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

April 2006

In This Issue

NEWS FROM THE DIRECTOR OF OER
R01 Electronic Timeline Adjusted and Multiple-PI Initiative Piloted

Dear Extramural Community,

Immediately below, you will find updates on two major NIH initiatives—Electronic Submission and Multiple Principal Investigators—which will have a significant effect on how NIH and extramural institutions do business. The success of these complex initiatives, which at NIH and likely at your institutions touch on many aspects of the conduct of biomedical research, depend heavily on our continuing to work together. I very much appreciate your feedback and hope that you will find these updates and the other items in this *Nexus* update both informative and helpful.

Recently, the Office of Extramural Research (OER) issued notices in the *NIH Guide* announcing adjustments to electronic submission and the rollout of the multiple Principal Investigator (PI) option on research grants. To summarize these changes:

Electronic Submission: The NIH has made considerable progress in transitioning to electronic applications. We have already received electronic SBIR/STTR, R13/U13, R36 and R15 applications and we will receive R03, R21/R33 and R34 applications beginning in June. Our commitment and enthusiasm for electronic submission remains unchanged. However, after considering input from the scientific community we have adjusted the implementation timeline for the electronic R01s to provide an additional four months to address business processes here and at applicant organizations. We will begin receiving R01 applications via Grants.gov and the SF424 (R&R) with the February 1, 2007, receipt date. We also have changed the submission deadline from 8:00 p.m. Eastern Time to 5:00 p.m. local time at the applicant organization. Additional information is available at the Electronic Submission Web site.

Multiple Principal Investigators: A pilot program, beginning in May with a few select RFAs and PAs, will permit the identification of more than one PI on applications for NIH research grants. This change is being taken to catalyze multidisciplinary research and team science in ways that have been difficult with a single-PI model. The database changes and the necessary modifications to the computer interfaces required to process grant applications are expected to be completed by May 1. We hope to make the multiple-PI option available for most investigator-initiated research grant

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mechanisms submitted for February 2007 and later application receipt dates. Initial features will include the ability to record the names of all PIs in NIH databases, display those names on the notice of grant award, and list all PIs in CRISP. In the future, we will consider ways to make linked awards, apportion funds to individual PIs and recognize all key personnel. We will continue to work with the scientific community to identify features that will stimulate collaborative research approaches. Additional information on the pilots and the project timeline is available in the *NIH Guide* and on the Multiple-PI Web site.

If you have questions about any aspect of the Multiple PI Project, send them by email to multi_PI@mail.nih.gov.

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

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Change in Time of Submission/Receipt of NIH Electronic Grant Applications to Grants.gov

Extension of the Expiration Date of the Ruth L. Kirschstein National Research Service Award Institutional Research Training Grant Funding Opportunity Announcement

May 1, 2006 Submission Date for AIDS and AIDS-related R03 and R21 Applications

Change in Funding

NIH OFFERS NEW SCIENTISTS A "PATHWAY TO INDEPENDENCE"

One of the most challenging transitions in any research career is the transition from postdoctoral trainee training to independence as a scientist. New investigators who successfully cross the bridge from research dependence to research independence have a new opportunity to act on fresh ideas and bring innovative perspectives to the research enterprise. These are critical to sustaining NIH's ability to push forward and advance the frontiers of medical research. In today's challenging budget environment, supporting a healthy cohort of NIH-supported investigators is the number one priority of NIH Director Elias A. Zerhouni, M.D.

Dr. Zerhouni formed the NIH New Investigators Committee, chaired by Dr. Norka Ruiz Bravo, the NIH deputy director for extramural research and Dr. Story Landis, director of the National Institute of Neurological Disorders and Stroke. The new NIH Pathway to Independence Award (K99/R00) program is an initial result of the committee's intensive efforts to develop and implement programs that facilitate an investigator's ability to receive their first R01 award earlier in their research career. All NIH Institutes and Centers are participating.

The NIH Pathway to Independence Award (K99/R00) program is a new and exciting opportunity for promising postdoctoral scientists. The award includes both mentored and independent research support. Features of the award, including eligibility, citizenship, review issues, fiscal matters, etc., are described in detail in the *NIH Guide* and on the New Investigators Web site. NIH will issue between 150 and 200 awards for

this program in its initial year, beginning in fall 2006, and anticipates issuing the same number of awards each of the following five years. During this time, the NIH will provide almost $400 million in support of this program.

