



THE OFFICE OF EXTRAMURAL RESEARCH

2009 OER REPORT

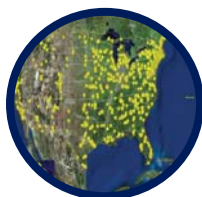
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2009 OER REPORT

The Office of Extramural Research provides the corporate framework for the NIH research administration and works to ensure the scientific integrity, public accountability, and effective stewardship of the NIH research grant portfolio.



A Welcome Message from Sally Rockey Director, Office of Extramural Research

A Look Back at 2009, A Look Ahead to 2010

In this inaugural edition of the 2009 OER Report, we would like to give you insight into the tremendous work that goes on within our six major offices, thanks to our 1,200 employees. Here you will find a multitude of achievements, a sense of the many high profile NIH initiatives where OER played a critical role in FY09, and a glimpse of the work that lies ahead.

Early in 2009, NIH was given a unique opportunity in the form of \$10.4 billion from the American Recovery and Reinvestment Act (ARRA). ARRA sought to place research funding in the hands of institutions the very next day it seemed, with the goal of jump starting jobs and the economy and creating jobs. ARRA arrived with little notice at NIH's door and upended NIH's traditional timelines for announcing opportunities and receiving and reviewing grant applications. OER rose to the challenge setting new policies, coordinating the activities of NIH Institutes and Centers, communicating with internal and external stakeholders, developing electronic systems support, solving problems creatively, and expediting processes along the way. We stand proud, knowing that our labor was well worth the while—the funding has found its way to scientists and labs across this country, and we eagerly await the scientific results.

Federal pronouncements often bring in their wake changes in policy. OER's relationships with NIH senior leadership, NIH Institutes and Centers, institutions and investigators, other government entities, and the public uniquely position us to fulfill the role of implementer. So it was in March 2009, when President Obama signed an executive order on research involving stem cells, leading to changes in the way NIH funds human stem cell research. Along with helping shape the new policy, OER set in place award policies and procedures for staff members in the ICs; implemented systems to support compliance and oversight; and developed the NIH Stem Cell Registry.

These initiatives are only a few examples of the many ways OER ensures scientific integrity, public accountability and effective stewardship of the NIH extramural research portfolio. We demonstrate the same commitment in all our day-to-day activities.

Sally J. Rockey, Ph.D.

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



**2009 Office of Extramural Research (OER) Report
Table of Contents**

Introduction	1
Program Stewardship	
• Peer Review Policy	6
• Enhancing Peer Review	7
• Program Policy	8
• New & Early Stage Investigator Policy	9
• Fellows/Interns	10
• Centralized Program Leadership	
– Research Training & Career Development	11
– Small Business Innovation Research (SBIR) / Small Business Technology Transfer (STTR)	12
– Academic Research Enhancement Award (AREA)	13
– Project Clearance	14
Scientific Integrity	
• Human Research Protections	16
• Research Animal Protections	
– Assurances	17
– Policy & Education	18
– Compliance Oversight	19
• Research Misconduct	20
• Intellectual Property & Resource Sharing	21
• Financial Conflict of Interest	22
Public Accountability	
• Grants Compliance and Oversight	24
• Grants Management Training	25
• Grants Policy Development, Implementation, & Oversight	26
• Research Condition & Disease Categorization (RCDC)	27
• Public Access	28
Services and Infrastructure	
• Electronic Systems & Data	
– Electronic Research Administration (eRA)	30
– Data Quality Branch	31
– Reporting & Analysis	32
– Electronic Tools/RePORT	33
– NIH Guide for Grants & Contracts	34
• Communications	
– Centralized, Authoritative Source of Grants Information	35
– Outreach to Research Community	36
– Help Desk Support	37
• Administrative Support	
– Extramural Staff Support	38
– Extramural Staff Training	39
– Loan Repayment Program	40
– Grants Closeout Center	41
– National Research Service Award (NSRA) Payback Service Center	42

2009 Office of Extramural Research Report Introduction

About OER: Making Grants Happen Without Funding a Single Project

Extramural grants represent more than 80% of the \$31.2B NIH budget. Through its approximately 1,200 individuals and \$113M 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.



OER takes a collaborative approach to supporting the research enterprise, interacting with major stakeholders (research institutions and extramural staff) and ensuring appropriate policies, procedures and systems for oversight are in place while, at the same time, considering the impact on our research partners.

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

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

Office of Laboratory Animal Welfare (OLAW): Responsible for guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, supports educational programs, and monitors 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 in 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.

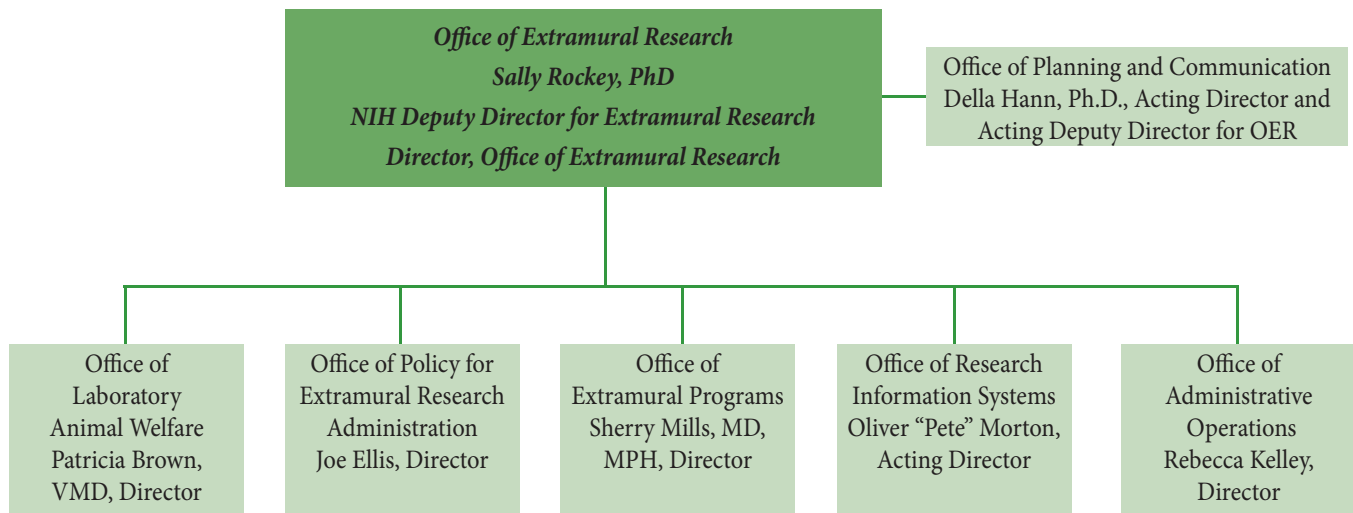
2009 Office of Extramural Research Report Introduction

Office of Extramural Programs (OEP): Provides leadership and expertise in science program management, including program and policy development, interpretation, coordination, oversight, evaluation, training and outreach for the extramural research community and NIH extramural staff, promoting the highest quality and sustained capability of research and training programs in order to improve public health.

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

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

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



2009 Office of Extramural Research Report Introduction

A Look Back at 2009: Putting It Into Perspective

American Recovery and Reinvestment Act of 2009

The American Recovery and Reinvestment Act (ARRA) provided incredible opportunities for NIH and OER. ARRA designated approximately \$10 billion directly to NIH for scientific research, scientific equipment, and intramural and extramural repair, improvements, and construction. This funding allowed NIH to give nearly 13,000 awards via new awards, supplements, and funding of grants beyond the pay line.

OER played a pivotal role in the distribution of these funds by facilitating rapid funding opportunity development, developing policies and procedures for ARRA funding, implementing electronic systems to support the unique requirements of these awards, and communicating the constant stream of decisions, policies and processes to NIH staff and our extramural partners. OER has also played a leading role in NIH's ARRA award monitoring, a Federal-wide initiative to increase transparency into the ways ARRA dollars are spent.

Financial Conflict of Interest

NIH faced several questions in FY09: Should the regulations governing financial conflicts of interests of extramural investigators be revised and, if so, how? Should investigators be required to disclose all of their financial interests? Should NIH make disclosures public? OER led the way for NIH and HHS by drafting and publishing an Advanced Notice of Proposed Rulemaking in May 2009 requesting comment on the "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors." OER analyzed and incorporated comments into a Notice of Proposed Rulemaking that was released in May of 2010.

Stem Cell Research

On March 9, 2009, President Barack Obama issued Executive Order (EO) 13505, "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells." After receiving approximately 49,000 comments from various advocacy groups, professional societies, Congress, academic institutions and private citizens, NIH published the "National Institutes of Health Guidelines for Human Stem Cell Research," which took effect July 7, 2009. In addition to helping shape the new policy, OER set in place award policies and procedures for staff members in the ICs, implemented systems to support compliance and oversight, and developed the NIH Stem Cell Registry.

Enhancing Peer Review

NIH has undertaken major changes to its Peer Review system, with the goal of funding the best science, by the best scientists, with the least amount of administrative burden. These changes affect all of OER's stakeholders—from grantees to NIH staff leading the reviews—making OER once again the logical place to coordinate implementation of the changes. OER, working with the Peer Review Oversight Committee, helped shape new policies; ensured staff were trained; developed a new application guide; changed electronic systems to support the new application format, scoring system and review meetings; rapidly revised 600 funding opportunity announcements to reflect the changes, and managed community expectations regarding the changes.

Early Stage Investigators

Entry of new investigators into the ranks of independent, NIH-funded researchers is essential to the health of this country's biomedical research enterprise. In order to encourage early transition to independence and ensure a pipeline of new investigators, the NIH announced a new policy in FY09 involving the identification of early stage investigators (ESIs). OER provided leadership during policy development, performed data and workforce development analysis to track trends, conducted environmental scans to anticipate future scientific workforce needs, and worked to get consensus on the new policy.

2009 Office of Extramural Research Report Introduction

A Look Ahead to 2010: Opportunities Await Us

Five Thematic Areas

On August 17, 2009, Dr. Francis Collins outlined five thematic areas to steer NIH into the future. OER will continue to support implementation of these themes, especially Theme 5: empowering the biomedical research community by considering future budgets, training, peer review, and workforce diversity. This will be the impetus for work on OER's Early Stage Investigator and workforce development issues.

Continuous Evaluation of Peer Review

A major outcome of the Peer Review Enhancement initiative is the statement of NIH's commitment to continually evaluate our peer review system. As part of OER's role in developing, monitoring and providing oversight for NIH peer review policy, OER will continue to evaluate the recent changes to ensure NIH continues to have the premier peer review system in the world.

eRA Evergreening

As eRA's IMPAC II system is nearing its 20th year, OER continues the process of updating eRA systems both through the implementation of new hardware and software infrastructure and by coordinating the cyclical redesigning and rebuilding systems hand-in-hand with the user community to reflect their changing needs. This Evergreening initiative will allow eRA to better serve the extramural (100,000 users and 9,500 institutions) and the intramural communities, allowing them to record, review, process, and manage grant applications and awards.

Increased Transparency

NIH is fully committed to making grant funding information and the associated research results available to the public. To this end, OER is responsible for the systems that capture funding information and provide the public high quality data. The RePORT Web site provides access to reports, data, publications and patents, and analyses of NIH research activities (no later than 12 months after publication). In addition, OER developed the NIH Public Access policy and coordinates systems integration that allow for oversight and monitoring.

American Recovery and Reinvestment Act of 2009

Although the remaining ARRA funds will be disbursed in 2010, OER's job is not yet completed. We will continue to monitor grantee reports, create data reports of our own, and perform impact analyses on the effects to the community when ARRA funding runs out.

Financial Conflict of Interest

OER is leading the way to tightening financial conflict of interest rules to improve scientific integrity and public trust in research. In 2010, OER will be analyzing the comments from the Notice of Proposed Rulemaking and working with other leaders within NIH's Office of the Director, HHS and the Office of Management and Budget to issue the final regulation.



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



Peer Review Policy

Contact: Sally Amero

The NIH peer review process is the cornerstone of the NIH extramural research enterprise. Within NIH, OER is the central locus for developing, implementing, coordinating, and overseeing policies and procedures that facilitate the scientific and technical evaluation of all applications for research grants, training awards, and R&D contract proposals that are submitted to NIH for funding. Thus, OER has the ultimate authority and responsibility for ensuring that applications and proposals submitted to NIH are evaluated in a process that is fair, equitable, timely, and unbiased.

Key Attributes

Peer Review Policy

- Involves a two-tiered process of initial peer review by Scientific Review Groups and subsequent review by NIH Advisory Councils or Boards.
- Is widely regarded as the premier system for peer review worldwide.
- Utilizes tens of thousands of outside experts each year.
- Requires objectivity, fairness, and scientific and technical competence—the core values of NIH peer review.
- Requires that all applications accepted for review are subjected to the same review process and standardized review criteria.
- Must comply with applicable federal laws and regulations, and HHS policy.

Major Accomplishments

Accomplishments

- Facilitated Enhancing Peer Review and ARRA initiatives from the agency through review policy.
 - Implemented objectives and goals of the Enhancing Peer Review initiative.
 - Facilitated the review of applications submitted to initiatives under ARRA.
- Developed and launched new critique templates for reviewers, scoring system, guidance for reviewers and staff, and other peer review enhancements.
- Standardized review criteria in Funding Opportunity Announcements that are issued in the NIH Guide and used in the evaluation of different types of applications.
- Performed outreach to the extramural community through NIH Regional Seminars, the NIH Nexus, and other presentations.
- Provided leadership for review staff in assimilating changes to the peer review system.

