The Office of Extramural Research

Supporting

NIH Office of the Director

NIH Institutes and Centers

Institutions and Investigators

Government Entities

The Public

providing the corporate framework for the NIH extramural research administration
The Office of Extramural Research provides the corporate framework for the NIH research administration and works to ensure the scientific integrity, public accountability, and effective stewardship of the NIH research grant portfolio.
# 2010 Office of Extramural Research (OER) Report
## Table of Contents

### A Message from the Director

### Introduction

### Program Stewardship

- **Peer Review Policy**
- **Program Policy**
- **New & Early Stage Investigator Policy**
- **Scientific Workforce**
- **Centralized Program Leadership**
  - American Recovery and Reinvestment Act
  - Research Training and Career Development
  - Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR)
  - Academic Research Enhancement Award (AREA)

### Scientific Integrity

- **Human Research Protections**
- **Research Animal Protections**
  - Assurances
  - Policy & Education
  - Compliance Oversight
- **Research Misconduct**
- **Intellectual Property & Resource Sharing**
- **Financial Conflict of Interest**

### Public Accountability

- **Grants Compliance & Oversight**
- **Grants Policy Development, Implementation, & Oversight**
- **Access to NIH Reports & Data / RePORT**
- **Public Access**

### Services and Infrastructure

- **Electronic Systems & Data**
  - Electronic Research Administration (eRA)
  - NIH Guide for Grants and Contracts
  - Reporting & Analysis
  - Research Condition & Disease Categorization (RCDC)
- **Communications**
  - Centralized Grants Information & Communications
  - Outreach to Research Community
- **Administrative Support**
  - Extramural Staff Support
  - Extramural Staff Training
  - Loan Repayment Program
A Message from Dr. Sally Rockey
Director, Office of Extramural Research

A Look Back at 2010, A Look Ahead to 2011

As you look through our second issue of the OER Report I hope you gain a deeper understanding of the breadth and depth of OER’s work and its critical role in many high profile initiatives in fiscal year 2010, while also garnering a taste of the projects that lie ahead for us in fiscal year 2011.

Last year was relatively quieter on the Recovery Act (the American Recovery and Reinvestment Act) front, as the two-year infusion of funds to jumpstart an ailing economy came to a close. We are proud to say that NIH obligated the entire $10.4 billion it received for the purpose—a herculean effort—but our work is not over and neither is that of our grantees. They are focusing on the science that will lead to advances in health, while also creating jobs and invigorating the economy. Our OER staff is doing its part, assisting grantees and monitoring the quarterly reporting that is required by the Recovery Act.

Fiscal year 2010 also marked a milestone for the NIH’s Enhancing Peer Review initiative, whose charge was to fund the best science, by the best scientists with the least administrative burden. OER spearheaded the implementation of the last set of major changes stemming from the initiative—the most notable being the shortening and realigning of grant applications with enhanced review criteria. We also embarked on a process of continually evaluating peer review, by surveying grant applicants, reviewers, council members and NIH staff on their reactions to the changes to the scoring system that were implemented during the initial round of changes in spring of 2009. Look for another round of surveys in 2010 asking about the more recent changes.

As we look to the future, you can also expect new rules governing financial conflict of interest. OER staff worked on and issued a notice of proposed rulemaking in May 2010 about these new rules. Since that time, we have been analyzing and incorporating the many comments we received and expect to issue the final rules—with the goal of promoting objectivity in research—in early 2011.

We are also looking at ways to standardize forms across federal agencies to make reporting easier on our grantee community. Our policy shop, in tandem with our systems and communications staff, partnered to launch the Federal Financial Report (FFR) in February 2011. The FFR replaces the Financial Status Report that is required for financial expenditures reporting. Also coming down the pike is the Research Performance Progress Report (RPPR), which will standardize information regarding interim reporting of scientific progress required of all federally funded research projects.

Certainly OER will be very involved in the organizational changes that are happening at NIH, including the creation of the National Center for Accelerating Translational Sciences (NCATS) and the Institute for Substance Use, Abuse and Addiction, as well as the expansion of services offered by the NIH Clinical Center to the extramural community.

On a more personal note, I recently started my own blog, Rock Talk, launching a new dialogue with our grantee community that will hopefully give the community new insight into the NIH perspective. I also hope to make more use of Webinars and other communication tools to help keep the information flowing to you despite the constraints imposed by tight fiscal times.

Here is to another great year ahead!

Sally J. Rockey, Ph.D.

NIH Deputy Director for Extramural Research
Director, NIH Office of Extramural Research

http://grants.nih.gov/grants/oer.htm
About OER: Making Grants Happen Without Funding a Single Project

Extramural grants represent more than 80% of the $31.2 billion NIH budget. Through its approximately 1,200 individuals and $112 million budget, the Office of Extramural Research (OER) provides the infrastructure that makes these grants happen. We provide the corporate framework for NIH research administration, ensuring scientific integrity, public accountability, and effective stewardship of the NIH research grant portfolio with the ultimate goal of preserving public trust in research.

Through interactions with major stakeholders, OER supports the research enterprise by ensuring appropriate policies, procedures and systems for oversight are in place while, at the same time, considering the impact on our research partners.

Our responsibilities span a wide breadth from developing policies and procedures, to providing approximately 600 administrative support staff to the NIH institutes and centers through the Division of Extramural Activities Support (DEAS), to providing electronic systems (eRA) for extramural staff and more than 100,000 investigators worldwide. For many of these activities we provide support for other agency partners as well.

The functions of OER are carried out through our six offices.

**Office of Laboratory Animal Welfare (OLAW):** Responsible for guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, support of educational programs, and monitoring compliance with the policy by assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities.

**Office of Policy for Extramural Research Administration (OPERA):** Provides leadership and oversight for grants management policy and compliance, intellectual property, and OMB clearances to the extramural research community and NIH extramural staff through policy development, expert guidance, analysis, outreach, and related information dissemination in order to promote effective stewardship of NIH extramural funds in support of health research.
Office of Extramural Programs (OEP): Provides leadership and expertise in science program management, including program and policy development, interpretation, coordination, oversight, evaluation, training, and outreach for the extramural research community and NIH extramural staff, promoting the highest quality and sustained capability of research and training programs in order to improve public health.