Since the program's announcement in the *NIH Guide* on January 27, 2006, there has been a high level of interest from the grantee community. To answer some of the most common questions regarding eligibility, citizenship, review issues, fiscal matters, etc., the NIH has posted several Questions & Answers.

Each candidate is encouraged to discuss their potential competitiveness for this funding opportunity with his/her advisor, department chair, and relevant NIH program staff prior to preparing an application. Only the most competitive candidates are encouraged to apply for this award.

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DO YOU BELIEVE THIS EXTRAMURAL URBAN LEGEND? "Preparing preliminary data for applications requires Investigators to 'fudge' their payroll certifications (effort reports)"

In the world of Principal Investigators (PIs), tracking the time and effort devoted to scientific, administrative, and institutional responsibilities for the purpose of payroll certification can be complex and more than a little confusing. It is commonly heard that the PI's time spent preparing a grant or contract proposal, including the collection of preliminary data, must be tracked and reported separately when certifying payroll. Many believe that these activities must be completed after-hours and 'off the books,' therefore not in compliance with Federal rules.

Is this an urban legend or is it true?...It is an urban legend! For additional information, read on...

Reporting requirements differ with institution category because while different types of institutions have similar Federal costing requirements, each is required to address distinct requirements under Federal cost principles. The Office of Management and Budget (OMB) Circular A-21 (Cost Principles for Educational Institutions) applies to colleges and universities, and OMB Circular A-122 (Cost Principles for Non-Profit Organizations) applies to non-profits.

College or university Investigators collecting preliminary data or preparing a competing application do not have to track this time separately from their other activities. There is no Federal requirement to consider 'Bid and Proposal' effort, including the preparation of preliminary data, in payroll certifications (effort reporting). It simply is not necessary.

Non-profit organization Investigators are required to track and certify time associated

Kirschstein National Research Service Award Institutional Research Training Grants (T32 and T35) Supported by the National Institute of Environmental Health Sciences

Salary Limitation on Grants, Cooperative Agreements, and Contracts

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with collecting preliminary data or preparing bids and proposals. Institutions that fall in this category have developed procedures to do this.

For non profit institutions OMB Circular A-122 (Cost Principles for Non-Profit Organizations) does not specifically address the treatment of these costs. However, the Code of Federal Regulations, 45 CFR Part 74.27(b) states that bid and proposal costs of the current accounting period are allowable as F&A. Accordingly, preparing preliminary data to support a competing application should be certified as part of the F&A costs, in accordance with the established policy and procedure of the non-profit organization.

Finally, it is important to remember that while these Federal rules are constant, each grantee institution implements Federal requirements locally, with their own policy and procedures. Therefore, it is always important to understand and be fully responsive to local policies and procedures.

For further reference, links are provided for the following documents in full:

Policy Information for Research Administrators
OMB Circular A-21
OMB Circular A-122
Code of Federal Regulations, Part 45

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Science in the News

H5N1 Avian Flu Virus Vaccine Induces Immune Responses in Healthy Adults, March 29, 2006

NIH Researchers Identify OCD Risk Gene, March 29, 2006

New Federally Funded Research Program Aims to Improve Survival from Cardiac Arrest and Severe Trauma, March 24, 2006

New Strategies Help Depressed Patients

NIH CREATES THE OFFICE OF PORTFOLIO ANALYSIS AND STRATEGIC INITIATIVES

NIH recently launched the Office of Portfolio Analysis and Strategic Initiatives (OPASI) in the Office of the NIH Director to transform the way NIH finds and funds cutting-edge research, improve our ability to identify public health challenges, and increase trans-NIH dialogue, decision-making and priority-setting.

“This process has essentially two goals,” said NIH director Dr. Elias A. Zerhouni. “To allow new science that falls through the cracks to be funded quickly, and to make sure new ideas have a chance.”

OPASI has three branches that will work together to accomplish its goals: the Division of Resource Development and Analysis (DRDA), the Division of Strategic Coordination (DSC), and the Division of Evaluation and Systematic Assessments (DESA).