Major Opportunities

Opportunities

- Develop more efficient systems for managing information flow, data capture and retrieval, and text mining throughout the peer review process (Evergreening).
- Incorporate advanced telecommunication technology to conduct review meetings.
- Develop policies that reflect the changing nature of research.
- Develop metrics for agency-wide reporting on the NIH peer review process.
- Assess current policy and regulatory documents for revisions as needed.
- Recruit the best talent as reviewers and review staff.
- Facilitate the electronic receipt of Research and Development (R&D) contracts.

Enhancing Peer Review

Contact: Sally Amero

The NIH has a long-standing history of supporting the most promising and meritorious biomedical and behavioral research. The NIH peer review system has been adopted internationally as the best guarantor of scientific independence. However, the increasing breadth, complexity, and interdisciplinary nature of modern research have created challenges for NIH's peer review system, the cornerstone of the research enterprise. As the scientific and public health landscape continue to evolve, the NIH recognizes the need for the processes used to support science to be fair, efficient, and effective. Therefore, in 2007, the NIH undertook a major evaluation of its peer review system through the Enhancing Peer Review initiative.

Key Attributes

Enhancing Peer Review

- At the end of a year-long diagnostic phase, the NIH released the final report, which identified the most significant challenges and proposed recommendations that would enhance the peer review system.
- The report outlined four implementation objectives:
 - o Engage the best reviewers
 - o Improve the quality and transparency of review
 - o Ensure balanced and fair reviews
 - o Continuously review peer review

Accomplishments

- OER was at the forefront of enhancing peer review in 2009:
 - o New NIH Policy on Resubmissions
 - o 9-Point scoring system
 - o Enhanced review criteria
 - o Formatted reviewer critiques
 - o Scoring of individual review criteria
 - o Clustering of New Investigator applications during review
 - o Shorter applications for R01s and other mechanisms
 - o Restructured applications to align with review criteria

Opportunities

- Revision of key policy and regulatory documents.
- Evaluation studies and metrics to monitor the success of enhancing peer review.

NIH Peer Review Policy

- The major enhancements to the NIH peer review system first were implemented in May 2009, with a second phase of implementation occurring in January 2010.

- Continuous review of peer review transferred to OER.
- All Funding Opportunity Announcements revised and re-issued.
- All instructional documents and critique templates for reviewers posted on one central OER Web site.

- Incorporation of review systems in other HHS agencies.

Major Accomplishments

Major Opportunities

Program Policy

Contact: Valery Gordon

The NIH Extramural Programs within the Institutes and Centers establish program priorities, select applications that are identified by scientific and technical review as most likely to achieve programmatic goals, and ensure that awards are administered in a manner consistent with high scientific and programmatic standards and pertinent policies. The Office of Extramural Research (OER) is the central locus for developing, implementing, coordinating, and overseeing policies and procedures that provide priorities and standards for processes involved in issuing and monitoring research conducted under NIH awards.

Key Attributes

Program Policy

- Involves developing and maintaining balanced individual and IC research portfolios.
- Includes program analysis and evaluation.
- Involves regular communication with investigators to stay current with research progress, challenges, and scientific advances.
- Involves monitoring of compliance with regulations and policies on NIH-supported research.
- Serves as a source of information and advocacy for programmatic decision-making.
- Requires that awards are fair, consistent, and subject to publicized standards.
- Requires that awardees comply with all applicable regulations and policies.

Major Accomplishments

Accomplishments

- Guided efforts to enhance NIH processes for data entry and collection through work with eRA advisory committees that will lead to greater accuracy of data on human subjects research in IMPAC II.
- Responded to inquiries from Congressional representatives about NIH applications and awards.
- Revised and drafted four Manual Chapters, two NIH policies, and Implementation Guidelines.
- Provided training on ARRA features in QVR and reminders for program staff for addressing issues related to NIH Enhancing Peer Review through the Program Leadership Committee.
- Published notices, advised ICs on standard operating procedures, updated FAQs for ClinicalTrials.gov to promote compliance with the Food & Drug Administration Amendments Act (FDAAA) of 2007.
- Participated in efforts to revise NIH policies and implementation of data and safety monitoring for clinical trials.

Major Opportunities

Opportunities

- Evaluation of program operation and accomplishments, including consideration of state of the art science, assessing contributions by the program to an overall mission, and assessing how outcomes meet the aim of an initial plan with a view of possible modification of the plan or program.
- Develop a pre-FOA development Web site.
- Conduct training for NIH staff and outreach to the extramural community.
- Continue to update and develop Manual Chapters and Grant Application and Management System (GAMS) as policies evolve.
- Optimize and standardize processes for establishing collaborations with foreign entities in conjunction with the Fogarty International Center (FIC).
- Update the Handbook for Program Officials.
- Provide training resources through Program Leadership Committee.

New & Early Stage Investigator Policies

Contacts: Walter T. Schaffer and James Onken

New Investigators (NI) are the innovators of the future. They bring fresh ideas and technologies to existing biomedical research problems, and they pioneer new areas of investigation. Their entry into the ranks of independent, NIH-funded researchers is essential to the health of this country's biomedical research enterprise. Increasing age and lagging entry rates into the pool of R01 funded investigators led to the establishment of targets and Institute and Center specific commitments starting in FY06. This resulted in an increased proportion of competing R01 awards going to New Investigators but had little effect on the duration of training and the age at entry. In FY09, the NIH established the Early Stage Investigator (ESI) policy that was designed to provide special incentives to NI who were within ten years of their terminal research degree or the completion of medical residency and encourage earlier completion of training and achievement of independence.

Key Attributes

New & Early Stage Investigator Policies

- NI are identified at the time they create a profile in the NIH Commons.
- The electronic system identifies investigators who have not previously received a substantial, competing NIH grant.
- NI then enter the date of completing their terminal research degree or medical residency and the NIH Commons calculates a ten year period of ESI status.
- The ESI status can be extended to account for breaks in research or research training because of family care, illness, disability, extended periods of clinical training (e.g. clinical fellowships), military service and other reasons.
- An Extensions Committee composed of senior NIH staff reviews the requests for extensions on a regular basis.
- Applications from New and from Early Stage Investigators are identified when they are received so that they can be clustered at review and accorded special consideration at the time of selection for funding.
- In FY09, the NIH policy set a goal of equalizing success rates for experienced and NI submitting new (type 1) R01 applications in order to achieve an approximate numeric target of 1,650 NI, the majority of whom would be ESIs.

Major Accomplishments

Accomplishments

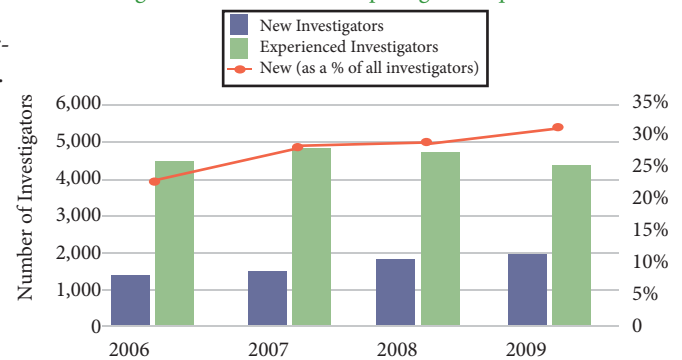
- Assembled hard working workgroups and developed a refined policy for NI and ESI and created an online form in the NIH Commons to collect necessary information to identify individuals with NI and ESI status.
- In FY09, the NIH funded 1,800 New Investigators (exceeding approximate target of 1,650). New Investigators also enjoyed a slightly higher success rate on type 1 R01 applications than did established investigators.
- The NIH ESI Extensions Committee reviewed 655 requests for extension and granted extensions to at least some part of the request for more than 72% of the requests.

Major Opportunities

Opportunities

- In FY10, the NIH will have the first full year of information on ESI.
- Policies were established reflecting those in FY09 equalizing success rates in order to achieve approximately 1,650 New R01 Investigators, a majority of whom will be ESIs.
- The complete information on ESIs should allow frequent status reports so that the ICs are continuously appraised of goal attainment.
- Remain committed to identifying and attracting new biomedical researchers and continue to explore novel ways to encourage early transition to independence. Institutions—our partners in this venture—must continue to look for ways to reduce the duration of graduate and postdoctoral training and to find new ways to enable new investigators to compete successfully for extramural funding.

Number of New & Experienced Investigators and New Investigators as a % of All Competing R01 Equivalent Awards



Fellows & Interns

Contact: Della Hann

The Office of Extramural Research offers a variety of rich experiences for fellows and interns from science and non-science backgrounds to learn more about NIH extramural policies, procedures, and communications. In 2009, fellows from the American Association for the Advancement of Science (AAAS) Science and Technology Policy Fellowship program, the Presidential Management Fellowship (PMF) program, and NIH's Administrative Fellows Program (AFP) pursued fellowship experiences in OER data and policy analysis, reporting, planning, evaluation, and communications.

Key Attributes

Fellows & Interns

- In FY09, OER had seven PMFs, 2 AAAS fellows, and an AFP Fellow.
- Fellows work throughout OER (OEP, ORIS, OPERA).
- Fellows participate in:
 - Reporting and Analysis
 - ARRA related projects
 - Communications
 - Planning

Opportunities for Fellows

- NIH Educational and Training Opportunities.
- AAAS and PMF specific training sessions, retreats, and networking events.
- Participation in and planning of national conferences, both science and policy related.
- Fellows can choose courses and training opportunities specific to their career goals.

Major Accomplishments

Accomplishments

- Helped with planning and implementing OER's centralized organization of ARRA Recipient Reporting.
- Worked on Enhancing Peer Review Policy and Assessments.
- Modeled priority scores of grant applications at NIH.
- Examined Early Stage Investigator and New Investigator Policies and the effects they have had on success rates in FY2009, specifically with respect to ARRA funding.
- Analyzed NIH pre- and post-doctoral research support.
- Carried out portfolio analysis of the market for new scientific Ph.Ds.
- Analyzed how to employ social network analysis in the evaluation of NIH funding initiatives and in broader portfolio analysis.
- Participated in evaluation projects involving IC Practices for Ensuring Compliance with the NIH Policy on Inclusion of Women and Minorities in Clinical Research.
- Drafted FOAs.

Major Opportunities

Opportunities

- Continue to provide opportunities for fellows throughout OER.
- Allow for assignments and projects to vary with the challenges being faced by NIH, as well as the interests and expertise of the particular fellow.
- In early FY10, a major focus for fellows will be the appropriations process, with a focus on ARRA and analysis related to how NIH allocated ARRA funds.
- Maintain OER's goal to provide rich experiences to facilitate the intellectual and leadership growth of all fellows.
- Encourage fellows to engage in a variety of activities throughout OER and offer a diverse exposure to daily functioning of OER.

Research Training & Career Development

Contact: Rod Ulane, Jennifer Sutton, and Henry Khachaturian

The Research Training and Career Development Group in the Division of Scientific Programs is responsible for developing and maintaining trans-NIH policies for research training, fellowship, and career development programs. This involves the study of broad areas of scientific workforce need including issues of diversity, evaluating NIH training initiatives, and coordinating efforts with the Division of Loan Repayment. The office oversees all NIH Guide announcements pertaining to training and career development awards, provides advice to ICs regarding the initiation of new training mechanisms, and develops policies consistent with NIH's training authorities and NIH's goal of ensuring an outstanding and diverse scientific workforce in biomedical, behavioral, and clinical sciences.

Key Attributes

Research Training & Career Development

- Develops and maintains programmatic policies for \$1.5 billion in NIH grants supporting research training and career development of more than 20,000 individuals.
- Coordinates trans-NIH training and career development program evaluations, including reports from the National Academies.
- Serves as the NIH liaison to the scientific community, Federal agencies, biomedical research funding organizations, and scientific societies regarding research training and workforce development.
- Monitors national statistics on graduate students, postdoctoral fellows, and the scientific workforce.
- Co-sponsors scientific workforce surveys with the National Science Foundation.
- Responds to more than 5,000 research training inquiries yearly.
- Collects information on research training issues from ICs and provides a forum for discussion of training policies through the Training Advisory Committee (TAC).
- Provides research training development policy advice to the Director of OEP and the NIH Deputy Director for Extramural Research.
- Maintains a Web site for individuals at all career stages.

Major Accomplishments

Accomplishments

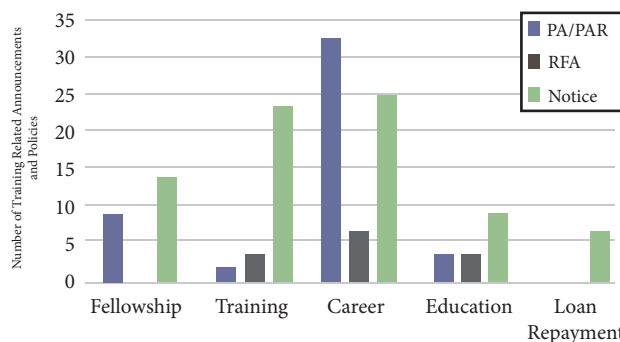
- Formulated and implemented the part-time policy for NIH career awardees to lower a potential barrier to individuals pursuing their scientific careers.
- Implemented a new family leave policy for NRSA trainees and fellows.
- Assessed and evaluated the impact of the FY06 NIH tuition policy on training and fellowship awards.
- Implemented the congressionally mandated institutional reporting of time-to-degree for graduate students.
- Participated in the development of new electronic submission instructions for training, fellowship, and career award applications.