Office of Research Information Systems (ORIS): Provides IT systems, data and reporting support for grants processing for NIH and other agencies (HHS operating divisions, Food and Drug Administration, Veterans’ Administration, and others) and works with the user community to provide efficient techniques for the conduct of extramural business. This effort is intended to guide the management of the NIH research portfolio and improve the nation’s health.

Office of Administrative Operations (OAO): Serves as an organizational liaison by providing information, guidance, administrative support, and analytical services to ensure that OER obtains and manages the resources needed to carry out its mission. The Division of Extramural Activities (DEAS) resides within OAO and provides centralized support activities for grants management, program and peer review activities.

Office of Planning and Communications (OPC): Oversees OER evaluation and planning activities such as program evaluations, strategic planning, and other activities that cross OER units where centralized coordination will assist in developing policy or guidance. OPC supports the NIH and OER missions by providing NIH staff and the extramural research community with a central source of accurate and timely information on grants policies, processes and systems. It also coordinates much of OER’s federal-wide reporting and is involved in the Congressional appropriations process as it relates to OER.
Program Stewardship

Proactive Assessment of Trends & Development of Policies & Programs

Policy & Procedures
Development, Implementation, and Oversight

Program Stewardship
Scientific Integrity
Public Accountability

Systems & Data
Communications
Administrative Support
Education & Training

NATIONAL INSTITUTES
OF HEALTH
The NIH has a long-standing history of supporting the most promising and meritorious biomedical and behavioral research. Widely regarded as the premier system for peer review worldwide, the NIH peer review system has been adopted internationally as the best guarantor of scientific independence. Within NIH, OER develops, implements, coordinates, and oversees the policies and procedures that enable tens of thousands of outside experts to evaluate about 80,000 proposals each year. These policies and procedures ensure all proposals receive a fair, equitable, timely, and unbiased evaluation of scientific and technical merit.

**Major Accomplishments**

**Applications Shortened**
Recognizing the increasing breadth, complexity, and interdisciplinary nature of modern research, NIH recently evaluated the peer review system. OER played a major role in the implementation of enhancements to the system. This year, the shortening and restructuring of the application concluded the major implementation goals.

**Enhancing Peer Review Changes Evaluated**
The Enhancing Peer Review initiative was conceived as an ongoing process of refinement to ensure that the NIH peer review system continues to evolve as science evolves. To determine whether enhancements made to the peer review system increased transparency and reduced burden on applicants and reviewers, OER led the development of five stakeholder satisfaction surveys and administered them to applicants, reviewers, advisory committee members, and NIH staff members.

**IMPACT**
Aligning application structure and content with review criteria will help ensure that both reviewer and applicant expectations coincide for a more efficient and transparent application process.

**IMPACT**
Assessing the first phase of enhancements has informed refinements to the NIH peer review system and will inform future enhancements.

**For further information:** http://grants.nih.gov/grants/peer/peer.htm
OER functions as the locus at NIH for developing, implementing, coordinating, and overseeing policies and procedures that provide priorities and standards for the critical processes involved in issuing and monitoring research conducted under NIH awards. By developing and implementing program policies and procedures centrally, OER provides consistency across all the NIH institutes, centers, and extramural business areas. As policies change over time, OER maintains, on behalf of NIH, centralized resources for program staff. Ultimately, these policies and processes help ensure that NIH awards are fair, consistent and comply with publicized standards.

**Major Accomplishments**

**Community Collaboration**
OER worked closely with NIH program staff through various policy development and implementation committees of the trans-NIH Program Leadership Committee to ensure that appropriate attention was given to the impact of new and ongoing issues on program staff, such as use of human embryonic stem cells, changes resulting from the Enhancing Peer Review initiative, and international collaborations.

**IMPACT**
Input from the program community contributed to the decision to add an overall impact paragraph to peer review summary statements, providing applicants and NIH staff with additional information necessary to understand peer review outcomes.

Increased numbers of collaborations between NIH institutes and centers and foreign governments have highlighted the importance of guidance for institute and center staff to facilitate international agreements prior to the publication of funding opportunity announcements.

**Program Website Developed**
In collaboration with the Program Leadership Committee, OER drafted a Program Resources website that will provide an organized set of current information for program staff. The site differentiates between documentation appropriate to share with the public and internal guidance. The new website will integrate with the OER Extramural Intranet and launch in early 2011.

**IMPACT**
By aggregating the resources program staff need, the new website will help them more effectively and efficiently perform their daily tasks.

For further information: http://grants.nih.gov/grants/oer_offices/oep.htm
As innovators of the future, new investigators bring fresh ideas and technologies to existing biomedical research problems and pioneer new areas of investigation. Their entry into the ranks of independent, NIH-funded researchers is essential to the health of this country’s biomedical research enterprise. OER makes policy recommendations regarding NIH support of new investigators, most recently spearheading the establishment of a policy in support of early stage investigators (those within ten years of their terminal research degree or medical residency training) that provides special incentives to encourage earlier completion of training and achievement of independence.

**Major Accomplishment**

**Increased Numbers of Funded New and Early Stage Investigators**

Beginning in fiscal year 2009, NIH pledged to support new investigators on R01 awards at success rates equivalent to that of established investigators submitting new R01 applications. In fiscal year 2010, more than 30 percent of all investigators receiving competing R01-equivalent awards were new investigators (2,097), replicating entry rates for new investigators that have not been seen since 1986. In addition, the average age of new investigators with a Ph.D., which has been increasing since 1980, has leveled off at 42 years.

**IMPACT**

Policies that support new investigators allow early career researchers to compete successfully for funding.

The NIH has long recognized the importance of broad participation within the biomedical, behavioral, clinical, and social sciences research workforce. Maintaining a diverse, NIH-funded workforce will ensure that we recruit the most talented researchers from all groups. A diverse workforce improves the quality of the education and training supported, provides balanced perspectives related to research priorities, improves the ability to recruit clinical research subjects from all backgrounds, and increases the capacity to address and eliminate health disparities. All grantees are encouraged to consider talented researchers from all backgrounds, including racial and ethnic groups that are underrepresented in biomedical research, persons with disabilities, and women.

