekly, short, health-related news stories distributed to radio stations throughout the United States. Archives of various stories are available through Web-based written transcripts, as downloadable MP3 files, and through streaming RealPlayer format.

Recent archived radio reports include:

NHLBI Offers Updated Guide with Practical Advice for Lowering High Blood Pressure Through Diet, July 2006

State of the Science Conference Discusses Multivitamins and Mineral Supplements, May 2006

Research Program Hopes to Improve Survival Rate for Cardiac Arrest and Traumatic Injury, April 2006

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> **Announcements**

NRSA F32 APPLICATION STREAMLINED REVIEW

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benefit health?

◆ Does the proposed initiative require participation from NIH as a whole and/or does it address an area(s) of science that does not clearly fall within the mission of any one IC or OD program office?

◆ Is the proposed initiative something that no other entity is likely or able to do, and is there a public health benefit to having the results of the research in the public domain?

NIH Institutes, Centers and Offices will be given an opportunity to develop Roadmap ideas this summer. Idea descriptions from both activities will be posted when the NIH launches a web-based Request for Information (RFI) soliciting a broad range of input and ideas from both science and lay communities this fall. The RFI will provide an opportunity for respondents to comment on the ideas already suggested and/or submit new ideas.

All idea nominations will be screened to make sure that they are consistent with the Criteria for Roadmap Initiatives, then clustered by topic area and summarized for further review and prioritization by NIH IC Directors. Implementation plans will be developed for high priority proposals in the following months and a final prioritization by IC Directors will be sent to the NIH Director, who will consult with the Advisory Council to the Director (ACD) prior to making funding decisions next spring.

Once selected, new Roadmap initiatives will be formally assigned a lead IC and a trans-NIH Project Team. Project Teams will generate solicitations for the types of projects required to fulfill the initiative's aims. Applications will be received, reviewed, approved and funded beginning in FY2008.

The RFI and summary information from each phase of the idea nomination process will be posted as it becomes available on the Office of Portfolio Analysis and Strategic Initiatives/Roadmap Web site. Additional information on this process will appear in the *NIH Guide for Grants and Contracts*.

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ELECTRONIC SUBMISSION NEWS:

Updated Forms For eSubmission Are Here: Grants.gov and NIH Update SF424 (R&R) and Agency-Specific Forms

GRANTS.GOV℠

Grants.gov and NIH recently updated the standard form SF424 (R&R) and agency-specific PHS 398 electronic grant application form components used for electronic submission of grant applications. The changes provide greater standardization among application forms and incorporate new policy requirements. All new NIH Funding Opportunity Announcements (FOAs) will use the

OPPORTUNITY FOR FUNDING EXTENSION AND/OR ONE-TIME SUPPLEMENTS FOR HURRICANE KATRINA-AFFECTED GRANTS

In an effort to assist grantees located in New Orleans with active NIH grants who have persevered through the challenges brought by Hurricane Katrina, the NIH will provide the opportunity for investigators and institutions to request up to a one-year funded extension at the same funding level as the current final year of the grant and/or one-time administrative supplements of up to $50,000 in direct costs. This applies to single project research project grants active at the time of the storm that remain in New Orleans.

revised application form. Over the next few months, NIH will update existing FOAs that use the older forms to reference the new application.

To summarize, we have updated sections and components of the grant application forms. New grant opportunity announcements will reference the revised application, and old announcements will be revised to reflect the new application form.

We will maintain and support the old and new application packages and their associated application instructions until we are sure that all applications approved to use the old form set have been received and processed.

What the new application form means for applicants:

- New FOAs will be posted citing the revised application packages. No special action needs to be taken.

- FOAs issued before June 15, 2006 that expire on or before December 31, 2006, will be allowed to close naturally without issuing any revised application form. No special action needs to be taken.

- For older FOAs with multiple future receipt dates, NIH will update the FOA to expire the old application form and reflect the revised application. Once the new application form is in place for a particular FOA, the old application will no longer be accepted by Grants.gov. Any application "in the works" will need to be moved to the new form package (i.e., download new forms and cut-and-paste content from one form to the other). Older FOAs will be updated as follows:
  - New forms will be in place by July 18 for the following grant programs: R03, R15, R21, R21/33, R33 and R34
  - New forms will be in place by September 15 for the following grant programs: R41, R42, R43, R44, R13/U13

- To differentiate between the old and new application, the new application will be labeled Version 2 Forms in the Competition ID field.