Major Opportunities

Opportunities

- New organization of the TAC, focusing on workforce, evaluation of NIH training programs, issues of diversity in workforce, and the NIH Loan Repayment Program in order to provide a broader view of NIH research training and NIH's role in preparing the next generations of biomedical, behavioral and clinical scientists.
- Enhancements to the training Web site that will assist applicants seeking NIH awards with advancing their scientific careers.
- The thirteenth congressionally mandated National Research Council Assessment of the Nation's Research Personnel Needs in the basic biomedical sciences, behavioral and social sciences, clinical sciences, oral health, nursing and health sciences will be released and presented to the NIH in spring of 2010. TAC and its newly constituted subcommittees will be studying this report, seeking input throughout the NIH and providing advice on NIH responses to its recommendations.

Numbers of Training Related Announcements & Policies by Activity Code (cleared for publication FY09)



Small Business Innovation Research / Small Business Technology Transfer

Contacts: Jo Anne Goodnight, Kay Etzler, and Lenka Fedorkova

Small businesses play a vital role in stimulating technological innovation and U.S. economic growth. The Small Business Innovation Research (SBIR) and the Small Business Technology Transfer (STTR) programs offer funding for U.S. small business concerns (SBCs) to undertake cutting-edge, meritorious, scientific research and development (R&D) that has potential for commercialization and economic payoff. SBCs funded through the NIH SBIR/STTR programs play an important role in achieving the NIH mission by conducting R&D to explore the technological feasibility of innovative ideas and to create medical solutions for public benefit. As Congressionally mandated, a total of 2.8% of NIH's extramural R&D budget is set-aside for these programs, representing \$672 million in FY09.

Key Attributes

SBIR / STTR

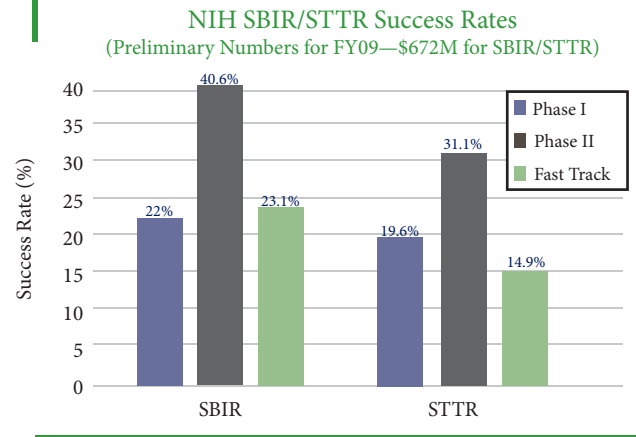
- Enables NIH to bridge gaps between basic science and translation of science discovery into tangible products and services.
- Directly ensures a return on NIH's investment through Technical Assistance Programs focused on training and mentoring of SBIR grantees since 2004.
- Is responsible for program coordination across 23 NIH funding components, oversight and implementation of agency, federal, and legislative policies, approval and development of funding announcements, and conducting nation-wide outreach.
- Advises OER and NIH Director-level parties on program matters.

Accomplishments

- Provided support to thousands of small businesses through outreach and in-person counseling.
- In FY09, trained 80 awardees in the Commercialization Assistance Program (CAP) that has trained almost 600 awardees to date.
- To date, provided technology assessment reports to 575 awardees through the Niche Assessment Program.
- Revised ~50 FOAs and the SBIR/STTR instruction guide to comply with new NIH Enhancing Peer Review criteria.

Accomplishments & Opportunities

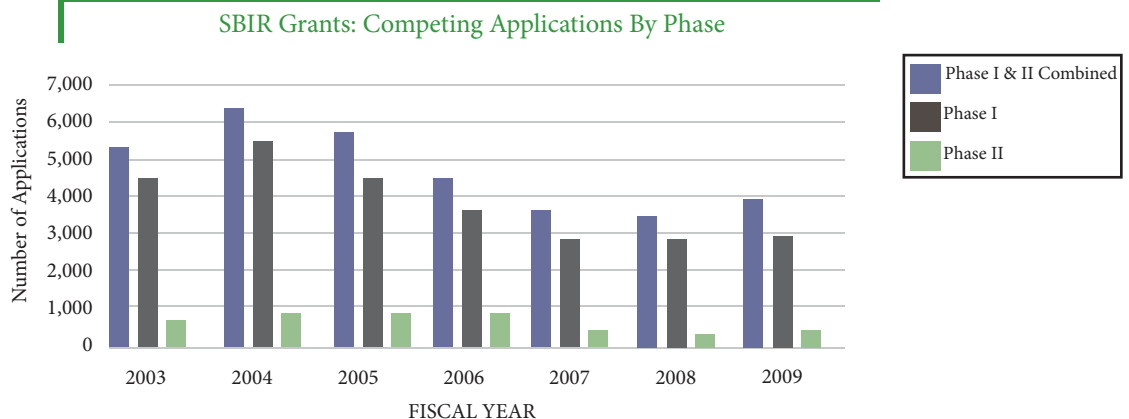
Major Opportunities



Program Stewardship

Opportunities

- Launch new Performance Outcomes and Data Systems database.
- Hold training webinars for small business community.
- Enhance resources on SBIR/STTR Web site.
- Expand outreach to under-served areas.
- Increase applicant pool.
- Develop training for intramural staff.
- Streamline process for handling grantee and applicant inquiries.



Academic Research Enhancement Award (AREA)

Contact: Mary Ann Guadagno

The Academic Research Enhancement Award (AREA) program supports small biomedical and behavioral sciences research projects conducted by faculty and students in health professional schools and other academic institutions. The focus is hands-on meritorious research to build research infrastructure in institutions that have not been major recipients of NIH research grant funds. Active involvement of undergraduate and graduate students in the proposed research is encouraged.

Data for AREA Awards

Fiscal Year	Applications Reviewed	Applications Awarded	Award Amount	Success Rate
2006	723	184	\$37.94M	25.4%
2007	862	216	\$45.23M	25.1%
2008	758	212	\$44.17M	28.0%
2009	805	178	\$37.30M	22.0%

Accomplishments

- Introduced enhanced funding limits in FY09. Awards were increased from \$150k/award to \$300k for up to three years of funding.
- Institutional eligibility was increased from \$3M to \$6M in NIH support.
- Introduced a special one-time Funding Opportunity Announcement using ARRA funds to generating an additional 75 awards.
- Provided 2 training webinars to stakeholders in partnership with the American Association for State Colleges and Universities.
- Information Applicants Can Use:
 - o Updated PA-10-070: Re-issued Dec. 09
 - o Due Dates: Feb. 25, June 25, Oct 25
 - o Eligibility: \$6 million
 - o Funding Level: \$300,000
 - o New Page Limit: 12-page Research Strategy
 - o Enhanced Review Criteria & New Rating System

Opportunities

- NIH anticipates continued growth of this program as universities and colleges respond to a challenging economic recovery.
- Success rates for AREA awards vary from institute to institute, but chances of obtaining an AREA award are slightly better than some other NIH grant mechanisms.

Academic Research Enhancement Award

- NIH has made a concerted effort to stimulate research in educational institutions that are not research intensive and do not receive substantial NIH support.
- AREA grants create research opportunities for scientists and institutions otherwise unlikely to participate extensively in NIH programs to contribute to the nation's biomedical and behavioral research effort.
- NIH invests about \$45 million annually in over 700 awards.

Key Attributes

Major Accomplishments

Major Opportunities

Program Stewardship

Project Clearance

Contacts: Joe Ellis and Mikia Currie

The Project Clearance Branch (PCB) is NIH's control point for the Office of Management and Budget (OMB) clearance functions regarding public information collection activities (e.g., surveys, applications, evaluations). OER's PCB processes information collection requests from all of the ICs and provides guidance for obtaining clearance by OMB. The PCB is responsible for interpretation and implementation of the Paperwork Reduction Act (PRA) at NIH as well as ensuring the quality and completeness of NIH requests for PRA approval. The PCB consists of the Project Clearance Officer and Program Analyst.

Key Attributes

Project Clearance

- Ensures the quality and completeness of the NIH portion of the HHS Information Collection Budget (ICB).
- Develops and implements NIH operating procedures.
- Maintains NIH records and inventories.
- Keeps ICs informed about information collection requirements and the policies and procedures associated with the clearance process.
- Responds to questions raised by HHS or OMB on information collection issues for NIH.

IC	Number of Information Collection Requests	IC	Number of Information Collection Requests
CC	3	NIAID	1
CSR	1	NICHD	6
FIC	2	NIDDK	2
NCCAM	2	NIEHS	3
NCI	18	NINDS	1
NCRR	1	NLM	2
NHLBI	12	OD	13
Total: 67			

Program Stewardship

Major Accomplishments

Accomplishments

- Continued development of the PCB (resource for preparation of materials for initiation of clearance process).
- Revised NIH Manual Chapter 1825.
- Created a Clinical Exemption online database for submission of clinical exemption requests, review and approval.
- OMB has requested, and we provided, comments on how to strengthen and improve implementation of the PRA.

Status of Information Collection Requests (2009)	
Revisions	9
Extensions	10
New	9
Discontinued	15

Major Opportunities

Opportunities

- Expand knowledge of PRA through training.





SCIENTIFIC INTEGRITY

Authoritative Point of Contact for Arbitrating Research Conduct Issues

Program Stewardship



Scientific Integrity



Public Accountability



Policy & Procedures

Development, Implementation, and Oversight



Systems & Data



Communications



Administrative Support



Education & Training



Human Research Protections

Contacts: Ann Hardy and Maria Stagnitto

The NIH Extramural Human Research Protections Program conducts activities to ensure the compliance of NIH grantees with federal regulations and NIH policies regarding the protection of human subjects in extramural research. Prior to funding, OEP staff assesses the proposed resolution of human subjects concerns identified during the peer review process. They also respond to requests to change the human subject codes designation of ongoing NIH extramural research projects. Other program activities include providing training for NIH extramural staff and the extramural scientific community on human subjects protections and developing policies and procedures to ensure that participants in NIH-funded research are adequately protected.

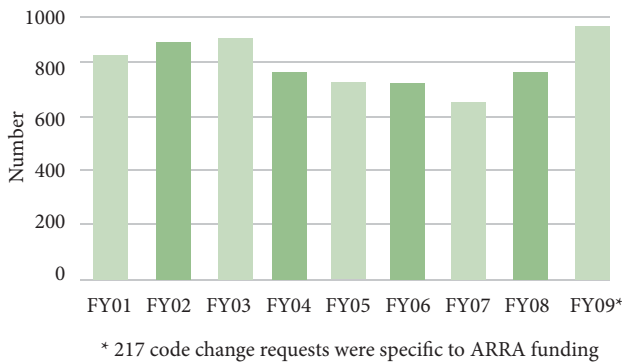
Key Attributes

Major Accomplishments

Major Opportunities

Scientific Integrity

Code Change Requests by Fiscal Year



Human Research Protections

- Reconciles all grant applications that have a bar to funding due to human subjects concerns.
- Conducts quality Assurance activities to monitor the compliance of NIH grantees with the federal regulations regarding human subjects protection.
- Provides expert advice and training to NIH extramural staff and the extramural research community regarding regulations and policies related to human subjects protections.

Accomplishments

- Processed 986 requests for code changes in FY09, 217 of which were specific to ARRA funding.
- Provided online “Protecting Human Research Participants” training for 206,298 individuals in 2009, 10% of which were international participants.
- Developed and implemented a new code change request system, the Human Subjects Protection Assessment System, to enhance efficiencies and communication with ICs.
- Streamlined the review process for requests to facilitate maximum throughput in the office and expedite ARRA requests.
- Coordinated and sponsored usability testing sessions to modernize the Human Subjects Intranet Web site.

FY09 ARRA Code Change Requests by IC

IC	Number	IC	Number
NCCAM	5	NICHD	7
NCI	18	NIDA	25
NCMHD	11	NIDCD	2
NCRR	3	NIDCR	5
NEI	1	NIDDK	13
NHGRI	4	NIEHS	4
NHLBI	18	NIGMS	3
NIA	10	NIMH	14
NIAAA	7	NINDS	10
NIAID	24	NINR	10
NIAMS	8	NLM	9
NIBIB	5	FIC	3

Opportunities

- Perform a risk assessment on the reconciliation process.
- Update the human subjects Manual Chapter(s).
- Conduct a formal evaluation of FOAs on human subjects research ethics.
- Conduct ongoing training for ICs.
- Update files in alignment with the records retention policy.
- Provide the extramural community with guidance on data and safety monitoring boards.
- Maximize detailed support during peak reconciliation times.
- Coordinate usability testing sessions for the extramural Human Subjects Protection web site.



Research Animal Protections: Assurances

Contact: Eileen Morgan

The NIH Grants Policy and the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals require that NIH-funded institutions conducting research using live vertebrate animals must have an Office of Laboratory Animal Welfare (OLAW)-approved Animal Welfare Assurance describing the institution's animal care and use program. OLAW's Division of Assurances coordinates with grants management personnel, negotiates Animal Welfare Assurances with research institutions, and provides liaison, guidance, and PHS Policy interpretation to research institutions, investigators, federal officials, and the public. The Division maintains existing Assurance mechanisms, advises awarding units of changes in PHS Policy implementation, reviews and accepts institutional annual reports, and evaluates the effectiveness of PHS animal welfare policies and programs through site visits of Assured institutions.