Become Symptom-Free, March 22, 2006

Male Fat Distribution Pattern and Coronary Risk Profile Linked to X Chromosome & Women Lacking Ovarian Function Shy, Anxious, March 21, 2006

Defective Immune System Response to Smallpox Vaccine Detailed, March 21, 2006

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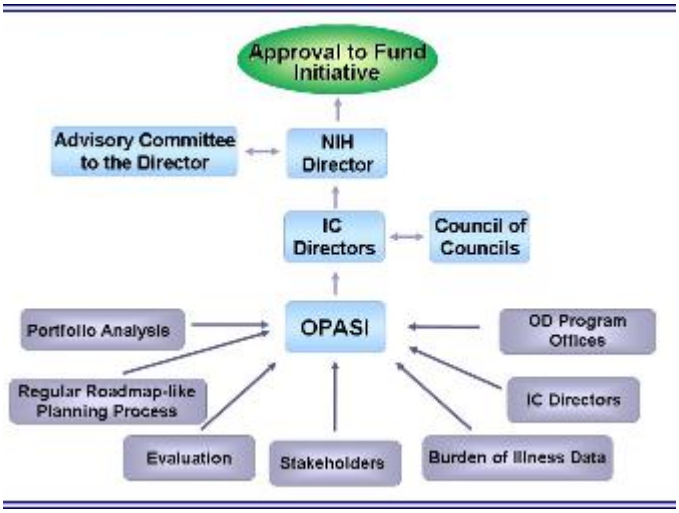

The OPASI Process

(image opens in new browser window in Acrobat format)

OPASI will build upon the model of the NIH Roadmap for Medical Research and will coordinate with NIH Institute and Centers (ICs) and external stakeholders to identify research priorities that will ultimately improve NIH's ability to be nimble, dynamic, and responsive to emerging scientific opportunities and public health needs. OPASI will solicit regular input from the biomedical and behavioral research community including proposals from individual scientists, stakeholders and organizations outside NIH; a regular, Roadmap-like planning process; data about the burden of illness; as well as considerable input from IC directors and such NIH Office of the Director components as women's health, behavioral science, and AIDS research. Although OPASI will not have grant-making authority, it will provide an "incubator space" to jump-start trans-NIH initiatives and support ICs that will take the lead on priority projects on a time-limited basis (5 to 10 years). These initiatives will be managed primarily by the ICs, and the turnover of projects will ensure that sufficient funds are available for continuous development of new, trans-NIH efforts.

These OPASI initiatives will be supported by the "Common Fund for Shared Needs," a central funding source built upon the Roadmap budget model. The Common Fund is derived from the ICs—and the Office of the Director—which will contribute a percentage of their annual budgets to the Fund. By pooling resources in this formal, structured way, NIH will eliminate the need to collect money in an ad hoc manner from ICs every time a trans-NIH opportunity presents itself. Building from current Roadmap funds, which amount to about 1.6 percent of NIH's total budget in fiscal year 2007, the Fund will increase to up to 5 percent of the total NIH budget depending on NIH budget growth, scientific opportunities and public health needs.

OPASI was formally introduced on September 28 with an announcement in the Federal Register. More information will be available on the OPASI Web site, which will be launched soon. Additionally, OPASI has been described in detail in the *NIH Record*.

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FREQUENTLY ASKED QUESTIONS: NIH PUBLIC ACCESS POLICY

Q: What is the NIH Public Access Policy?

A: The Public Access Policy requests NIH-funded investigators to submit an electronic version of the author's final manuscript upon acceptance for publication to the NIH National Library of Medicine's PubMed Central (PMC). This includes all manuscripts resulting from research supported in whole or in part, with direct funds from NIH.

Q: Why should there be a

public resource of published peer-reviewed research findings of NIH-funded research?

A: The Public Access Policy has three goals: develop a central archive of NIH-funded research publications—for now and in the future, preserving vital medical research results and information for years to come; advance science by creating an information resource that will make it easier for scientists to mine medical research publications, and for NIH to manage better its entire research investment; and, provide electronic access to NIH-funded research publications for patients, families, health professionals, scientists, teachers, and students.

Q: What is PubMed Central (PMC)?

A: PubMed Central (PMC) is the NIH digital repository of full-text, peer-reviewed biomedical, behavioral, and clinical research manuscripts. It is a publicly accessible, stable, permanent, and searchable electronic archive that is fully integrated with other National Library of Medicine databases. Anyone with entry to the Internet can access PMC.

Q: When do I submit my manuscript?