- There will be a short period of time when both the old and new application packages will be available to download. Whenever there is a choice, the package labeled Version 2 Forms in the Competition ID field should be used.

- If your business office provides versions of the application packages to Principal Investigators that are pre-populated with your organization's information, be sure your application package templates use the revised application package.

- The existing and revised application guides will be labeled Version 1 and Version 2 on the cover page and within the footers. The FOA will continue to link you to the appropriate application guide.

The following table shows when to use the new forms:

Complete information, including details of documents to submit, deadlines and contact information are available in the *Guide* notice.

NIH TO SEEK PUBLIC INPUT ON CHANGES BEING CONSIDERED ON USE OF APPENDIXES IN GRANT APPLICATIONS

NIH is evaluating guidelines for grant application appendixes in an effort to streamline the grant application and review processes. NIH soon will issue a Request for Information (RFI) in the *Federal Register* that seeks input from applicants, reviewers and other members of the research community regarding the utility of appendix materials in the grant submission, review and management process. Look for the notice in early August.

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≫ *Guide* Notices

NIH/AHRQ Reminder to Use Updated SF424 (R&R) and Agency-Specific Electronic Forms in Reposted FOAs

Posting/Release Date of FOA	Grant Mechanism	Use New Forms
Before June 15, 2006*	R03, R15, R21, R21/33, R33 and R34	After July 18
Before June 15, 2006*	SBIR/STTR (R41, R42, R43, R44), R13/U13	After Sept. 15
On or after June 15, 2006	All application packages will contain the new forms	√

* Only FOAs that expire after December 31, 2006

For more information, visit the eSubmission Frequently Asked Questions Web page.

ALERTS!

Issue with Version 2 Application Package

An issue with the PureEdge™ version of the Research & Related Senior/Key Person Profile component included in the Version 2 packages has been identified. The section of the PureEdge form that allows attachments for Additional Senior/Key Person Profiles, Biographical Sketches and Current and Pending Support is missing. Without this section applications are limited to eight Senior Key Persons. NIH will be issuing a notice in the NIH Guide for Grants and Contracts providing a workaround for applicants to use when more than eight Senior Key Persons need to be listed on an application. This workaround will remain in place until the Research & Related Senior/Key Person Profile component is corrected by Grants.gov.

Version 2 Application Form Automated Emails

In an effort to keep Applicants informed of changes to Funding Opportunity Announcements (FOAs), Grants.gov provides an automated email process to subscribers. The new Version 2 application package triggered recent emails that have caused some confusion for Applicants.

For more information regarding the automated emails visit the eSubmission News and Updates Web page.

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Did You Check Your Assembled Application?

Applying for an NIH grant opportunity, you filled in all the application fields, included the required attachments and forwarded your application package to your Authorized Organization Representative (AOR) in time to meet the receipt deadline. But, your job does not stop there. Did you track the status in the eRA Commons? Did you check your assembled application?
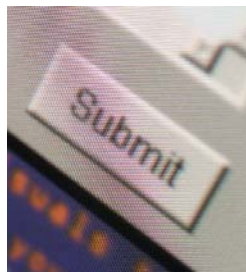
We continue to receive calls, well after the two-day viewing window has elapsed and the application has moved forward to the Division of Receipt and Referral, from panicked PIs who have just noticed serious issues with their applications. One applicant attached the NIH application guide to their application by mistake! Another applicant had a a an upside down PDF image in the assembled application. Unfortunately, after the two-day viewing period and once the application has moved forward to the Division of Receipt and Referral, Help Desk staff no longer can assist with changes to the application.

Nobody cares more about your grant application than you do. Take advantage of the two-day viewing window to give your application that final check—then relax knowing your part of the submission process is truly complete.

Check out our new Frequently Asked Questions on Checking Assembled Applications.

