



2011-2012 OER REPORT

NATIONAL INSTITUTES OF HEALTH 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



grants.nih.gov



Dedicated To the Memory of
Milton J. Hernández, PhD
1943 - 2012

In 2012, the Office of Extramural Research lost a dear member of its workplace family, Dr. Milton J. Hernández. Milton was the Director of the NIH Loan Repayment Programs (LRP) when he passed away on June 14, eighteen months after his diagnosis with pancreatic cancer. Milton was an extraordinary man, friend and NIH colleague. He was also a pioneer in the pursuit of diversity in the biomedical workforce, beginning with his own extraordinary career path in the early 1970s.

Earning a research doctorate degree in zoology from Texas A&M University in 1971, Milton was one of less than 25 Hispanic-Americans to do so that year. Putting this remarkable accomplishment in perspective, by 2012, there were over 350 PhD degrees in biological science earned by Hispanic-Americans. For almost two subsequent decades, he enjoyed a very successful academic career at both Penn State Hershey Medical Center and Howard University, before joining the NIH in 1988.

Of his initial NIH experiences Milton was quoted once as saying “since my heart was really in training, I took a position with NIAID (where) I was in charge of training grants, fellowships, career development awards and diversity programs.” Typical of Milton, his reflection on this experience at NIAID was greatly understated. In fact, Milton’s tenure at NIAID included his shepherding a new Career Award Program, a precursor to our present-day, and very popular, NIH Pathway to Independence Program. In overseeing this program, he was passionate about personally advising his young awardees in all matters concerning their professional development. He treated each grantee with personal attention in advising ways to navigate the academic hiring labyrinth. His extensive understanding and knowledge of academic institutions’ incentives, practices and policies in faculty hiring were invaluable to countless young scientists.

Milton’s dedication extended to helping to develop individual careers and the biomedical science workforce to his most recent position at the NIH Loan Repayment Center. He led the NIH LRP for only three years, yet his tenure will have a lasting impact. He understood biomedical research training issues at the national level, and championed the LRP’s tremendous benefits for young biomedical scientists with large educational debts. Among his accomplishments leading LRP, Milton created the LRP Ambassador Network to mobilize successful past LRP recipients to help spread the word about the program. He implemented policy changes that streamlined the business operations underpinning the LRPs, allowing NIH’s institutes and centers to increase the number of awards they supported.

Milton was always cheerful and took a thoughtful approach to challenges large and small. He was admired both professionally and personally by those who worked with him. Milton’s death was a huge loss for the NIH, but especially for the Office of Extramural Research.

Milton will be deeply missed. We dedicate this report to him.

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A Message from Dr. Sally Rockey Director, Office of Extramural Research

A Look Back at 2011-2012

As I look back on the last two years, I am proud of the impact OER has made on ensuring sound program stewardship of the grants portfolio, scientific integrity, public accountability, transparency, open communications and in giving careful thought to the future of the biomedical workforce.

I found my online voice with my Rock Talk blog and struck up a conversation with the extramural community that has been richly rewarding and, I hope, evidence of the transparency that I want as a centerpiece of my tenure at NIH.

We began a huge effort to examine the future of the biomedical research workforce and have been planning ways to ensure its sustainability. Along with a sustainable workforce, OER was heavily involved with the efforts to understand biomedical workforce diversity. The analyses we have undertaken to help us better understand and be able to characterize the workforce have been enlightening. I have enjoyed sharing this information and seeing readers' own interpretation of and reactions to the data on the blog.

In a related analysis, OER developed the first census of the NIH extramural research workforce, which provides new insights into the occupations, age and education of NIH-funded researchers.

On the scientific integrity and program stewardship fronts, OER issued a revised policy for managing reviewer conflict of interest at the first level of peer review, designed to effectively manage bias in this critical process. We also evaluated the peer review changes we had implemented in 2009, through detailed surveys of grant applicants, peer reviewers and Advisory Council members; changes were implemented to improve the peer review process as a result of the Phase I survey, while the Phase II survey results are under consideration. On another front, OER established new processes for tracking and managing allegations of research misconduct to ensure research integrity.

We helped stand up the new National Center for Advancing Translational Sciences (NCATS) by leading the extramural policy and process aspects of issuing new NCATS grants within 3 months and redistributing grants from the dissolved National Center for Research Resources (NCRR) to 12 other Institutes and Centers. We laid the foundation for research administration for the NIH-FDA Tobacco Research Program, to assist in conducting research to support FDA's regulatory activities over tobacco products.

RePORTER, which lifts the veil on NIH funded research projects for the public, was enhanced to allow extramural investigators and institutions to supplement their grant records in RePORTER with links to their own faculty profiles and lab webpages. Incidentally, I am delighted to note that RePORTER was a winner in Round 5 of the 2012 HHS Innovates, a program created to celebrate HHS innovation.

As we look to the future, initiatives spawned by our biomedical workforce report will be front and center. We will embark soon on work to better track researchers who get NIH funding through their entire career. Changes in small business regulations, due to Congressional reauthorization of the SBIR/STTR programs nationwide, will mean changes to the SBIR /STTR research programs. In 2012, many paper processes transitioned to electronic and we are thrilled that with the pilot launch of ASSIST, the new module for electronic submission of multi-project applications, we are on our way to completely receiving all grant applications electronically. We also stand ready to help NIH extramural staff and the broader research community navigate new changes that come along the way.

As we look ahead to all these changes, I hope you follow along on my blog.

Until then...

Sally J. Rockey, PhD

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



Office of Extramural Research 2011-2012 Report

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

OER functions 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.

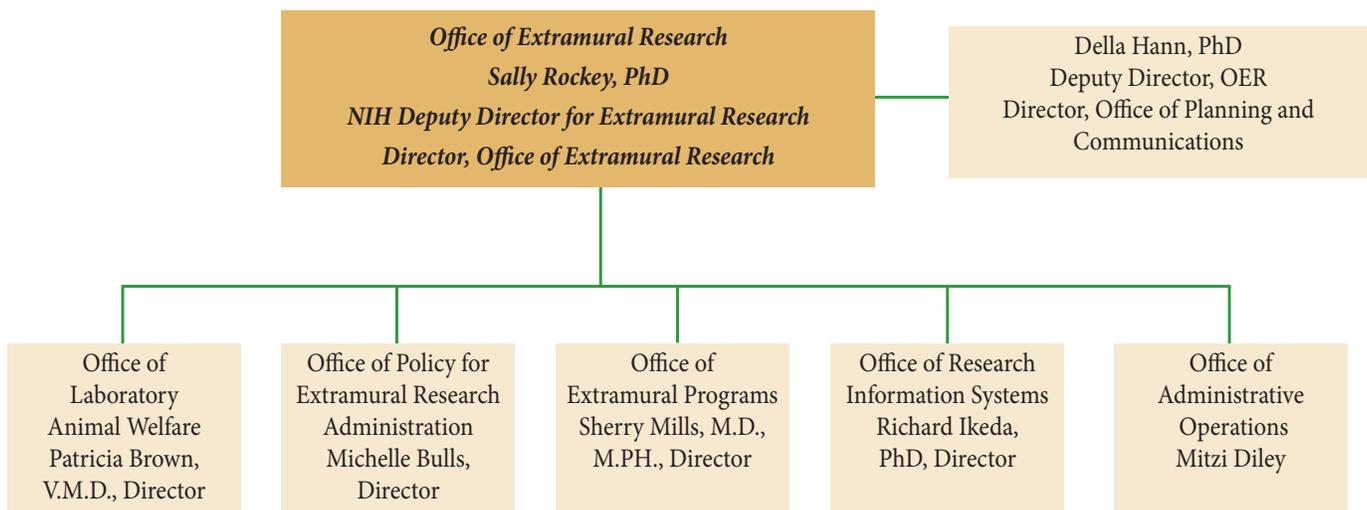
Office of Extramural Research 2011-2012 Report