Key Attributes

Assurances

- Provides guidance to research institutions, investigators, federal officials, and the public.
- Reviews institutional annual reports.
- Resolves grant award clarifications or restrictions involving animal subjects.
- Works with grants management personnel to determine the type of Assurance required of an institution.
- The Division of Assurances is currently responsible for the following
 - o 1010 Domestic Animal Welfare Assurances
 - o 419 Foreign Animal Welfare Assurances
 - o 2365 Inter-institutional Assurances

Major Accomplishments

Accomplishments

- Reviewed and approved 304 domestic Animal Welfare Assurances (both new and renewals).
- Processed 100 Foreign Assurances (both new and renewals).
- Processed 485 Inter-institutional Assurances.
- Reviewed and accepted 958 Annual Reports.
- Performed 9 site visits of Assured institutions.
- Participated in educational outreach.
- Reviewed and approved an unprecedented number of vertebrate animal sections (VAS) of grants for ARRA awards.
- Provided grants and contracts training to nine groups consisting of IC grants managers, program officials, grant administrators, and contract specialists.
- Served as lead in development of a new OLAW database.

Major Opportunities

Opportunities

- Provide an updated Animal Welfare Assurance sample document for foreign institutions.
- Continue to work with grants and contracts personnel on grants and contracts processing issues.
- Review VAS for grant awards, including ARRA grants.
- Continue to review Assurances and Annual Reports.
- Perform site visits and provide training to the NIH grantee community.

Research Animal Protections: Policy & Education

Contacts: Susan Brust Silk and Lori Hampton

The OLAW Division of Policy and Education (DPE) is responsible for a national education program to promote the highest standards of animal care and use in Public Health Service (PHS)-supported research, teaching, and testing. Approximately 50% of the NIH extramural portfolio includes activities that involve animal subjects, thus education in quality animal care and use standards to promote both quality science and humane research is imperative. Policy changes and interpretations have national and international implications as most research organizations choose to comply with PHS animal welfare standards regardless of funding source.

Key Attributes

Policy & Education

- Develops policy guidance, coordinates policy guidance with other NIH offices and sister agencies, and disseminates policy guidance to the research community.
- Produces and coordinates conferences and workshops that focus on animal welfare issues in PHS-funded animal activities.
- Promotes cooperative education opportunities and program development with external groups to increase educational opportunities for Institutional Animal Care and Use Committees (IACUC) and other personnel at Assured institutions that are involved in PHS-funded animal activities.
- Develops, updates, maintains, and distributes hard copy and electronic educational resources.
- Provides assistance and guidance to institutions engaged in PHS-supported animal activities.
- Manages an OLAW speakers bureau, including requests for support, coordination of OLAW professional staff in presentations at national meetings, and preparation of slides, data, illustrations, speaker content, and schedules.

Major Accomplishments

Accomplishments

- Conducted and supported ten national one- and two-day workshops at locations across the U.S. with estimated average daily attendance of 100 participants.
- Developed, conducted, recorded, and posted eight online seminars for targeted audiences on current policy topics in humane animal care and use. Registrants are from 48 states, two possessions and four countries. Average attendance is estimated to be 1,000 participants.
- On 56 occasions, OLAW staff presented animal welfare education topics at professional outreach meetings and seminars.
- Distributed more than 16,000 hard copy resources.
- Maintained OLAW Web site content. There were more than 100,000 hits to the OLAW home page in 2009.
- Answered approximately 300 telephone and E-mail inquiries. Developed two new FAQs in response to frequency and urgency of policy inquiries received.
- Wrote, developed, edited, and illustrated speeches, letters, columns, articles, and editorials released by OLAW.
- Coordinated educational outreach with professional organizations, other NIH offices, and sister agencies, including a Memorandum of Understanding with the FDA, USDA, and VA.

Major Opportunities

Opportunities

- Develop outreach opportunities to reach maximum number of stakeholders at minimum expense in a targeted format that is efficient and effective for the stakeholder.
- Develop and produce educational materials that use cutting edge electronic technology, including audio and video training tools that will be disseminated through the OLAW Web site.
- Develop and conduct an educational outreach symposium to celebrate the 25th anniversary of the Public Health Service Policy on Humane Care and Use of Laboratory Animals.
- Comments from the OLAW Online Seminar
 - “I wanted to let you know that the attendees at this location all thought the program was excellent and very worthwhile. Thank you.”
 - “We really enjoyed the Webinar today and we would like to register for the rest of the series of seminars. Thank you in advance for such wonderful information.”
 - “Very well done, informative and extremely user-friendly. This is a very good idea, a service to all of us out here. Thanks.”

Research Animal Protections: Compliance Oversight

Contacts: Axel Wolff and Brent Morse

OLAW is responsible for oversight of compliance by awardee institutions with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. As a condition of PHS support, institutions must commit to full compliance with the PHS Policy through an Animal Welfare Assurance. The Division of Compliance Oversight provides guidance and PHS Policy interpretation to research institutions, investigators, federal officials, and the public. The office investigates reports of non-compliance from third parties and institutional self-reports. The Division of Compliance and Oversight also works with institutions to develop corrective plans that facilitate resolution of problems and to prevent reoccurrences.

Key Attributes

Compliance Oversight

- Evaluates institutional self-reports and third party allegations of noncompliance with the PHS Policy.
- Evaluates action plans developed by institutions to ensure correction of problems and prevention of recurrence.
- Awardee institution commitment includes the reporting requirement that the Institutional Animal Care and Use Committee (IACUC)

promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to the following:

- o any serious or continuing noncompliance with the PHS Policy;
- o any serious deviation from the provisions of the Guide for the Care and Use of Laboratory Animals; or
- o any suspension of an activity by the IACUC.

Major Accomplishments

Accomplishments

- From October 1, 2008 through September 22, 2009, 645 compliance cases were opened and 649 cases were closed.
- As of September 22, 2009, 103 open compliance cases were pending.
- Successfully completed over 600 noncompliance cases.
- Participated in site visits to grantee institutions.
- Participated in professional outreach seminars.
- Contributed input into development of the Compliance Oversight portion of the new database.

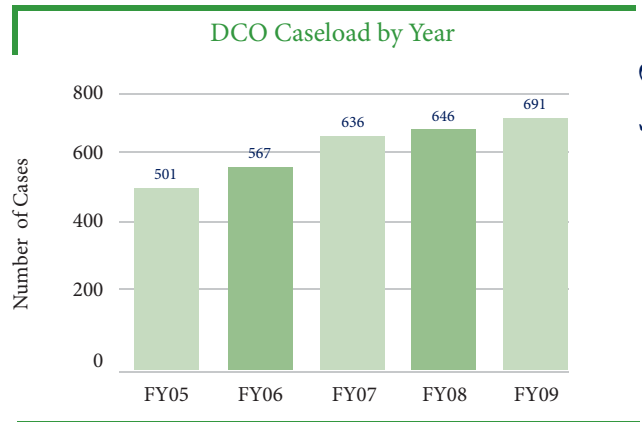
Major Opportunities



Opportunities

- Continue processing increased numbers of noncompliance reports.
- Participate in site visits.
- Participate in educational outreach.
- Potentially implement a new database to aid in carrying out the work of the Division of Compliance Oversight.

Scientific Integrity



Research Misconduct

Contacts: Sally Amero and Maria Stagnitto

OER bears the ultimate responsibility at NIH for handling allegations of research misconduct that are received by any member of the NIH extramural staff or involve NIH-supported extramural research. As defined by regulation 42CFR Part 50, Subpart A, research misconduct is defined as fabrication, falsification, and/or plagiarism, and ultimate investigative authority is given to the Office of Research Integrity (ORI) in HHS. OER also has responsibility for other aspects of research integrity, such as training grantees in the responsible conduct of research, creating and implementing policies for protection of human subjects and vertebrate animals in research, ensuring compliance with grants policy, and sharing of research data.

Key Attributes

Research Misconduct

- Each NIH Institute and Center has a designated Research Integrity Officer (RIO).
- Each member of the NIH extramural staff is instructed to direct all allegations of research misconduct to the IC RIO immediately and with utmost confidentiality.
- OER conducts a preliminary review of each allegation and forwards it to ORI or other HHS offices as appropriate.
- Extramural staff receives annual training in the proper handling of allegations of research misconduct.

Major Accomplishments

Accomplishments

- Launched online training for IC RIOs and extramural staff.
- Presented an overview and case studies on research misconduct to the Extramural Scientist Administrator (ESA) Seminar Series.
- Launched an evaluation study of the Research on Research Integrity program, a collaborative effort between ORI and NIH.
- Provided leadership to the NIH Task Force on Scientific Integrity.
- OER received 113 allegations from extramural staff, ORI, the Office of Management Assessment, or other sources, such as directly from complainants.
- ORI made findings of research misconduct in twelve cases.

Major Opportunities

Opportunities

- Design a new OER Web site on research integrity and bioethics.
- Define policy for handling allegations of research misconduct against members of the NIH extramural staff.
- Define metrics for annual reporting on OER's responsibilities for handling research misconduct.
- Develop a database to monitor and track allegations within NIH.
- Update files in alignment with the records retention policy annually.
- Develop a position description, interview and hire a senior research integrity analyst.

Scientific Integrity



Intellectual Property & Resource Sharing

Contact: J.P. Kim

The Division of Extramural Inventions and Technology Resources (DEITR) is the central NIH point of contact for the extramural research community on extramural intellectual property and resource sharing issues. Along with providing expert guidance and support for compliance and implementation of the Bayh-Dole Act, DEITR hosts the interagency extramural discovery and invention system for oversight and notifications (iEdison.gov). iEdison is the premier repository of information on inventions developed under federal funding agreements and assists DEITR with maintaining updated invention information of NIH funding recipients. Under the auspices of OPERA, DEITR develops, implements, and monitors policies for extramural invention reporting, resource sharing, and related intellectual property issues under NIH funding agreements and works directly with the scientific community on facilitating advancement of inventions and resource sharing to further research and public health.

Key Attributes

Intellectual Property & Resource Sharing

- Serves as the official NIH point of contact for reporting of all NIH-funded extramural inventions under grants, cooperative agreements, and contracts.
- Serves as the central NIH resource for information and policies on invention reporting and related intellectual property policies and resource sharing.
- Hosts the iEdison system for collecting invention information, serving the NIH and over 29 other federal agency offices.
- Provides NIH program staff and grants management staff with expert guidance, tools, and support for advancing resource sharing and invention reporting.

Invention Records Created by CY	
Year	Number of Inventions
2006	5,834
2007	5,211
2008	5,493
2009	7,039

Scientific Integrity

Major Accomplishments

Accomplishments

- Received and processed over 7,000 NIH-funded inventions.
- Over 11,000 federally funded inventions were reported into iEdison for over 29 federal agencies.
- Led a trans-NIH workgroup to develop tools to assist program staff and applicants with promoting compliance with resource and data sharing.
- Provided NIH policy guidance, presentation materials, and other input for an international European Union meeting for developing international mouse and data resource sharing standards and for a subsequent Nature piece promoting sharing of mice and associated data.
- Provided policy guidance and logistical support on invention reporting policies and procedures to defend NIH and HHS interests on legal issues.
- Received and processed over 40 invention waiver requests for facilitating development and commercialization of federally-funded inventions.
- Assisted the PROMIS NIH Roadmap initiative with addressing sharing and sustainability issues for timely issuance of awards.
- Contributed policy guidance and related compliance information to the U.S. Government Accountability Office (GAO) on NIH extramural inventions and the Bayh-Dole Act.

Major Opportunities

Opportunities

- Continue to lead a trans-NIH effort to further assist program staff and extramural researchers towards improved data sharing and compliance among NIH funding recipients.
- Increase interagency cooperation with iEdison and invention reporting through enhanced communications and added value to the system.
- Facilitate improved federal invention reporting compliance under the Bayh-Dole Act through ongoing outreach efforts and training opportunities for NIH funding recipients, NIH extramural staff, and other federal agencies.

Financial Conflict of Interest (FCOI)

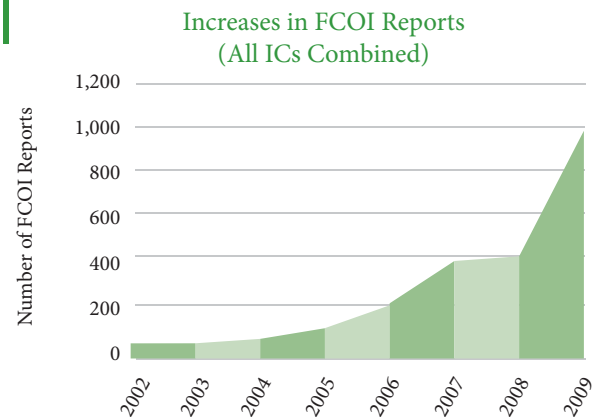
Contacts: Diane Dean, Kathy Hancock, and Joe Ellis

In keeping with its mission to provide the leadership, oversight, tools and guidance needed to administer and manage NIH grants policies and operations, OER is the focal point for policy development and institutional oversight of the Financial Conflict of Interest (FCOI) regulation (42 CFR Part 50 Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought). The FCOI regulation was promulgated in 1995 to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements is biased by any conflicting financial interest of an investigator.

Key Attributes

Financial Conflict of Interest

- OER provides oversight, policy interpretation, and guidance to NIH ICs and to the extramural grantee community. Activities include developing web-based resources, conducting compliance activities, responding to public inquiries, and conducting outreach.
- In FY09, NIH received 986 institutional FCOI reports, which is more than a 100% increase over the number of reports received in 2008. We believe this increase is due in large part to OER's increased outreach and compliance oversight activities.