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NIH Easily Handles June 1 Application Submission Date

The NIH has received over 9,000 unique research grant applications electronically through Grants.gov since launching its electronic submission program in August 2005. The June/July submission round marked a significant milestone in NIH's eSubmission program with the transition of the Small Grant (R03), Exploratory / Developmental Research (R21/R33) and Clinical Trial Planning (R34) grant mechanisms to electronic submission. NIH received applications submitted to Grants.gov using PureEdge™ forms, from institutions that have developed system-to-system solutions, and from commercial service providers. It was not only the largest transition to date; it was the smoothest for the applicant community! NIH received over 4,000 applications for the June/July transition round, which is right in the expected range.

eRA Commons processing ability and software continue to improve. System improvements, aggressive education efforts and many well-prepared Offices of

INFORMATION AND RESOURCES:
Small Business Innovation Research and Small Business Technology Transfer Programs

As a participant in the Federally mandated Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, the NIH funds innovative biomedical and behavioral research ideas with commercial potential through a set-aside program totaling two and one half percent of the NIH extramural budget. A wealth of information and resources are available for individuals and entities interested in pursuing these unique opportunities:

About the SBIR/STTR Programs

Small Business Funding Opportunities

SBIR/STTR Collaboration Opportunities and Research Partnerships

Success Stories

SBIR/STTR State Support Entities

A Roadmap to Starting a Successful Business

And, for those interested in conducting business with the NIH, the following resources are available:

The Department of Health

Sponsored Research dramatically reduced the number of submission attempts per successful submission and the number of support calls to the eRA Commons Help Desk.

Many people were looking at the June 1 submission date as an early indication of what to expect with the transition of the traditional Research Project Grant Program (R01) applications in February 2007. "Applications are getting in the door and ready for processing by the Division of Receipt and Referral much more quickly than for previous eSubmission receipt dates. We now see very few system issues that require NIH intervention to process applications. The Help Desk is better able to handle call volume. Communications efforts are paying off and many applications now are going through on the first try. We have a long way to go and some tough challenges ahead, but the continuous improvements are encouraging. We are looking forward to the February R01 transition," commented Megan Columbus, NIH Program Manager for the Electronic Submission of Grant Applications.

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MULTIPLE PRINCIPAL INVESTIGATOR UPDATE:
Applications Indicate that the Multi-PI Option is Attractive

After decades of associating a single Principal Investigator (PI) with each grant, on May 11, the NIH received its first Multiple PI applications in response to a Request for Applications (RFA). A recent NIDDK RFA designed to stimulate research on the Obese and Diabetic Intrauterine Environment permitted Multi-PI applications under the test initiative. Nearly 30 percent of the applicants selected the multiple PI option. Almost 50 percent of the applications received in response to the NCI's RFA for Small Animal Imaging Resource Program displayed more than one PI. A smaller proportion of the applications for the NLM Research Grants in Biomedical and Bioinformatics program, received on June 1, involved multiple PIs. The pilot's current level of response in the Multiple-PI option indicates considerable interest in selected research areas. The receipt and processing of the first multiple-PI applications are important milestones in the implementation of what is anticipated to be a broadly transforming Roadmap activity.

The Multiple-PI option is on track to be available for nearly all research project grant opportunities starting with the February 1, 2007, receipt date. More complex grant opportunities will allow a Multiple-PI option as they transition to electronic submission format. Updates on the pilot will be posted on the Multiple PI Web site.

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WHO IS A NEW INVESTIGATOR?
An Update

The May 2006 issue of the *NIH Extramural Nexus*, included an article on the NIH definition of a new investigator.

Since then, NIH has received the following question on this issue:

QUESTION: I became the PI on an NIH Traditional Research Project Grant (R01) when my supervisor retired. Will I be eligible to compete as a new investigator when this grant comes up for competing renewal?

ANSWER: No. The definition of New Investigator (see PHS 398 Instructions; Section I: Preparing Your Application, Part C: Specific Instructions, Item 1: Face Page) is someone who has not previously **served** as a PI on a PHS-supported research grant (with some exceptions, as detailed in the definition). This particular scientist has been fortunate to serve as PI even though he did not compete. Based on the definition, however, he is no longer eligible to compete as a new investigator.

Additional information is available at the New Investigators Program Web site.

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INTERACTIVE STATE AND CONGRESSIONAL DISTRICT AWARD DATA NOW AVAILABLE

NIH's Award Trends Web site now lists current and historical data on NIH awards to states, congressional districts, universities and other institutions. That information is now available through an interactive interface and through the NIH Research Results for the Public Web page.

The new state trends funding site layout provides the opportunity to access award data interactively. Site visitors can click either a specific state on the map, or the hyperlink listed below the map to see more detail, including dollars awarded to each congressional district and to organizations in the selected state.