A: NIH-funded investigators are requested to submit an electronic version of the author's final manuscript to NIH upon acceptance for publication. The policy gives

PUBLIC PRIVATE PARTNERSHIPS: A Component of the NIH Roadmap for Medical Research

As researchers tackle ever more complex biomedical problems, strategic partnerships between NIH, private industry and nonprofit organizations will become more important. Promoting and facilitating new and ongoing partnerships is the mission of the Program on Public-Private Partnerships, located in the Office of Science Policy (OSP) within the NIH's Office of the Director.

The NIH Program on Public-Private Partnerships (PPP) represents an important aspect of the NIH Roadmap. The PPP Program is designed to promote and facilitate the formation of partnerships that will foster excellent science in the public interest and leverage NIH and non-NIH resources. The NIH takes a broad view of partnering and will work cooperatively with other federal agencies, academic scientists and institutions, charitable foundations, patient advocacy groups and individuals, industry, and others. Partnerships may take many forms and range widely in size and scope. Partnerships provide an opportunity for NIH to participate in the greater scientific community and for non-NIH entities to participate in science that is in the interest of the public health.

With an eye toward keeping pace with changes in the business sector and dealing with concerns about intellectual property, patents, and licensing rights, the PPP office will work with relevant NIH Institutes, Centers and Offices to review existing partnership mechanisms and provide recommendations for policies or legal authorities needed to achieve NIH's objectives. The PPP also will work closely with the Foundation for the National Institutes of Health, a private charitable foundation chartered to help support NIH activities. The PPP also will serve as a point of contact for entities wanting to partner with NIH, and can provide contact information and advice regarding the initiation, establishment and implementation of new partnerships. This effort will complement, not replace, the role of the Institutes and Centers as they work with the private sector to serve their missions.

There are a number of successful public-private partnerships that are ongoing within NIH, such as the Osteoarthritis Initiative (OA), The Alzheimer's Disease Neuroimaging Initiative (ADNI), and the recently launched Genetic Association Information Network (GAIN). Additionally, there are several others in development. For information about specific partnership opportunities, contact the relevant NIH Institute or Center. For additional information or advice, visit the Public-Private Partnerships Web site or contact the Program on Public-Private Partnerships.

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DO I REALLY NEED TO READ THE APPLICATION GUIDE?

Whether you've been writing grant applications for 20 years or 20 minutes, you will benefit from reading the Department of Health and Human Services Grants.gov

authors the flexibility to designate a specific timeframe for public release of the document—ranging from immediately after final publication to 12 months.

Q: How do I submit a manuscript?

A: Manuscripts can be submitted through the NIH Manuscript Submission (NIHMS) system. This password-protected, Web-based system allows for easy identification of NIH grant numbers (past and present) and NIH intramural project numbers by associating them with the corresponding Principle Investigator (PI). For detailed instructions on how to submit a manuscript, refer to the *Authors Manual*.

Q: Can authors and journals continue to assert copyright in scientific publications resulting from NIH funding?

A: Yes. The Public Access Policy does not affect the ability to assert copyright. Funding recipients can continue to assert copyright in works arising from NIH-funded research, and they can assign these copyrights to journals, as is the current practice. Copyright holders can enforce these copyrights as before. A member of the public viewing or downloading a copyrighted document from PubMed Central (PMC) is subject to the same rights and restrictions as when copying an article from the library.

Q: How can I be sure that

Application Guide SF424 (R&R). The National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ) are converting to the electronic SF424 Research and Related (R&R) grant application forms. The Application Guide is a comprehensive resource for applicants that covers the new electronic submission process, the new SF424 (R&R) application form set and current policy information.

The NIH/AHRQ electronic submission of grant applications process and the SF424 (R&R) form set are new to everyone. The Application Guide, together with the funding opportunity announcement instructions, provides all the information you need to submit your grant application successfully.

Additional benefits of reading the Application Guide are as follows:

- The new process automatically checks the application to ensure it follows the instructions in the Application Guide and funding opportunity announcement. These automated checks may catch and flag as errors things that customarily passed unnoticed through the paper application process. Errors can halt an application in its tracks. You cannot complete the submission process without correcting all errors in the application and submitting a corrected application through Grants.gov. Following along in the Application Guide as you fill out your application will help you avoid errors and save you the time and frustration of submitting a corrected application.