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. OEP promotes 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 Support (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 centralized 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*

Program
Stewardship



Scientific
Integrity



Public
Accountability

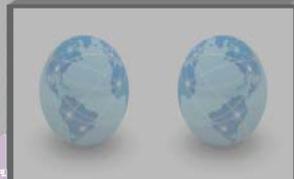


Policy &
Procedures

Development,
Implementation, and
Oversight



Systems &
Data



Communications



Administrative
Support



Education &
Training



Ensuring Integrity of Peer Review

Contact: Sally Amero, PhD

OER develops peer review policies and procedures for use across NIH to ensure all grant applications and research and development (R&D) contract proposals receive a fair, equitable, timely, and unbiased evaluation of scientific and technical merit. 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 rigor and integrity.



Major Accomplishments

Enhancing Reviewer Conflict of Interest Policy

Reflecting the increasingly interdisciplinary and collaborative nature of biomedical research, NIH revised policy for managing conflict of interest (COI) in the first level of peer review ([NOT-OD-11-120](#)). The revised COI policy provides a thorough explanation to the extramural scientific community, peer reviewers, the press, and other federal officials of the many rigorous safeguards we use to manage potential bias in the peer review process. For the first time, the policy was issued as a Public Notice to increase transparency.

IMPACT

Given the tens of thousands of outside experts involved in NIH peer review each year, proper management of COI mitigates a major potential risk to the integrity of the agency.

Issuing Guidance on Videos

To accommodate ever-changing technology used in biomedical and behavioral research, OER issued interim guidance ([NOT-OD-12-141](#)) for handling videos submitted as grant application materials. Although the optimal solution will involve improving the ability of NIH information systems to seamlessly accommodate video, the interim guidance will provide fair standards for all applicants and allow NIH to accommodate research fields where video technology is critical.

IMPACT

The new policy recognizes that using video can be vital in conveying the science in grant applications and provides a uniform standard for all applicants.

Ensuring Integrity of Scientific Programs through Policy

Contact: Sherry Mills, MD, MPH

OER develops and implements program policies centrally to provide consistent standards across NIH. These policies are critical for ensuring that NIH programs are clearly based on compliance with applicable laws, regulations and policies.



Major Accomplishments

Updating NIH Program Policy

OER oversees the NIH Manual chapters that articulate program policy and guide program implementation for NIH staff. During FY11 and FY12, OER proactively identified areas for policy revision to mitigate risk, rescinding four outdated NIH Manual chapters, and issuing three new Manual chapters covering NIH national advisory councils and boards, extension applications and awards (type 4s), and human subjects review in NIH grants and contracts. In addition, seven major program policy announcements were issued, each of which clarified policy and mitigated risk to the Agency.

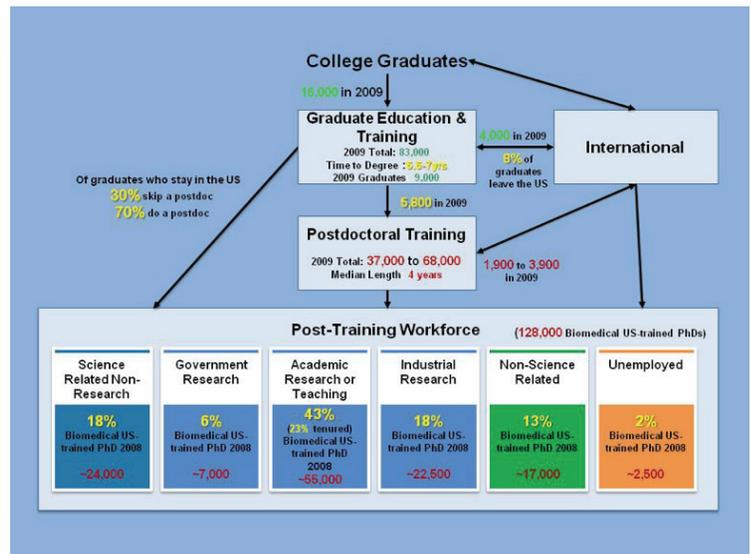
IMPACT

Updating internal program policies will result in a more consistent approach across NIH to the management of on-going awards that involve human subjects. These updates will also further NIH's goal of supporting projects with scientific merit, integrity, and program relevance.

Fostering a Robust Scientific Workforce Development

Contacts: Wally Schaffer, PhD and Dorit Zuk, PhD

OER develops policies and procedures that foster the development of a robust and diverse biomedical research workforce to ensure that we have the most talented individuals entering the biomedical research disciplines. A diverse workforce improves the quality of educational and research activities, provides balanced perspectives related to research priorities, and enhances our ability to recruit clinical research subjects from all backgrounds as we seek to address and eliminate health disparities.



Major Accomplishments

Identifying Ways to Sustain the Biomedical Workforce

OER assumed a leadership role in supporting the development of two reports for the NIH Advisory Committee to the Director (ACD): a report on the status and needs for fostering the biomedical research workforce (BMW); and a report on workforce diversity. Both reports were issued in June 2012. Recommendations from these reports address a variety of important issues including: the quality, duration, and content of biomedical research training; strengthening the transition from training positions to scientific independence; improving the accuracy and breadth of data collected on the NIH supported workforce; improving the income and benefits available to those in graduate and postdoctoral training; and enhancing the effectiveness of NIH diversity efforts.

IMPACT

These recommendations and subsequent implementation plans will transform the culture of training in the biomedical sciences and provide higher quality information for future assessments.

Monitoring New Investigator Policies

OER continuously monitors the implementation of NIH policies on new investigators, i.e., that new and experienced investigators are comparably successful in obtaining awards for Type 1 R01 equivalent grants and that at least half of the of the new investigators receiving these awards are within 10 years of completing their terminal research degree or their residency training (Early Stage Investigators).

IMPACT

In FY12 new and experienced investigators were nearly equally successful on R01 equivalent applications and more than 55% of the new investigators were Early Stage Investigators. OER attention to these policies sustains the influx of talented, innovative, independent investigators to ensure that a robust stream of new investigative talent is entering the biomedical research enterprise.

Launching New Programs and Partnerships

Standing up new extramural research programs in collaboration with other agencies or for new organizations within NIH involves weaving together numerous peer review, programmatic, and grants management policies and procedures. OER provides such expertise on behalf of NIH to ensure that new research programs operate with the same robust standards and high quality of long-standing NIH programs.

Major Accomplishments

Helping to Launch PCORI

The new Patient-Centered Outcomes Research Institute (PCORI) needed assistance in conducting high-caliber peer review for its first ever competitive grants program. OER negotiated the regulatory and policy challenges, as well as the numerous procedural issues, that permitted the Center for Scientific Review to help PCORI with their first merit review.

IMPACT

PCORI successfully launched its first ever competitive grants program in November 2010, reviewed the scientific merit of 800 applications, and was able to make award decisions by March 2011. This assistance permitted PCORI to create its own infrastructure for supporting high-caliber peer review and supporting the science necessary for fulfilling its mission.