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NIH ENCOURAGES DATA SHARING:
Multiple Resources Available

NIH maintains a long-standing policy on sharing results and accomplishments of NIH-funded research with the public. As an extension of this policy, the Office of Extramural Research (OER) introduced the Final NIH Statement on Sharing

Research Data. Data sharing helps the community at large as it improves access to existing resources, reduces duplication of effort and allows the NIH to focus on its primary goals. Today, particularly with budget constraints, data sharing has become more important as the NIH continues to fund groundbreaking research.

Several resources are available on NIH Web pages on how to develop and implement data-sharing plans, including the NIH Data Sharing Policy and Implementation Guidance Web page, the Data Sharing Policy Web page, a Frequently Asked Questions page and the Other Data Sharing Document and Resources page.

For issues not found in these resources, assistance with addressing data-policy issues or for help in developing data-sharing strategies, contact J.P. Kim (301-435-0679), Division of Extramural Inventions & Technology Resources (DEITR) within the Office of Policy for Extramural Research Administration (OPERA), OER.

PEER REVIEWER INFORMATION:

Pilot Study in Progress—Air Travel Costs for NIH Peer Reviewers under Evaluation

Increasing costs in airfares and fuel prices have a direct impact on the budget of the NIH Scientific Review and Evaluation Award program, under which NIH Scientific Review Meetings are held and travel arrangements are made for NIH Peer Reviewers. As a general policy, NIH has typically provided fully refundable air travel tickets to Scientific Reviewers. As a proactive alternative, NIH Institutes and Centers including CSR, NIDCD, NIDA, NIEHS, NIA, NIDDK, NICHD, NINDS, and NCRR are participating in a pilot study whereby World Travel Services (one of NIH's travel service agencies) will purchase non-refundable (restricted coach) fares for Scientific Reviewers. The pilot study will compare costs between restricted fares and unrestricted fares. Participation in the pilot started on May 28, 2006, and will continue through December 31, 2006. The data analysis of the study will be assessed by the NIH Scientific Review and Evaluation Governance Committee. Should cost savings be realized, the Committee will consider recommending an NIH non-refundable airfare policy for Scientific Reviewers.

For additional information, visit the Center for Scientific Review's *Peer Review Notes*.

NIH Peer Reviewers Required to Renew CCR Registration

The Central Contractor Registration (CCR) is the primary payment database for the U.S. Federal Government. CCR validates the payee information and electronically shares the secure and encrypted data with the federal agencies' finance offices to facilitate paperless payments through electronic funds transfer (EFT). NIH peer reviewers are required to complete a one-time registration to provide basic information relevant to financial transactions and keep this information current with a once yearly renewal. Peer reviewers will be asked to renew their registration to maintain an active status. NIH peer reviewers who registered last summer in preparation for October/November 2006 review meetings will be receiving an e-mail from CCR (subject line: CCR 30 Day Renewal Notice) with an expiration notice. Please promptly complete the renewal with the instructions provided. If you have any questions, please contact Mr. David Faustin by email or 301-435-1129 by telephone, of the NIH Scientific Review Evaluation Award (SREA) Service Center.

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OLAW NEWS:

OLAW Publishes Brochure for Investigators

The Office of Laboratory Animal Welfare's (OLAW) new brochure communicates to investigators their responsibilities under PHS Grants Policy and PHS Policy on Humane Care and Use of Laboratory Animals. *What Investigators Need to Know About the Use of Animals* is a succinct resource for investigators who need to know the main expectations and requirements when animals are involved in PHS supported research.

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NIH Seeks Candidates for OLAW Director

The NIH seeks applications for the position of Director, OLAW, located in the Office of Extramural Research (OER). The OLAW Director provides executive leadership and direction to OLAW, which is responsible for developing and coordinating appropriate PHS regulations, policies, and procedures on the humane care and use of laboratory animals. The OLAW Director reports directly to the NIH Deputy Director for Extramural Research.

For information concerning the duties and responsibilities of this position, salary and benefits available, required qualifications and application procedures, interested candidates should visit the OER Senior Level Vacancies Web site.

National Institutes of Health
OFFICE OF EXTRAMURAL RESEARCH

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.

To subscribe to the *NIH Extramural Nexus*, send a plain text email to Listserv@list.nih.gov including only the words **Subscribe EXTRAMURALNEXUS** in the body of the message. To unsubscribe, follow the same procedure, using the words **Unsubscribe EXTRAMURALNEXUS** in the message body.

NIH Extramural Nexus Web site and archives