



# 2013-2014 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

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# 2013-2014 OER REPORT



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

## Looking Back at 2013 and 2014



In spite of many budget challenges that NIH and Federal government faced in FY 2013 and FY 2014 that included Sequestration and the shutdown, we have been able to fund extraordinary science to achieve the NIH mission of improving health. I am particularly proud of my outstanding OER staff for pulling together and continuing to provide exceptional service to NIH and the extramural community. We have had a great impact on ensuring scientific program and research integrity; facilitating the grants application and award processes through continued advancement of electronic

systems; and improving open communication, collaboration, and transparency across NIH, the federal government, and the extramural research community.

In this report, you'll find many examples of these successes, such as:

- launching and expanding electronic systems and tools, such as SciENCv, Federal RePORTER and ASSIST
- changing policies to address research needs, such as revising our resubmission policy
- supporting research affected by Hurricane Sandy through targeted relief funding
- continuing to closely monitor and evaluate the biomedical workforce

These are just a few of the many examples in this report that demonstrate the dedication of OER staff, and the positive impact of OER on NIH's extramural research activities. Enjoy this look back. The best is yet to come!



Dedicated To the Memory of  
**Rod Ulane, Ph.D.**  
**1943 - 2013**

2013-2014 OER REPORT

In 2013, the Office of Extramural Research lost a member of our workplace family, Dr. Rod Ulane, NIH Training Officer and Director of the Division of Scientific Programs in the Office of Extramural Programs. He was an ardent and dedicated supporter of biomedical research workforce training. His impact was felt across the NIH and extended to other government agencies, foundations, societies, and institutions with a stake in training the next generation of biomedical scientists. At the time of his death, Dr. Ulane was playing a key role in implementing the recommendations of the Advisory Committee to the Director's working group on the Biomedical Workforce. Over the next few years, as these initiatives take shape, Dr. Ulane's influence will be felt.

Dr. Ulane earned his Ph.D. in yeast genetics and developmental biology from Southern Illinois University in 1971. He served as associate dean and director of M.D./Ph.D. programs at both the New York University School of Medicine and at the Graduate School of Biomedical Sciences at the University of Texas Southwestern Graduate and Medical Schools in Dallas, and remained in touch with many of his former students. He had a wealth of NIH experience, from his early work as an intramural staff scientist at the National Institute of Arthritis and Metabolic Diseases and the Eunice Kennedy Shriver National Institute of Child Health and Human Development, to his later leadership positions within the Center for Scientific Review and as a program director in the National Institute of General Medical Sciences. Dr. Ulane will be sorely missed by his colleagues. He is remembered for his dedication to young scientists and their training.



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## Office of Extramural Research 2013-2014 Report

Extramural grants represent more than 80% of the NIH's approximately \$30 billion budget. Through its 514 individuals and \$75 million budget, the Office of Extramural Research (OER) provides the infrastructure that makes these grants happen. OER provides 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 in the biomedical research enterprise and the federal government, 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, from developing policies and procedures to providing electronic systems (eRA) for extramural staff across NIH's Institutes and Centers (ICs) and offices, and for more than 166,000 external users in 24,000 research institutions worldwide. For many of these activities we provide support to other federal agencies as well. OER's functions are carried out through our seven offices:

**Office of Data Analysis Tools and Systems (DATA Systems):** Develops and maintains databases, and provides visual and analytic tools that allow both the public as well as NIH staff to interrogate the NIH portfolio. Such tools include the Research Portfolio Online Reporting Tools ([RePORT](#)), the Scientific Publication Information Retrieval and Evaluation System ([SPIRES](#)), and the Query, View, and Report system ([QVR](#)).

**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. The office supports educational programs and monitors compliance with the policy by assured institutions and PHS funding components, ensuring the humane care and use of animals in PHS-supported research, testing, and training, and 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 Office of Management and Budget (OMB) clearances to the extramural research community and NIH extramural staff. Through policy development, expert guidance, analysis, outreach, and related information dissemination, OPERA promotes effective stewardship of NIH extramural funds in support of health research.

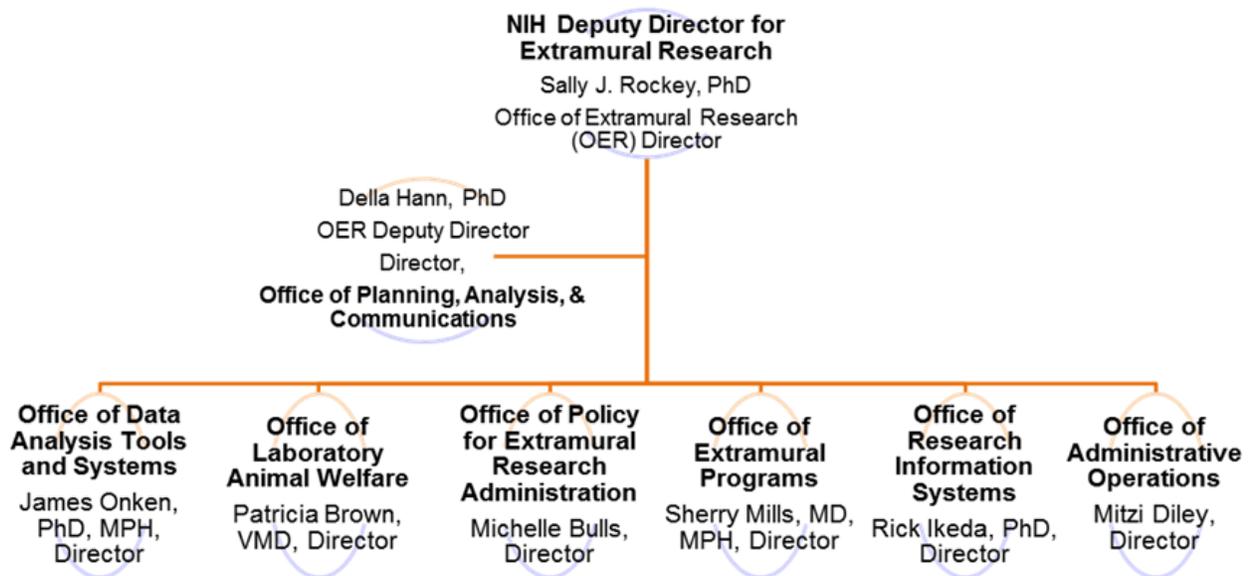
**Office of Extramural Programs (OEP):** Provides leadership and expertise in science program management, including program and policy development, interpretation, coordination, oversight, evaluation, training, and outreach for the extramural research community and NIH extramural staff. OEP promotes 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 of grants processing for NIH and other agencies (Department of Health and Human Services (HHS) operating divisions, Department of Veterans Affairs (VA), 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 Extramural Research 2011-2012 Report

**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 Central Grants Processing resides within OAO and provides centralized grant closeout and related grant processing for all NIH grant-making ICs.