Building the Extramural Infrastructure for a New NIH Institute

In standing up the new National Center for Advancing Translational Sciences (NCATS), OER led the extramural policy and procedural efforts that permitted the timely and successful redistribution of over 6700 applications and awards to 12 Institutes and Centers; the reissuance of approximately 50 FOAs; and, the development of numerous communications to applicants, awardees, and staff.

IMPACT

The NCATS extramural program was successfully launched and fully operational within three months, permitting this new organization to receive grant applications and issue grant awards in the Spring of 2012.

Laying the Research Foundation for the NIH-FDA Tobacco Regulatory Research Program

The NIH-FDA Tobacco Regulatory Research Program is a large-scale partnership involving NIH peer review, program, and grants management assistance for awards and projects that will inform the manufacture, distribution and marketing of tobacco products related to the regulatory authority of the FDA Center for Tobacco Products. OER provided leadership to stand up this program by coordinating the development of funding opportunities, modifying peer review criteria, negotiating peer review with CSR, and setting up a budgetary accounting structure by which to monitor and report expenditure of FDA funds for the program.

IMPACT

In FY 12, the NIH-FDA Tobacco Regulatory program issued four FOAs and awarded \$27.9 m for research grants. In addition, an administrative infrastructure was created to monitor applications, awards, and spending for this program that will continue into FY 13 and beyond.

Evaluating and Analyzing NIH Programs

Contacts: Katrina Pearson, Luci Roberts, PhD, and Robin Wagner, PhD

OER provides data, analyses, reports and evaluations of NIH programs and policies. These products provide NIH leadership with critical information for strategic decision making as well as aiding NIH's transparency and accountability to the public.

Major Accomplishments

Evaluating Peer Review Changes

OER coordinates NIH's dynamic survey effort to collect the opinions of NIH's grant applicants, peer reviewers and Advisory Council members, as well as NIH program and review staff to assess the cumulative effects brought about by changes to NIH's peer review system. The Phase 1 surveys were completed in 2010 and the Phase 2 surveys were completed in 2012. Both surveys revealed perceived weaknesses, pointing to potential opportunities to improve the peer review system.

IMPACT

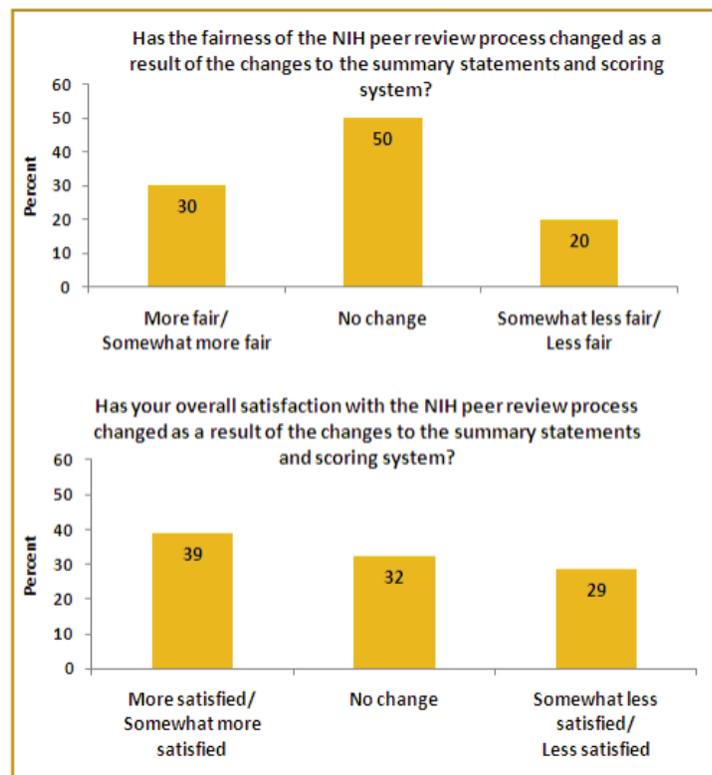
Mid-course improvements to the peer review process were made as a result of the Phase 1 evaluation results, and the Phase 2 results are under consideration by NIH leadership.

Characterizing the Extramural Workforce

OER developed the first census of the NIH extramural research workforce which provides new insights into the occupational roles, age distribution, and educational attainment of persons devoting time and effort to NIH grants awarded in 2009.

IMPACT

Better understanding the extramural workforce is critical to developing and implementing new policies to strengthen the future research enterprise.



Sustaining a Diverse Biomedical Research Workforce

NIH is committed to a strong biomedical research workforce, which depends on robust participation of the diverse groups that comprise the nation's population. To facilitate this goal, OER has conducted extensive analyses of grant applicants, identifying risks and opportunities for improving participation and successful career progression and outcomes for racial, ethnic and gender groups that have not historically been engaged in biomedical research at levels representative of the population.

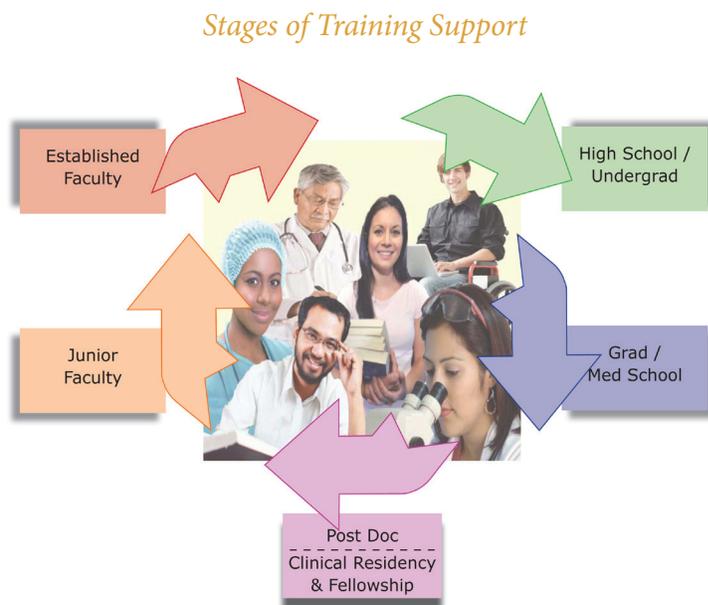
IMPACT

These diversity analyses inform the creation of more successful strategies to attract and retain underrepresented groups in the biomedical research workforce.

Developing Policies to Support Research Training

Contacts: Henry Khachaturian, PhD; Jennifer Sutton; Rod Ulane, PhD

OER develops NIH policies for research training, fellowship and career development programs, assists NIH institutes and centers in their implementation of new training programs, initiates evaluations of trans-NIH training and career development programs, and interacts with the extramural community and other Federal science agencies on issues related to research training and scientific workforce development.



Major Accomplishments

Supporting the Next Generation of Scientists

OER developed detailed scenarios on how in the future NIH might support the training and development of the next generation of biomedical research scientists. This was accomplished by assembling veteran staff across the NIH ICs with both working knowledge and expertise in research training and career development programs. The result of this effort, the NIH-Training Advisory Committee Working Group (NTW) Report, provided a range of new approaches for consideration in supporting training the next generation of the biomedical research workforce. A number of these approaches were incorporated into recommendations made by the Biomedical Workforce Working Group to the NIH Director.