**Major Accomplishments**

**Scientific Workforce**

*Contact: Wally Schaffer*

**Workforce Composition Analyzed**

OER initiated a study to identify the benefits that might accrue from a diverse biomedical research workforce. It undertook a number of other analyses as well, publishing a study on the participation rates and attrition points by gender, race, and ethnicity and on the differences between application, success, and funding rates based on gender (in press).

**Family-Friendly Policies Implemented**

OER issued a new policy that increased the period of parental leave available under National Research Service Award (NRSA) training grants and fellowships, clarified federal policies related to parental leave and replacement support, and required recipients for NIH conference grant support to identify family care options at the conference site.

**IMPACT**

*Understanding the current workforce composition will allow NIH to adjust policies to encourage broad participation in NIH-funded programs.*

*The new policies will help retain newer investigators in the biomedical workforce.*

For further information: [http://grants.nih.gov/grants/oer.htm](http://grants.nih.gov/grants/oer.htm)
The Recovery Act designated approximately ten billion dollars directly to NIH for scientific research, scientific equipment, and intramural and extramural repair, improvements, and construction. OER played a pivotal role in the distribution of more than 20,000 awards by facilitating rapid funding opportunity development, developing policies and procedures for Recovery Act funding, implementing electronic systems to support the unique requirements of these awards, and communicating the constant stream of decisions, policies and processes to NIH staff and our extramural partners. OER has also played a leading role in NIH’s Recovery Act award monitoring, a federal-wide initiative to increase transparency into the ways Recovery Act dollars are spent.

Major Accomplishments

Jobs Created
Section 1512 of the Recovery Act requires those receiving support to report information on projects and activities funded on a quarterly basis to a federal website. OER conducted outreach and provided guidance to our grantee community to ensure their timely submission of these reports. In 2010, grantees submitted reports for more than 15,000 Recovery Act awards, for a compliance rate that consistently exceeded 99 percent.

Biomedical Research Stimulated
In August 2010, the vice president’s office published *The Recovery Act: Transforming the American Economy through Innovation*. Medical research was one of the four topics highlighted in the report and included NIH-supported research topics: the genomics of schizophrenia; the identification of genetic contributors to cardiovascular disease by sequencing the DNA of the long-running Framingham Heart Study; the expansion of the Cancer Genome Atlas Project to more than 20 types of cancer; and studies of the genomics and changes in brain structure of patients with Autism Spectrum Disorder.

Consistent with NIH’s goal to ensure an outstanding and diverse scientific workforce in biomedical, behavioral and clinical sciences, OER studies broad areas of the scientific workforce to determine need. Using this information, OER develops NIH policies for research training, fellowship and career development programs and assists institutes and centers in their implementation of new training programs. Serving as the NIH liaison to the extramural community on issues related to research training and scientific workforce development, OER represents 24 NIH institutes and centers that award more than $1.5 billion annually in support of more than 20,000 individuals.

**Major Accomplishment**

**Career Development Award Programs Studied**

Career development programs play a critical role at the end of the pipeline that delivers the next generation of biomedical researchers. This is especially true for physicians and physician-scientists as the economics of health care delivery places greater demands on their professional activities. During the past year, OER established and oversaw a comprehensive study of the effectiveness of the three major NIH career development programs. Career development awards target individuals who are about to embark on careers as independent scientists.

**IMPACT**

Compared to a similar group of scientists who did not receive NIH career grants, the recipients of these awards were found to be significantly more successful in continuing to publish important scientific discoveries, receive additional NIH research grant support, and remain in the biomedical research workforce.

The evaluation also yielded important demographic information on gender and race/ethnicity of the scientists supported by the career awards that will provide valuable information in future policy decisions related to the programs.

For further information: http://grants.nih.gov/training/extramural.htm
Small businesses play a vital role in stimulating technological innovation and U.S. economic growth. OER coordinates the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs across 23 NIH funding institutes and centers, providing oversight and implementation of policies, development of funding announcements, and outreach. The programs offer funding for small businesses to undertake cutting-edge research and development that has potential for commercialization and economic payoff. As mandated by Congress, 2.8 percent of NIH’s extramural research and development budget is set-aside for these programs, representing $690 million in fiscal year 2010.

**Major Accomplishment**

### Additional Small Businesses Funded

The American Recovery and Reinvestment Act allowed NIH to develop two new, one-time opportunities for small businesses. The Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Pilot Program addressed the funding gap between promising research and development and the transition to the market. The Small Business Catalyst Awards aimed to accelerate innovation through high risk, high reward research and development with commercial potential.

### Technical Assistance to Small Businesses Provided

Understanding that companies need to traverse what is often called the “valley of death” as they move their technology from the laboratory to the marketplace, OER created technical assistance programs to help bridge the gap. The Commercialization Assistance Program, now in its sixth year, provides expertise to help companies with business planning and commercialization strategies, as well as providing an opportunity for small businesses to present their technology to potential investors and strategic partners. The Niche Assessment Program provides third party assessment of appropriate market niches for products/services that are being developed.

**IMPACT**

*Nearly 100 awards were made to small businesses through these opportunities, catalyzing new research and development and spurring the transition of promising research to market.*

**IMPACT**

*In 2010, the Commercialization Assistance Program trained 80 awardees and the Niche Assessment Program provided assessment reports to 50 awardees.*

For further information: [http://grants.nih.gov/grants/funding/sbir.htm](http://grants.nih.gov/grants/funding/sbir.htm)
NIH has made a concerted effort to stimulate research in educational institutions that are not research intensive and do not receive substantial NIH support. Coordinated by OER, the Academic Research Enhancement Award (AREA) program supports small biomedical and behavioral sciences research projects conducted by faculty and students in health professional schools and other academic institutions. With a focus on hands-on, meritorious research, AREA awards help build research infrastructure at institutions that have not been major recipients of NIH research grant funds.

**Major Accomplishment**

**AREA Investments Increased**
Changes implemented last year that doubled funding limits from $150,000 to $300,000 and broadened institutional eligibility, as well as additional Recovery Act funding, stimulated interest in the AREA program in fiscal year 2010. There was a 19 percent increase in the number of applications reviewed in fiscal year 2010, with a total 2010 investment of $52.35 million. This represents an increased investment in AREA awards by $15 million, up from $37.3 million in 2009.