Scientific Integrity

Major Accomplishments

Accomplishments

- Issued an Advanced Notice of Proposed Rulemaking (ANPRM) on May 8, 2009 to solicit public comments on whether and how the regulation should be amended.
- Formed a trans-NIH Task Force to consider comments received in response to the ANPRM and developed a new proposed rule to be issued as a Notice of Proposed Rulemaking after the clearance process is completed.
- Addressed significant FCOI compliance issues at two high profile Universities.
- Continued the compliance initiative to review and analyze institutional FCOI policies and procedures,

identify deficiencies and weaknesses, and provide feedback to institutions about required modifications.

- Instituted a mandatory requirement for grantees to use the eRA Commons FCOI Module to submit and manage reports of identified FCOIs to NIH.
- Provided guidance and consultation to NIH extramural staff regarding review of institutional FCOI reports, follow up inquiries, and database administration.
- Provided NIH response to a significant Office of Inspector General report on Grantee Management of FCOI.

Major Opportunities

Opportunities

- Issue a new final rule for FCOI.
- Develop an implementation plan for the new final rule.

- Provide outreach activities surrounding the requirements of the new final rule.
- Develop and initiate proactive FCOI compliance initiatives.



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



Grants Compliance & Oversight

Contact: Diane Dean

The Division of Grants Compliance and Oversight (DGCO), in the Office of Policy for Extramural Research Administration, is responsible for compliance oversight responsibilities and promoting external compliance with policy and legislative mandates and enhancing compliance oversight by recipient institutions. NIH and its recipient institutions share responsibility for compliance and oversight to ensure stewardship of federal funds. The relationship between NIH and its grantees is predicated on trust. Grantees are expected to properly administer sponsored activities and comply with applicable regulations and policies. In addition to external compliance, DGCO oversees and manages the NIH Grants Management Professional Certification Program, a certification program to ensure that NIH grants managers are highly trained, competent professionals. Education and outreach are key components of compliance, to which DGCO devotes significant resources.

Key Attributes

Compliance & Oversight

- Oversees and manages the NIH Grants Management Professional Certification Program. Approximately 400 extramural grants management staff are subject to the requirements of the certification program.
- Oversees and manages OER's Management Control Program to determine IC compliance with OPERA-initiated policies and to identify and address the cause (s) of non-compliance.
- Manages corrective action process for cases of grantee institution noncompliance resulting from settlement agreements, self-reported issues, and other sources.
- Manages and coordinates NIH and OER audit activities.
- Participates in several Federal-wide committees concerned with compliance issues, including:
 - o Research Business Models (RBM), a Subcommittee of the Committee on Science (a chartered committee of the National Science and Technology Council) Institutional Compliance Program Guidance Task Group (Co-Chair)
 - o RBM Executive Committee
 - o Federal Grants Management Competencies Workgroup

Major Accomplishments

Accomplishments

- Addressed compliance issues and corrective actions with over 20 recipient institutions.
- Managed review of four rounds of 121 grants management certification applications.
- General Audits:
 - o Managed and prepared response to the FY09 Improper Payment Information Act (IPIA) ARRA Risk Assessment Report on extramural construction and research grants.
 - o Managed and coordinated 2009 A-123 Audit / Appendix A of OMB Circular A-123, Management's Responsibility for Internal Control.
- Office of Inspector General ARRA Oversight Audits:
 - o On-site OIG review team reviewing internal controls over awarding ARRA Funds
 - o ARRA Contract and Grant Personnel Staffing and Qualifications
 - o ARRA Extramural Construction
 - o NIEHS Review of Internal Controls over Awarding ARRA Funds
- Gave eight presentations for internal NIH functional committees as well as for outside groups attended by extramural recipients, including the National Council of University Research Administrators and the NIH Regional Seminars.

Major Opportunities

Opportunities

- Revitalize proactive compliance initiatives.
- Enhance the Management Control Program.

Public Accountability



Grants Management Training

Contact: Marcia Hahn

Outreach/Education is an important part of the OER mission. OER plays a key role in training NIH extramural staff, particularly as part of the development and implementation of new and revised NIH policies and procedures. For the Grants Management (GM) business area, the Office of Policy of Extramural Research Administration (OPERA) facilitates customized training geared to the duties and responsibilities of the GM community.

Key Attributes

Grants Management Training

- Periodically provides faculty for monthly training seminars and roundtable discussions, coordinated by the Grants Management Advisory Committee (GMAC) subcommittee.
- Provides logistical support by funding webcast capabilities for seminars, which will ultimately create a training archive.
- Plays a key role in development, providing content, and supporting the NIH Grants Management Fundamentals annual class.
- Manages broad communication of new and changing policy and procedures to the Grant Management Community.

Extramural Community Outreach/Education

- Provides faculty for seminars sponsored by both NIH and NIH-groups for the extramural grantee community.
- Maintains the NIH Update, a resource for NIH extramural staff to use during outreach/education opportunities.

Major Accomplishments

Accomplishments

- Provided training and education through bimonthly GMAC meetings and E-mail communications, which was particularly critical to enact the policy, procedures, and business process changes necessary to implement three of NIH's priorities—ARRA, human embryonic stem cells, and Enhancing Peer Review.
- Participated in training through presentations to EPMC, PLC, and TAC.
- Provided faculty for a seminar held by the GMAC Subcommittee on training.
- Organized the annual Orientation to NIH Grants Management course in preparation for January 2010 class.
- Provided faculty for:
 - 2 NIH Regional Seminars
 - 1 NIH Mini-Regional
 - 7 NIH staff seminars
 - 17 meetings sponsored by organizations outside NIH

Major Opportunities

Opportunities

- Participate as faculty for the Annual Orientation to NIH Grants Management course.
- Provide formal and informal training to the NIH extramural staff, particularly Grants Management, on new emerging priorities as well as existing activities as appropriate.
- Scheduled to provide faculty for over a dozen seminars, including two NIH Regionals and other events sponsored by external organizations.

Grants Policy Development, Implementation, & Oversight

Contacts: Marcia Hahn

OER is responsible for coordinating the development, implementation and oversight of NIH and applicable Federal grants policies as they affect the NIH grants process. This includes centralized implementation of emerging initiatives and priorities to provide consistency across all the NIH ICs and extramural business areas while addressing the flexibility required by individual programs. Grants policy assists in developing, implementing, and maintaining new NIH policies and procedures, ongoing maintenance of a wide range of internal and external policy resources; e.g., NIH Manual Chapters and GAM Chapters; OER and GMAC Policy Announcements; NIH Grants Policy Statement; and OER intranet and internet Web sites.

Key Attributes

Development, Implementation & Oversight

- OER coordinates centralized implementation of emerging initiatives and priorities on behalf of all the NIH ICs and represents NIH on federal-wide initiatives.
- Implements new Federal policies issued through Executive Orders, Public Law, or regulation.
- Represents NIH at, and coordinates the implementation of, HHS-level initiatives.
- Implements trans-NIH initiatives, resulting in the development and issuance of new NIH policies and procedures.
- Updates existing policy source documents and provides training to the NIH and extramural grantee community regarding these changes.
- Maintains over 60 Grants series NIH Manual Chapters on behalf of NIH including NIH Grant Administration Manual Chapters that implement HHS Policy Directives.
- Issues and maintains OER and GMAC Policy Announcements, interim tools for issuing new policy.
- Maintains the NIH Grants Policy Statement, a consolidated resource and term of award for all NIH grant awards as well as numerous internal and external OER Web sites.

Major Accomplishments

Accomplishments

- Implemented ARRA, which required the modification of every part of the NIH grants business process to accommodate the special requirements of ARRA.
- Issued and maintained ARRA guidance to NIH extramural staff, posting everything on an ARRA-dedicated intranet site. NIH Guidance for the grantee community was developed and issued through NIH Guide Notices.
- Implemented the new Executive Order on human embryonic stem cells (hESC). NIH developed a new OMB-approved form to support the new review and approval process, which was implemented through an OER-developed web system.
- Developed a new web-based process to manage the request and approval process for new hESC lines as well as resources for both NIH staff and the grantee community.
- Implemented goals from priorities 1 & 2 under the Enhancing Peer Review Initiative.
- Peer Review implementation resulted in numerous new resources for NIH staff and the community at large; e.g. new summary statement templates, reviewer guidance, and revised application forms and instructions.

Major Opportunities

Opportunities

- Policy coordination and implementation will continue for the three emerging priorities as necessary.
 - o This will primarily entail refinements to guidance and other policy source documents issued in 2010.
- As other emerging initiatives are developed, OER stands poised to continue to develop and maintain critical resources for NIH staff and the extramural community at large.
- Policy maintenance in 2010 will focus on updating policy source documents; in particular the NIH Grants Policy Statement and NIH Manual Chapters.

Public Accountability



Research Condition & Disease Categorization (RCDC)

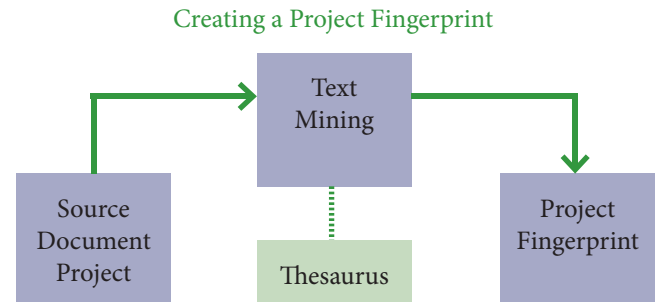
Contact: Richard Ikeda

The RCDC system provides a consistent NIH-wide categorization process for all Extramural grants, Intramural projects, R&D Contracts and Inter/Intra Agency Agreements. Categorization of NIH's research is accomplished by analyzing word frequency in the project description. Reports are generated by combining financial and administrative data from eight different data sources, analyzing the data, and associating the data with the projects in various research categories. RCDC currently provides project and funding data for >260 different research categories as mandated by Congress, provides data for many NIH systems (e.g. QVR, RePORTER, IMPACII) and is used to generate spending totals and project listings for other reports that are required by HHS/OMB and requested by Congress.

Key Attributes

Research Condition & Disease Categorization

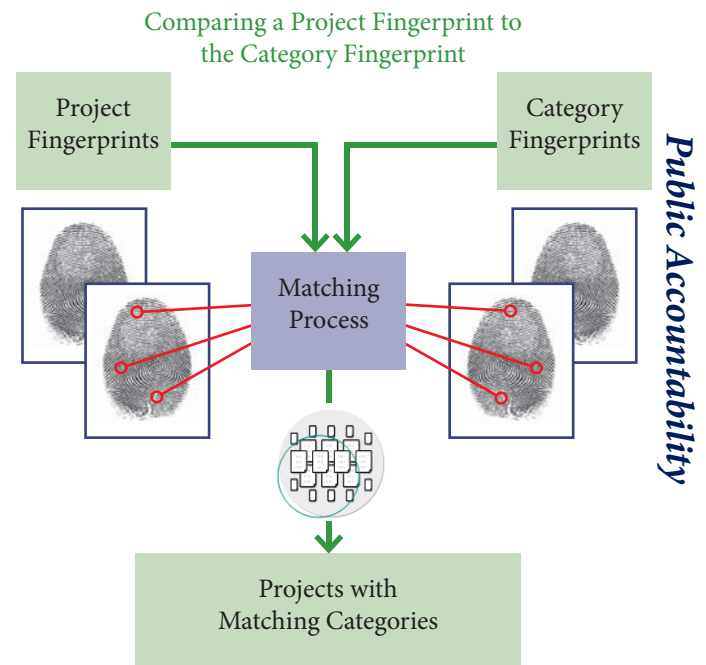
- RCDC is a greatly improved categorization process over the previous system.
- Allows for reproducible reporting.
- Provides transparency (through published project listings for publicly reported categories).
- Improves public understanding of NIH spending on research.
- Promotes public trust in the NIH.
- Enables NIH to better understand its own spending for future planning.



Major Accomplishments

Accomplishments

- Completed 215 publicly reported categories complete with downloadable project listings.
- Completed additional categories, data and reports for required Office of Budget reporting on areas of science not publicly displayed.
- Performed a crosswalk comparison of FY07 data to FY08 data using the RCDC categorization process.
- Successfully published the first public release of funding data produced by the RCDC process in January 2009.



Major Opportunities

Opportunities

- Integrate of the RCDC tool at the IC level.
- Implement IC specific categorization services.
- Categorize all electronic applications.

Public Access

Contacts: Lynn King and Dorit Zuk

The NIH Public Access Policy ensures that the public has access to published results of NIH-funded research. Any manuscript which arises from such research must be submitted to PubMed Central (PMC), the National Library of Medicine's digital archive, no later than 12 months after publication. Rapid, widespread access to scientific findings enables faster information dissemination and thereby advances science and improves human health. In addition to submitting applicable papers to PMC, anyone submitting an application, proposal, or report to NIH must include the PMC reference number (PMCID) when citing these papers.

Key Attributes

Public Access

- Offers multiple deposit methods for authors and publishers to submit papers to PubMed Central (PMC).
 - Publishers supply articles to PMC through formal agreements between the Journal and the National Library of Medicine.
 - Author manuscript submission is through the NIH Manuscript Submission system (NIHMS).
- Protects the interest of Journals by not posting papers in PMC for up to 12 months post-publication.
- Compliance can be monitored by authors, investigators and NIH staff.
- NIH-funded research produces an estimated 80,000 peer reviewed journal articles a year.
- The public has free access to full text papers on PMC generally within 12 months of publication.