Evaluating Effectiveness of the K99/R00

OER initiated and led the formative evaluation of the Transition to Independence Award. OER collected and analyzed critical information on the award's initial effect on recipients' careers, such as successful attainment of an independent position, time to search that position and time to first NIH research award, as well as award success rates, time of first application, and proportion of successful re-submitted applications.

IMPACT

A range of new approaches have been identified to support training the next generation of the biomedical research workforce.

IMPACT

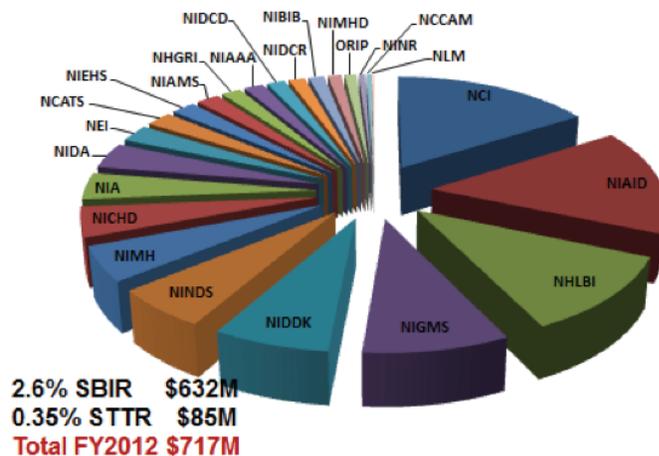
The findings of the Transition to Independence Award evaluation provided the critical information to make significant modifications and adjustments to this important program.

Leading NIH's Small Business Programs

Contacts: Lenka Fedorkova, PhD, Matthew Portnoy, PhD, Robert Vinson

OER coordinates the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs across NIH, providing oversight and implementation of policies, development of funding announcements, and outreach.

NIH SBIR/STTR Budget Allocations FY2012



Major Accomplishments

Coordinating NIH SBIR/STTR Programs

OER coordinated and managed FY11 and FY12 NIH SBIR/STTR programs where more than \$1.4B over two years was awarded to small businesses to commercialize their technology and further the NIH mission.

Leadership in the SBIR/STTR

Reauthorization and Implementation

Working with NIH Institutes, the Small Business Administration (SBA), SBIR/STTR agencies, and Congress, OER provided substantial input and feedback promoting the successful reauthorization of the SBIR/STTR programs nation-wide in December 2011. OER is playing a central role in planning, coordinating and starting the implementation of this complex legislation at NIH.

IMPACT

The NIH SBIR/STTR programs provided funding for over 1,700 projects to be conducted by U.S. small businesses to undertake cutting-edge research and development that has potential for commercialization and economic payoff for the nation.

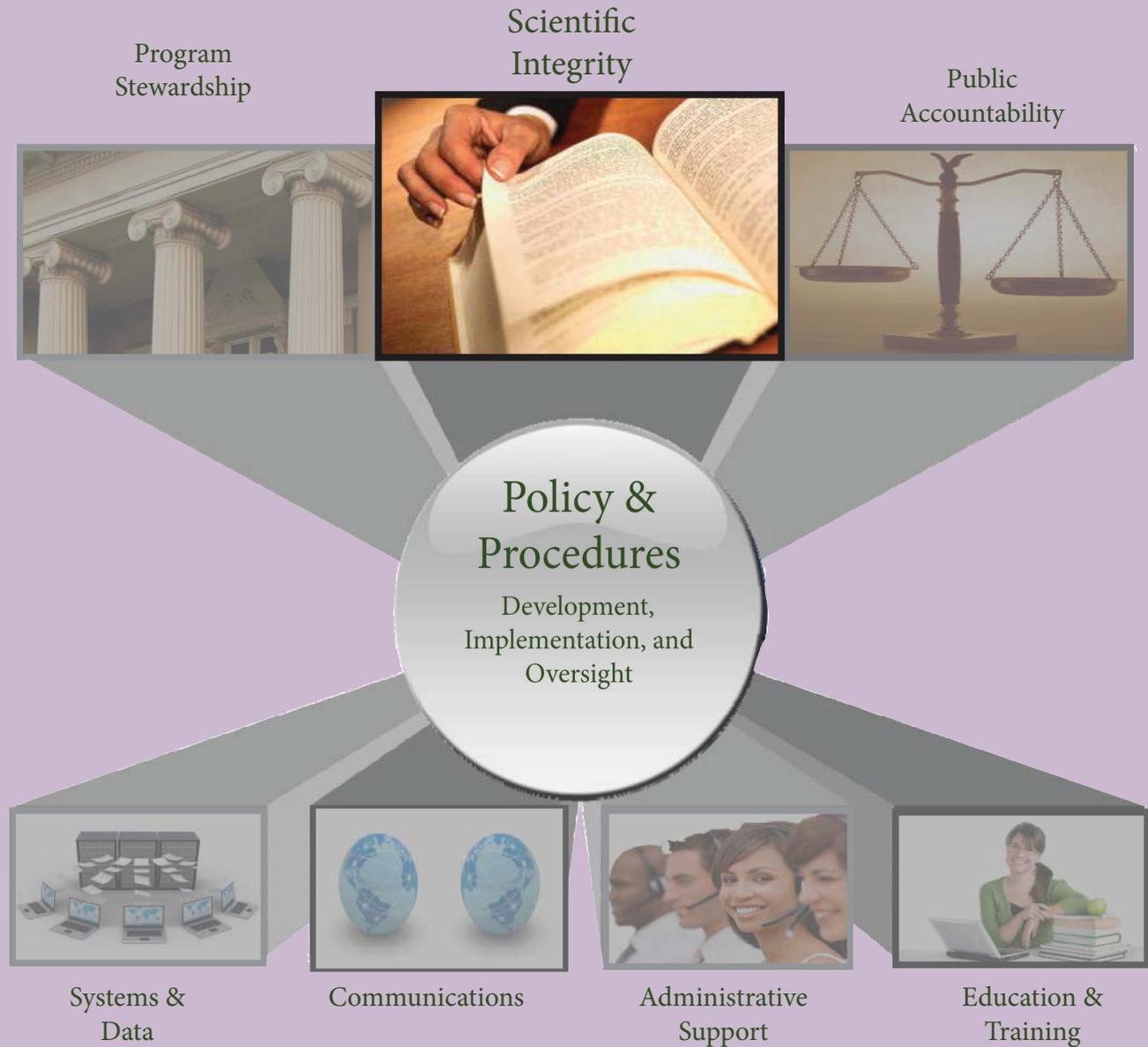
IMPACT

Implementation of the SBIR/STTR reauthorization will provide new flexibilities for the American small business community, including program switching at Phase II, venture-backed company participation, and switching agencies at Phase II.