**IMPACT**
AREA grants create research opportunities for scientists and institutions otherwise unlikely to participate extensively in NIH programs, allowing them to contribute to the nation’s biomedical and behavioral research effort.
Scientific Integrity

Authoritative Point of Contact for Arbitrating Research Conduct Issues

- Program Stewardship
- Systems & Data
- Communications
- Administrative Support
- Education & Training
- Public Accountability

Policy & Procedures
Development, Implementation, and Oversight
The NIH Extramural Human Research Protections Program conducts activities to ensure the compliance of NIH grantees with federal regulations and NIH policies regarding the protection of human subjects in extramural research. OER staff assesses the proposed resolution of human subjects concerns identified during the peer review process and reconcile all grant applications that have a bar to funding due to human subjects concerns. They develop policies and procedures to ensure that participants in NIH-funded research are adequately protected and train NIH extramural staff and the extramural scientific community on human subjects protections.

**Major Accomplishments**

**Workflow Metrics and Tools Developed**
Annually, OER receives large numbers of requests to assess proposed resolution of human subjects concerns on grant applications. In fiscal year 2010, OER developed and implemented new electronic tracking tools to improve the efficiency of these requests and to better manage staffing.

**Impact**

OER resolved a higher proportion of requests by the end of the fiscal year than in prior years (87 percent resolved by end of fiscal year 2010 compared with 69 percent resolved by end of fiscal year 2009).

OER reduced the time from submission of request to assessment to three weeks in fiscal year 2010, as compared to four to six weeks in fiscal year 2009.

**Outreach Program Launched**
Educating the extramural community on human subjects protections is critical to ensuring compliance with policy. In fiscal year 2010, OER launched a new program to reinvigorate outreach on human subjects protection targeted at both NIH staff and the extramural community. Part of these efforts involved reestablishment of the NIH-wide Human Subjects Protection Liaison Committee and developing a Spanish version of the online human subjects training.

**Impact**

More than 223,700 individuals took the online training in human subjects protection.

Since becoming available in August 2010, more than 1,600 individuals have taken the Spanish version of the online human subjects protection training.

Institutions that receive support for research involving laboratory animals from NIH must provide a written assurance and submit annual reports consistent with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. To assess the adequacy and accuracy of each institution's compliance with the policy, OER's Office of Laboratory Animal Welfare (OLAW) staff review all annual reports and conduct site visits to select institutions. Additionally, OER staff provide training for NIH extramural program staff and the extramural scientific community on the assurance process and the role of OER in the oversight of grants and contracts involving animal activities.

**Major Accomplishment**

**Institutional Animal Programs Evaluated**

OER conducted a cross-sectional evaluation of all NIH-supported institutions that house chimpanzees. The objectives of the evaluation were to determine whether the institutions' programs and facilities for the care and use of the animals were consistent with their animal welfare assurance with OLAW and to evaluate the current state of social housing, husbandry, enrichment, veterinary care, and training practices.

**Sample Assurance for Foreign Institutions Updated**

In a foreign assurance, the institution agrees to conduct their animal care and use program in compliance with the policy, or the institution provides evidence that acceptable standards for the humane care and use of the animals in Public Health Service conducted or supported activities will be met.

**IMPACT**

Conducting site visits provides assurance that institutions are in compliance with applicable policies and regulations, and ensures that the quality-of-care and commitment to the psychological well-being of the animals is high.

**IMPACT**

OER released an updated animal welfare assurance for foreign institutions, clarifying essential information for institutions with the goal of enhancing institutional compliance with the requirements.
OER is responsible for a national education program to promote the highest standards of animal care and use in Public Health Service-supported research, teaching and testing. Approximately 50 percent of the NIH extramural portfolio includes activities that involve animal subjects, thus education in quality animal care and use standards to promote both quality science and humane research is imperative. Some of the educational programming OER provides includes one-day and two-day workshops at locations across the U.S., online seminars, and Web and hard copy resources.

**Major Accomplishments**

**National Symposium Organized**
NIH served as the lead agency with the U.S. Department of Agriculture (USDA) and Institutional Animal Care and Use Committee 101 in the development of a three-day, national symposium recognizing 25 years of biomedical research conducted under the Public Health Service Policy on Humane Care and Use of Laboratory Animals and the USDA Animal Welfare Act and regulations. A total of 650 attendees participated in the multiple symposium sessions that featured talks and panel discussions by more than 40 nationally recognized animal welfare and policy experts, and basic and translational biomedical researchers.

**Application Assistance Provided**
For each submitted application that involves the use of animals, applicants must describe how they will ensure the humane care and use of the animals used in their research. To assist applicants in writing this section of their application, OER staff developed checklists and supporting materials.

**IMPACT**
The symposium recognized the valuable contributions researchers and policy makers have made to the history, current practices, and future of research animal care.

**IMPACT**
Providing a checklist of items that must be covered in this section of the application helps applicants ensure they are in compliance with the requirements.

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**For further information:** [http://grants.nih.gov/grants/olaw/olaw.htm](http://grants.nih.gov/grants/olaw/olaw.htm)
OER oversees compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals for all institutions that receive support for research involving the use of laboratory animals. With approximately half the grants in the extramural research portfolio including a component that involves animal subjects (nearly 22,000 grants in 2010), education is key to ensuring compliance. OER provides guidance and policy interpretation to research institutions, investigators, federal officials, and the public. Additionally, OER investigates reports of noncompliance from third parties and institutional self-reports, working with institutions to assess corrective plans that facilitate resolution of problems and to prevent recurrences.

**Major Accomplishment**

**Compliance Cases Closed**
Each awardee institution has an Institutional Animal Care and Use Committee, or performs it’s animal activities at an institution that does. The Institutional Animal Care and Use Committee reports to NIH any serious noncompliance with applicable animal welfare policies. NIH either acknowledges the institution’s report of noncompliance and accepts the proposed corrective/preventive action or notifies the institution of the possible noncompliance, and, as necessary, requests that the institution investigate the matter and report back by a specified date. These self-reports in combination with third party reports resulted in 694 compliance cases opened between October 1, 2009 and September 15, 2010. During the same period, 661 cases were evaluated and closed.