- The SF424 (R&R) forms are used by all Federal agencies that provide Research and Related grant funding. Unless a form field is required by multiple agencies, it will not be marked as required on the federal-wide form. For this reason, not all fields that are required by NIH/AHRQ are marked as required on the form. For example, the “Credential, e.g., agency login” field in the PD/PI section of the Senior/Key Person Profile component is required by NIH/AHRQ, but not marked as such on the federal-wide form. If you pay special attention to the agency-specific instructions included in the Application Guide and denoted by the HHS logo, you will know exactly what NIH/AHRQ is looking for in each form field.

- Although Grants.gov will accept attachments in multiple formats, NIH accepts attachments only in PureEdge™ or Portable Document Format (PDF) format. The Application Guide provides tips for creating acceptable attachments.

Details relating to all aspects of electronic grant applications are available on the Electronic Submission of Grant Applications Web site.

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my journal publication contract allows me to also publish in PubMed?

A: Individual publication arrangements are made between authors and publishers, and can take many forms. NIH encourages investigators to sign agreements that specifically allow the manuscript to be deposited with NIH for public posting on PubMed Central as soon as possible after journal publication. Institutions and investigators may want to develop particular contract terms in consultation with their own legal counsel, as appropriate. As an example, the kind of language that an author or institution might add to a copyright agreement includes the following: "Journal acknowledges that Author retains the right to provide a copy of the final manuscript to NIH upon acceptance for Journal publication or thereafter, for public archiving in PubMed Central as soon as possible after publication by Journal."

Q: Will the NIH Public Access Policy apply to NIH-supported investigators in foreign countries?

A: Yes. The Policy applies to all NIH-funded investigators, including those in foreign countries. The PMC archive will be available through the Internet, so all investigators will have access to it, provided they have a computer with an Internet connection.

CONTINUING SERIES ON PROGRAMS IN THE OER

Click on graphic to expand (opens in new window)

ANIMAL CARE IS THE FOCUS OF THE OFFICE OF ANIMAL LABORATORY WELFARE

OLAW, or the Office of Laboratory Animal Welfare, is an office in the Office of Extramural Research that supports the NIH research enterprise by administering the PHS Policy on Humane Care and Use of Laboratory Animals (Animal Policy). Appropriate animal care and use are integral components of good research because they affect research findings, reproducibility of results, and reliability of data. OLAW promotes compliance with the PHS Animal Policy through educational outreach, communication, negotiation of Animal Welfare Assurances, and evaluation of institutional self-reports of noncompliance.

Congress delegated authority and responsibility for Animal Policy to the NIH Director in the 1985 Health Research Extension Act, which established a system of oversight by local Institutional Animal Care and Use Committees (IACUCs). The system is based on institutional self-evaluation, self-monitoring, self-identification and self-correction of noncompliance. Within the scope of the Policy, IACUCs exercise autonomy in reviewing and approving research and the use of performance-based standards found in the Guide for the Care and Use of Laboratory Animals. Institutions are able to identify and report deficiencies and non-compliance as well as correction of deficiencies and non-compliance without fear of regulatory reprisal due to the emphasis in the law on providing grantees reasonable opportunity to take corrective actions. Refer to the Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals for complete details.

OLAW is divided into a Division of Assurances, a Division of Compliance Oversight, and the Office of the Director. Educational outreach activities are a function of the Office of

Q: Where can I send questions or comments about the NIH Public Access Policy?

A: Send email questions or comments, or visit the NIH Public Access Web site.

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the Director. Many educational conferences and workshops are co-sponsored each year, and educational resources developed in conjunction with outside scientific experts are available. The OLAW Web site is a rich source of information and guidance. You can send questions to OLAW Help or find information for the grantee community on the OLAW listserv.

Left to Right: Axel Wolff, Director, Division of Compliance Oversight;

Carol Wigglesworth, Acting Director, Office the Director;

Denis Doyle, Director, Division of Assurances

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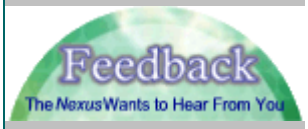

COMMUNICATE WITH THE *NIH EXTRAMURAL NEXUS* — WE WANT TO HEAR FROM YOU

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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Printer Friendly Version
(Adobe Acrobat Reader Required)