SCIENTIFIC INTEGRITY

*Authoritative Point of Contact for Arbitrating
Research Conduct Issues*

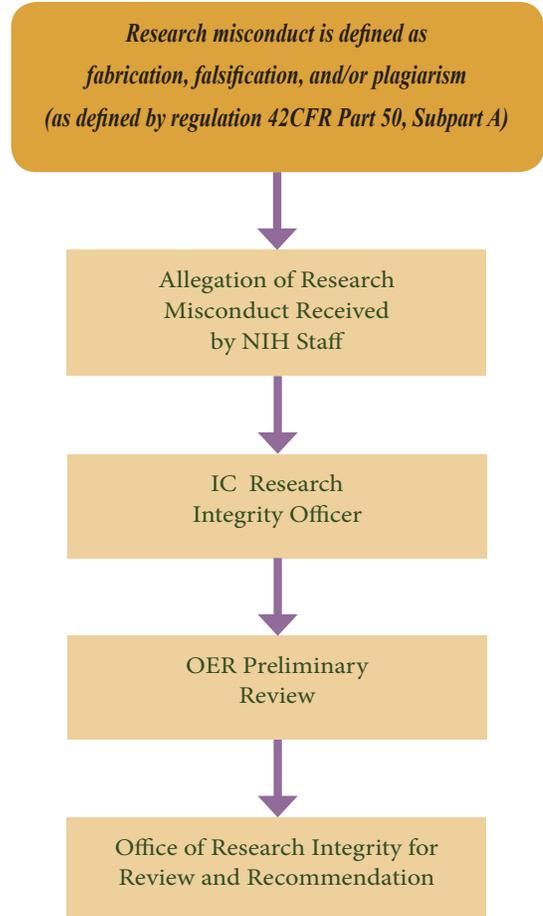


Ensuring Research Integrity

Contacts: Yvonne Lau, MD, PhD

OER research integrity staff liaisons between the HHS Office of Research Integrity (ORI) and NIH institutes, centers and offices on matter relating to allegations of research misconduct that involve extramural activities. OER provides training on the handling of research misconduct allegations and on topical issues related to research integrity to NIH staff and NIH IC Research Integrity Officers.

Process for Reviewing Research Misconduct



Major Accomplishments

Training Staff in Research Misconduct

OER conducted a staff training on research integrity and the handling of research misconduct allegations entitled “Understanding Research Misconduct; Striving for Ethical Excellence” in July 2012. In addition to providing NIH staff with the knowledge and skills to handling allegations of potential research misconduct, which are central to the agency’s commitment to research integrity, the training also sparked staff’s interest in aspects of responsible conduct of research.

Streamlined Handling of Research Misconduct Allegations

OER established new processes for tracking and managing allegations of research to facilitate prompt and efficient communications of research misconduct allegations amongst designated stakeholders.

IMPACT

Providing staff with the tools and information necessary to handle allegations of research misconduct appropriately helps ensure the public trust in NIH funded research.

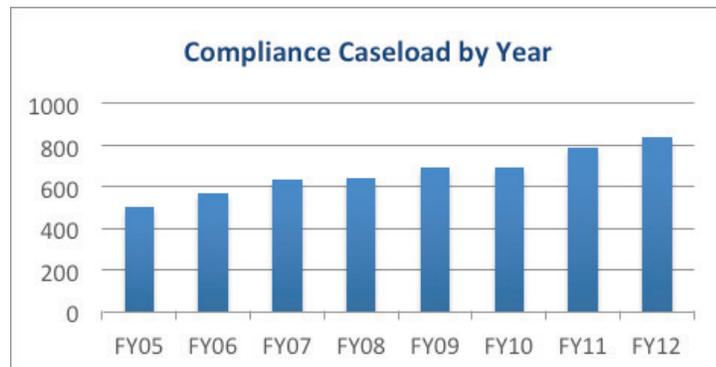
IMPACT

Use of the new processes reduces processing time for allegations and improves tracking, thus ensuring that NIH attends to allegations promptly and appropriately.

Ensuring the Protection of Animals in Research

*Contacts: Patricia Brown, VMD, MS, Eileen Morgan, Susan Brust Silk, MS
Axel Wolff, DVM, MS*

OER's Office of Laboratory Animal Welfare (OLAW) oversees compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals for all institutions that receive support for research, testing or training involving the use of laboratory animals. Education is the key to ensuring compliance, and OER provides guidance and policy interpretation to research institutions, investigators, federal officials, and the public.



Major Accomplishments

Compliance Cases Closed

Each awardee institution has an Institutional Animal Care and Use Committee that reports to OLAW any serious noncompliance with applicable animal welfare policies. This self-reporting in combination with third party reports resulted in 1,626 compliance cases opened between October 1, 2010 and September 30, 2012. During the same period 1,579 cases were closed.

Conducting Extensive Public Engagement

Following the 2011 publication of the National Academy of Science's Guide for the Care and Use of Laboratory Animals, Eighth edition, OLAW conducted extensive engagement with the public to ensure concerns were addressed about NIH's adoption and implementation of the new standards and to provide responsive clarification and guidance. Three special webinars were presented, 10 position statements were released and 9 resources were updated to aid institutions in local implementation.

IMPACT

Ensuring institutions comply with all applicable policies regarding the care and use of animals in PHS-funded research results in increased accountability to the public.

IMPACT

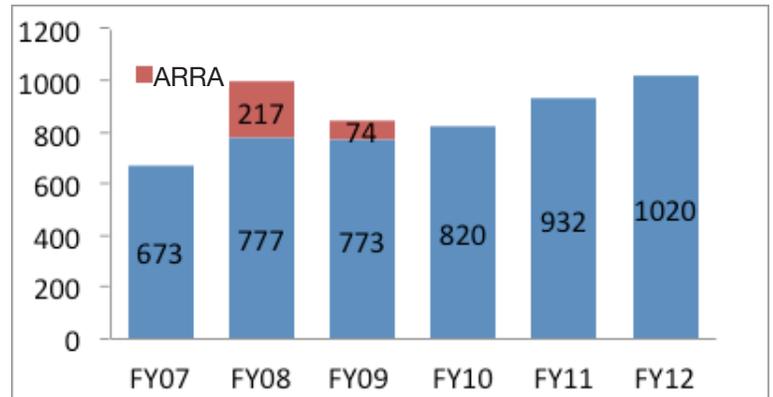
Adoption of the 8th Edition of the Guide empowers continued advancement in the humane care and use of animals in PHS-funded research. Through the use of outcome-based performance standards, these guide updates provide institutions with the flexibility to meet their responsibility to ensure better animal care that benefits scientific research.

Ensuring the Protection of Human Subjects in Research

Contact: Ann Hardy DrPH, Maria Stagnitto RN, MSN

OER conducts activities to ensure the compliance of NIH grantees with federal regulations and NIH-specific policies regarding the protection of human subjects. It assesses the proposed resolution of human subjects concerns identified during the peer review process and reconciles bars to funding arising from human subjects concerns. OER conducts ongoing training to NIH staff and the extramural community.

Human Subjects Code Change Requests by Year



Major Accomplishments

Developing Policies and Resources

OER issued policy for extramural staff and the public to (1) ensure that standards for reconciliation of NIH grants with human subjects concerns are applied consistently to NIH R&D contract proposals with human subjects concerns; and (2) ensure prior NIH approval for changes in the approved involvement of human subjects in on-going awards. OER also developed and launched a new system to support reconciliation of human subjects concerns in R&D contract proposals, and implemented NIH-wide training for NIH extramural staff.

Reconciling Human Subject Questions and Concerns

During FY12, OER processed over 1,000 requests to reconcile human subjects questions and concerns – the largest number of requests in a single fiscal year to-date - while maintaining the highest standards for timeliness. This increase was a result of revised policies and extensive outreach conducted by the NIH Human Research Participant Protection Officers educating extramural staff on human subjects protections regulations, laws, policies, and processes.

IMPACT

The new policies and procedures will result in improved NIH oversight of research involving human subjects and will reduce the risk that NIH sponsored research could result in harm to subjects or be non-compliant with federal regulations.

IMPACT

The reconciliation of the most requests ever received by OER without diminishing timeliness or quality of review demonstrates the fundamental strength of the business processes established for human subjects reconciliations.