**Compliance Evaluation Outcomes**

- Operating in accordance with applicable policies
- Operating in accordance with applicable policies but certain actions to enhance compliance recommended
- Approval of an institution's assurance restricted
- Approval of an institution's assurance withdrawn

**DCO Caseload by Year**

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**IMPACT**

Ensuring institutions comply with all applicable policies regarding the care and use of laboratory animals results in increased accountability to the public.
NIH’s Agency Extramural Research Integrity Officer in OER conducts a preliminary review of each allegation of research misconduct received by NIH extramural staff or involving NIH-supported extramural research and forwards it, as appropriate, to the HHS Office of Research Integrity, which has ultimate investigative authority. OER also has responsibility for other aspects of research integrity, such as training grantees in the responsible conduct of research, creating and implementing policies for protection of human subjects and vertebrate animals in research, ensuring compliance with grants policy, and sharing of research data.

Major Accomplishment

New Website Launched
The new NIH Research Integrity website provides comprehensive information on research integrity and research misconduct for applicants, staff and the press. An associated staff intranet details internal policy and procedures for staff. Flowcharts help the community and staff understand the processes and various roles and responsibilities involved in handling reports of research misconduct.

IMPACT
The policies and processes whereby the NIH handles allegations of research misconduct involving NIH-supported extramural research were not well documented across NIH websites.

IMPACT
The centralized availability of this information fosters compliance and increases the transparency of the NIH extramural program’s handling of research misconduct allegations.

For further information: http://grants.nih.gov/grants/research_integrity/
OER serves as the central NIH point of contact for the extramural research community on extramural intellectual property and resource sharing issues. By developing, implementing and monitoring policies for extramural invention reporting, resource sharing, and related intellectual property issues, OER works directly with the scientific community to facilitate the advancement of inventions and resource sharing to further research and public health. In addition, OER provides NIH staff with expert guidance, tools, and support for advancing resource sharing and invention reporting.

**Major Accomplishment**

**iEdison Enhanced**

Along with providing expert guidance and support for compliance, OER hosts [iEdison.gov](http://iEdison.gov), the premier federal-wide repository of information on inventions developed under federal funding agreements. A confidential, electronic reporting system, iEdison serves the NIH and more than 29 other federal agency offices. This year, OER worked with various offices to enhance iEdison’s infrastructure and accessibility to improve invention reporting oversight by the federal government.

**IMPACT**

iEdison supports the utilization of inventions arising from federally funded research in accordance with the goals of the Bayh-Dole Act.

In 2010, more than 8,500 federally funded inventions were reported into iEdison, 5,577 of which were NIH-supported inventions.
OER provides oversight, policy interpretation, and guidance to NIH staff and to the extramural grantee community to promote objectivity in research and ensure research is not biased by any conflicting financial interest. Some of these activities include developing web-based resources, conducting compliance activities, responding to public inquiries, and conducting outreach. In addition, OER acts as the focal point for policy development and institutional oversight of the financial conflict of interest (FCOI) regulation (45 CFR Part 50 Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought).

**Major Accomplishment**

**Notice of Proposed Rulemaking Issued**

OER has led the effort to revise and update the original financial conflict of interest regulation on behalf of NIH and HHS. On May 21, 2010, NIH issued a notice of proposed rulemaking soliciting public comments on proposed changes to the regulations. Following the close of the comment period, OER reconvened a trans-NIH task force to consider comments received in response to the proposed rule and to develop a new final rule. A final rule is expected in 2011.

**IMPACT**

*Strengthening the existing regulations is key to assuring the public that NIH is taking a rigorous approach to managing the essential relationships between the government, federally funded research institutions, and the private sector.*

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**Financial Conflict of Interest**

*Contacts: Diane Dean, Kathy Hancock, and Joe Ellis*

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**How a New Rule Is Made**

1. Publish an Advanced Notice of Proposed Rulemaking in the Federal Register (optional)
2. **Public Comment Period**
3. Publish a Notice of Proposed Rulemaking in the Federal Register
4. **Public Comment Period**
5. Publish the Final Rule in the Federal Register

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**FCOI Reports**

- 2002: 0
- 2003: 200
- 2004: 400
- 2005: 600
- 2006: 800
- 2007: 1,000
- 2008: 1,200
- 2009: 1,200
- 2010: 1,200

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Consistent Monitoring & Oversight Process for Policy Development & Compliance

Policy & Procedures
Development, Implementation, and Oversight

- Program Stewardship
- Scientific Integrity
- Public Accountability
- Systems & Data
- Communications
- Administrative Support
- Education & Training
NIH and its recipient institutions share responsibility for compliance and oversight to ensure proper stewardship of federal funds. OER promotes NIH staff and grantee compliance with policies and legislative mandates and enhances compliance oversight. OER also oversees and manages the NIH Grants Management Professional Certification Program, which ensures that NIH grants managers are highly trained, competent professionals. Education and outreach are key components of compliance, to which OER devotes significant time and resources.

### Major Accomplishments

**Review of Out-of-Rank Funding Conducted**
Both the NIH and the General Accounting Office have determined out-of-rank funding to be an NIH-wide risk. In fiscal year 2010, OER conducted an NIH-wide review of internal controls over out-of-rank funding to determine compliance with HHS and NIH policy requirements and to identify good practices. This effort is part of a larger management control program to review NIH institute and center compliance with NIH-wide grant policies.

**Response Prepared to Improper Payment Information Act**
A new presidential executive order in fiscal year 2010 brought increased attention to the issue of improper payments. OER conducted an assessment of risks in the grants management arena that could result in improper payments and coordinated preparation of a response to the fiscal year 2010 Improper Payment Information Act for NIH’s extramural research and career development grant programs.