**Office of Planning, Analysis, and Communications (OPAC):** 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. OPAC 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



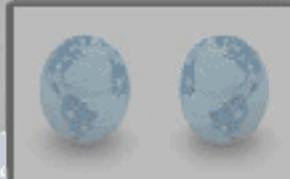
Public  
Accountability



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 by nearly 500 Scientific Review Officers across NIH, and by nearly 25,000 reviewers a year, to ensure all 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

#### Issuing a New Application Submission Policy

The new NIH application submission policy allows unsuccessful applicants to submit projects in subsequent applications without major changes in scientific direction ([NOT-OD-14-074](#)). Former policy to accelerate funding for meritorious projects forced unsuccessful applicants to develop new research projects to re-apply.

#### Managing Breaches of Confidentiality

Confidentiality in peer review allows free exchange of scientific opinion, protects confidential information, and is critical to keeping undue influence out of the process. Our guidance and certification agreements for reviewers were upgraded to address new ways that breaches of confidentiality may occur due to advances in communication technology. (See [NOT-OD-14-073](#) and the [Confidentiality in Peer Review website](#).)

#### IMPACT

*Unsuccessful applicants now have unlimited opportunities to compete for funding with the same research project, which could be particularly beneficial for new investigators who may find such a transition challenging. The long-term impact of the new policy will be assessed in subsequent years.*

#### IMPACT

*Maintaining confidentiality in the review process helps to mitigate the risk of undue influences in identifying meritorious research for funding consideration and the risk of losing public trust in the NIH grants process.*

# Ensuring Inclusion of Women and Minorities in Clinical Research

Contact: Meredith Temple-O'Connor, PhD



OER implements policies and procedures to ensure compliance with statutory and policy requirements for the inclusion of women and minorities in clinical research. The goal of this inclusion policy is to ensure that women and minorities are included in a scientifically appropriate manner in clinical research studies conducted or supported by the NIH.

## Major Accomplishments

### Deployment of the Inclusion Management System (IMS)

In October 2014, the Office of Extramural Research deployed the Inclusion Management System (IMS), a new eRA (electronic Research Administration) module which enables grantees to report and update inclusion enrollment data, and NIH staff to monitor and manage inclusion data through one integrated system. The IMS is automatically populated with inclusion data provided by grantees in their competing application submissions, directly through eRA Commons, or through their submitted progress reports.

#### IMPACT

*This new system promotes increased transparency and enhanced communication about the sex/gender and racial/ethnic characteristics of people enrolled in NIH clinical research, because grantees and NIH staff will see and interact with the same information.*

### Re-Engineered Business Processes for Monitoring Inclusion

In 2014, OER updated some of its processes for inclusion monitoring and oversight, including revised peer reviewer guidelines, clarified staff roles and responsibilities, new/updated training materials and resources for staff and investigators, new procedures related to the IMS deployment, and new tools for staff to use in monitoring inclusion.

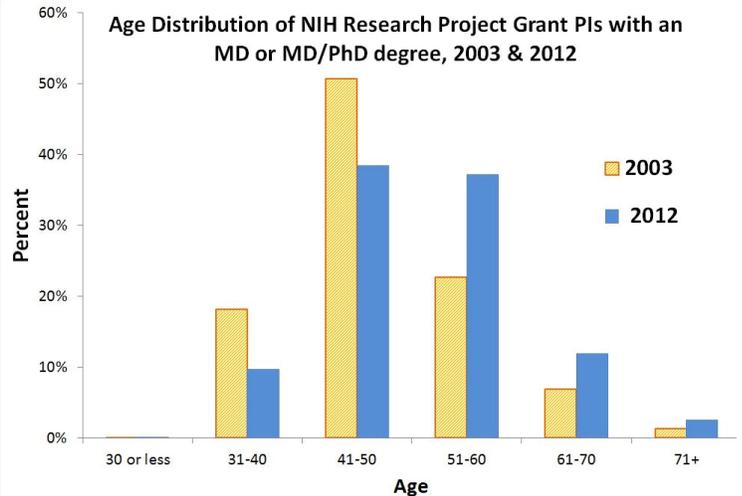
#### IMPACT

*These updated business processes enhance the monitoring of inclusion in clinical research and the understanding of the goals of inclusion policy. These re-engineered business processes also emphasize that inclusion is an important factor to be considered in the context of the science.*

## Fostering a Robust Scientific Workforce

Contacts: Lisa Evans, JD; Misty Heggeness, PhD; Henry Khachaturian, PhD; Jennifer Sutton

OER develops policies and procedures that foster the development of a robust biomedical research workforce and ensure the participation of talented individuals from all disciplines and backgrounds, including individuals from underrepresented and disadvantaged groups, and new investigators. A diverse workforce fosters scientific innovation, enhances global competitiveness, contributes to robust learning environments, improves the quality of the researchers, advances the likelihood that underserved or health disparity populations participate in and benefit from health research, and enhances public trust.



### Major Accomplishments

#### Sustaining the Biomedical Workforce

OER led the implementation of recommendations contained in [the NIH Advisory Committee to the Director \(ACD\) report](#) on the status and needs of the biomedical research workforce. This includes initiating the development of new electronic systems that will improve the accuracy and breadth of data on training and career outcomes, enhancing career planning and mentoring by promoting the use of Individual Development Plans (IDPs) for all NIH-supported graduate students and postdoctorates, and collaborating with the NIH Common Fund on creating the Broadening Experiences in Scientific Training (BEST) awards to support innovative career exploration opportunities.

#### IMPACT

*These steps will transform the culture of training in the biomedical sciences and provide higher quality information for understanding career outcomes.*

#### Identifying Ways to Enhance the Physician-Scientist Workforce

OER assumed a leadership role in developing implementation plans to support the recommendations contained in the NIH Advisory Committee to the Director report on the physician-scientist workforce. The report recommended the strong support of the training of MD/PhDs; steps to reduce the educational debt burden of individuals at the start of their career trajectories; development of assessment and tracking tools to monitor the strength and of the physician scientist workforce; and efforts to increase the diversity of the physician scientist workforce.

#### IMPACT

*The OER implementation will provide NIH leadership with effective strategies to evaluate and address the unique trajectories, barriers, and successful strategies of physician-scientists, to enhance the diversity of the physician-scientist workforce, and to develop the necessary tools, programs and financial supports to enhance the physician-scientist workforce.*

## Launching New Programs and Partnerships

Contact: Della Hann, PhD

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.