PUBLIC ACCOUNTABILITY

*Consistent Monitoring & Oversight Process for
Policy Development & Compliance*

Program
Stewardship



Scientific
Integrity



Public
Accountability

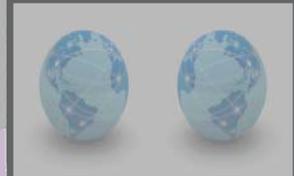


Policy &
Procedures

Development,
Implementation, and
Oversight



Systems &
Data



Communications



Administrative
Support

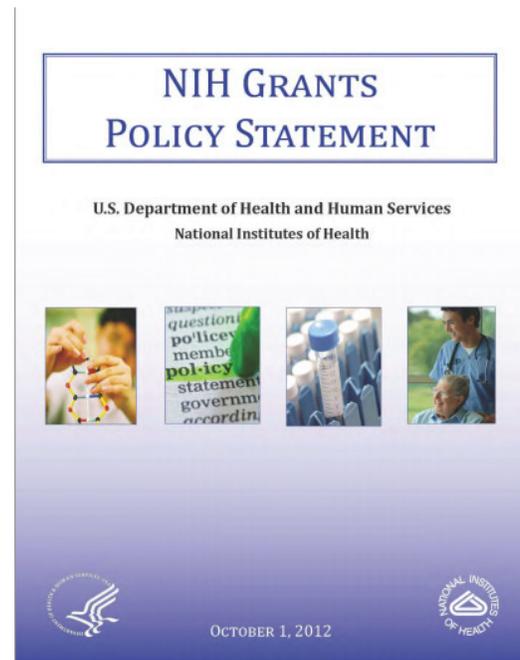


Education &
Training

Ensuring Integrity of NIH Programs through Grants Policy

Contact: Marcia Hahn

OER provides centralized development, implementation and oversight of NIH and applicable DHHS and federal grants policies as they affect the NIH grants process. OER maintains centralized policy documents that help ensure consistency across the NIH, such as the NIH Grants Policy Statement, manual chapters, policy websites, and grant-related forms.



Major Accomplishments

Updating Policy Resources

Annual revisions to the NIH Grants Policy Statement were issued. For NIH staff, the Co-funding Manual chapter was revised and all OER Policy Topic Intranet pages redesigned. External OER policy webpages were created for new policy topics and existing pages revised to align with ever-changing policy and procedure.

Increasing Electronic Business Processing

Mandated the use of eRA Commons electronic business processes for No-Cost Extension, Just-in-Time, and the Federal Financial Report. Developed and piloted electronic business processes for Change of Grantee Organization, Change in Grantee Organizational Status, Administrative Supplements, Research Performance Progress Reports, Archiving Electronic Official Files, and Changing the Payment Method for Foreign Grantees.

IMPACT

Providing updated policy resources to the applicant/grantee community and the NIH extramural community assures comprehensive and current resources are available to all. The annual NIH Grants Policy Statement update is particularly essential as it is a term and condition of all NIH Grants.

IMPACT

Electronic business processes improve efficiency for both grantees and NIH staff. They also provide the opportunity for business process redesign, improving NIH policy and procedure, and improving data and the ability to do in-depth analyses on NIH grants.

Promoting Compliance with Grant Policies and Regulations

Contact: Diane Dean

OER promotes NIH staff and grantee compliance with regulations, policies and legislative mandates and enhances compliance oversight. OER also devotes significant time and resources to education and outreach, key components of any compliance program, and manages internal programs like NIH's Grants Management Professional Certification program and internal control reviews.



Major Accomplishments

Reviewing Internal Controls

OER conducted three NIH-wide reviews of internal controls over the following policy areas: Facilities & Administrative Costs; Scientific, Budgetary, and Commitment Overlap; and Special Award Conditions. The results of these reviews inform NIH staff of needed process improvements, policy clarifications, and/or enhanced training needs. Best practices are also identified and shared with the NIH extramural staff.

Initiating a Proactive Compliance Program

OER has initiated a proactive compliance oversight program on Financial Conflict of Interest (FCOI) to assess institutional implementation and compliance with the revised final rule. The objective of the initial phase of the program is to evaluate publicly accessible FCOI policies and assist grantees' compliance actions by offering technical assistance. OER plans to continue and expand the proactive FCOI compliance program during FY2013.

IMPACT

Proactive internal control reviews help NIH identify and address risks before they become compliance or audit issues.

IMPACT

OER will provide constructive feedback to assist grantees in fully developing and implementing their FCOI policies. The results of the compliance reviews will be shared with the research community as part of NIH's continuing educational efforts to improve and enhance compliance with FCOI regulatory requirements.

Providing Transparency into NIH Grant Programs

Contact: James Onken and Brian Haugen

OER hosts the NIH Research Portfolio Online Reporting Tools (RePORT) site, which provides the public with a comprehensive view of NIH data and 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 expenditures and results.



Major Accomplishments

Leveraging Data Sources

In 2011 and 2012, our publicly-accessible repository of funded research projects (RePORTER) was enhanced to allow extramural investigators and institutions to supplement their grant records in RePORTER. Investigators can now add hyperlinks to their own websites, such as faculty profile and lab webpages. Institutions can use the EurekaAlert! Science news service to publish research findings. They can also make these news items available in RePORTER by tagging their press releases in the EurekaAlert! newsfeed with the relevant grant numbers.

IMPACT

By making it easier for members of the public to access more information on NIH research from a variety of sources, we provide a richer and more complete depiction of the research NIH supports and meaningful results of these investments.

Developing New Tools

A new tool added to RePORT, Funding Facts (<http://report.nih.gov/fundingfacts/index.cfm>), has become a popular resource for members of the public who are searching for statistics on NIH's extramural funding. Funding Facts is a database of thousands of statistics—numbers of applications and awards, success rates, award sizes, and funding amounts—with a simple-to-use query interface. We recently made these queries even easier by adding a natural language capability so users can enter data and get quick answers to questions such as: “What was the success rate for new NIH R01 applications in fiscal year 2012?”

IMPACT

Tools like Funding Facts can save hours of time for the public, media and others in searching for reports or a particular statistic of interest.



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

Developing and Maintaining the Electronic Research Administration (eRA)

Contact: Oliver "Pete" Morton

OER provides Electronic Research Administration (eRA) information systems to NIH, AHRQ, CDC, FDA, SAMHSA, and the Veteran's Health Administration in support of the full grants administration life cycle. eRA partners with the extramural business community to anticipate customer requests and policy changes, while processing over \$30 billion in grants awarded by NIH and eRA's partner agencies.



Major Accomplishments

Accommodating Electronic FCOI Reporting

Developed electronic capacity for improved Financial Conflict of Interest (FCOI) reporting. Together, OER offices worked to enhance the policy and supporting e-systems to better assist NIH applicants and grantees in identifying and reporting an FCOI and its management.

Facilitating Electronic Grants Processing

Developed capability to handle nearly all remaining paper grants management transactions electronically. OER has helped NIH embrace the electronic age through the implementation of electronic solutions in areas including: change a grantee institution; submit administrative supplement requests; submit progress reports using the new electronic, federal-wide Research Performance Progress Report (RPPR); develop new capabilities and strategies to archive electronic official files; among many other developments.

IMPACT

OER is helping to ensure that public trust in NIH's research portfolio is strengthened through development of new policy requirements and changes in eRA systems. The FCOI changes allow for additional disclosure of information to NIH, facilitate transparency in the institution's management of their FCOIs and enhance reporting to the agency.