**IMPACT**
*Proactive internal controls helps NIH identify and address risks before they become compliance problems and/or audit issues.*

**IMPACT**
*Continual assessment of risks helps ensure proper stewardship over NIH grant funds.*
OER coordinates the development, implementation and oversight of NIH and applicable federal grants policies as they affect the NIH grants process. Representing NIH on federal-wide emerging initiatives and priorities, OER is uniquely positioned to develop and issue new NIH grant policies and procedures. By developing grants policies and procedures centrally, OER provides consistency across all the NIH institutes and centers and extramural business areas. As policies change over time, OER maintains, on behalf of NIH, policy resources such as NIH Manual chapters and Grants Administration Manual chapters, the NIH Grants Policy Statement, and intranet and internet websites.

**Major Accomplishments**

**NIH Grants Policy Statement Revised**
In 2010, OER updated the NIH Grants Policy Statement, a consolidated resource of all the policies and procedures that apply to NIH grant awards. Last revised in 2003, this 2010 version was an extensive undertaking lasting three years as input was sought from subject matter experts across NIH and other HHS offices.

**IMPACT**
A term and condition of all NIH grants, the revised Grants Policy Statement gives the grantee community a comprehensive and current resource of grants policies.

With new chapters on multiple investigators and career development awards and a new robust chapter and section/subsection numbering system, the revised Grants Policy Statement provides substantially improved usability.

**Electronic Progress Reports Expanded**
In an ongoing effort to implement electronic business processes, OER mandated the use of eRA Commons to submit the majority of annual progress reports electronically. OER also developed the business process and systems needed to accommodate electronic submission of annual progress reports for projects whose budget period spans more than one year, so-called multi-year funded awards.

**IMPACT**
Before 2010, NIH had no consistent business process in place and no electronic way to notify about or receive progress reports for multi-year funded awards. These efforts will be critical for assuring the proper oversight of all multi-year funded projects.

Electronic business processes improve efficiency for both grantees and NIH staff.

For further information: http://grants.nih.gov/grants/policy/policy.htm
On behalf of NIH, OER hosts the Research Portfolio Online Reporting Tools (RePORT) site, which provides the public with a comprehensive view of NIH programs. The site serves as a one-stop portal with unprecedented access to reports, data and analyses of NIH-funded research and training programs, including detailed information on NIH expenditures and on the results of NIH-supported research. Through a single user interface, RePORT provides access to a variety of databases and reports separately maintained across multiple NIH websites, including the NIH Biennial Report of the Director, funding by areas of research, conditions and diseases, IC strategic plans, and funding maps.

**Major Accomplishments**

**ExPORTER Launched**
The Research Portfolio Online Reporting Tools’ Expenditures and Results (RePORTER) database provides the public with a way to query NIH awards and find detailed information on NIH expenditures and on the results of NIH-supported research. For the first time, OER made the information in this database available in its entirety to the public this year for download through an export utility called ExPORTER.

**IMPACT**
Designated as one of four Department of Health and Human Services high-value data sets, ExPORTER is featured on the HHS Open Government website and on Data.gov.

The ability to download NIH’s RePORTER database allows for extensive analysis of NIH funding by researchers, science policy analysts, and institutions.

**Awards By Location Released**
The Awards by Location mapping tool provides a new way for the public to visualize where NIH-supported institutions are located, view the grants and contracts each institution received, and obtain detailed project descriptions from RePORTER.

**IMPACT**
By providing easy-to-use self-help capabilities, Awards by Location allows NIH to provide the public with the information it seeks.

To facilitate the analysis of award data by the public, the results can easily be exported into spreadsheets.

For further information: http://report.nih.gov
Quick and broad access to scientific publications enables faster information dissemination and thereby advances biomedical research and improves human health. The NIH Public Access Policy ensures that the public has access to the results of NIH-funded research by requiring investigators to submit a copy of their final peer-reviewed journal manuscript to the National Library of Medicine’s digital archive, PubMed Central. The policy also requires the article to be made available to the public no later than 12 months after the date of publication. The public has free access to all the journal literature in PubMed Central, a trove that contains more than two million articles.

**Major Accomplishment**

**Citation Management Improved**

To provide investigators a better way of managing their citations, OER forged a new partnership that allows investigators to use a National Center for Biotechnology Information online feature called “MyBibliography” to populate eRA Commons with their publication information. The linking of the two systems allows investigators to associate papers with grants, manage compliance with the public access policy, and start the manuscript submission process.

**IMPACT**

The partnership allows scientists to quickly and efficiently create and manage their professional bibliographies in relation to their NIH grants.

The new feature supports oversight of and compliance with the NIH Public Access Policy, increasing the amount of scientific research results freely available to the community.

**Public Access**

*Contacts: Lynn King, Neil Thakur, and Dorit Zuk*
SERVICES & INFRASTRUCTURE

Essential Foundation for Day-to-Day Grants-making

Program Stewardship  Scientific Integrity  Public Accountability

Policy & Procedures
Development, Implementation, and Oversight

Systems & Data  Communications  Administrative Support  Education & Training
The Electronic Research Administration (eRA) provides information systems to support full life cycle grants administration. eRA supports 28 complementary electronic modules facilitating the receipt and referral of grant applications, review, award and post-award reporting. eRA partners with the extramural business community to anticipate customer requests and policy changes, while processing over $30 billion in grants awarded annually by NIH (and eRA’s partner agencies) in support of NIH’s mission of improving human health.

**Major Accomplishments**

**Financial Systems Integrated**
OER partnered with stakeholders across NIH budget, grants management, systems, and administrative business areas to implement funds control in NIH systems. This very large effort of integrating the NIH Business System, the Center for Information Technology, and the Office of Financial Management systems allows grants management and budget staff to track their grant obligations and prohibit awards beyond funding limits in real time.

**IMPACT**
Unprecedented coordination among multiple NIH systems will ensure compliance with congressional and executive branch mandates to implement systemic funds control.

**Innovative Scientific Content Matching Tool Launched**
The newly developed “Like” feature of the NIH staff QVR electronic reporting tool uses a sophisticated algorithm to mine the science from grant applications to match it to the expertise of scientists and their publications or find applications scientifically similar to a selected grant application.

**IMPACT**
The QVR“Like” feature has enabled extramural NIH staff to quickly identify reviewers, find scientifically similar grants, and identify areas of science that have not previously received scientific funding, often saving weeks of time per search.