THE AMERICAN PHYSIOLOGICAL SOCIETY ISSUES A RESOURCE BOOK FOR THE DESIGN OF ANIMAL EXERCISE PROTOCOLS

With sponsorship from the NIH Office of Laboratory Animal Welfare (OLAW), the American Physiological Society (APS) has published the Resource Book for the Design of Animal Exercise Protocols. Experts in the fields of exercise physiology and animal research models developed the book, intended for researchers, Institutional Animal Care and Use Committees (IACUCs), and those involved with research oversight. The authoring committee, which comprised exercise physiologists and laboratory animal veterinarians, reviewed reference material and drew upon their own experience to compile suggestions about how to design, review, and implement experimental paradigms involving animals and exercise. The APS Resource Book was peer reviewed by other exercise physiologists and laboratory animal veterinarians.

The opening chapter of the Resource Book outlines the scope of the document and addresses the relevance of studying exercise in general as well as the specific question, why study exercise in animals? It explains how the use of animals in exercise protocols contained in the APS Resource Book fit into the context of U.S. animal welfare requirements, including the Animal Welfare Act, the Public Health Service Policy on Humane Care and Use of Animals, and the Institute of Laboratory Animal Resources Guide for the Care and Use of Laboratory Animals. Specifically, the APS Resource Book is intended to promote an informed dialogue that can help researchers

and their IACUCs arrive at satisfactory answers to questions about how to assure the welfare of animals in exercise research protocols.

Single copies of the APS Resource Book are available free of charge from OLAW while supplies last; contact OLAW to request a free copy. Copies also may be purchased for $9.50 from the APS store.

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NIH BALANCED SCORECARD GRANTEE SATISFACTION SURVEY: COMING IN MAY 2006

Starting in May 2006, you may be selected to participate in a Grantee Satisfaction Survey to asses the performance of NIH Grants Management Offices and Program Offices. Your feedback as a grantee is important to helping us improve the grants management function at NIH.

In 2000, NIH began undertaking periodic self-assessments based on Balanced Scorecard (BSC) methodology, a strategic management tool developed in recent years. BSC methodology attempts to evaluate a system's operation from multiple perspectives to provide an overview of the effectiveness of the operational process under review. In doing so, it identifies areas needing improvement and can further serve as tool for effective strategic management within an organization. All HHS Operating Divisions are now conducting assessments via BSC surveys. An NIH-wide Grantee Survey was last conducted in 2002.

The Grantee Satisfaction Survey is Web-based and by invitation only. The survey will be sent to a random sample of grantees, including Principal Investigators, Business Offices, and Program Directors, so more than one individual from an organization may be selected. Selected participants will receive an e-mail invitation which will include a link to the survey.

Survey respondents will be asked to evaluate both the Grants Management Office and Program Offices they interact with on all phases of the grants process from the pre-award phase to reporting and post-award administration, and overall satisfaction.

The contractor for this effort is LMI Government Consulting, located in McLean, VA. They will host the Grantee Survey on their servers and will contact those selected to participate directly. The Office of Extramural Research's Office of Policy for Extramural Research Administration is assisting LMI in coordinating the survey effort.

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NATIONAL LEADERSHIP FORUM ANNOUNCES WORKSHOP ON NIH ROADMAP—INVENTORY AND EVALUATION OF CLINICAL RESEARCH NETWORKS

The National Leadership Forum (NLF) will present findings from the NIH-sponsored Inventory and Evaluation of Clinical Research Networks (IECRN) on May 31 and June

1, 2006, at the DoubleTree Hotel in Rockville, MD. The NLF will discuss ways to improve the infrastructure of clinical research networks and make recommendations for increasing the efficiency and effectiveness of research networks. The target audience includes principal investigators, epidemiologists, behavior scientists, clinical study coordinators, pharmacists, biostatisticians, clinicians, data managers, bioinformatics and information technologists. Registration will be limited to the first 500 participants due to room capacity. The Forum is open to the public. The plenary sessions will be simultaneously Web cast. Details are available through the NIH Roadmap Web site.

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OHRP ANNOUNCES NEW WEB RESOURCE

The HHS Office for Human Research Protections (OHRP) invites you to visit the new OHRP human subject protections Web resource page. It provides links to reference documents, historical materials and Common Rule departments and agencies. Additional materials will be added as they become available.

OHRP encourages all in the research community to use this reference page.

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NATIONAL INSTITUTES OF HEALTH
Office of Extramural Research

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