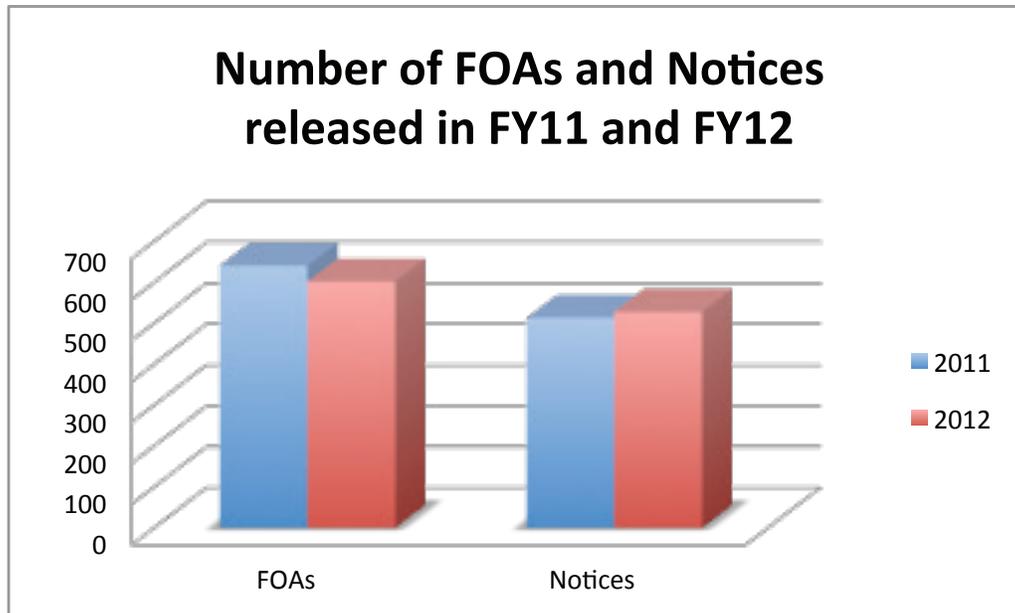
IMPACT

OER has saved grantee and NIH staff considerable time and effort by adding the capability to electronically submit, review and approve an online progress report, a change of institution, a successor in interest and requests for supplemental funds.

Issuing the NIH Guide for Grants and Contracts

Contacts: Erica Brown, PhD, Susan Grove, Mary Ann Guadagno, PhD

OER publishes the NIH Guide for Grants and Contracts to notify the NIH extramural community about funding opportunities, new policies, and updates in support of NIH and three sister agencies within HHS. OER reviews, processes and publishes funding opportunities on behalf of all NIH institutes and centers.



Major Accomplishments

Reengineering Business Processes

OER conducted a business process evaluation of the NIH Guide clearance process and implemented interim recommendations to improve the efficiency of the process and the accuracy of published announcements. This included the development and launch of an improved publishing system to facilitate the internal clearance and publishing process for funding opportunity announcements and policy notices.

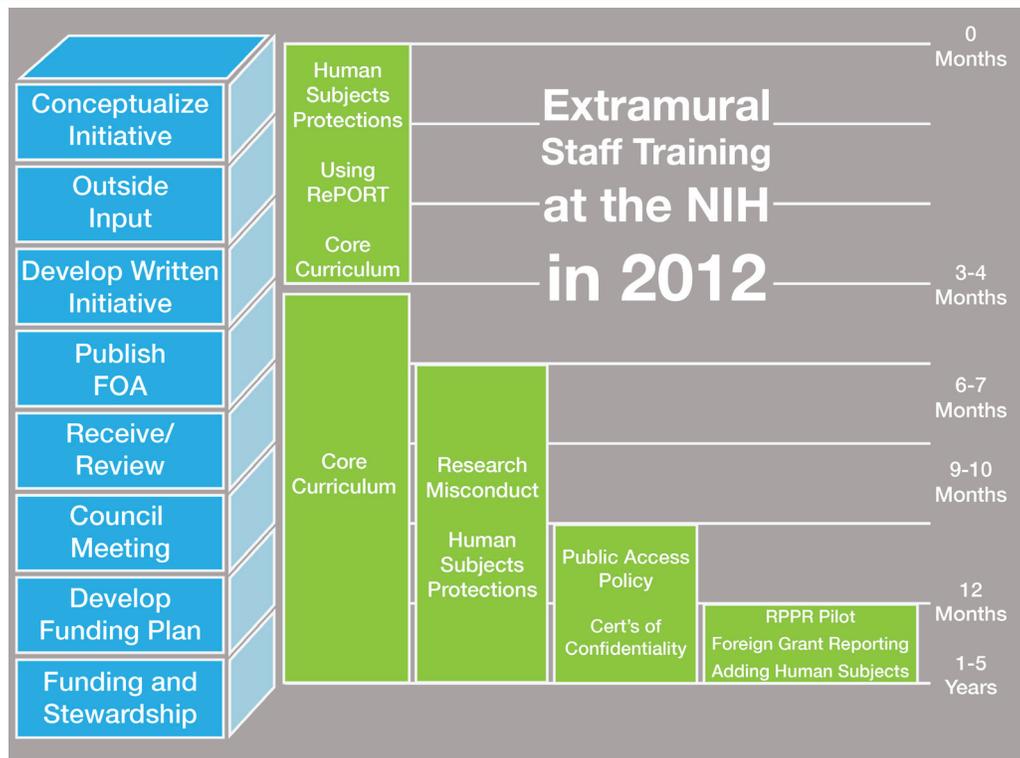
IMPACT

The interim recommendations and improved interim NIH Guide Publishing System have allowed improved process efficiencies and accuracy of funding opportunity announcements and notices. These changes help the NIH Guide for Grants and Contracts to improve communication to its extramural stakeholders, including over 55,000 national and international subscribers to its listserv.

Training Extramural Staff

Contacts: Charles Selden, PhD

OER provides NIH extramural staff with training on policy, practice, and business processes to administer grants and R&D contracts. The training program offers four programs: Core Curriculum (a 5-part training series for newly hired HSAs), Extramural Scientist Administrator (ESA) Seminar Series (a 16 week seminar series covering the functions of 30 offices at NIH and her sister granting agencies), Ad Hoc training (trainings developed to address emergency policy issues), and Staff Training in Extramural Programs (STEP), an event series providing continuing education in special topics.



Major Accomplishments

Training Extramural Staff

More than 200 new NIH hires underwent training in their roles in the grants process. An additional 100 learned about 30 major offices and entities and high level administrative functions that will further improve their functioning as NIH extramural staff. Over 3,000 NIH staff broadened their understanding of NIH programs and principles that will allow them to interact more efficiently with their community. Over 5000 staff members learned more about such topics as Adding Human Subjects, Human Subjects Protections, Research Misconduct, Financial Conflict of Interest, International Awards, Conflict of Interest in Review, Financial Conflict of Interest Reporting, and counseling grant writers.

IMPACT

Improved staff understanding of their roles and responsibilities and ensuring staff understand NIH policies and procedures mitigates risks and helps ensure staff can provide appropriate oversight to NIH funded research.