Major Accomplishments

Accomplishments

- NIH has been able to make over 100,000 papers publicly available on PubMed Central (PMC) through the Public Access Policy.
- PMC contains just under 2 million articles, most of these submitted by publishers that have been participating in PMC since 2000.
- Currently, more than 800 journals go beyond the requirement of the Public Access Policy by making the final published version of all NIH-funded articles publicly available in PMC within 12 months of publication, without author involvement.
- Performed an evaluation of the efficiency and effectiveness of the Program Officer Public Access Checklist for monitoring compliance of continuing award applications.
 - Identified key areas to improve compliance, including modifying the Checklist process in the eRA Program Module, update staff training and establish guidelines for follow-up.
- Established the NLM Process Evaluation of the NIH Public Access Policy.
- Public Access staff conducted 16 presentations in 2009 for training, education, and outreach, including 4 NIH staff training sessions.

Major Opportunities

Opportunities

- Increase compliance.
- Encourage PIs to manage compliance using My NCBI accounts and the My Bibliography feature and associated eRA Commons accounts.
 - The eRA Commons **Awards View** can be used to establish publication-active grant associations, monitor and report compliance, start the manuscript submission process, and designate delegates to manage their bibliography via My NCBI.
- Expand NLM pilot to top 100 or more grantee institutions.
- Continue My Bibliography and eRA Commons integration to improve NIH data quality, reporting and policy compliance, and to achieve fully automated compliance monitoring.
- Continue educating and informing NIH staff and awardees regarding Public Access Policy requirements.
- Continue to work with publishers on a voluntary basis to help them facilitate compliance with the Public Access Policy on behalf of their authors.



SERVICES AND 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



Electronic Research Administration

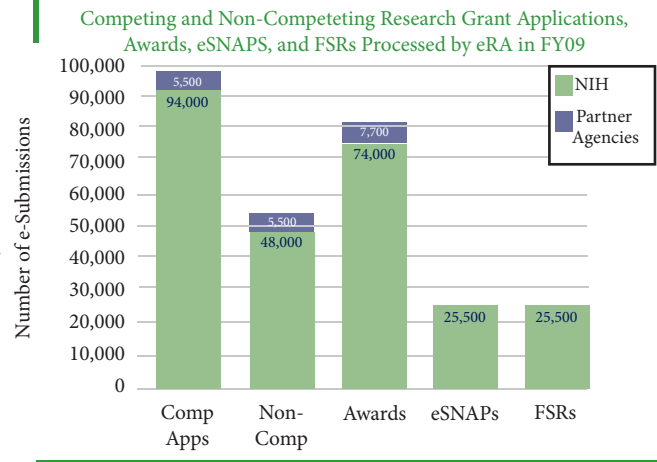
Contact: Oliver "Pete" Morton

The Electronic Research Administration (eRA) systems provide the information system capabilities and services necessary to support the entire cycle of grants administration. The eRA systems align with Grants.gov, allowing for end-to-end electronic grants processing from the initial application submission to the award closeout process. eRA processes billions of dollars of NIH (and eRA's partner agencies) research and non-research grants annually. eRA is used by over 210,000 scientists and research administrators at universities, medical schools, and research institutions in the U.S. and around the world.

Key Attributes

Electronic Research Administration

- eRA Commons, used by the grant applicant community worldwide, recorded about 5.4 million log-ins for FY09, a 30 percent increase over the previous year.
- Serves NIH as well as four operating divisions within HHS and the Veterans Health Administration. In addition, iEdison, a module that facilitates reporting of government funded inventions and patents, is used by over 29 agencies.
- eRA applications used by grantors (i.e., all eRA applications with the exception of eRA commons), recorded 1.85 million log-ins in FY09.

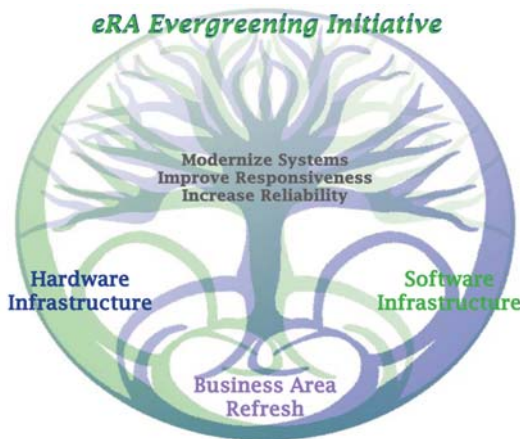


Major Accomplishments

Accomplishments

- Added system-wide capabilities to support NIH funding of grants through the American Recovery and Reinvestment Act (ARRA).
- Implemented key electronic components of NIH's Enhancing Peer Review initiative, including a new 1 to 9 scoring scale and review criteria scoring.
- Developed capability for systems to determine the eligibility of applicants as Early Stage Investigators/ New Investigators.
- Upgraded eRA's hardware infrastructure as part of a larger systems modernization effort called Evergreening.
- Processed 1,033 Commons registrations in April 2009, the highest monthly number recorded since the previous high of 646 set in December 2005.
- Transitioned grant applications for Career Awards (Ks) and Fellowships (Fs) to electronic submission.
- Added the capability for grantees to electronically report Financial Conflict of Interest to NIH.
- Aligned the eSNAP system for electronically submitting progress reports with the new OMB-approved 2590 form.
- Developed the electronic Tracking and Analysis (eTA) system, a comprehensive extramural grant planning and management tool for the NIH budget community.

Major Opportunities



Opportunities

- Work with stakeholders to make business process improvements that pave the way to refreshing eRA systems, starting with Receipt and Referral/eReferral and moving on to Peer Review (both are part of eRA's Evergreening Initiative—see graphic).
- Eliminate the need to send CDs to reviewers
- Maximize the performance and reliability of the modules by retrieving rarely used historical data separately, so accessing data is not a drag on performance.
- Continue to support the American economic recovery with projects funded through ARRA.

Services & Infrastructure



Data Quality Branch

Contact: Mark Siegert

The mission of the Data Quality Branch is to provide data monitoring, updating, and reporting along with software testing and monitoring services to facilitate decision-making and grant related activities within the NIH and other federal agencies. The DQB also provides accountability and transparency of NIH and other federal agencies' data to the public.

Key Attributes

Data Quality Branch

- Responsible for the oversight and maintenance of data quality for grant applications, awards and authoritative tables within the Electronic Research Administration (eRA) system.
- Responsible for the establishment and maintenance of organizations seeking research support from NIH, HHS OpDivs, and other government agencies using eRA systems.
- Through the efforts of the branch, data can be used to provide reporting and analysis for management and transparency in reporting to Congress, HHS, and the public.

Major Accomplishments

Accomplishments

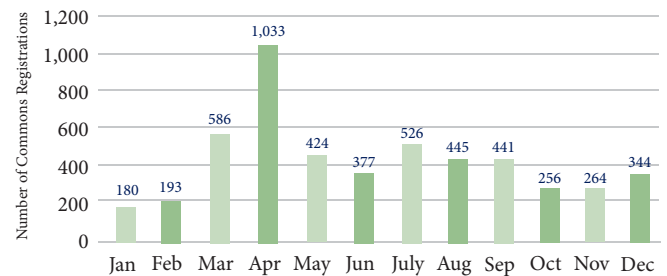
- Processed over 5,000 new Commons organization registrations.
- Researched and collapsed over 6,000 person profiles that were duplicates of other profiles in the database.
- Developed and implemented a system to evaluate and join authoritative databases from the American Association of Medical Colleges and the National Science Foundation to the data contained in the eRA system in order to provide analytical analysis of the individuals that NIH has supported through its research and training programs.

Major Opportunities

Opportunities

- Align Data Quality staff with the eRA teams in order to provide better customer support and increase the knowledge base within the staff.
- Increase the use of external data sources in gathering and verification of data inputs.

Commons Registrations Completed CY09



- Completed the end-of-year reports for the Office of Budget of the FY09 awards by Disease Category.
- Processed an additional 20,000 applications for organizational assignments of department and major components without an increase in staffing.
- Handled over 1,000 registrations for new organizations in the Commons due to ARRA announcements.
- Managed a 250% increase the number of help desk tickets assigned to the branch, from 1075 in calendar year 2008 to 2,685 in CY09.

Reporting & Analysis

Contact: Robin M. Wagner and Katrina C. Pearson

The Reporting Branch provides data, analyses, and reports on NIH's research investments to support strategic decision-making, and provide public information and accountability. Detailed information on grants, contracts, and intramural research are disseminated to NIH internal and external stakeholders, including NIH, other federal agencies, academia, Congress, the media, non-profits and the public. Characteristics of organizations and researchers who receive NIH support are also described. These data are used to assess and communicate trends on the NIH-supported workforce and research projects; ensure NIH compliance with federal regulations; generate information for budget hearings; inform NIH policy development; and supply external researchers with data to publish their own analyses of NIH's research portfolio.

Key Attributes

Reporting, & Analysis

- Supports mandatory and statutory report requirements for the NIH research enterprise.
- Provides analyses and reports in response to internal and external stakeholder-requests.
- Conducts customer-driven descriptive and analytical research on NIH research investments.
- Provides analytical support to NIH leadership to guide management decisions and policy development.
- Develops strategic alliances to improve data quality for reporting purposes.
- Disseminates data and reports to a wide public audience through the NIH RePORT website, journals, and other media.

Major Accomplishments

Accomplishments

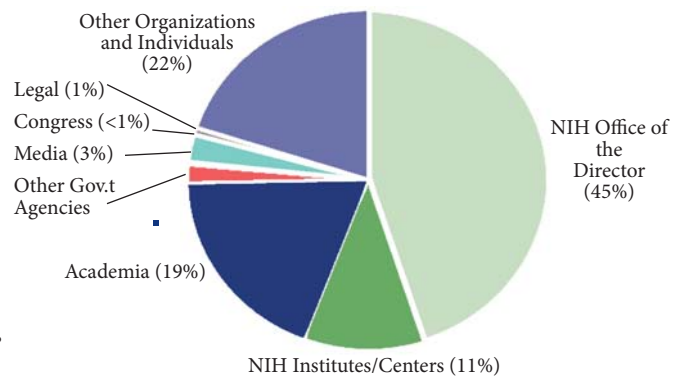
- Completed 884 information requests in 2009; 82% met goal of completion by due date.
- Characterized how NIH distributed \$5 billion of stimulus funds to improve health.
- Provided analytical support for high profile NIH policies.
- Partnered with other NIH offices to improve contracts and intramural data quality in IMPACII.
- Disseminated analyses via national conferences, scholarly journals, and RePORT website.
- Hired eight staff, including five Presidential Management Fellows, from diverse disciplines to enhance analytic capabilities.

Major Opportunities

Opportunities

- Continue to expand staff capacity to move beyond simple descriptive statistics to sophisticated data analyses, and research and policy evaluation.
- Apply advanced data analysis techniques, such as social network analyses and visualization tools, to better characterize NIH's research impact.
- Increase collaborations with internal and external partners to address critical research policy questions through analyses.
- Disseminate analyses more widely to lay and scientific audiences through traditional and new communication channels such as podcasts, wikis and smart phone applications.

Reporting Branch Stakeholder Groups Serviced FY09
Total Number of Completed Requests = 884



- The Reporting Branch Provides Analyses for Wide Ranging Policies and Reports including:
 - o NIH Data Book
 - o First-Time and Early Stage Investigator Policies
 - o Inclusion of Women and Minorities in NIH Clinical Research Policy
 - o Government Performance Results Act
 - o American Recovery and Reinvestment Act
 - o Assessment of Peer Review Enhancement Implementation
 - o High-Risk / High Reward Research
 - o Scientific Workforce Analyses
 - o Grant Application Success Rates

The Reporting Branch Applies Broad Expertise

Disciplinary Training		
Anthropology	Economics	Mathematics
Biological Sciences	Epidemiology & Public Health	Medicine
Demography	Information Technology	Public Policy
Sociology	Statistics	Urban Planning
Skills		
Data Management	Research Evaluation	Policy Analysis
Econometric Modeling	Advanced Statistical Analysis	Survey Design
GIS / Spatial Analysis	Programming Languages	Web site Design
Program Evaluation		

Services & Infrastructure



Electronic Tools/RePORT

Contact: James Onken

The Research Portfolio Online Reporting Tools (RePORT) site provides the public with a coherent view into NIH programs. The RePORT Web site act as a one-stop portal providing the public with unprecedented access to reports, data, and analyses of NIH-funded research and training programs, including detailed information on NIH expenditures and on the results of NIH-supported research. Through a single user interface, RePORT provides access to a variety of databases and reports separately maintained by the Office of the NIH Director and the NIH's 27 Institutes and Centers and distributed across multiple NIH Web sites.

Key Attributes

Electronic Tools/RePORT

- Provides reports and data on NIH programs including the NIH Biennial Report of the Director; funding by areas of research, conditions, and diseases; IC strategic plans; and funding maps.
- The RePORT Expenditures and Results (RePORTER) system is a database of NIH-funded, grants, R&D contracts, and intramural research projects, and publications and patents citing support from this funding.
- Provides data for the annual NIH Data Book, a collection of graphs and tables that are exportable to Microsoft Word or PowerPoint for use in reports and presentations.