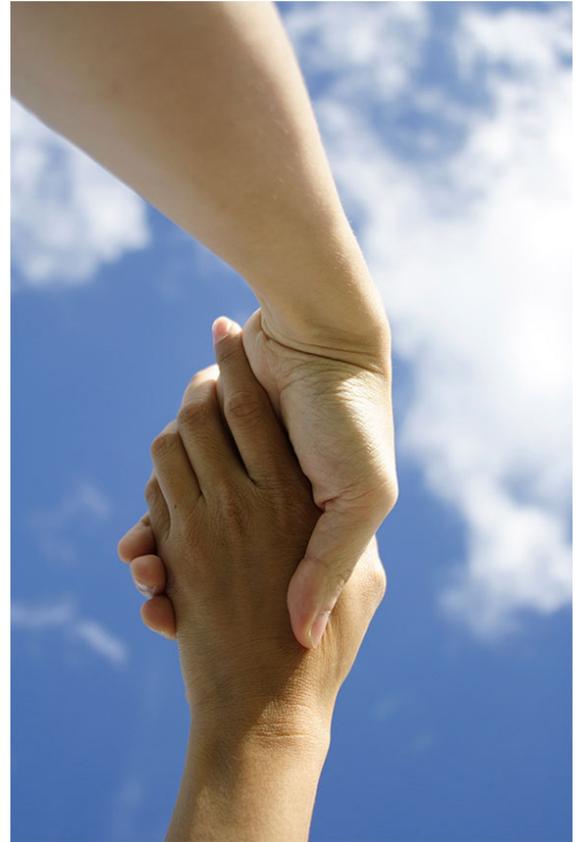
### Major Accomplishments

#### Leading NIH's Hurricane Sandy Assistance

Superstorm Sandy was a devastating storm that hit the northeast coast of the United States in fall 2012. Major research institutions in the affected area lost equipment, valuable resources, and significant time in pursuing vital biomedical research. OER served as the focal point in coordinating NIH efforts to restore investments already made in biomedical research and infrastructure severely damaged by this storm.

#### Helping to Implement NIH-PCORI Partnerships

OER assisted in negotiating numerous regulatory and policy challenges that permitted the full implementation of the NIH-PCORI (Patient Centered Outcomes Research Institute) partnerships for supporting research of high interest to both organizations.



#### IMPACT

OER developed and worked with the NIH ICs to implement a spend-plan for \$148 million to support five funding opportunity announcements (FOAs) for restoring the research and research infrastructure to biomedical research institutions affected by Hurricane Sandy. All FOAs were issued and awarded in fiscal year (FY) 2013 and 2014.

#### IMPACT

OER assisted in creating a memorandum of understanding template that allows interested ICs to set up partnerships with PCORI to support research. One research program, the Falls Injuries Prevention Partnership, was awarded in FY14.



# Providing Centralized Program Leadership Supporting the Research Training of the Biomedical Workforce

Contacts: Henry Khachaturian, PhD; Jennifer Sutton

OER develops NIH policies for research training, fellowship, and career development programs, assists NIH ICs 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

OER led the implementation of a series of recommendations, made by the NIH ACD working group on the biomedical workforce, to enhance NIH training programs through a variety of modifications to existing training programs. These changes include:

- Allowing graduate students in all health research-related fields an opportunity to compete for an NIH graduate fellowship (F30 and F31) by extending these programs to all NIH ICs.
- Permitting more postdoctorates to transition to faculty positions more quickly, by increasing NIH's overall support for the K99/R00 Pathway to Independence program and refocusing the eligibility period towards earlier-stage investigators.
- Increasing stipends for NIH trainees and fellows to better reflect their skills and level of education.



## IMPACT

NIH expects that these changes, in synergy with new programs and policies that arose from ACD recommendations, will enhance existing NIH programs and better launch current graduate students and postdoctorates into the next phase in their careers.

# Leading the NIH Loan Repayment Programs (LRP)

Contact: Sherry Mills, MD, MPH

The NIH Loan Repayment Programs (LRPs) are a human capital investment in the nation's research enterprise. The programs support the research workforce by making research careers a competitive option for promising clinical researchers with significant educational debt. The program repays the qualified education debt of biomedical and behavioral scientists in exchange for one- or two-year research commitments. OER administers the application process, financial review, and contract servicing of the LRPs.



## Major Accomplishments

### Retaining Promising Clinical Researchers in the Research Career Track through the LRPs

A major survey, the first of its kind, gathered information from 3,000 past and current LRP participants regarding their LRP and career experiences. With a 60% response rate, results indicated that approximately 95% of past LRP participants continued to participate in research activities after exiting the LRP.

### Improving and Enhancing Business Functions to Support the LRPs

OER completed several evaluations and analyses of its operations including the completion of a two-year customer service survey project, which indicated that LRP awardees were highly satisfied with the operational and programmatic aspects of the program.

#### IMPACT

*In the short-term, the NIH LRPs are achieving the major program goal of helping researchers stay in research; further follow-up evaluation will be conducted to determine the persistence of this effect.*

#### IMPACT

*Survey results pointed to new directions and elements that the LRP will consider pursuing to continue meeting the needs of future applicant and awardee cohorts.*

## Leading NIH's Small Business Programs

Contacts: Matthew Portnoy, PhD; Lenka Fedorkova, 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. In FY13 and FY14, more than \$1.4B was awarded for over 1,900 projects allowing small businesses to commercialize their technology and further the NIH mission.

### Major Accomplishments

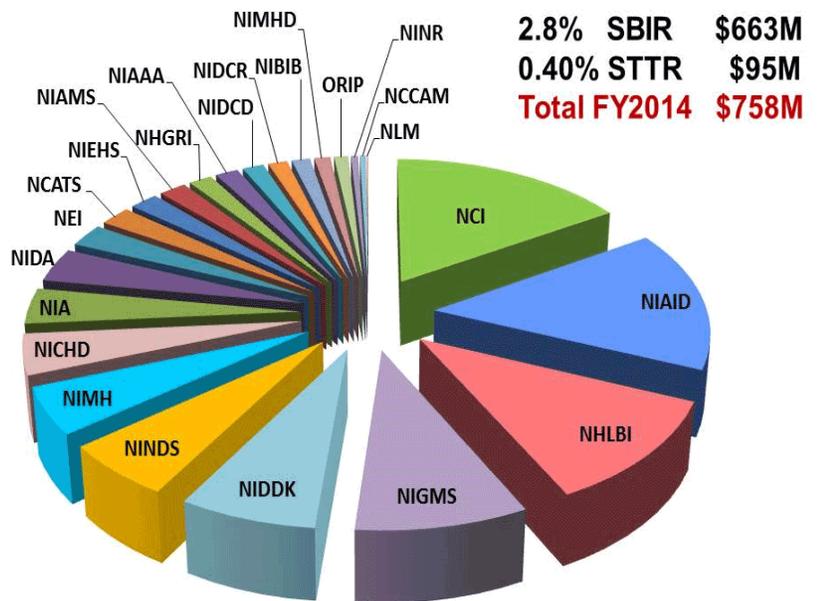
#### Leadership in Outreach to Women-Owned and Socially/Economically Disadvantaged Businesses, and IDeA States

As the lead HHS agency, NIH made a concerted effort to raise the consciousness of these groups and the SBIR/STTR community to provide assistance that will raise the number of applicants for awards.

#### IMPACT

Outreach to these groups included trans-NIH working groups to help identify the challenges and attempt to find viable solutions. Training sessions were conducted throughout 2014 to focus on increasing the number of applicants and their success rates for awards. The 16th annual NIH SBIR/STTR conference dedicated a half-day workshop that provided presentations on lessons learned, potential funding partners, and feedback and guidance, and special sessions dedicated to these groups.

### NIH SBIR/STTR Budget Allocations FY2014



#### Leadership in the SBIR/STTR Reauthorization and Implementation

Working with HHS, NIH ICs, the Small Business Administration (SBA), SBIR/STTR agencies, and Congress, OER provided substantial input and feedback implementing the successful reauthorization act of the SBIR/STTR programs nationwide in December 2011. OER continues to play a central role in planning, coordinating and starting the implementation of this complex legislation at NIH.