Providing Outreach to the Research Community

Contacts: Megan Columbus and Cynthia Dwyer

OER proactively disseminates information to tens of thousands of scientists and research administrators annually and provides forums for listening to the needs of the communities we serve. OER sponsors in-person seminars, webinars and podcasts, provides NIH grants process-related presentations to visitors, supports the OER Grants Website, and provides staff for meetings and events which include the biomedical research community.

Engaging over 50,000 people



22
podcast
episodes

100 blog
posts

17 public
webinars

Major Accomplishments

Blogging OER's Director

Dr. Sally Rockey, began the Rock Talk blog as a way to connect the research community with the NIH management perspectives on issues affecting NIH grants and funding. In 2011 and 2012, she posted over 100 blog posts and the blog received ~40,000 page views a month with a steady stream of comments from the research community.

IMPACT

Rock Talk has increased the transparency into the NIH grants process, as well as creating a valuable channel for two way communications with the community.

Developing Virtual Education Opportunities

OER dramatically increased its use of webinars as an Educational tool for the grantee community in 2011 and 2012. At least 20 webinars were held across a wide range of topics related to grants and funding. The webinars allow for real time questions and answers as well as later viewing.

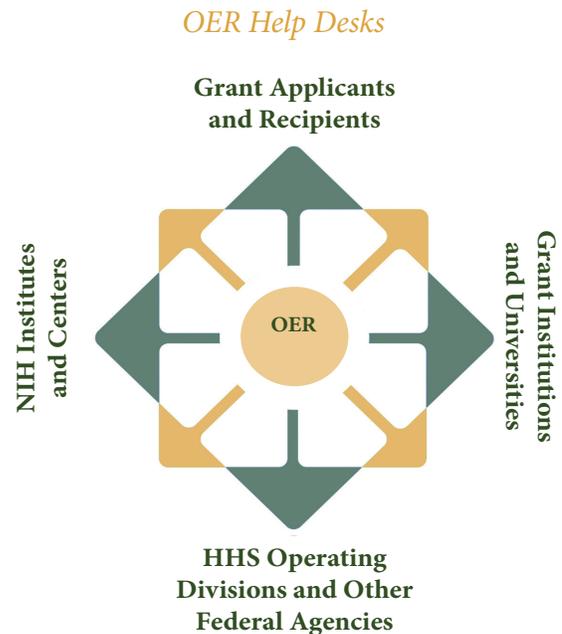
IMPACT

Webinars are another way OER increases the accessibility of free educational opportunities to people worldwide.

Providing Centralized Help Desk Support for NIH Grants

Contacts: Dave Hunter and Megan Columbus

OER provides centralized help desk services to the entire extramural community, including NIH staff, to clarify NIH grants policies, procedures and electronic systems support.



Major Accomplishments

Responsive to Inquiries

Between 500 – 1000 requests for support are addressed daily by OER help desk staff on behalf of NIH. Examples of this assistance vary from helping NIH applicant organizations and investigators navigate the grant process, working with applicants to submit electronic applications, assisting organizations in understanding the new FCOI requirements, to answering questions about the new Fed-wide progress reports, and all topics in between.

Identifying Resource Needs

OER help desk staff rely heavily on existing web resources and system documentation to respond to questions from the scientific community and NIH staff. The staffs quickly identifies areas of confusion with existing guidance or the need for additional resources to help our community.

IMPACT

Providing centralized assistance to applicants and grantees improves consistency of responses and helps to free-up IC staff to focus on their critical duties by reducing the need for them to field calls from the extramural research community.

IMPACT

Close integration between the help desks and NIH policy, systems, and communications staff results in improved communications and training resources.

Managing NIH's Loan Repayment Programs

Contact: Sherry Mills, MD, MPH

OER administers the application and financial review process for NIH's Loan Repayment Programs (LRPs), which repay qualified education debt of biomedical and behavioral scientists in exchange for a two year research commitment.



Major Accomplishments

Developing State-of-the-Art Applicant Resources

The Division of Loan Repayment (DLR) created a new webinar and interactive infographic that provide step-by-step application guidance for potential applicants.

IMPACT

Using these resources, applicants can easily identify key elements in completing their applications including institute and center program contacts, repayment calculators, tip sheets and former/current participants who serve as program ambassadors.

Planning for Program Evaluation

DLR took major steps in developing a qualitative survey for current and past program participants. Accomplishments included finalizing the survey instrument, creating the online survey process, finalizing plans for deploying the survey in 2013.

IMPACT

This evaluation will build upon an initial evaluation that showed 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.

Providing Extramural Staff Support to NIH

Contact: Mitzi Diley

OER provided extramural staff support to NIH's ICs via more than 500 employees who comprised the Division of Extramural Activities Support (DEAS). OER centrally managed DEAS, which distributed its staff throughout the ICs, conducted recruitments, and provided an in-house specialized training program to ensure continuity and consistency of service across NIH's primary extramural business areas.

IC	Staff Count	IC	Staff Count
CSR	73	NICHD	28
FIC	6	NIDA	22
NCATS	8	NIDCD	5
NCCAM	7	NIDCR	7
NCI	89	NIDDK	23
NEI	4	NIEHS	13
NHGRI	7	NIGMS	28
NHLBI	30	NIMH	31
NIA	15	NIMHD	5
NIAAA	11	NINDS	23
NIAID	68	NINR	4
NIAMS	9	NLM	4
NIBIB	9	Central	30

Major Accomplishments

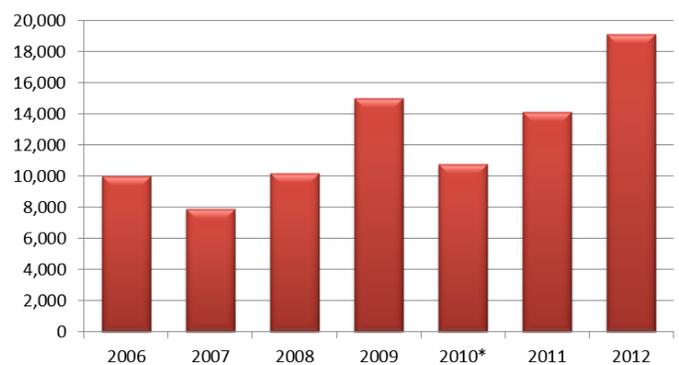
Supporting Extramural Programs

DEAS provided exceptional extramural administrative support to the NIH in a cost-effective manner.

IMPACT

Over its eight-year contract period, concluding at the end of September 2012, DEAS saved the government in excess of \$175 million.

Number of Grants Closed per FY



*Decrease reflects fewer overall backlogged grant closeouts

Coordinating Grants Closeout

DEAS continued, through its Centralized Operations Center, to serve as a central coordination and receipt location for documents submitted from grantees or principal investigators. This center provides closeout of grants and cooperative agreements for all 24 NIH ICs that make awards.

IMPACT

DEAS closed 19,150 grants in fiscal year 2012, more than in any prior year, earning it a continuing home in the OER.

Preparing for DEAS Close Out and Transition to the ICs

Throughout 2012, DEAS management collaborated across the NIH – from budget and administration to information technology and human resources – to assure the seamless stand down of DEAS and the transition of its staff and extramural support activities to the ICs.

IMPACT

All pre-planning for the end of the DEAS contract and return of its more than 500 employees was in place for the effective transition date of Oct. 1, 2012.

To view the 2011-2012 Office of Extramural Research Report online, please visit:

<http://grants.nih.gov>

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

<http://grants.nih.gov/grants>



U.S. Department of Health and Human Services
National Institutes of Health
2011-12 Office of Extramural Research Report