Strategic Plans



Budget & Spending



Success Rates



Categorical Spending



Funded Organizations



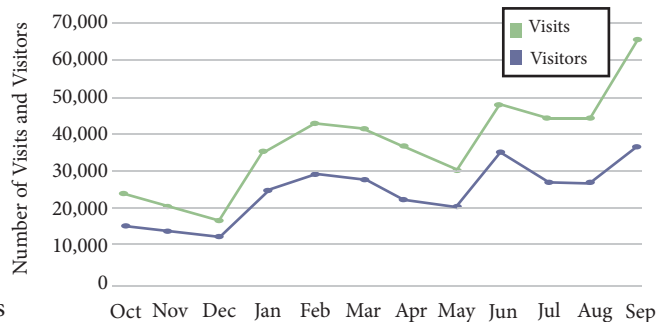
Investigators and Trainees

Major Accomplishments

Accomplishments

- Provided graphs and tables exportable to Microsoft Word and PowerPoint through the new NIH Data Book.
- Provided maps and downloadable spreadsheets of ARRA awards by state and congressional district on the RePORT Recovery Act page (<http://report.nih.gov/recovery>).
- Launched the RePORT Expenditures and Results system, which provides users the ability to search NIH-funded programs and access the publications and patents citing support from this funding.
- Was acknowledged by Government Computer News in 2009 as one of "10 Projects Worth Watching."

The Number of Visits and Visitors to the RePORT Site (numbers tripled in FY09)



Major Opportunities

Opportunities

- Expand reporting on ARRA investments.
- Create IC-specific versions of the NIH Data Book.
- Create IC-specific RePORT pages.
- Provide more intelligent search capabilities so users can more easily find information on NIH funding and programs.
- Provide new tools for reporting on investments in global health research.
- Expand InPORT, an internal Web site for NIH staff to share information and reports with other staff.
- Launch MyRePORTER, providing users the ability to save favorite RePORTER searches, store project listings, and set E-mail alerts.
- Expand the current export capabilities of RePORTER.
- Launch ExPORTER, a site where the public can download the RePORTER database.
- Explore potential links between RePORTER records and other databases, such as ClinicalTrials.gov, FDA databases, and NIH-issued reports.
- Participate in the White House's Open Government Initiative and provide access to RePORT and RePORTER through <http://www.data.gov>.

NIH Guide for Grants and Contracts

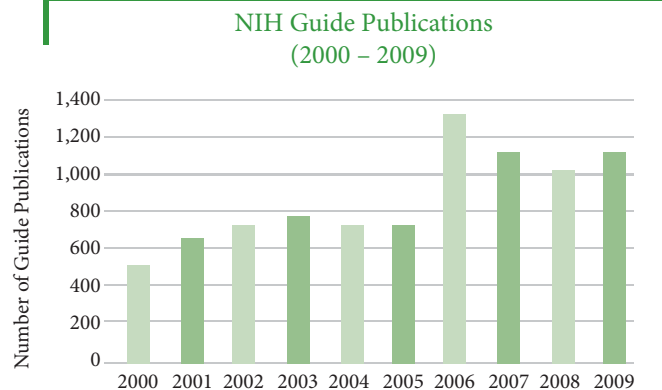
Contacts: Mary Ann Guadagno and Susan Grove

The NIH Guide for Grants and Contracts is the premier communication vehicle for NIH and other HHS agencies to notify applicants of NIH funding opportunities and policy updates in support of biomedical and health-related behavioral research. Funding Opportunity Announcements (FOAs) and Notices are reviewed, processed, and published daily and a weekly Table of Contents is published on Fridays. The majority of NIH's annual investments in health-related research are announced via the NIH Guide. About 40,000 scientists in universities, medical schools, and research institutions in the U.S. and around the world subscribe to the public ListServ for the Guide.

Key Attributes

The NIH Guide

- Serves NIH as well as nine sister agencies within HHS.
- Responsible for developing, reviewing, editing, and publishing public announcements of over \$30 billion in NIH investments in medical research in the U.S. and abroad, plus \$10.4 billion from ARRA funds.
- The Guide web page, linked to the OER home page, allows users to search for RFAs, PAs, and notices and provides links to the weekly Table of Contents and application forms.



Major Accomplishments

Accomplishments

- Processed 1,200+ Funding Opportunity Announcements (FOAs) in 2009.
- Introduced enhancements to a SharePoint System used by all NIH IC's, Offices and other HHS Agencies to develop, edit, and publish FOAs.
- Designed three unique templates for NIH to use to develop FOAs to announce RFAs using ARRA funds.
- Systematically revised and republished 600+ existing NIH FOAs to comply with new NIH Enhancing Peer Review criteria.
- Provided two training webinars to stakeholders.

Institutes Using SharePoint for Review & Publication

IC	Number	IC	Number
OD/OER	147	NCRR	34
NCI	108	NCCAM	22
NIDA	100	NIDCR	21
NIMH	89	NIEHS	17
NICHD	73	NIDCD	17
NIAID	67	FIC	16
NINDS	60	CDC	16
NIDDK	57	NINR	15
RM	51	AHRQ	14
NIGMS	50	NCMHD	13
NHLBI	45	NIAMS	9
NIA	41	NIBIB	8
FDA	4	NEI	3
NLM	3		

Major Opportunities

Opportunities

- Update all FOAs to reflect changes in NIH Peer Review Policy, particularly with respect to page limits and the new scoring criteria.
- Anticipate continued growth of service demands for The Guide by NIH and HHS.
- Continue to process ARRA FOAs.
- Update the NIH Grants Administration Manual (GAM) to provide timely policy enhancements and document Guide business standards and procedures.

Services & Infrastructure



Centralized, Authoritative Source of Grants Information

Contact: Megan Columbus

OER provides NIH and the extramural research community with a central, authoritative source of information on NIH grants. Due to OER's unique position at NIH, it is able to engage the full range of those involved in the research community in an on-going dialog: professional associations, grantee institutions, other Federal agencies, each of the NIH Institutes and Centers (IC) extramural staff and leadership, other offices within the NIH Office of the Director, and more. It is through these interactions that OER can best understand the biomedical research landscape, refine business practices, and develop communications resources that optimally meet the needs of the communities it serves.

Key Attributes

Centralized, Authoritative Source of Grants Information

- OER Web sites log more than 1 million user sessions per month and provide access to 35,000 documents, systems and tools with consistent, up-to-date grants information.
- OER makes available collections of comprehensive communication resources for use by the research community to reduce redundant resource development and provide clear, common messages for use in the education and outreach efforts of grantee institutions and NIH ICs.
- Nexus, OER's monthly e-publication, provides timely information about the latest extramural happenings to more than 38,000 subscribers.
- Rapid development of ad-hoc Web-based tools facilitates information sharing with the internal and external research community.

Major Accomplishments

Accomplishments

- Promoted rapid community awareness of ARRA opportunities, policies, and procedures by immediately developing external and internal ARRA Web sites, sending weekly ARRA updates to extramural staff, developing an ARRA specific ListServ, establishing dedicated ARRA mailbox for questions, creating tools to assist the grantee community with quarterly reporting, and developing presentations and other materials to educate the community.
- Launched an intense, multi-phased communications campaign on changes resulting from the Enhancing Peer Review initiative to help ensure common understanding of business process changes by NIH staff, reviewers, and applicants.
- Simplified the new stem cell policy development and implementation by developing systems to handle stem cell registration and acceptance and processing of over 49,000 public comments.
- Diversified communication strategies by establishing Twitter feeds for the NIH Guide postings and announcing newly registered stem cell lines.

Major Opportunities

Opportunities

- Improve access to OER seminars and educational opportunities by creative use of technology assistance.
- Improve collaboration within NIH extramural management committees and working groups by providing SharePoint working spaces.

OER's Relationships Promote Healthy Partnerships

Office of the Director	Institutions & Centers	Institutions & Investigators	Government Entities	The General Public
				
<ul style="list-style-type: none"> • OD Offices 	<ul style="list-style-type: none"> • Grants Mgmt • Program Offices • Comm Offices • IT Offices • Review 	<ul style="list-style-type: none"> • Office of Sponsored Programs & Dept. Staff • Mentors & Advisors • Trainees & Fellows • Investigators • Domestic and International 	<ul style="list-style-type: none"> • Congress • Other Federal Agencies • Domestic and International 	<ul style="list-style-type: none"> • General Public • Advocacy & Organizations • Other Funders

Services & Infrastructure

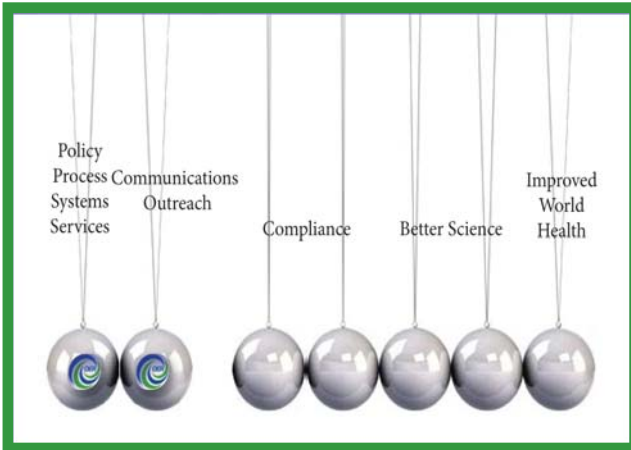


Outreach to Research Community

Contacts: Megan Columbus and Cynthia Dwyer

OER's outreach programs are a critical component of the overall communication strategy with the extramural community. Outreach provides NIH staff with opportunities not only for proactive and targeted information dissemination, but also for listening to the needs of the communities we serve. Through efforts such as OER-sponsored seminars and events, presentations at professional society meetings, and exhibits at major meetings, OER is able to engage the research community in a dialogue. This conversation helps to improve the grants process, enhances compliance with grants policies, and provides a common understanding of the funding process, ultimately leading to support of better science and improved health.

Key Attributes



Outreach to Research Community

- Engage NIH Institute and Center staff and applicant/grantee institutions to leverage opportunities to carry common messaging about grants policies and procedures.
- Sponsor seminars and events do the following:
 - o Reach more than 3,000 scientists and research administrators annually.
 - o Provide a forum to highlight the latest grants issues.
 - o Offer extensive opportunities for personal interaction between NIH staff and attendees.
 - o Involve key policy officers and staff with a wide variety of expertise from across NIH and HHS.

Major Accomplishments

Accomplishments

- Successfully promoted major initiatives, such as ARRA and the Enhancing Peer Review initiative.
- Provided opportunities for interactive engagement at twice-yearly regional seminars, animal welfare workshops, a one-day grants process seminar, an annual small business conference, IACUC educational seminars, and more.
- Provided policy and program experts at professional meetings across the country.
- Increased use of video conference technology to expand NIH staff outreach to applicant institutions.

Map of OER Conferences & Seminars FY09



Major Opportunities



Opportunities

- Explore new technologies that facilitate virtual interactions with internal and external communities including:
 - Podcasting
 - Social media
 - Virtual conferences
 - Virtual exhibit halls

Services & Infrastructure



Help Desk Support

Contacts: Dave Hunter and Megan Columbus

The OER help desks provide centralized support services to NIH and the extramural research community. Interactions with a broad spectrum of people involved in biomedical research within and outside of NIH provide valuable insight into the clarity of NIH grants policies, processes and systems and identify any systemic mis-perceptions. Partnerships with Grants.gov, the Center for Information Technology, the National Library of Medicine, and other organizations external to OER help ensure appropriate and expeditious handling of inquiries.

Key Attributes

Help Desk Support

- Grants Information service responds to ~14,000 requests per year, providing guidance on finding funding opportunities and the overall NIH grants process.
- eRA Help Desk guides more than 200,000 system users through the process of registering and navigating NIH's electronic Research Administration systems.
- NIH policy support mailboxes provide expert interpretation and assistance regarding NIH grants, program, review and animal welfare policy.
- OER program support mailboxes serve as resources for specialized communities and initiatives, such as small business and Academic Research Enhancement Award (AREA) programs and ARRA.
- Dedicated mailboxes for reporting tools provide direct access to personnel best able to assist.

Major Accomplishments

Accomplishments

- Collectively, OER help desks responded to more than 80,000 inquiries.
- Served as a key resource to clarify changes resulting from major high priority initiatives, including ARRA, the Enhancing Peer Review initiative, new stem cell policies, and more.

Help desk	Contact Information
General Grants Info	grantsinfo@od.nih.gov
eRA Commons	http://itservicedesk.nih.gov/eRA/
OER Comm Office	oyer@od.nih.gov
Grants Policy & Guidance	GrantsPolicy@od.nih.gov
Compliance & Oversight	GrantsCompliance@nih.gov

Major Opportunities

Opportunities

- Increase availability of online self help resources.
- Continue to expand training and education for help desk staff.

Extramural Staff Support

Contact: Mitzi Diley

The Division of Extramural Activities Support (DEAS) is an organization of over 650 employees providing extramural staff support to 25 ICs and servicing \$15 billion of extramural grants. DEAS was created in 2005 as the result of a competitive sourcing study (A-76) to most efficiently provide administrative and technical support in the development, review, and management of extramural grants and contracts. DEAS is a centrally managed organization with most staff located at the ICs. This structure provides a conduit for assessing trans-IC business processes and encourages knowledge sharing of best practices, operational improvements, and workload management, while maintaining the structural framework for activities to be operated and monitored centrally.

Key Attributes

Extramural Staff Support

- Provides administrative support to over 3,000 extramural scientists.
- Collaboratively works with the ICs to provide the appropriate resources to accomplish tasks efficiently and effectively.
- Centralized recruitment and training programs for all extramural support staff assures continuity and consistency of service across all ICs.
- Allocates staff to the ICs based on 25 extramural workload indicators. Annual workload validation is placed in a staff algorithm.
- Workload indicators include the number of applications, new competing awards, review meetings, travel vouchers, program conferences and workshops, and customers.
- DEAS staff are trained and organized in accordance with the three primary business areas of the NIH Extramural Community: Program, Review, and Grants Management.