For further information: [http://era.nih.gov/](http://era.nih.gov/)
To notify applicants of NIH funding opportunities and policy updates in support of biomedical and health-related behavioral research, OER publishes the NIH Guide for Grants and Contracts. OER reviews, processes, and publishes funding opportunity announcements and notices daily on behalf of all NIH institutes and centers, representing more than $30 billion in NIH investments in medical research. Nearly 40,000 scientists and administrators from universities, medical schools, and research institutions in the U.S. and around the world subscribe to the Guide. The NIH Guide for Grants and Contracts serves NIH and nine sister agencies within the Department of Health and Human Services.

**Major Accomplishments**

**More Guide Postings Processed**
OER staff review every funding opportunity and notice released in the NIH Guide for Grants and Contracts to ensure announcements are in compliance with applicable regulation and policy, and to promote consistency across the NIH.

**Funding Opportunity Format Simplified**
OER sought input from more than 1,000 stakeholders, including other federal agencies and university grant administrators, to simplify and shorten NIH funding opportunity announcements. The resulting shorter format eliminates redundancy, limits the amount of administrative detail, and directs applicants to the most up-to-date source of information.

**IMPACT**
OER review improves the quality and consistency of funding opportunity announcements and notices and helps to ensure that applicants have the information they need for successful submission.

In 2010, OER processed 1,104 funding opportunity announcements and policy updates, representing a twelve percent increase over 2009.

**IMPACT**
Shorter, simplified funding opportunity announcements have been lauded by the scientific community for making it easier for applicants to find the information they need to apply for funding.

OER provides data, analyses and reports on NIH’s research investments to support strategic decision-making and provide public information and accountability. Detailed information on grants, contracts and intramural research are disseminated to other federal agencies, academia, Congress, the media, non-profit organizations, and the public. This data is used to assess and communicate trends on the NIH-supported workforce and research projects; ensure NIH compliance with federal regulations; generate information for budget hearings; inform NIH policy development; and supply external researchers with data to publish their own analyses of NIH’s research portfolio.

**Major Accomplishment**

**Research Knowledge Production Measured**

NIH research knowledge production, as measured by publications citing NIH grant support, grew from 2001 to 2009. However, the growth rate in publications was higher immediately after the doubling of the NIH budget as compared to later in the period when the budget was flat.

**Criterion Scores Analyzed**

A sophisticated, multivariate analysis on “How Criterion Scores Influence the Overall Impact Score for NIH Peer-Reviewed Applications” provided NIH staff and external audiences new insights on how the criterion scores influence peer review outcomes.

**IMPACT**

The analysis confirmed that NIH grantees are highly efficient producers of research knowledge, and amongst new grants that generated publications, about two-thirds were cited by papers published within the first three years of funding.

**IMPACT**

These evaluations support the continuous assessment of peer review, providing NIH leadership with knowledge to guide future policy decisions on how to improve the peer review process.

For further information: http://report.nih.gov
The Research Condition and Disease Categorization (RCDC) system provides a consistent, NIH-wide categorization process for all extramural grants, intramural projects, research and development contracts, and inter/intra-agency agreements. RCDC currently provides project and funding data for more than 270 research categories as mandated by Congress. This data populates many NIH systems, and it is used to generate spending totals and project listings for other reports requested by Congress or required by the Department of Health and Human Services or the Office of Management and Budget. RCDC allows for reproducible reporting, provides transparency, improves public understanding of NIH spending on research, and promotes public trust in NIH.

**Major Accomplishments**

**Data Mining Expanded**
OER is using fingerprinting in new ways to help NIH assess its portfolio, and, for the first time, OER fingerprinted publications associated with the last 10 years of NIH grants.

**IC-Defined Fingerprinting Capability Developed**
The RCDC system now allows NIH institutes and centers to develop their own fingerprint categories. Replacing or supplementing their own coding systems, the RCDC system can also be used as a tool to handle ad hoc requests for information in research areas not typically tracked at NIH.

**IMPACT**
Fingerprinting applications and publications enabled the development of an innovative feature that allows NIH staff to electronically find grant applications and publications similar to a selected base application. (see Electronic Research Administration page)

**IMPACT**
The creation of custom RCDC fingerprints provides NIH staff a tool that can change and adapt to individual institute or center needs and the changing nature of biomedical research.

For further information: [http://report.nih.gov/rcdc](http://report.nih.gov/rcdc)
OER provides NIH staff and the extramural research community with a central, authoritative source of information on NIH grants. OER makes available collections of comprehensive communication resources for use by the research community to reduce redundant resource development and provide clear, common messages for use in the education and outreach efforts of grantee institutions and NIH institutes and centers.

**Major Accomplishments**

**Web Resources Expanded**
OERs public and staff Intranet websites provide vast amounts of information to the extramural community. In addition to maintaining information on the existing sites, this year OER developed a number of brand new sites, such as pages for foreign grants information, research integrity, podcasts, and the stem cell registry. OER significantly enhanced content in its redesign of the eRA and Applying Electronically websites and gave the main OER grants home page a mini face-lift to make it friendlier and easier to use.

**Essential Tools Developed**
OER regularly develops tools to facilitate communications and interactions with the extramural community. In 2010, OER developed the database system for submission, review, and approval of stem cell lines for use in NIH funded research. It has also facilitated the work of NIH management committees and working groups by establishing an OER SharePoint site.

**IMPACT**
The extramural community accessed OER’s roughly 44,000 Web pages/documents approximately 1.4 million times per month in fiscal year 2010.

**IMPACT**
In addition to facilitating stem cell line submission, the registry provides transparency into the approved stem lines and facilitates their use by grantees.

Hosting SharePoint allows OER to provide trans-NIH management committees and working groups new and enhanced abilities to collaborate and manage their own information.

For further information: [http://grants.nih.gov](http://grants.nih.gov)
OER's outreach programs are a critical component of the overall communication strategy with the extramural community. OER-sponsored seminars and events reach more than 3,000 scientists and research administrators annually, providing NIH with opportunities not only for proactive and targeted information dissemination, but also for listening to the needs of the communities we serve. This dialogue provides a common understanding of the funding process and enhances compliance with grants policies, ultimately leading to support of better science and improved health.