#### IMPACT

Implementation of the SBIR/STTR reauthorization will provide new flexibilities for the American small business community, including venture-backed company participation and additional versatility for the SBIR Phase II award. These flexibilities will also enhance proposed plans to shorten the SBIR/STTR grant cycle and time between application receipt date to award.



# SCIENTIFIC INTEGRITY

*Authoritative Point of Contact for Arbitrating  
Research Conduct Issues*



# *Ensuring Integrity of Scientific Programs through Policy*

Contact: Sherry Mills, MD, MPH

OER develops and implements program policies centrally to provide consistent standards for processes across NIH. These policies are critical for risk mitigation and ensuring that NIH programs are founded on clear, consistent, up-to-date implementations of laws, regulations and policies.



## *Major Accomplishments*

### **Reissuing Manual Chapters for NIH Staff Policy Implementation**

OER oversees NIH Manual Chapters that provide internal guidance on program policy and program implementation. During fiscal FY13 and FY14, OER proactively identified areas for policy revision to mitigate risk: OER rescinded four outdated NIH Manual Chapters, and issued 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. OER also issued seven major policy announcements, each of which clarified policy and mitigated risk to the agency.

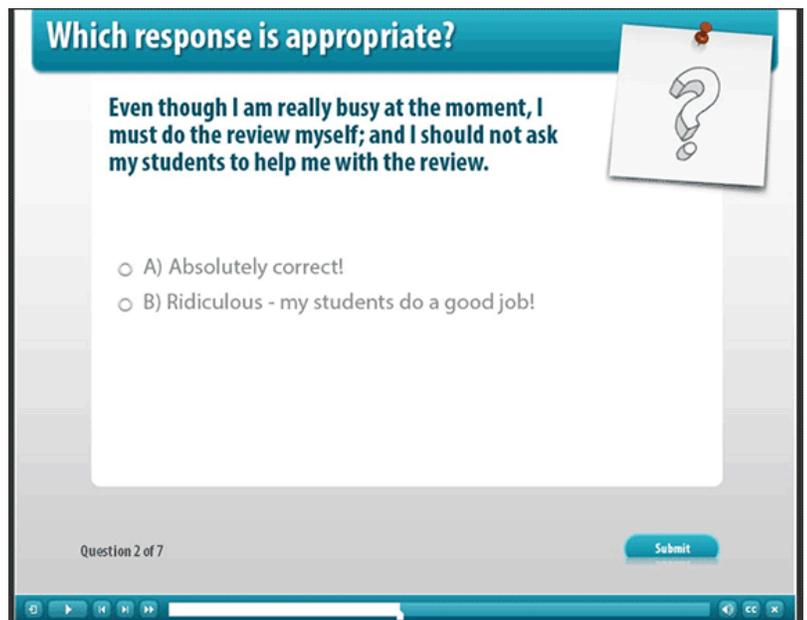
#### **IMPACT**

*Reissuing new manual chapters and rescinding outdated ones ensures that NIH extramural staff develop and implement IC programs using correct and consistent information regarding laws, regulations and policies. These, in addition to the new policies issued, will result in a more consistent approach across NIH to the management of ongoing awards that involve human subjects, and will further NIH's goal of supporting projects with scientific merit, integrity, and program relevance.*

## Ensuring Research Integrity

Contact: Patricia Valdez, PhD

OER provides training to NIH extramural staff and research integrity officers on the handling of allegations of research misconduct in NIH-funded extramural activities. OER supports NIH research integrity officers by providing a preliminary review of allegations of research misconduct and serving as a liaison between the HHS Office of Research Integrity (ORI) and NIH ICs.



### Major Accomplishments

#### Trained Staff in the Handling of Research Misconduct Allegations

OER's annual extramural research integrity training, held in September 2014, featured a dynamic presentation by behavioral economist Dr. Dan Ariely of Duke University entitled [“Why It May Not Be Just a Question of a Few Bad Apples.”](#) OER also provided in-depth training to NIH IC research integrity officers on handling research misconduct allegations using the new Research Misconduct Allegation Review System (RMARS).

#### Streamlined Handling of Research Misconduct Allegations

OER developed a new online communication and records management tool, Research Misconduct Allegation Review System (RMARS), to enhance secure communication between agencies. OER also improved linkage of NIH eRA IMPACII with the PHS Administrative Alert System that records administrative actions imposed on individuals found to have committed research misconduct.

#### IMPACT

*Enhancing staff awareness of the procedures for handling allegations of research misconduct helps expedite the review of allegations and maintains the integrity of the investigation.*

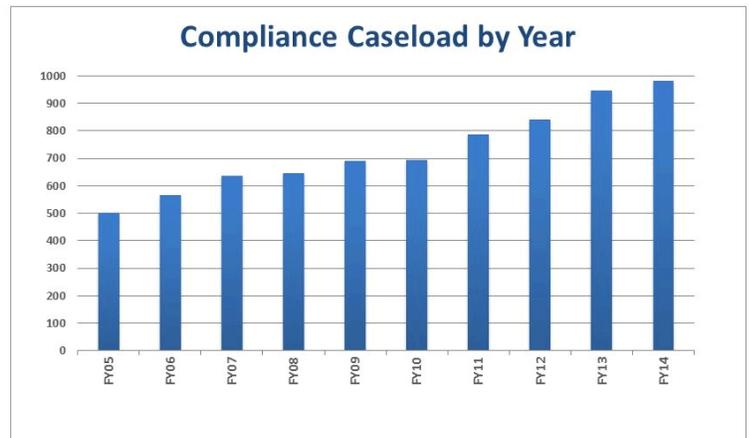
#### IMPACT

*RMARS allows for efficient sharing of documents and communications regarding allegations of research misconduct between OER, NIH research integrity officers, ORI, and other HHS agencies. Enhancing the linkage between NIH eRA IMPACII and the PHS Administrative Alert System has helped to maintain the integrity NIH peer review by identifying individuals with administrative alerts.*

## 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) negotiates assurance documents and oversees compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals for all institutions that receive PHS support for research, testing or training involving laboratory animals. Education is key to ensuring compliance, and OLAW 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 (IACUC) that reports to OLAW any serious noncompliance with applicable animal welfare policies. This self-reporting in combination with third-party reports resulted in 1,853 compliance cases opened between October 1, 2012 and September 30, 2014. During the same period 1,926 cases were closed.

#### Conducting Public Engagement and Reducing Burden

In 2014, OLAW sought public input on proposed guidance regarding what is considered a significant change to an ongoing animal activity requiring IACUC review. In response to the public comments and to reduce regulatory burden, NIH and USDA issued joint guidance allowing the administrative handling of some significant changes in certain defined categories. A special webinar was presented, new web resources were created, and existing guidance was updated to aid institutions in implementation.

**Support for U.S. Small Business Research** The number of Inter-institutional Animal Welfare Assurances negotiated over the past 4 years continues to increase in relation to the grants for the Small Business Innovation Research (SBIR) and the Small Business Technology Transfer Research (STTR) programs. An average of 77% of these Assurances are negotiated as a result of SBIR/STTR grants involving research with animals.

#### IMPACT

*Ensuring compliance with all federal policies regarding the use of animals in PHS-funded research increases accountability to the public, enhances animal welfare and leads to better scientific outcomes.*

#### IMPACT

*During the negotiations OLAW provides guidance to small businesses to ensure the proposed cutting-edge research meets federal animal welfare standards.*

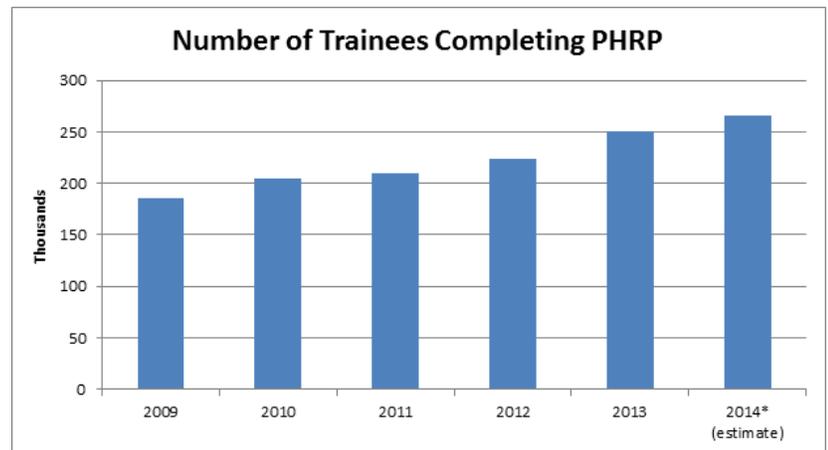
#### IMPACT

*Adoption of the new guidance on significant changes by both agencies supports institutions in their use of performance standards, and allows for professional judgment and flexibility by the IACUC and veterinary staff in creating workable policies, thus reducing regulatory burden to the research community.*

# Promoting Human Subjects Protection in Research through Training

Contact: Ann Hardy, DrPH

OER helps promote NIH awardees' compliance with federal regulations and NIH policies for the protection of human subjects (HS) through a multi-faceted training program that meets the needs of both internal and external customers. For NIH staff training, our goal is to provide the necessary information in an accessible format so that staff can understand how to apply knowledge about HS protections to the conduct of their particular job functions. We also provide resources and information on HS protections to the extramural communities that NIH serves.



## Major Accomplishments

### Implemented Multi-tiered Staff Training

OER developed a set of narrated e-learning modules on HS protections that range from a basic module for all extramural staff, to in-depth modules for staff who work with HS awards. OER also began advanced training of IC staff using a mock Institutional Review Board (IRB) review format and organized workshops for IC staff who are involved in HS code change requests. In 2014, OER launched a case-study-of-the-month on our intranet site to address common staff questions.

### Improved Outreach with the Extramural Research Community

OER enhanced the utility of our public online training module, "Protecting Human Research Participants" (PHRP), by partnering with Virginia Commonwealth University to allow physicians to earn continuing medical education (CME) credit for completing PHRP. In the first-year implementation, approximately 1,100 physicians had earned CMEs. OER also presented on HS protections in NIH awards at annual meetings of the National Conference of University Research Administrators and the Eastern Nursing Research Society held locally.

#### IMPACT

*Our training provides staff with both basic knowledge about HS protections in NIH-supported research as well as practical information and resources about how to apply that knowledge in their daily jobs. These efforts help foster an NIH extramural workforce that is knowledgeable and better able to ensure the ethical conduct of NIH-funded human subjects research.*

#### IMPACT

*PHRP is an increasingly used resource for the extramural community as documented by course completions. Improvements to PHRP have enabled us to target an important external group: physicians involved in clinical research. Our targeted presentations have allowed us to interact with key extramural communities in an efficient and cost effective manner.*



# PUBLIC ACCOUNTABILITY

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

Program  
Stewardship



Scientific  
Integrity



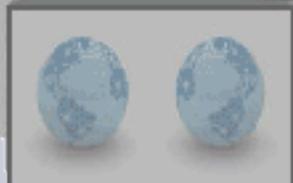
Public  
Accountability



**Policy &  
Procedures**  
Development,  
Implementation,  
and Oversight



Systems &  
Data



Communications



Administrative  
Support



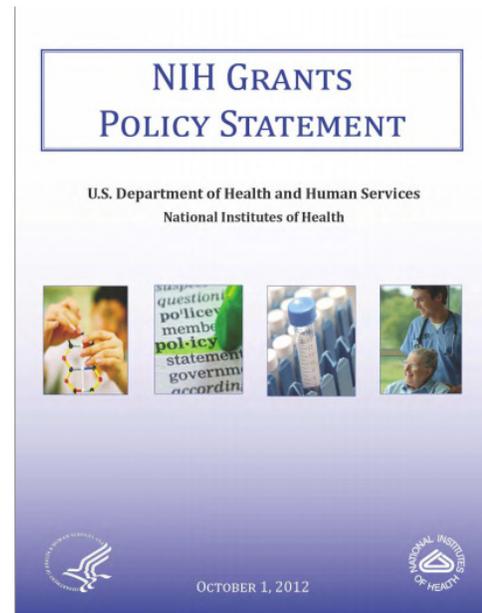
Education &  
Training



# Ensuring Integrity of NIH Programs through Grants Policy

Contact: Michelle G. Bulls

OER is the authoritative source of grants policy for NIH. Through our efforts, applicable HHS and federal grants policies are integrated into 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

### Implementing HHS Policy Changes and Updating Policy Resources

OER completed the payment transition to subaccounts for all foreign grantees and began a phased approach for this transition for domestic grantees. In addition, OER implemented new closeout requirements for NIH grants, and began implementation on HHS implementation of OMB-issued Uniform Guidance. As policy changes and implementations progressed, OER updated essential resources to provide guidance to both the extramural community and NIH staff, including annual revisions to the NIH Grants Policy Statement, updates to application and progress report instructions, new guidance documents for new policy topics, and aligning existing guidance with ever-changing policies and procedures.

### Ensured Policy Enforcement through Electronic Systems Implementation

OER's implementation of electronic systems enhanced the efficiency of policy enforcement. These implementations include: the transition of competing applications to electronic submission through Grants.gov; mandating the use of eRA Commons electronic business processes for Research Performance Progress Reports (RPPRs); implementing Commons ID requirements for sponsors in individual fellowship applications and for all postdocs, graduate and undergraduate students on RPPRs; and continued pilots of electronic business processes for change of grantee organization, change in grantee organizational status, and administrative supplements.

#### IMPACT

*HHS changes in payment (subaccounts) and closeout serve to improve financial integrity for the agency and grantees. Providing updated policy resources to the applicant/grantee community and NIH staff assures the integrity of the grants management process by providing comprehensive and current resources are available to all. The annual NIH Grants Policy Statement update is critical 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. Ensuring compliance is critical for mitigating risk to the NIH. OER also devotes significant time and resources to education and outreach—key components of any compliance program, and manages internal programs such as NIH’s Grants Management Professional Certification program, and internal control reviews.



## Major Accomplishments

### Reviewing Internal Controls

OER has conducted a series of NIH-wide reviews of internal controls over policy areas including: out of rank funding; facilities & administrative costs; scientific, budgetary, and commitment overlap; and special award conditions. 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 phases of the program is to evaluate grantees’ FCOI policies for compliance with regulatory requirements and assist grantees’ compliance actions by offering technical assistance. OER plans to continue and expand the proactive FCOI compliance program.

#### 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.*

# Outreach to Ensure Proper Use of NIH-funded Intellectual Property

Contact: Ann Hammersla, JD

OER develops, implements, and monitors extramural intellectual property policies and invention reporting under the Bayh-Dole Act. OER also promotes the proper utilization of NIH-funded patents and inventions in extramural programs, and facilitates the distribution and sharing of research resources.



## Major Accomplishments

### Revitalized Educational Outreach to Other Federal Agencies and the Extramural Community

OER completed three webinars in an ongoing series that will be publicly available on the internet for easy access by all NIH grantees. These webinars educate the extramural community regarding required submissions—including confirmatory licenses, government support clauses, and invention disclosures—using the iEdison system. OER also participated in meetings and webinars hosted by external stakeholders to address outstanding issues, answer questions, present recent updates regarding intellectual property and technology transfer policies, and solicit input from our stakeholders to improve our services.

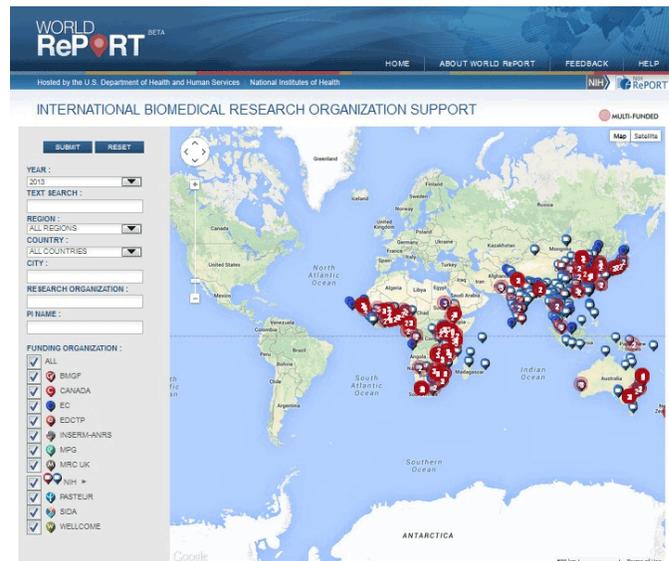
#### IMPACT

*Proactive outreach to the extramural community improves their business processes by providing information necessary for streamlining their workflows, reducing redundant practices, and training individuals new to federal perspectives on the fields of intellectual property and technology transfer.*

## Providing Transparency into NIH Grant Programs

Contacts: James Onken, PhD; Brian Haugen, PhD

OER hosts the NIH Research Portfolio Online Reporting Tools (RePORT) website, 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 expenditures and results.



### Major Accomplishments

#### Creating New Tools to Help the Research Community

In the fall of 2013, the Matchmaker feature was added to RePORTER, our publicly-accessible repository of funded research projects. Matchmaker allows users to paste in a block of text of up to 15,000 characters (for example, a research project description or journal article abstract) and find NIH-funded research funded on similar topics. Matchmaker uses text-mining tools to identify topics in the user's text and find related research in RePORTER.

#### IMPACT

*In addition to returning lists of similar projects, Matchmaker provides users with information on which NIH institutes and centers most often fund research on related topics, which grant mechanisms have been commonly used, and which study sections have reviewed similar proposals. This is useful information for researchers looking for collaborators or potential applicants considering submitting a proposal to NIH.*

#### Providing a World-wide View of Research

The World Research Portfolio Online Reporting Tool (World RePORT) located at <http://worldreport.nih.gov>, is an online database and map of research funded by NIH and other members of the Heads of International Research Organizations worldwide. In July 2013, NIH Director Francis Collins and the heads of eight other major research-funding and research organizations published [an article](#) on World RePORT in Lancet Global Health.

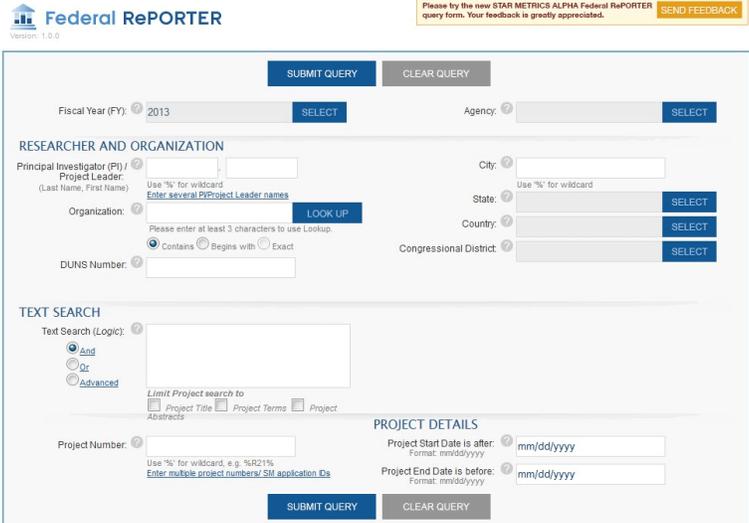
#### IMPACT

*As Dr. Collins, et al., note in their article, the availability of a comprehensive database of funded research—including names of investigators and research abstracts—can be of significant value to governments, donor agencies, investigators, and the broader global health research community, particularly for those working in the regions covered by the map (currently sub-Saharan Africa, southeast Asia, and Pacific regions).*

# Collaborating with External Organizations and Establishing Interagency Systems

Contacts: Bill Duval, PhD; Brad Hendrick; Neil Thakur, PhD

OER frequently partners with other federal organizations and stakeholder groups, such as the Federal Demonstration Partnership, to establish common solutions to issues affecting our grantee community. Through these partnerships, we establish standards across multiple funding agencies, avoid duplication, and reduce administrative burden for our grantees.



## Major Accomplishments

### Creating a Single Database for Information on Federally Funded Science

In 2014, as lead agency for the STAR METRICS consortium, OER launched [Federal RePORTER](#), a repository of research projects funded by multiple federal agencies. Federal RePORTER currently includes research funded by NIH and other HHS divisions, the National Science Foundation (NSF), National Aeronautics and Space Administration, Department of Agriculture, Environmental Protection Agency, Department of Veterans Affairs, and portions of the Department of Defense. New agencies are expected to join Federal RePORTER in the near future.

#### IMPACT

*Federal RePORTER provides a central repository where the public can explore federal research investments in science. A simple interface allows users to search the database for specific keywords and other project-related information, and text-mining tools are available to find related research projects.*

### Creating a Tool for Federal-wide Biosketch Generation

In 2014, we launched Science Experts Network Curriculum Vitae ([SciENCv](#)), an electronic system that helps researchers assemble the professional information needed for participation in federally funded research. The system currently supports the development of biosketches for NIH grant applications and, starting in 2015, users will be able to create biosketches for use in grant applications to the NSF.

#### IMPACT

*From a single SciENCv profile, users can automatically create biosketches in the various formats required by different federal agencies. This will ease the burden for applicants who will have to maintain only a single repository of their professional information, rather than manually generating a separate biosketch for each grant application.*



# 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



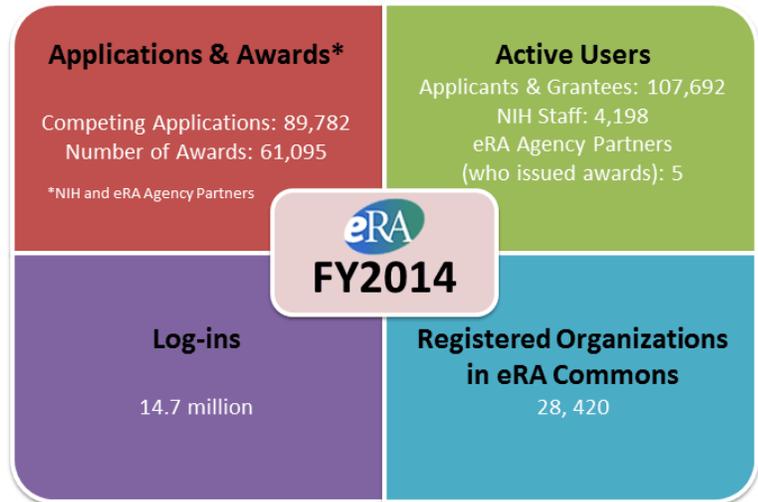
Education &  
Training



# Developing and Maintaining the Electronic Research Administration (eRA)

Contact: Inna Faenson

OER provides electronic Research Administration (eRA) information systems to NIH, the Agency for Healthcare Research and Quality, Centers for Disease Control, Food and Drug Administration, Substance Abuse and Mental Health Services Administration, and the Veterans Health Administration in support of the full grants administration life cycle. eRA partners with the grants 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

### Launched New and Redesigned Systems for Enhanced Grants Processing

Developed and launched several new and redesigned electronic systems to enhance grants processing: ASSIST (to prepare and submit multi-project applications); IMS (to report inclusion of women and minorities in clinical research); FACTS (to accurately track and report NIH investments in research grants and contracts involving foreign collaborations; and RR (for receiving and referring grant applications to study sections).

### Improved Quality of Data in Grants Systems

eRA adopted a universal computing standard called Unicode that allows eRA systems to accept Greek characters as they appear in the original scientific text submitted by grantees. Thus, Greek characters in progress reports, for instance, are processed and appear as submitted.

#### IMPACT

*Using ASSIST, applicants for all multi-project applications submissions to NIH are able to take advantage of online application development and submission, pre-populated forms, and upfront error checking and image previewing; FACTS provides a unified source of foreign component information and better data quality; IMS provides a user-friendly way of electronically entering, storing, and reporting inclusion enrollment data that promotes increased transparency for grantees and grantor agency staff; and RR provides for streamlined receipt and referral of grant applications.*

#### IMPACT

*This major effort benefits applicants, grantees, and peer reviewers as the implementation of Unicode improves the quality of data in uploaded summary statements, progress reports, and reporting systems. It also eliminates the need for NIH or agency staff to manually correct the data, resulting in time and cost savings.*

## *Issuing the NIH Guide for Grants and Contracts*

*Contact: Erica Brown, PhD*

OER publishes the NIH Guide for Grants and Contracts to notify the extramural community about funding opportunities, new policies, and updates in support of NIH and three other agencies within HHS. OER reviews, processes and publishes Funding Opportunity Announcements (FOAs) and Notices on behalf of all NIH ICs.

### *Major Accomplishments*

#### **Improving the Publication of Funding Opportunities and Policy Announcements**

In 2011, OER conducted a business process evaluation of the NIH Guide clearance process, and in 2012 implemented recommendations to improve the efficiency of the process and the accuracy of published announcements. The efficiencies of the new business process were realized in 2013 and 2014 through a reduction in the time of the FOA clearance process from 38 days to 13 days.

#### ***IMPACT***

*As a result of the efficiencies created by the new NIH Guide business process, Guide reviewers are able to focus their efforts on the policies, regulations, and legal requirements of FOAs, and the NIH provides more consistent and accurate FOAs to the extramural community.*

#### **Providing a Better Understanding of NIH Guide Workflow**

Throughout 2014, the NIH Guide team initiated major outreach efforts to IC stakeholders to demystify the FOA clearance process. Training involved explanations of the role of OER in the clearance process as well as timelines, processes, and policies related to the review and publication of FOAs and Notices.

#### ***IMPACT***

*IC staff are becoming increasingly aware of the many steps involved in the production of high-quality FOAs and incorporating this knowledge when considering how to issue new scientific initiatives through the Guide.*

# Training Extramural Staff

Contacts: Charles Selden, PhD

OER provides NIH extramural staff with training on policy, practice, and business processes to perform their jobs as scientific administrators of grants and R&D contracts. The training program offers four programs: Core Curriculum (a 5-part training series for newly hired health scientist administrators), Extramural Scientist Administrator (ESA) Seminar Series (a 16 week seminar series covering the functions of 30 offices at NIH and partner granting agencies), ad hoc trainings addressing emergent policy issues, and Scientific Program and Review Special Interest Group (SPRIG), an administrative topics discussion course.



## Major Accomplishments

### Training Extramural Staff

More than 300 new NIH health scientist administrators underwent training in their roles shepherding the extramural research program. An additional 61 learned about NIH's major offices and entities and high level administrative functions to further improve their work as NIH extramural staff. Over 3,600 NIH staff broadened their understanding of NIH programs and principles that will allow them to interact more efficiently with their community. More than 2,000 staff members learned more about a wide array of topics including research integrity, human subjects protections, genomic data sharing, the NIH Inclusion Policy, research training programs, and administering grant supplements.

#### IMPACT

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

### Implementation of New Staff Training Strategic Plan

In 2013, a formal evaluation of the extramural staff training program assessed the effectiveness of the program in meeting its goals. As a result, OER developed and is implementing operational and strategic plans to improve the management, content, and evaluation of extramural training, and to apply the best practices and tools related to adult learning.

#### IMPACT

*The NIH extramural staff training program is transforming to be efficient, effective, and responsive to the needs of the NIH extramural staff and managing risk to the agency. Implementing objective course assessments will continuously increase training effectiveness for improving staff knowledge, skills and attitudes to improve efficiency and scientific administration of grants and contracts.*

## *Providing Outreach to the Research Community*

*Contacts: Megan Columbus; Cynthia Dwyer; Nicole Garbarini, PhD*

Each year, OER proactively disseminates information on NIH grants and funding to tens of thousands stakeholders in NIH's extramural research community, most significantly scientists and research administrators seeking or receiving NIH funding. Using a variety of communication methods, OER provides forums for dialogue with the communities we serve. OER coordinates in-person seminars, such as the annual NIH Regional Seminar which reaches over 800 global attendees each year, as well as booths at numerous research administration meetings. OER also presents to NIH campus visitors; hosts online webinars, podcasts, and blogs; and maintains and updates the NIH grants website (<http://grants.nih.gov>).

### *Major Accomplishments*

#### **Blogging OER's Director**

OER began a blog called "Rock Talk" to connect the research community with Dr. Sally Rockey, OER's director and the NIH Deputy Director for Extramural Research, and thereby inform the research community of NIH management's perspectives on NIH grants and funding. With over 100 posts in 2013-2014 Rock Talk received about 45,000 page views each month, and 700-1,500 unique visitors per day.

#### ***IMPACT***

*Rock Talk has increased the transparency of NIH grants information and funding data, created a valuable channel for 2-way communication with the community, and allows for expedient and high-impact communication of important topics to the research community.*

#### **Developing Virtual Education Opportunities**

As a means of maximizing outreach potential to its global community, OER consistently increased its use of virtual education opportunities. OER uses its YouTube channel, "NIH Grants", to provide webinars and video tutorials on numerous grant-related topics. Social media also plays an important part in sharing information and links with our community through platforms such as Twitter, LinkedIn and Google+.

#### ***IMPACT***

*Social media and online educational opportunities, such as webinars, are valuable ways to increase the accessibility of information to attendees worldwide at no cost, plus provide a voice to NIH with live events hosted online.*

## Providing Centralized Help Desk Support

Contacts: Dorsey Gaines; Jim Seech; Sheri Cummins

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

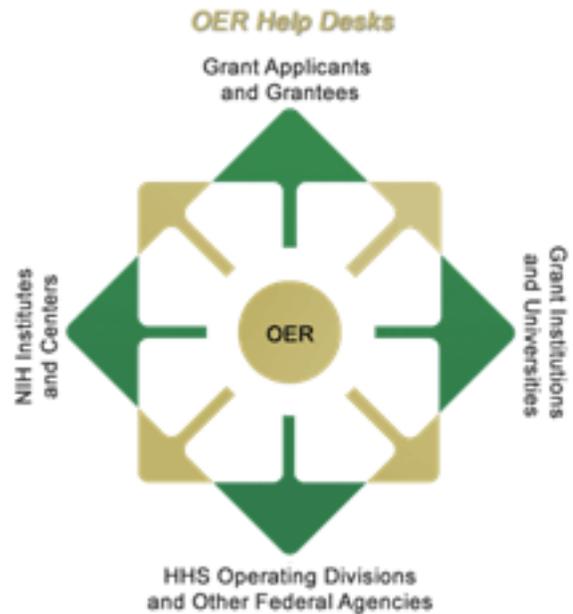
### Major Accomplishments

#### Responding to Inquiries

Every day, OER help desk staff addresses between 500 to 1000 requests for support on behalf of NIH. Examples of this assistance vary from helping NIH applicant organizations and investigators navigate the grants process, submit electronic applications, understand the new FCOI requirements, complete the new federal-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 staff 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, allowing IC staff focus on their critical duties by reducing the need for them to field calls from the extramural research community.*

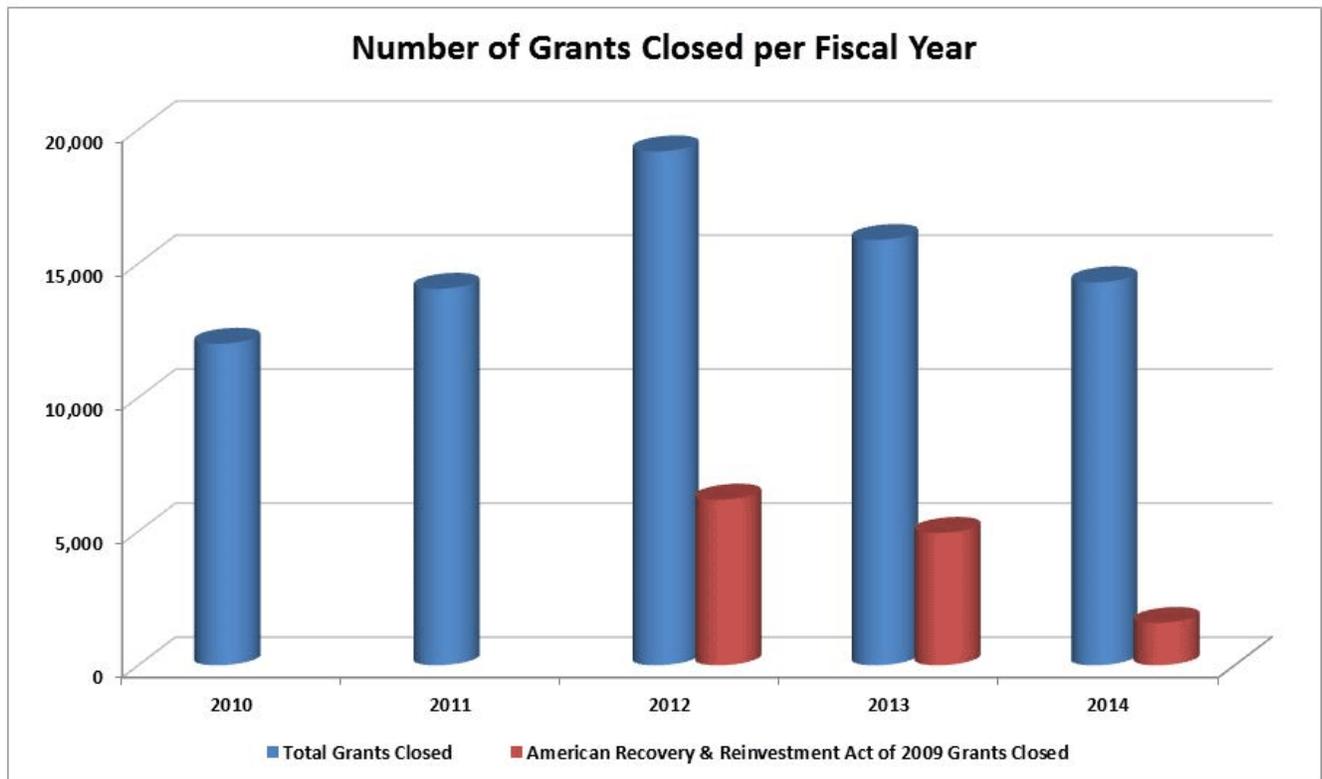
#### IMPACT

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

## Providing Centralized Grant Closeout for NIH

Contact: Mitzi Diley

Through its Division of Central Grants Processing (DCGP), OER centrally manages and provides a dedicated workforce of specialized staff who conduct grant closeout and processing of grant applications on behalf of 24 NIH ICs that make grant awards. The DCGP ensures continuity and consistency of service for grant closeout and related activities.



### Major Accomplishments

#### Tripled Closeout Volume

DCGP increased its total grant closeout volume by nearly 31% for fiscal year 2013 and by 11% for fiscal year 2014, as grants awarded via American Recovery & Reinvestment Act of 2009 (ARRA) funds came to an end.

#### **IMPACT**

*NIH achieves timely and accurate closeout of grant awards.*

***To view the 2013-2014 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>***



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National Institutes of Health  
2013-14 Office of Extramural Research Report  
Publication #xx-xxxx | Printed XXXXX