Major Accomplishments

Accomplishments

- Continued support for over five years to the NIH extramural community.
- Reported savings to OMB of over \$100 million (approximately \$20 million per year) since the competitive sourcing study 5 years ago.
- Created the centralized closeout center to optimize closeout of grants and processing of Types 3, 4, 5, and 7.
- Utilized on-going surveys of IC customers and internal staff to determine any problem areas for correction.
- Over 40,000 hours of training completed since inception of DEAS. Provided comprehensive training programs for new staff as well as re-fresher courses with over 70 different types of classes are offered.
- Utilized standard operating procedures, training follow-up assessments, and quality control to maintain a high level of service.

Major Opportunities

Opportunities

- Provide opportunities for entry into the Federal workforce and NIH at the GS-5/6/7 level.
- Allow for upward mobility at NIH; many staff have been hired by the ICs as grants management specialists and other positions due to their knowledge of extramural processes.
- Central management of DEAS insulates NIH from negative impact of localized IC staffing turnover.
- Recent reductions in turnover have created a more stable organization and less reliance on contractors.

Number of DEAS Staff Per IC

IC	Staff Count	IC	Staff Count
NCCAM	8	NIDA	25
NCI	99	NICHD	36
NCMHD	5	NIDCD	5
NCRR	10	NIDCR	7
NEI	5	NIDDK	27
NHGRI	8	NIEHS	9
NHLBI	40	NIGMS	32
NIA	22	NIMH	39
NIAAA	13	NINDS	29
NIAID	83	NINR	7
NIAMS	10	NLM	5
NIBIB	11	FIC	5
CSR	87	Central	29

Extramural Staff Training

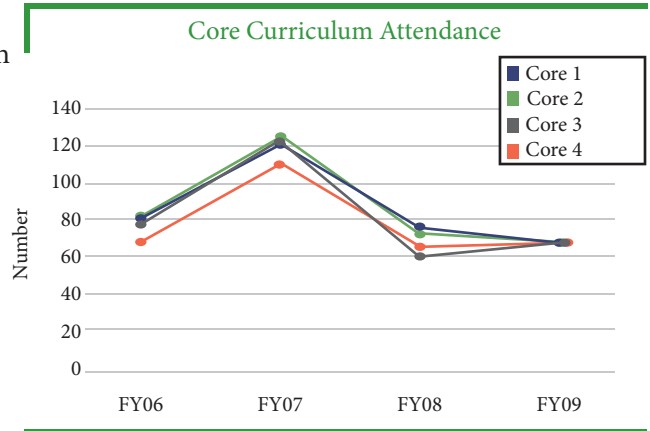
Contact: Chuck Selden

The Extramural Training Staff develops introductory and continuing staff training on policy and procedure for NIH's Extramural Program Administration. This training provides background information on policies, outlines staff responsibilities, and equips staff with the knowledge they need to conduct the technical administration of grants and contracts, from both the program and review perspectives, as well as to implement new policies. With the Staff Training Extramural Programs (STEP) we produce special seminars of interest to all NIH extramural staff on scientific and administrative topics. The Extramural Scientist Administrator Seminar Series (ESA Seminar) provides an in-depth look into the functions of NIH Office of the Director and Institutes and Centers, as well as the function of our sister agencies.

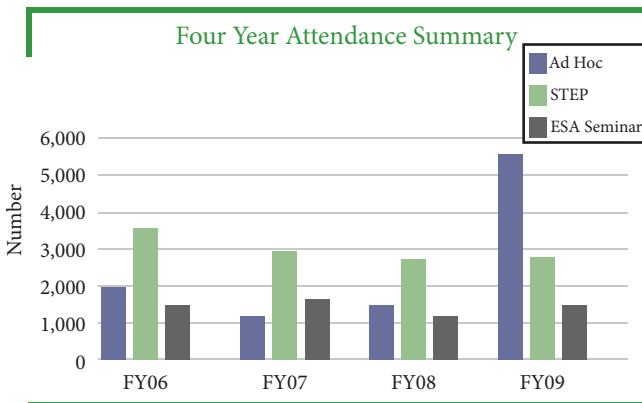
Key Attributes

Extramural Staff Training

- Manages the main course for newly hired Health Scientist Administrators, "Orientation to NIH Extramural Activities."
- Presents "Fundamentals of NIH Extramural Activities" course, which provides an overview of how NIH works.
- Offers a "Core Curriculum" series
 - o Core One: Funding mechanisms
 - o Core Two: The program official job
 - o Core Three: The review official job
 - o Core Four: Staff interactions to do the work
 - o Core Five: R&D contracting (new for 2010)



Major Accomplishments



Accomplishments

- Provided ad hoc training in new policies and procedures.
- Produces eight training activities per year with STEP, a committee of volunteer staff from ICs.
- Offered the ESA Seminar Series every Friday for 16 weeks where two speakers each afternoon talk about their role and their department at NIH or another agency.

Major Opportunities

Opportunities

- Provide program staff training on the stewardship of renewal grants, in regard to policies for student training on Responsible Conduct of Research
- Produce training for program staff on how to facilitate awardees' compliance with the registration requirement at ClinicalTrials.gov.
- Develop Core Curriculum Part Five on Extramural R&D Contracting.

- Produce staff training updates on implementation of the "Enhancing Peer Review" initiative.
- Continue to strive for excellence in staff training.
- Monitor developments in policy and procedure.
- Coordinate policy implementation groups to produce user-friendly training.

Services & Infrastructure



Loan Repayment Program

Contacts: Milton J. Hernandez and Stephen J. Boehlert

The NIH Loan Repayment Programs (LRPs) repay qualified educational debt of biomedical and behavioral scientists in exchange for a two-year research commitment. Opportunities exist in five research areas: clinical, pediatric, health disparities, contraception and infertility, and clinical research for scientists from disadvantaged backgrounds. The Division of Loan Repayment (DLR) administers the application and financial review process and provides services for program participants. Each year, DLR receives approximately 3,500 applications, and about 1,600 awards are funded. Initial evaluation has shown that program participants stay in research careers longer, apply for and receive more research grants, and become independent investigators more frequently than peers without LRP funding.

Key Attributes

Loan Repayment Program

- Repay qualified educational debt up to \$35,000 per year for two years. Competitive renewals are available after the initial two-year period.
- Collaborate with 23 NIH ICs.
- Service early career researchers (94 percent of LRP participants received their qualifying degrees within 10 years of their application to the program).
- Reach potential applicants through an information center, online advertisements, ListServ messages, and professional society meetings and presentations.

Major Accomplishments

Accomplishments

- Completed program evaluation and found that LRP is attaining its programmatic goals and may be a model for recruiting and retaining early career researchers who otherwise might leave the biomedical research workforce after earning a doctoral degree.
- Launched a new participant portal and Web site design.
- Reduced financial vetting fee from \$900 to \$800 per participant, creating a savings of approximately \$100,000 for FY09.
- Refined program vision under the leadership of a new director.

Major Opportunities

Opportunities

- Change the income status of LRP awards to non-taxable.
- Create a defined path or link between LRP awards and Career Development (K) funding.
- Introduce additional programming to further foster careers of current and past participants.
- Collaborate with ICs on outreach projects.
- Partner with professional societies to educate members about LRP awards and potentially increase the quality of the applicant pool.
- Analyze applicant data to ensure outreach to key audiences.

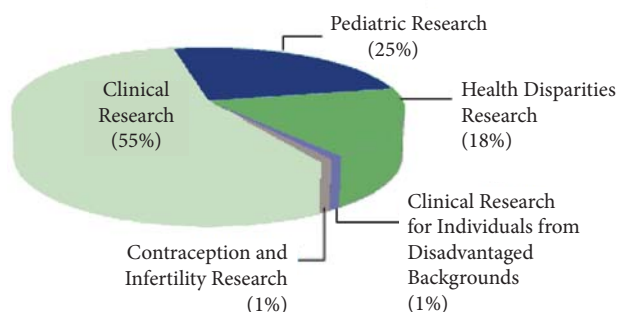
Applications, Awards, and Success Rates

LRP	New		Renewal		Total	
	Awards	Funds*	Awards	Funds*	Awards	Funds*
Clinical Research	410	\$25.2	469	\$15.0	879	\$40.3
Pediatric Research	175	\$10.6	213	\$7.6	388	\$18.2
Health Dispar. Research	168	\$9.1	127	\$4.0	295	\$13.1
Individuals w/ Disadvantaged Backgrounds	8	\$.62	10	\$.31	18	\$.94
Contraception & Infertility	15	\$.86	9	\$.20	24	\$1.1
Total	776	\$46.5	828	\$27.1	1,604	\$73.6

*Funds in Millions of Dollars

- Awarded nearly \$73.6M through 1,600 awards.
- Twenty-three ICs funded at least one new and/or renewal LRP contract.
- Maintained a 47% success rate, a significantly higher rate than other NIH funding opportunities.
- Processed 24,871 payments and credits.
- Answered more than 15,000 phone and 15,500 e-mail inquiries.
- Participated in 25 meetings, presentations and medical school visits.

Percent of Total Awards by LRP



Grants Closeout Center

Contact: Mitzi Diley

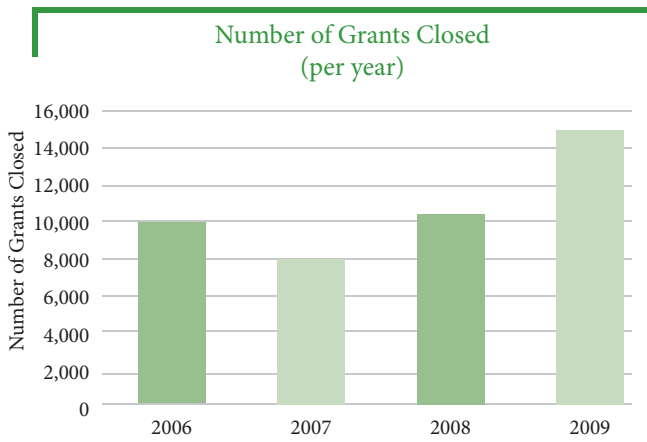
The centralized Grants Closeout Center is a sub-entity of the Division of Extramural Activities Support (DEAS) that serves as a central coordination and receipt location for documents to be submitted from grantees or principal investigators. The Closeout Center provides closeout of grants and cooperative agreements as well as processing of Type 3, 4, 5, 6, and 7 grant applications. The Closeout Center's goal is to provide current and accurate electronic grant files available for use. This centralized function started operations in 2006 for some ICs and gradually increased service for all 24 ICs that make awards.

Key Attributes

Grants Closeout Center

- The centralized closeout center provides NIH with an efficient and timely method for handling closeout and has helped decrease backlog across all ICs.
- The office currently receives and processes reports submitted by regular U.S. mail, courier and overnight services, as well as by E-mail and fax. They also process information submitted electronically through the Closeout feature in the eRA Commons.
- The center handles all documents in accordance with NIH records policies.
- Grant recipients must submit a Final Financial Status Report (FSR), a Final Progress Report, and a Final Invention Statement and Certification (as applicable) within 90 calendar days after the final budget period of an award.
- Centralization allows for the monitoring of closeout progress across all of NIH to identify delinquent and non-compliant institutions/grantees.
- DEAS staff located at the ICs properly archive or dispose of hardcopy official grant files in accordance with the NIH Policy Manual (Chapter 1743, Keeping and Destroying Records).

Major Accomplishments



Accomplishments

- Helped to greatly decrease the closeout backlog at various ICs that was cited in a Government Accountability Office (GAO) audit.
- Provided operating procedures and data for A-123 audits.

Major Opportunities

Opportunities

- Provide centralized support to streamline processes for grantees.
- Provide infrastructure for further centralization of other functions, such as NRSA grants.

National Research Service Award (NRSA) Payback Service Center

Contacts: Milton J. Hernandez and Stephen J. Boehlert

The National Research Service Award (NRSA) Payback Service Center (PSC) monitors and processes the payback obligation of postdoctoral scientists who receive appointments to NIH training grants and fellowships under the Ruth L. Kirschstein National Research Service Award. The NRSA legislation requires postdoctoral trainees to repay the U.S. Government by engaging in health-related biomedical or behavioral research and/or teaching for a length of time equal to the period of NRSA support received, up to 12 months.

Key Attributes

NRSA Payback Service Center

- Oversees entire service payback process.
- Services all NIH ICs that award training grants and fellowships, as well as the Agency for Healthcare Research and Quality.
- Ensures that postdoctoral trainees and fellows engage in acceptable payback activities within two years of their award termination.

Major Accomplishments

Accomplishments

- Improved programmatic tracking by leveraging the capabilities available in the Training Activities module of IMPAC II.
- Started using CLEAR from Westlaw, a people locator product that increased the accuracy and dramatically reduced the costs of locating trainees.
- In collaboration with eRA, developed an improved QVR-based tracking and reporting.
- Monitored 2,000 training grants and 1,400 postdoctoral fellowships.
- Processed 1,938 new files.
- Closed 1,663 files.
- Sent 2,882 payback notification letters.

Major Opportunities

Opportunities

- Continue collaborating with the ICs to improve timely submission of termination notices and receipt of trainee files.
- Incorporate processing into xTrain, a tool that gives program directors, university administrators, and trainees the ability to electronically process and submit appointment forms and termination notices.

To view the 2009 Office of Extramural Research Report online, please visit:

http://grants.nih.gov/grants/2009_oer_report.pdf

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

http://grants.nih.gov/grants/2009_oer_report_508.pdf



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