**Major Accomplishment**

**Podcast Series Released**

Launched in April 2010, All About Grants is OER's first podcast channel. Designed for investigators, fellows, students, research administrators, and others, the goal of each podcast is to provide insights on grant topics through informal conversations with NIH staff members well versed in the topic at hand. Each episode is available for download via iTunes and the OER website, or those who are interested can subscribe to the RSS feed and get episodes delivered automatically to their computer or mp3 player. Between April and September 2010, OER released 12 episodes explaining the types of funding early stage investigators might be considering and what actually happens during the application review process.

**IMPACT**

Using podcasts as a new way to disseminate information, OER accommodates the broadening learning styles of our current and future grantees.

Between May and July 2010, hits per month on the RSS feed tripled, with more than 12,000 total downloads.
OER provides extramural staff support through the Division of Extramural Activities Support (DEAS) to 25 NIH institutes and centers (ICs), servicing $15 billion of extramural grants. More than 600 employees support approximately 3,000 extramural scientists. DEAS is a centrally managed organization with most staff located at the ICs. This structure provides a conduit for assessing trans-IC business processes and encourages knowledge sharing of best practices, operational improvements, and workload management, while maintaining the structural framework for activities to be operated and monitored centrally. In addition, centralized recruitment and training programs for all extramural support staff assures continuity and consistency of service across all NIH institutes and centers.

**Major Accomplishments**

**Reporting Assisted**
A subset of applications funded by the Recovery Act were renegotiated to fit within the two-year Recovery Act award time frame. For these 600 plus applications, DEAS staff members helped to ensure that the renegotiated specific aims were captured accurately by the NIH’s Research Condition and Disease Categorization (RCDC) system.

**IMPACT**
Assistance from DEAS staff ensured that NIH could meet its congressional mandate to accurately and transparently report on the types of research funded.

**Closeout Backlog Relieved**
DEAS serves as a central coordination and receipt location for documents to be submitted from grantees or principal investigators. The Closeout Center provides closeout of grants and cooperative agreements for all 24 NIH institutes and centers that make awards.

**IMPACT**
In fiscal year 2010, the Closeout Center closed 11,892 grants, a decrease from 2009 reflecting fewer backlogged grant closeouts.

For further information: [http://grants.nih.gov/grants/oer_offices/suboao_deas.htm](http://grants.nih.gov/grants/oer_offices/suboao_deas.htm)
OER develops and provides introductory and continuing staff training on policy and procedure for NIH’s extramural staff. This training provides background information on policies, outlines staff responsibilities, and equips staff with the knowledge they need to conduct the technical administration of grants and contracts. Training opportunities range from special seminars of interest to all NIH extramural staff to specific training for program officials, review officials, the grants management community, and extramural support staff.

**Major Accomplishment**

New Segment to Core Curriculum Added
Research and development (R&D) contracts are a key component of NIH's extramural programs. OER added a new segment (Part 5) to the core curriculum, “NIH Extramural R&D Contracting Policy and Procedure,” to ensure that new staff members receive orientation into how this key mechanism fits into their portfolio.

Extramural Support Staff Trained
The OER Division of Extramural Activities Services provides a fully integrated and strategic organizational, leadership and workforce development program, offering 108 customized courses covering 42 different competencies in addition to extensive leadership and executive coaching.

**IMPACT**
Ensuring staff work within the Federal Acquisition Regulations helps ensure appropriate stewardship over federal research and development contracts.

In one day, 235 staff members received training on the research and development contracting process.

**IMPACT**
The training team is continually sought out by other NIH training programs for advice, consultation and course facilitation.

For further information: http://grants.nih.gov/grants/oer.htm
The NIH Loan Repayment Programs (LRPs) repay qualified educational debt of biomedical and behavioral scientists in exchange for a two-year research commitment. OER administers the application and financial review process for approximately 3,500 applications and provides services for program participants on behalf of 23 NIH institutes and centers. Initial evaluation has shown that program participants stay in research careers longer, apply for and receive more research grants, and become independent investigators more frequently than peers without LRP funding.

### Major Accomplishments

#### Policies Streamlined

To simplify benefits and increase the number of funded researchers, OER no longer requires participants to pay a portion of their debt, has ensured quarterly payments will remain constant over the life of the contract, and specified that only the 39 percent tax payment required by law will be paid by NIH.

#### Professional Development Programming Initiated

This year, OER developed the NIH LRP Ambassador Network to serve as a bridge between past and future participants through the sharing of success stories, program experiences and application tips. Alumni participated in the outreach by informing colleagues about the LRP opportunity. As of October 2010, 378 alumni have registered.

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**Applications, Awards, and Success Rates**

<table>
<thead>
<tr>
<th>LRP</th>
<th>New Funds</th>
<th>Renewal Funds</th>
<th>Total Funds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research</td>
<td>$25.2M</td>
<td>$15.0M</td>
<td>$40.3M</td>
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<tr>
<td>Pediatric Research</td>
<td>$10.6M</td>
<td>$7.6M</td>
<td>$18.2M</td>
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<tr>
<td>Health Dispar. Research</td>
<td>$9.1M</td>
<td>$4.0M</td>
<td>$13.1M</td>
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<tr>
<td>Individuals w/ Disadvantaged Backgrounds</td>
<td>$0.62M</td>
<td>$0.31M</td>
<td>$0.94M</td>
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<tr>
<td>Contraception &amp; Infertility</td>
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<td>$0.20M</td>
<td>$1.1M</td>
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<tr>
<td>Total</td>
<td>$46.5</td>
<td>$27.1M</td>
<td>$73.6M</td>
</tr>
</tbody>
</table>

**Percent of Total Awards by LRP**

- Clinical Research (55%)
- Pediatric Research (25%)
- Health Disparities Research (18%)
- Clinical Research for Individuals from Disadvantaged Backgrounds (1%)
- Contraception and Infertility Research (1%)

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**IMPACT**

- These policy changes will result in 60 to 100 additional researchers funded in calendar year 2011.
- Evaluations have shown that a vast majority of applicants hear about the program from colleagues and mentors.

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**For further information:** [http://www.lrp.nih.gov/](http://www.lrp.nih.gov/)
To view the 2010 Office of Extramural Research Report online, please visit:


To view the Accessible 508 Compliant Version online, please visit:
