



Current Issues at NIH Spring 2009

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Office of Policy for Extramural Research
Administration



NIH Budget News and Priorities



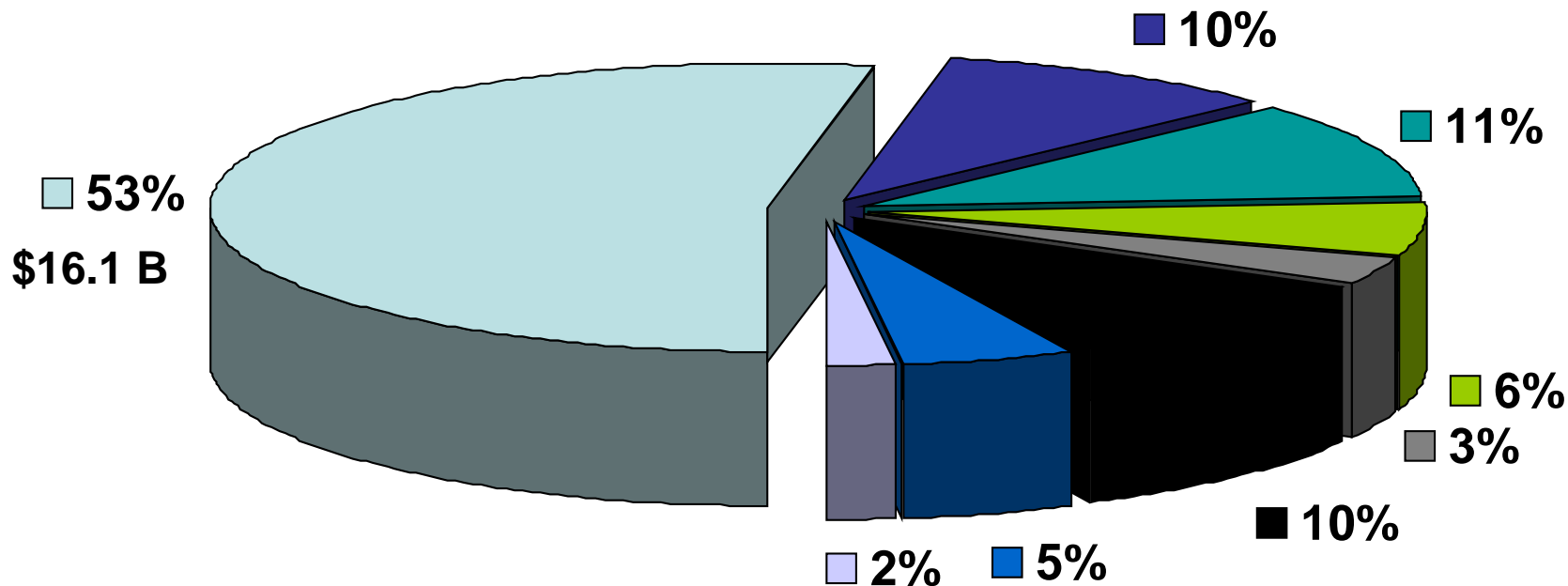
Final NIH Appropriations FY 2009

- NIH received a total of \$30.4 billion in new budget authority.
 - Increase of 3.2% from FY 2008
 - Supports 9,800 new and competing RPGs
- Average competing award expected to increase by 3%
- Noncompeting awards will be supported at the most recently committed levels.
- NIH will support a 1% increase in all NRSA stipend levels.





Breakdown of \$30.4 Billion Appropriated to NIH for FY 2009

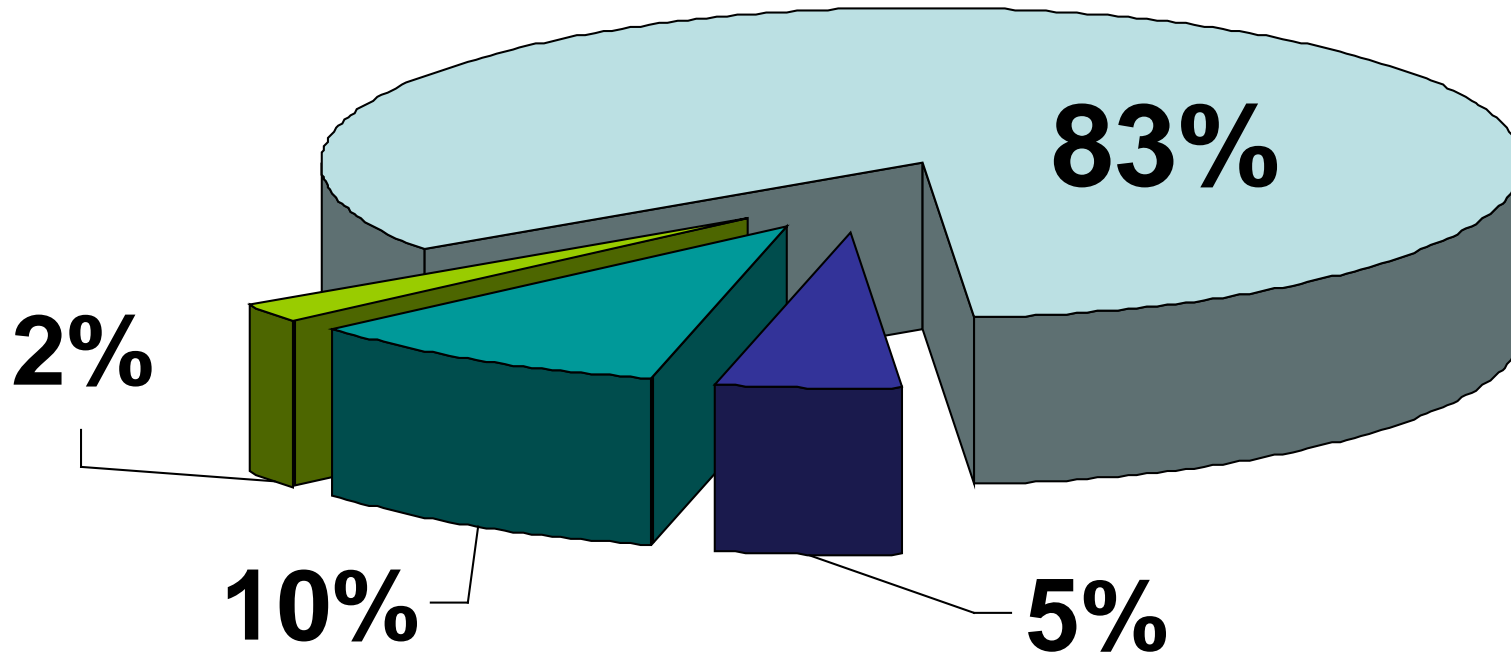


- | | |
|-------------------------------|---------------------------|
| Research Project Grants (53%) | Research Centers (10%) |
| R&D Contracts (11%) | Other Research (6%) |
| Training (3%) | Intramural Research (10%) |
| Research Mgmt & Support (5%) | All Other (2%) |



Extramural Funding (Research and Training)

Extramural Funding = 83% of Total Budget



Extramural Funding

Intramural Funding

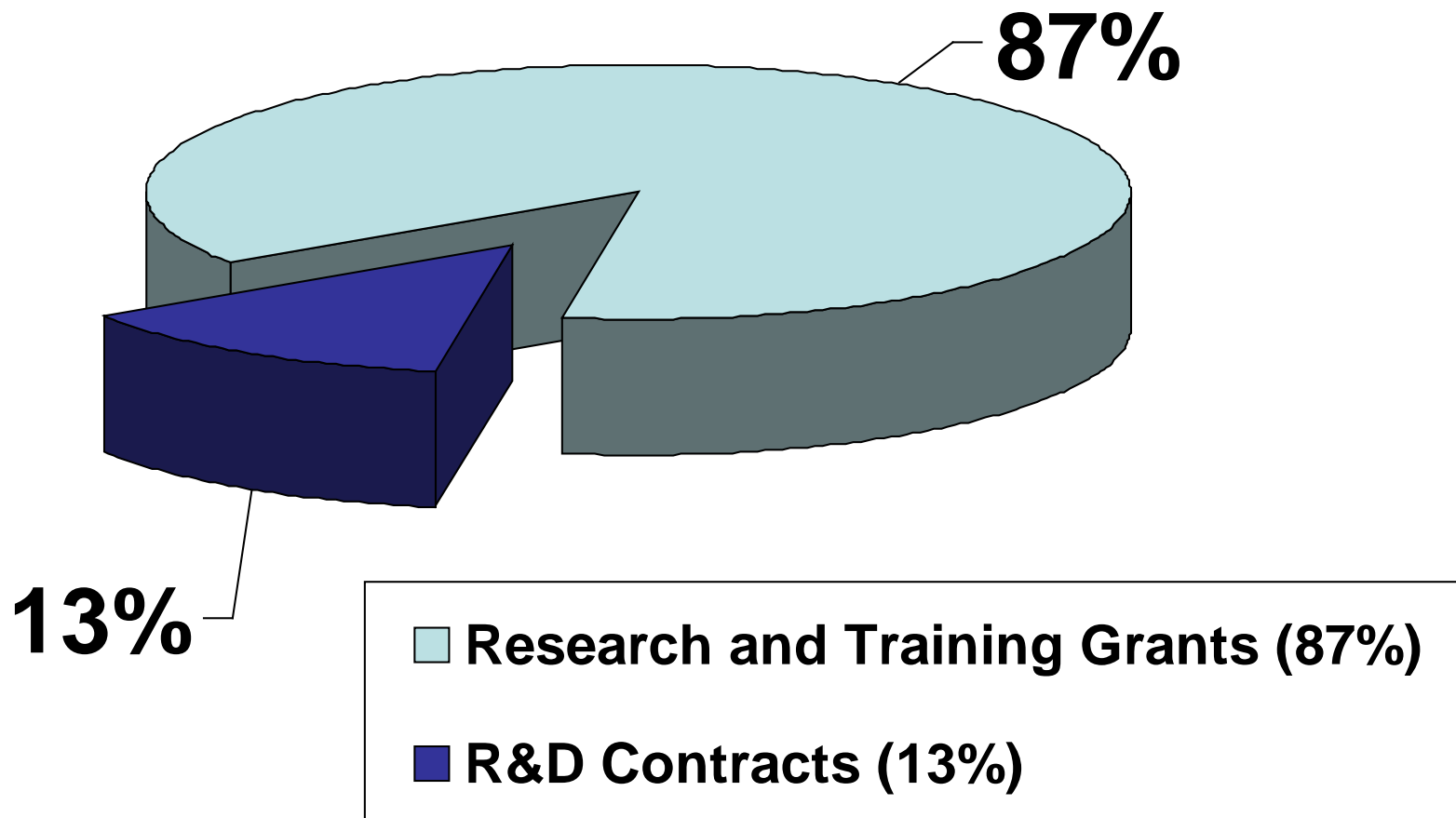
Research Mgmt & Support

All Other



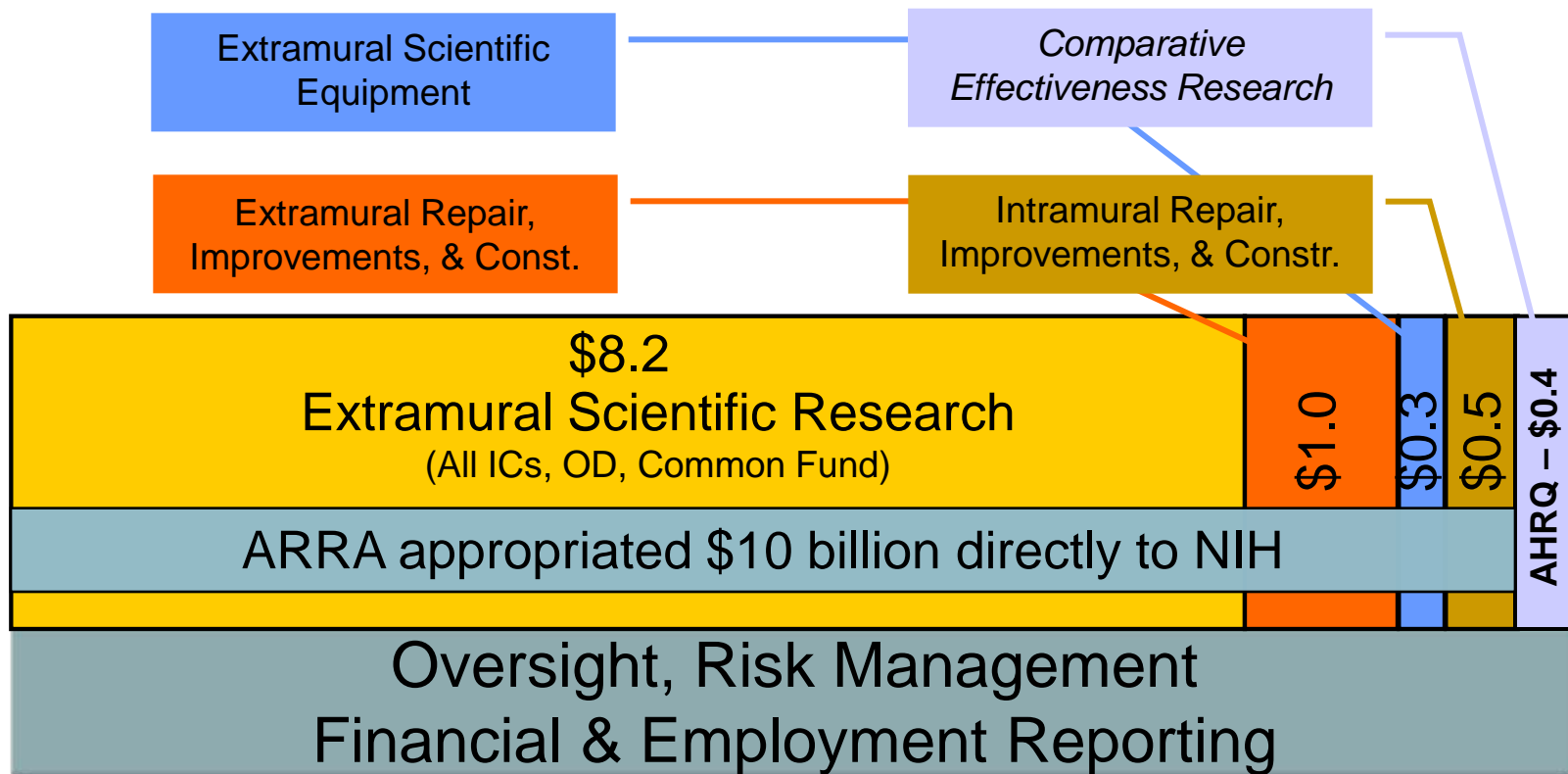
Extramural Funding

Extramural Funding = 83% of Total Budget





NIH Allocation of ARRA Funds Dollars In Billions





Quick and Easy Search: New Tools to Search NIH Funding

- New reports, data and analyses website released in March, 2008 and expanded significantly in January, 2009 with addition of RCDC data (Research, Condition and Disease Categorization process)
- Replaces the current Award Information and Data web page and will provide:
 - Quick access to “Frequently Requested Reports”
 - FAQs on how success rates are computed and questions on the NIH budget
 - Search tools for locating data and reports quickly and easily
 - Links to funding estimates for certain research areas, conditions, and diseases.
- Foundation for broader NIH-wide Research Portfolio Online Reporting Tool (RePORT)



New Tools to Search NIH Funding (continued)

- This is the first time a complete list of all NIH-funded projects related to each category will be available.
- RCDC combines data from NIH ICs explaining research spending and priorities to Congress and the public in 215 disease, condition, and research areas.
- Reports actual and estimated spending figures for FY 2005-2010; not “set-asides” or “allocations”.

| Research/Disease Area (Dollars in Millions and Rounded) | FY 2007 Actual | FY 2008 Actual | FY 2009 Estimate |
|--|---------------------------|---------------------------|-----------------------------|
| Acute Respiratory Distress Syndrome | \$87 | \$82 | \$84 |
| Agent Orange and Dioxin | \$15 | \$13 | \$14 |
| Alzheimer’s Disease | \$411 | \$412 | \$423 |



NIH Priority: Roadmap for Medical Research

- NIH Focusing on Three Broad Roadmap “Themes”:
 - Research Teams of the Future
 - Re-engineering the Clinical Research Enterprise
 - New Pathways to Discovery
- Transformative R01 Program supports highly creative, “out-of-the-box” projects. Areas include:
 - Understanding and Facilitating Behavior Change
 - Complex 3-D Tissue Models
 - Functional Variation in Mitochondria in Human Disease
 - Transitions from Acute to Chronic Pain
 - Formulation of Novel Protein Capture Reagents
 - Providing an Evidence Base for Pharmacogenics



***NIH Priority:* Blueprint for Neuroscience Research**

- Cooperative effort among 16 ICs to accelerate Neuroscience research.
- RFAs in 2007-2009 will focus on three themes, respectively:
 - Neurodegeneration during disease and aging;
 - Neurodevelopment throughout the lifespan; and
 - Neuroplasticity, from molecular to behavioral levels.
- Available neuroscience resources include: animal models; imaging tools; neuroinformatics (computational biology); core facilities; cells, tissue, and DNA; gene and protein expression; and training.



NIH Priority: Continued Focus on New Investigators

NIH Remains Committed to Identifying and Attracting New Biomedical Researchers.

- Assistance to New and Early Stage Investigators
- NIH Director's New Innovator Award
- Pathway to Independence Awards
- I/C-Specific Policies



NIH Director's New Innovator Award (DP2)



- Stimulates highly innovative research and supports promising new investigators.
- Awards provide up to \$1.5 million in direct costs for (up to) a 5 year project period.
- 2009 applications were in two stages: a formal pre-application and a full application. See PAR-09-013 and RFA-RM-09-003 for more information.
- New FAQs on eligibility, application requirements, and program features is now available!

More at: <http://nihroadmap.nih.gov/newinnovator>



NIH Priority: Assistance to Early Stage Investigators

- NIH commits to identifying Early Stage Investigators (ESIs) so that appropriate consideration of their career stage can be applied during review and award selection stages.
- Identification of ESIs will occur in the Personal Profile section of the eRA Commons. Investigators who enter degree and residency completion dates will be notified of their ESI status by email.
 - **ESI Definition:** A new or first time investigator who is within 10 years of completing his/her terminal research degree or medical residency (or equivalent).
 - More at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-103.html> and <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-034.html>.

More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html>



NIH Director's Bridge Award (R56)

- Continued, limited funding for new and established PIs who have submitted a competing renewal, who just miss the nominal funding payline for the IC.
- Additional funded time for PIs to strengthen a resubmission.
- Selectees will receive one-year of funding up to \$500,000 direct costs + applicable F&A
- **Cannot apply, cannot self-nominate!** Criteria:
 - Must have < \$400,000 in other support (total costs) from all sources to fund research
 - A1s and only the most meritorious A2s are now eligible
 - Applications submitted in FY2008 that are still being considered for funding & FY2009 submissions



New Scientific and Grants Management Policies



Draft NIH Stem Cell Guidance

- On April 17, 2009, NIH posted draft guidelines for implementation of Executive Order 13505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells.
 - Draft guidelines were also published in the Federal Register for public comment.
 - Public comment period closed May 26, 2009. NIH is now reviewing all comments.
- In addition, NIH has released Guide Notice NOT-OD-09-085 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-085.html>) that explains how NIH applicants and grantees should proceed with applications and/or awards that include the use of human embryonic stem cells.



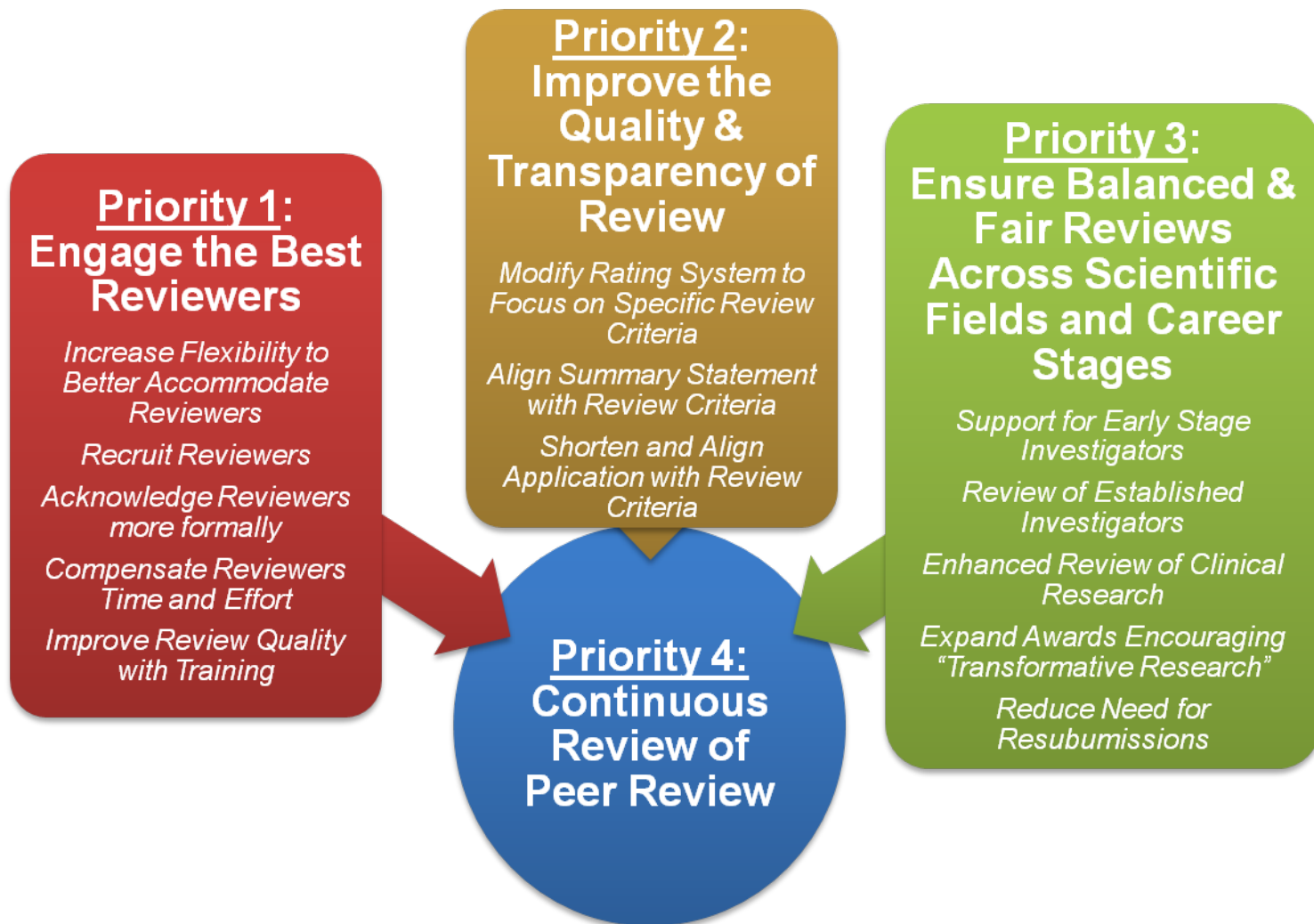
NIH Policy on Similar, Identical, or Essentially Identical Applications

- Reminder of NIH policies with goal of reducing burden on NIH review committees, PIs, and institutions.
 - Submission of identical applications to one or more PHS agencies is not allowed.
 - NIH will not review applications with one or more similar/identical specific aims until the peer review process is complete.
 - Resubmitting an application under a new activity code is allowable once the peer review process is complete and if the application follows the new FOA's requirements.
 - Non-compliant applications identified at any stage will be withdrawn from funding consideration.
- Resubmission of Challenge Grant applications not expected until August, 2009 once peer review is completed.

More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-100.html>



Enhancing Peer Review: Summary of Recommendations





New NIH Policy on Resubmission Applications

- NIH limiting all original new (i.e. never submitted) and competing renewal applications to only one resubmission.
 - Applies to all applications submitted for January 25, 2009 due date and beyond.
 - Previously submitted applications will be allowed two resubmissions (“grandfathered”) until January 7, 2011.
- Based on recommendations from the Peer Review Oversight Committee to increase the number of high quality and first resubmissions that can be funded earlier.
 - Reduces applicant burden of multiple resubmissions.
 - Removes delays in funding for meritorious science.



New Funding Policy for New and Early Stage Investigators

- For R01 applications in FY2009, NIH expects to support New Investigators at success rates equivalent to that of established investigators submitting new applications.
 - Majority of New Investigators are expected to be Early Stage Investigators
- Applications will be clustered during initial peer review to the extent possible.
- NIH encourages New Investigators and ESIs to apply for R01 grants when seeking first-time funding from NIH.



Implementation Update

- **Improve Scoring** – *Implementation in May, 2009.*
 - Applications will receive an overall score from each panel member from 1-9; scores will be averaged and multiplied by 10. Thus priority scores will range between 10-90.
 - Priority scores will be percentiled against an appropriate base and reported in whole numbers.
- **Improve Critiques** – *Implementation in May, 2009.*
 - Reviewer critiques will be compiled into a summary statement that will be shorter and more focused than currently due to standardized organization and reporting of strengths and weaknesses.
 - ALL applications (including streamlined applications) will

receive feedback. More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-024.html>



Implementation Update

- **Enhance Criteria for Peer Review** - *Implementation for FY 2010 begins with applications received during January 25, 2009 submission date*
 - Core Review Criteria – Reviewers will provide a separate score in each of the following categories: Significance, Investigator(s), Innovation, Approach, and Environment.
 - Additional Review Criteria – As applicable, reviewers will consider but not score separately: Protections for Human Subjects; Inclusion of Women, Minorities, and Children; Vertebrate Animals; Biohazards; and Revision/Resubmission issues.
- **Shorten Research Plans** – *Implementation in Fall, 2009 for January, 2010 application submissions.*
- **Implementation Timeline** – Available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-023.html>

More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-025.html>



New Threshold for Negotiating F&A Rates on SBIR/STTR Grants

SBIR/STTR applicants proposing F&A rates of 40% of direct costs or less will not be required to provide further justification at the time of award, and F&A costs will be awarded at the requested rate.

- NIH retains authority to require well-documented proposals for F&A rates on an ad-hoc basis.
- If applicant has a currently effective rate, such rates should continue to be used in NIH applications.
- Policy applies to all competing SBIR/STTR applications submitted for FY2009 funding and beyond. Non-competing awards funded in 2009 or earlier will continue to be funded at the committed level if between 25%-40%.



Policy on Submission of Additional Grant Application Materials

- Prior to initial peer review applicants may need to submit additional materials such as revised budget pages, biographical sketches, updated or supplemental pages, letters of support or collaboration, and publications.
- Original application is kept intact with additional materials sent separately to reviewers.
- This opportunity should not be used to circumvent submission deadlines, page limitations, or content requirements and should not substantially enhance, alter, or add to original application.
- Additional materials must be submitted to Scientific Review Officer with consent of applicant organization's AOR/SO.

Best Practices guidelines are now available; see NIH Guide Notice NOT-OD-08-082 for more information.

More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-082.html>



Revised NIH Parental Leave Policy for NRSA Awards

“Trainees on institutional training grants and individual fellowships may receive stipends for up to 60 calendar days (equivalent to 8 work weeks) for parental leave per year.”

- NRSA programs affected: F30, F31, F32, F33, T32, T34, T35 and NRSA portion of T90 awards.
- Applies to adoption or birth of a child when those in comparable training positions at the grantee organization have access to this level of paid parental leave.
- Either parent is eligible for leave.
- The use of parental leave must be approved by the training Program Director.



Revised Policy on Concurrent Support from K Awards and Research Grants

“Recipients of mentored career development (K) awards may reduce effort on their K award in its final two years when they successfully compete for a peer-reviewed research grant from ***any Federal agency.***”

- Effort may be reduced to no less than 6 person-months (or 50% full-time professional effort) and replaced with effort from the research award so the total research effort commitment remains at 9 person-months (75% effort).
- K awardee must be one of the named PIs on a competing research grant application or sub-project director on multi-component research or center grant or cooperative agreement.



Additional New Policies on “K” Career Development Awards

- K recipients may request NIH permission to reduce their full-time appointment to less than full-time (but not less than 75%) for a period not to exceed 12 continuous months during the K award period. Option available only after K award is issued.
- Under certain circumstances, (such as accommodating parental leave, child care, medical conditions, or disability, but not job opportunities, clinical practice/training, or joint appointments.) K awardees may request NIH permission to reduce professional effort to less than 75% (but over 50%) for up to 12 continuous months.
- A temporary career development experience at another institution for 3 months or less allowable without NIH permission.
- A leave of absence may be taken without award support but may not exceed 12 months.



New Registration Process for Peer Reviewer Reimbursement

- Required to process reviewers' honoraria and reimbursements for participation in NIH peer review meetings.
- Reviewers must log in to the eRA Commons, update their personal profiles, and link to the Secure Payee Reimbursement System (SPRS) to provide payment information.
- Replaces the previous CCR (Central Contractor Registry) system used until May, 2008.
- New process implemented on January 17, 2009.

All information will be kept secure and confidential!



Public Access Policy – Now Made Permanent

“All investigators funded by NIH must submit to PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication.”

- Compliance mandated by Public Law 110-161
- Applicable to:
 - Peer-reviewed articles,
 - Accepted for publication on or after 4/7/08, and
 - Arising from direct grant or contract funds active in FY 2008, and beyond.
- Full-text articles to be made publicly available on NLM's PubMed Central no later than 12 months after date of publication

More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html>



How to Comply

- **Address copyright issue:** Institutions and investigators are responsible for ensuring that publishing/copyright agreements allow submission.
- **Submission of articles to NIH:** Upon acceptance for publication, deposit final manuscript in NIH Manuscript Submission (NIHMS) system. Many journals will submit articles on behalf of author.
- **Citing Articles in Applications & Progress Reports:** Beginning with 5/25/08 submission date, when citing articles authored or co-authored by the applicant(s) that fall under the Policy, include the PubMed Central ID or NIH MS ID number for each article.



Registration of Clinical Trials

“The FDA Amendments Act (P.L. 110-85) mandates registration and results reporting at ClinicalTrials.gov by sponsors of applicable clinical trials.”

- Expansion of existing ClinicalTrials.gov registry.
- Includes Phase II-IV clinical trials of drugs and devices subject to FDA regulation.
- Increased number of data elements that must be submitted.
- Not limited to trials for serious or life threatening diseases.
- Competing applications and progress reports grants with NIH-funded trials must include a certification of submission.
- ***NIH encourages registration in ClinicalTrials.gov of ALL clinical research trials funded by NIH, whether required under the law or not.***



Mandatory Registration of Clinical Trials; Reporting of Results

- **Mandatory Registration**
 - All “applicable clinical trials” of drugs and biologics and devices are to be registered in the ClinicalTrials.gov database by the responsible party
 - NIH will verify registration before funds are released.
 - Civil penalties to be levied for noncompliance if trials are not properly registered.
- **Results Reporting**
 - P. L. 110-85 mandates the establishment of a clinical trials results database. Effective September 27, 2008, the NIH launched an expanded ClinicalTrials.gov database that can accept “basic results” information.



FY 2009 NIH Salary Cap

Effective January 1, 2009, salary and wages on NIH grants limited to an annual rate of \$196,700 (equal to Executive Level I).

- An individual's base salary is NOT constrained by the legislative provision for a limitation of salary. An institution may pay an individual's salary amount in excess of the salary cap with non-federal funds.
- Grantees should provide information on full salary needs (if more than the cap) so NIH can adjust based on future limits.
- Salary Cap Summary (Historical Information):
http://grants.nih.gov/grants/policy/salcap_summary.htm

More at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-069.html>



Federal Funding Accountability and Transparency Act (FFATA)

“Public Law 109-282 requires information on every grant, including 1) the amount, 2) descriptive purpose of the grant, and 3) name and location of recipient of primary performance location.”

- Prepare for potential increased attention and scrutiny when data is made publicly available.
- NIH is actively involved with a variety of Federal-wide committees to implement the act and is tailoring processes to meet its requirements.
- FFATA has required form changes in the 424 (R&R) and PHS 398 to capture performance site information. – *Stay Tuned!*
- Requires reporting on all subawards over \$25,000. Pilot system for collecting currently in development – *Stay Tuned!*



New NIH Web Site to Assist Foreign Grantees

- Focused on NIH grant policies that apply to grants awarded to foreign institutions, international organizations, and domestic grants with foreign components.
- Addresses elements of the grant process (from submission to post-award management) specific to foreign applicants/grantees.
- Includes information on:
 - Foreign-specific programs and foreign research opportunities.
 - Foreign collaborations and partnerships.



Updates and Reminders on NIH Policy for Foreign Grantees

- **Change in allowability of minor Alterations & Renovations**
 - Costs for minor A&R (\leq \$500,000) may now be included and justified in any detailed budget of a foreign competing application.
 - Rebudgeting to accommodate minor A&R is now also allowable for active foreign grants; however, this requires NIH prior approval of the Grants Management Officer (GMO).
- **Policy Reminders**
 - Application Review Criteria
 - Detailed Budgets
 - Payment
 - Annual FSRs
 - Transfers
 - F&A Costs
 - Unallowable Costs
 - Audit Requirements
 - Intellectual Property Rights and Obligations



Highlights of New and Existing Grant Requirements



Financial Conflict of Interest (FCOI) Activities

NIH continues to enhance and promote compliance with the FCOI Regulation (42 CFR Part 50, Subpart F)

- NIH system-wide review of FCOI policies, procedures, and guidance
- eRA Commons FCOI module/reporting tool for grantees
- Updated FAQs and a Web-based tutorial
- Articles in NIH Extramural Nexus
- NIH Web based reporting and tracking tool for NIH staff
- Pilot Compliance Program on FCOI
- NIH Targeted Site Reviews
- FCOI mailbox (FCOICompliance@mail.nih.gov)
- NIH Guide Notices
- Development of an Advanced Notice of Proposed Rule Making (ANPRM) to gather public comment on possible revisions to the FCOI regulation.



Advanced Notice of Proposed Rulemaking (ANPRM)

- “NIH Requests Comments on Proposed Amendment of Regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors”
 - Published May 8, 2009 in the NIH Guide to Grants and Contracts: NOT-OD-09-099
 - Published in the Federal Register (Vol. 74, No. 88) May 8, 2009
- 60-day comment period – closes July 7, 2009
- Comments accepted in Regulations.gov, by mail, fax or hand delivery (comments may not be submitted by email) See NIH Guide Notice for details.
- Could subsequently lead to NPRM and a new Final Rule



Advanced Notice of Proposed Rulemaking (ANPRM)

- Addresses various topics including:
 - Expanding the scope of regulation and disclosure of interests;
 - Definition of “Significant Financial Interest”;
 - Identification and management of conflicting interests by institutions;
 - Assuring institutional compliance;
 - Requiring institutions to provide additional information;
 - Broadening the regulations to address institutional conflict of interest
- Programmatic Inquiries only
 - Email: FCOI-ANPRM@NIH.GOV
 - Note: No comments may be submitted by email.



eRA Commons FCOI Module/ reporting tool

- Enables grantees to report identified FCOIs to NIH through the eRA Commons
- System allows institutions to:
 - Initiate and send a new FCOI report electronically through the eRA Commons
 - Search previously created records
 - Edit a previously submitted record
 - Respond to a request for additional information
 - Rescind a previously submitted record
 - View history of actions
- Effective July 1, 2009, system will be mandatory for all NIH grants and cooperative agreements.
- To prepare, institutional Signing Officials must assign FCOI roles to users in eRA Commons.



Updated and Expanded FAQs on FCOI

- For all NIH-supported Institutions
- Categorized for ease of reference:
 - General Questions
 - Institution-Specific Questions
 - Investigator-Specific Questions
- Web Postings and Resources at:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-063.html> and
<http://grants.nih.gov/grants/policy/coifaq.htm>



NIH Announces Web-based Tutorial on FCOI

- Reviews requirements of and responsibilities for compliance with Federal FCOI regulations
- Designed for use by:
 - **Institutional officials** responsible for managing NIH-funded grants, cooperative agreements and/or contracts
 - **Individuals** who are responsible for the design, conduct or reporting of NIH-supported research.
- Includes quizzes to test understanding and a Certificate of Completion

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-106.html>



FCOI

Definition of Investigator

- **Investigator** – Principal Investigator (PI) and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. *The term “Investigator” includes the Investigator’s spouse and dependent children.*
 - An **Investigator** is not just the Principal Investigator or Senior/Key Personnel conducting the PHS-sponsored research.
 - Recipient institutions are encouraged to broadly consider an individual’s role, rather than title, and their degree of independence when applying the definition.



FCOI Summary of Reporting Requirements

- 1. At the time of application:** Investigators must submit known significant financial interests to the institution.
- 2. Prior to the expenditure of funds:** The institution must report a financial conflict of interest to the NIH and assure that it has been managed, reduced, or eliminated.
- 3. FCOI identified after the initial report:** The institution must report within 60 days of identification and assure that it has been managed, reduced, or eliminated.



FCOI - Subrecipients

- If the grantee institution performs NIH-funded research through “subgrantees, contractors, or collaborators,” the grantee institution must take reasonable steps to ensure compliance by requiring either:
 - Subrecipient Investigators to comply with the grantee institution’s policy OR
 - Subrecipient institutions to provide assurances to the grantee institution that will enable it to comply

Subrecipients should report identified FCOIs to grantee institution. Grantee institution reports to NIH.



FCOI

Information to be Reported

- **All FCOI reports should include the following information:**
 - Grant number;
 - Name of Principal Investigator (PI) or contact PI if multiple PI award;
 - Name of Investigator with the FCOI;
 - Distinguish which method was used to protect the research from bias (e.g., managed, reduced, or eliminated).



FY 2009 OIG Audit Work Plan Selected Highlights

- Colleges' and Universities' Compliance with Cost Principles
 - Cost transfers, effort reporting, and other areas
- Use of Data and Safety Monitoring Boards in Clinical Trials
- Financial Conflicts of Interest in Research Funded by the NIH
 - Monitoring of FCOIs, nature of FCOIs, and how FCOIs are managed (for FCOIs reported to NIH in FY 2006)



Audit Requirements

All NIH Grantees that expend \$500,000 or more within a year in Federal awards are subject to an audit requirement.

- Audits are due within the earlier of 30 days after receipt of the auditor's report(s) or 9 months after the end of the grantee's audit period.
- Grantees delinquent in submitting audits risk the imposition of sanctions and potential loss of Federal funds.



Summary of Audit Requirements

| Grantee Type | Source of Audit Requirement | Where to Submit Audit Reports |
|--|---|---|
| State & Local Governments Colleges & Universities Non-Profits Hospitals | OMB Circular A-133 | Federal Audit Clearinghouse 1201 E. 10th Street Jeffersonville, IN 47132 Questions: 1-800-253-0696 |
| For-Profits | 45 CFR Part 74.26 (d) | National External Audit Review Center HHS Office of Inspector General HHS Office of Audit Services 1100 Walnut Street, Suite 850 Kansas City, MO 64106-2197 Phone: 800-732-0679/816-426-7725 |
| Foreign | NIH Grants Policy Statement (same as For-Profits) | (same as For-Profits) |



Closeout Final Reports

*Grantees are **strongly encouraged** to submit closeout documents electronically through the eRA Commons!*

- Documents are due within 90 days of project period end date
 - Final Financial Status Report (now required electronically)
 - Final Inventions Statement & Certification
 - Final Progress Report
- Failure to submit timely reports may affect future funding to the organization!





NIH Centralized Processing Center

- NIH encourages electronic submission of closeout documents through the eRA Commons.
- Centralized office accepts receipt of all non-financial, paper-based closeout documents
 - Final Progress Report
 - Final Invention Statement and Certification
- Mail to the Central NIH unit at:
 - NIH Centralized Processing Center
 - 6705 Rockledge Drive, Room 2207, MSC 7987
 - Bethesda, MD 20892-7987 (for regular or US Postal Service Express mail)
 - Bethesda, MD 20817 (for other courier/express mail delivery only)



Protecting Confidentiality in the NIH Peer Review Process

- NIH is now password-protecting data on the compact disks sent to peer reviewers prior to study section meetings. This includes:
 - Grant application information
 - Previous summary statements
 - Appendix materials
 - Additional materials (“eAdditions”) in the grant folder
- Specific instructions for accessing data will be sent to reviewers with the CDs



Requirements and Compliance Assistance for OHRP / OLAW



Registration Requirements for Institutional Review Boards

- Published in Federal Register on January 15, 2009 and effective July 14, 2009.
- OHRP has added a new subpart E to the HHS protection of human subjects regulations, which requires IRBs to register with HHS.
- Registration information includes contact information, approximate numbers of all active protocols and active protocols involving research conducted or supported by HHS, and IRB staffing.
- Initial registration must be submitted by September 14, 2009.
- Registration does not mean OHRP has determined the IRB is in compliance with Protection of Human Subjects regulations at 45 CFR Part 46.



Updated Guidance from OHRP

- Final Guidance on Engagement of Institutions in Human Subjects Research
 - Published October 23, 2008 in Federal Register.
 - Finalizes previous draft guidance and describes:
 - Scenarios that, in general, would result in an institution being considered engaged in a human subjects research project.
 - Scenarios that would result in an institution being considered not engaged in a human subjects research project
 - IRB review considerations for cooperative research in which multiple institutions are engaged in the same non-exempt human subjects research project.



Updated Guidance from OHRP (continued)

- Revised Guidance on Research Involving Coded Private Information or Biological Specimens
 - Provides guidance on when coded private information or specimens is or is not research involving human subjects.
 - Reaffirms OHRP policy that, under certain limited conditions, this research is not human subjects research.
 - Clarifies distinction between:
 - Research involving coded private information or specimens that does not involve human subjects, and
 - Human subjects research that is exempt from the requirements of HHS regulations.



OLAW

Compliance Assistance

- “What Investigators Need to Know About the Care and Use of Laboratory Animals”
 - Brochure explains the requirements for using animals in PHS-supported research
 - Contact OLAW to request multiple copies
- FAQs on “PHS Policy on Humane Care and Use of Vertebrate Animals” available on the OLAW website
- IACUC 101 is a series of workshops on the roles and responsibilities of IACUCs, including federal policies and regulations regarding animal welfare.
 - June 24-25, 2009 – Niagara Falls, NY
 - October 7-8, 2009 – Chicago, IL





Consortium Agreements: Subawards and Animals (Cont.)

- Prime grantee is accountable to NIH and must confirm Assurance and IACUC approval (dated within 3 years)
- Animal welfare requirements apply to all consortium participants and sub-projects
 - **Inter-Institutional Assurance is needed:**
 - Prime grantee has no animal program; animal work is being conducted at an Assured performance site
 - **Foreign Assurance is needed:**
 - Direct support to a foreign institution
 - Domestic prime grantee with a foreign performance site using animals (Domestic grantee's IACUC approves animal activities performed at foreign site)



Adobe Application Forms and Electronic Submission

*Changes to electronic applications are on the way.
Learn how this affects **YOU** today!*



Adobe: Not very different...

- The new Adobe forms look very similar to PureEdge forms -- Changes are cosmetic and navigational (see comparison at:
http://era.nih.gov/ElectronicReceipt/files/PureEdge_v_Adobe.pdf
- Overall electronic submission process remains the same:
 - Find opportunity
 - Download application package
 - Develop research plan and other PDF attachments
 - Complete forms
 - Submit application
 - Check assembled application in eRA Commons

Works on both Macs and PCs



... but follow these important tips to ensure success

- Adobe Reader 8.1.3 or 9.0 **required** to open forms (8.1.5 and 9.1.1 are **recommended**)
 - Stay tuned to Grants.gov's Download Software page for changes (http://www.grants.gov/help/download_software.jsp)
 - A pop-up usually warns if you have a wrong version
 - If using an Adobe Acrobat product to create PDFs, check Grants.gov's Web site for help on settings
 - To ensure the application reader opens in the correct version of Adobe



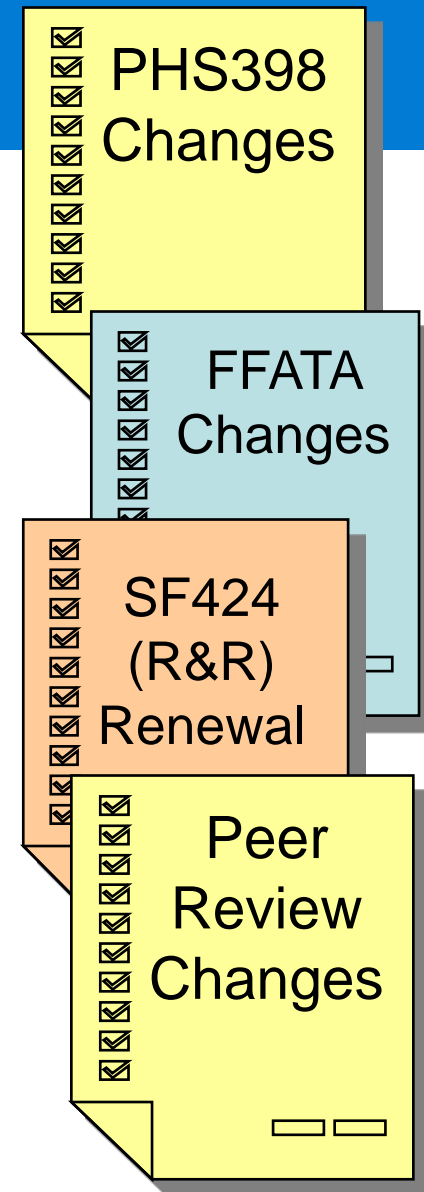
Electronic Submission: *Update*

- Adobe-based grant application forms are now available for all FOAs requiring electronic submission.
- Career Development Awards (Ks) transitioned to electronic submission.
- Individual Fellowship Awards (Fs) are in the middle of transitioning for August 8 Submission Date.
- Next set of transitions:
 - New PHS 398 and SF 424 (R&R) Application forms expected in Fall, 2009.
 - Transition of Training (T) and complex mechanisms.



Sample Changes to Application Forms

- R&R Senior/Key Person Profile
 - Added Degree Type and Year (*note this will allow NIH to remove Degree fields from PHS 398 Cover Pg Supplement*)
- R&R Project/Performance Site Location(s)
 - Moved Congressional District data from R&R Cover Component
 - Added DUNS Number field
- R&R Other Project Information
 - Re-ordered and revised Human Subjects fields
 - Revised fields on Environmental Impact
 - Added field for impact on Historical Places
- PHS 398 Checklist
 - Added Disclosure Permission Statement
- PHS 398 Research Plan
 - Alignment with enhanced peer review criteria and shortening of the application.

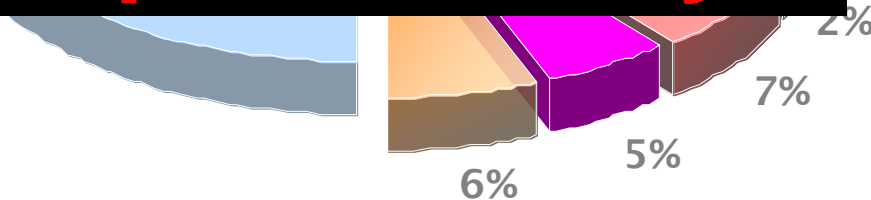
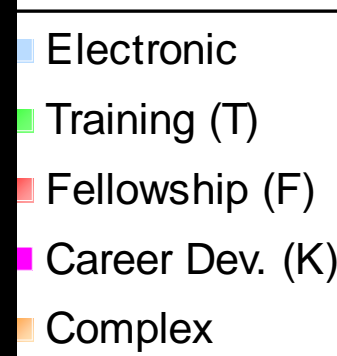




Future Transitions to Electronic Submission with Adobe Forms

- Fellowship (F): August 8, 2009 (in process)
- Training (T): September 25, 2009 (tentative)
- Complex

Timeline is subject to change due to Grants.gov form development delays





Reminder: Avoid Common eSubmission Errors

- Use **PDF** format for text attachments and do not embed movies or other materials in **PDF** attachments.
- R&R Senior/Key Person Profile(s) form
 - Include eRA Commons Username in the ‘Credential, e.g., agency login’ field for all individuals assigned a PD/PI role.
 - Include the Organization Name for all Senior/Key Persons listed.
- R&R Budget form - Senior/Key Person effort must be greater than zero.

Clicking ‘Submit’ is not the last step. Remember... if you can’t view it (in Commons), we can’t review it !



Support

Follow the usual process for seeking support with any electronic submission issues arising with the new Adobe Reader forms.

- Contact [Grants.gov Contact Center](#) for questions on form functionality or submission of the forms to Grants.gov.
- Contact the [eRA Help Desk](#) at NIH for technical issues that threaten NIH's timely receipt of your application.
 - Work with the Grants.gov Contact Center and be sure to document the issue and provide NIH with the tracking number received from Grants.gov Contact Center.



Available Resources

Resources for the Adobe transition can be found on:

- **NIH Electronic Submission of Grant Applications Web site:**

<http://era.nih.gov/ElectronicReceipt/>

- **Grants.gov Web site (Applicant Resources):**

http://grants.gov/applicants/app_help_reso.jsp



eRA Commons



X-Train

- X-Train is a new system to improve the administration of NIH Training Grants.
 - Allows PIs and staff to electronically submit appointment forms and termination notices
 - Allows institutional staff to track status and timing of appointment actions
 - Will be available through eRA Commons
- Pilot testing expanded to all FDP institutions and other interested grantees in June, 2008.
- Full production release expected in 2009.



Profile Maintenance

- PIs have an obligation to keep information in their Personal Profile current and need to update it regularly
- Profile data used in other electronic processes (e.g., Summary Statements, eNotifications)
 - Degrees
 - Position Titles
 - Addresses - e-mail & postal
- Especially critical for researchers applying for early-stage and new investigator status.





Helpful NIH Technical Assistance Resources



Web Page on NIH Extramural Response to Natural Disasters

Part of NIH's commitment to the health of the biomedical community in the impacted areas, and concern for the health and safety of people and animals in the programs we oversee.

Includes:

- Links to Recent Guide Notices and event-specific web page
- Links to other Federal web sites for disasters
- NIH Emergency Contact Information
- Examples of extramural assistance provided to previous natural disasters and emergencies
- Frequently Asked Questions



Summary of Helpful NIH Web Pages

- Office of Extramural Research (OER) Web Page
<http://grants.nih.gov/grants/oer.htm>
- NIH Searchable Database of RFAs, PAs, and Guide Notices
<http://grants.nih.gov/grants/guide/index.html>
- NIH Grants Policy Statement (Rev. 12/03)
http://grants.nih.gov/grants/policy/nihgps_2003/index.htm
- NIH Extramural Nexus – Monthly newsletter (previously bimonthly) for the extramural community
<http://grants.nih.gov/grants/nexus.htm>
- CRISP database - Search to analyze an Institute's portfolio of funded projects, research areas, and more
<http://report.nih.gov/crisp.aspx>
- Grant Application Basics
http://grants.nih.gov/grants/grant_basics.htm



NIH Regional Seminars on Program Funding and Grants Administration

2009 Regional Seminars:

Seminar #1: April 16-17, 2009 in Atlanta, GA - **Past**

Seminar #2: June 25-26, 2009 in Las Vegas, NV – **Today!**

NIH electronic research administration labs offered in conjunction with the two-day seminar.

- Yearly seminars to educate research administrators, investigators new to NIH, and trainees.
- Due to the popularity of these seminars and availability of space - **Early Registration is Highly Recommended!**
- Seminar and Registration Information:
<http://grants.nih.gov/grants/seminars.htm>

Interested in hosting?
Contact us!



Community Outreach

- HealthierUS.gov



- HHS Initiative to promote healthy lifestyles and improve community health and wellness.
- Web site highlights important health topics such as:
 - Encouragement for increasing physical activity
 - Recommendations for eating a nutritious diet
 - Tips on avoiding risky behaviors
 - Information on preventive health screenings



NIH OER Listserv Addresses and Instructions

- Office of Biotechnology Activities (OBA):
 - https://list.nih.gov/archives/oba_news.html
- Office of Human Research Protections (OHRP):
 - <http://www.hhs.gov/ohrp/news/distributionlist.html>
- Office of Laboratory Animal Welfare (OLAW):
 - <http://grants.nih.gov/grants/olaw/references/list.htm>
- eSubmission:
 - <http://era.nih.gov/ElectronicReceipt/listserv.htm>
 - Separate listservs available for scientists and administrators
- NIH Guide for Grants and Contracts:
 - <http://grants.nih.gov/grants/guide/listserv.htm>
 - The official publication for NIH medical and behavioral research Grant Policies, Guidelines and Funding Opportunities



Grants Information: Who to Contact!

- **Institutional Resources** – First, utilize the expertise of your organization's ***Office of Sponsored Programs***

Application Specific Questions

- **Administrative** - Contact the Grants Management Specialist at the awarding Institute/Center
- **Scientific/Programmatic** - Contact the designated Program Official/Director at awarding Institute/Center
- **Review Questions** - Contact the assigned Scientific Review Officer




Grants Information: Who to Contact!

- Grants Administration individuals at all NIH ICs:
 - http://grants.nih.gov/grants/staff_list_grants_admin.htm
 - NIH Chief Grants Management Officers:
 - http://grants.nih.gov/grants/stafflist_gmos.htm
-
- Grants Policy Interpretation & Consultation:
 - E-Mail: GrantsPolicy@mail.nih.gov
 - Phone: 301-435-0949
 - Compliance Issues:
 - E-Mail: GrantsCompliance@mail.nih.gov
 - Phone: 301-435-0949



Grants Information: Who to Contact!

- General Application Questions: (e-Submission guidelines, resources & referrals, application review & award process, etc.)
 - E-Mail: GrantsInfo@nih.gov
 - Phone: 301-435-0714
- Customer Support for Grants.gov: (navigating forms, aspects of submitting through the system, resources available, etc.)
 - E-Mail: support@grants.gov
 - Webpage: <http://grants.gov/>
 - Phone: 1-800-518-4726
- eRA Commons Help Desk: (Commons registration help, application verification, Commons functionality questions, etc.)
 - Webpage: <http://ithelpdesk.nih.gov/era/> 
 - Phone: 301-402-7469 (Toll Free: 866-504-9552)

Enter your own
help ticket!



Thank You!

Any Questions?



Frequently Asked Questions



#1 – How do I change a Single PD/PI application to Multiple PD/PI?

- This can only be done through a competing application; e.g, renewal, resubmission, or competing revision.
 - For renewals & resubmissions: The PD/PI of the previous grant should be listed as the Contact PD/PI on the Multiple PD/PI grant. If another PD/PI is listed as a contact PD/PI, the application must also show as a Change of PD/PI.
 - For competing revisions: The Contact PD/PI must be the individual previously noted as the PD/PI.
 - The renewal, resubmission, or revision application must now include the Multiple PD/PI leadership plan
- You cannot change this through an administrative supplement request.



#2 – Are there any fellowship programs for individuals from minority or disadvantaged groups?

Yes.

However, note that a revised FOA includes the following changes:

- Effective January 1, 2007: Now 3 submission dates--**April 13, August 13, and December 13.**
- Added new bullet in “Content and Form of Application Submission” section to require information that must be submitted by applicant Institution in a letter certifying the applicant’s eligibility (See FOA for further details.)
- Updates information on Tuition/Fees and Institutional Allowance, published in the NIH Guide: [NOT-OD-06-093](http://grants.nih.gov/grants/guide/pa-files/PA-07-106.html).



#3 - Does NIH still accept unsolicited grant applications?

Yes. Use Parent Announcements (available on Grants.gov and NIH web pages) for “unsolicited” or “investigator-initiated” applications.

Other funding opportunity announcements include:

- Program Announcements
 - Statement of new or ongoing NIH interest in a certain research area.
- Requests for Applications (RFAs)
 - Statement soliciting applications in a well-defined scientific area to accomplish specific program objectives.



#4 – Can foreign applicants submit modular budgets?

No.

- Receiving detailed budgets from foreign applications allows NIH staff to assist applicant community with applicable regulatory and policy requirements for grant funding expenditure.
- However, domestic (U.S.) institutions with subawards to foreign (non-U.S.) institutions may use modular budgets.



#5 – Are fellowship candidates required to register in eRA Commons?

Yes. Applicant organizations should register any individual fellows submitting applications to NIH and AHRQ

- PI Role in the Commons does not provide special status – only a record in the system that provides administrative authority to see pertinent application documents (e.g. summary statements, scores, submission status, etc.)
- Individual Fellows registered by any organization other than the sponsoring organization should not have more than one eRA Commons account.



#6- Are consortium F&A costs included as part of an applicant's direct costs?

No. Applicants are to exclude the facilities and administrative (F&A) costs requested by consortium participants when determining if the budget exceeds a direct cost limit.

- This policy applies to:
 - **\$250K direct cost calculation for modular budgets**
 - **\$500K direct cost calculation for NIH data sharing policy and requirement to contact IC staff for unsolicited applications requesting over \$500K**
- This policy does not apply to:
 - **Small Business Innovation Research (SBIR) grants**
 - **Small Business Technology Transfer (STTR) grants**



#7- What are the requirements for recombinant DNA research?

- Institutional Biosafety Committees must review and certify proposed recombinant DNA research.
- Serious adverse events in human gene transfer research must be reported promptly!
 - Usually within 15 days, but
 - Within 7 days if life threatening or fatal.
 - Annual reporting is also required.
- Full text of the guidelines are available:
 - <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>.
 - Site also includes available training opportunities.



#8 – Does NIH have a cap on consultant fees?

No. There is no cap on consultant fees and the NIH salary cap does not apply.

HOWEVER,

- Grantees must have written policies for paying consultants that:
 - Are consistently applied regardless of fund source.
 - Include conditions for paying consultant fees.
- Consultants must be properly classified.
 - Consultants are defined as individuals who provide professional services or advice for a fee, but normally are not employees of the organization. This also includes firms that provide advice or services.



#9 – How different does a “new application” have to be?

“New applications” are expected to be substantially different in content and scope

- More significant differences than normally encountered in resubmission applications.
 - Rewording the Title and Specific Aims is not sufficient.
 - Incorporating minor changes in response to reviewer comments is not sufficient
- Research Plan changes should produce a significant change in direction and approach. All research plan sections should have substantial changes, particularly the Specific Aims and Research Design and Methods sections.



#10 – As PI, what happens if I change institutions mid-grant?

Prior, written approval is required for transferring legal and administrative authority for a grant to a different organization.

- Transfer approval ***is not automatic*** and requires approval from both NIH and the original grantee organization.
- Contact your GMO ***before moving*** to initiate the transfer process.
- Grants to individuals may not be transferred but individual fellowships may transfer to a new sponsoring institution.