NIH Update
NCURA Region IV Mtg
April 27, 2010

Marcia Hahn, Director,
Division of Grants Policy, OPERA, NIH

New NIH Director

- Francis S. Collins, M.D., Ph.D., was officially sworn in on Monday, August 17, 2009 as the 16th director of the National Institutes of Health (NIH).
- Served as Director of the National Human Genome Research Institute (NHGRI), NIH from 1993-2008.

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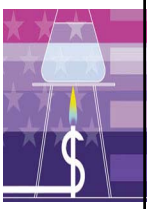
NIH OFFICE OF EXTRAMURAL RESEARCH

NIH Budget and Recovery Act News

OPERA

NIH Budget FY 2010 & 2011

- NIH 2010 Budget $31.2 billion
  - Strategic priorities include: Cancer Research; Autism Research; Nanotechnology-related Environment, Health and Safety Research; NIH Common Fund; Bioethics; Oversight
- President's 2011 Budget Request $32.2
  - Increase of 3.2% from FY 2010
  - Increase will support Innovative high throughput technologies, including DNA sequencing, imaging, and computational biology



Director's Bridge Award program (R56) temporarily suspended (because of ARRA).

More at: http://officeofbudget.od.nih.gov/br.html

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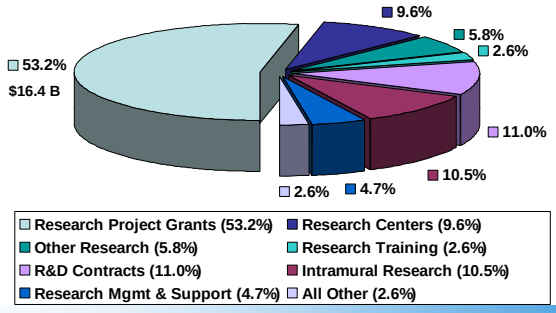
Breakdown of FY 2011 President's Budget Request for NIH – $32.2 Billion



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NIH FY 2010 Fiscal Policy for Grant Awards

- **Non-Competing Research Awards**: each IC will use its own discretion to implement compliance with the 2% inflation allowance provided in FY10.
- **Competing Research Awards**: each IC will manage its own portfolio, with average increase of 2% over FY09.

More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-039.html

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NIH FY 2010 Fiscal Policy for Grant Awards

- **New Salary Cap** Summary (equal to Executive Level I) is $199,700 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-041.html
- New **NRSA Stipend levels** http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-047.html
- Policy for Tuition, Fees, and Health Insurance on Training Grants and Fellowships finalized: See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-073.html

7 More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-039.html

American Recovery and Reinvestment Act (ARRA)

- Purpose
  - Stimulate the economy; preserve/create jobs
  - Support NIH's biomedical, behavioral, and clinical research agenda
- Funding
  - $10.4 billion in funding: Scientific Research ($8.2 billion); Shared Instrumentation ($300 million); Extramural Construction ($1 billion) & Intramural Buildings/Facilities ($500 million)
    - 13,674 ARRA Grants Funded in 2009
  - Current Opportunities
    - Global Health, Comparative Effectiveness Research, NIH Basic Behavioral and Social Science Opportunity Network (OppNet), Research and Research Infrastructure, Research On Biosamples

8 More at: http://www.grants.nih.gov/recovery/

ARRA Recipient Reporting

- Reports entered at www.FederalReporting.gov and publicly available at www.recovery.gov
  - Includes web based form, MS Excel template and XML schema options for report submission
- OMB Data Model v.3.0
  - OMB released the Recipient Reporting Data Model v3.0 for ARRA, Quarter Ending December 31, 2009.
  - Includes a Data Dictionary describing the data elements specifically required for recipient reporting
  - Additional NIH guidance (*based on the OMB Data Model*) see Data Dictionary 3/19/10: http://grants.nih.gov/recovery/recipient_reporting.html.

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ARRA Recipient Reporting

- NIH Guide Notice Reminders for reporting associated with ARRA awards: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-066.html and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-065.html
- NIH FAQs address ARRA recipient reporting NIH-specific concerns: http://grants.nih.gov/recovery/faqs_recovery.html
- ARRA Quarterly Report Sample Templates: http://grants.nih.gov/recovery/sample_quarterly_reports.html
- ARRA Data Reports: http://report.nih.gov/recovery/index.aspx
  (*includes most data needed for quarterly reports*)

10 **More at http://grants.nih.gov/recovery**

Omissions, Errors, and Problems

- Material Omissions = Report Not Submitted
  - 99.9% reporting rate for January reporting period
- Significant Errors reviewed by NIH:
  - NIH identified 750 reports with errors for January reporting period; 157 of these were significant errors
  - Most commons significant errors: Over reporting of jobs and award amount
  - Other errors: TAS code, agency code, or CFDA number differs from agency records
- Problems
  - Funding Agency Code –
    - NIH Code 7529; this code is vital for us to find your report
  - Congressional District –
    - Grantees should ensure that they are using the appropriate district even if it passes FR.gov validations.

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Accessing ARRA $$$ in the Payment Management System (PMS)

- Unique “P” accounts required to access ARRA funds.
  - Cash pooling is not permitted. Grantee account for ARRA funds separately by subaccount/grant document.
  - If a grantee has more than one “P” account, the grantee MUST request funds by subaccount (grant document).
  - Existing PMS users can access the “P” accounts using already established login & password.

12 **More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-080.html**

New “P” Accounts and the SF272

- If grantee received both appropriated and ARRA funds, they will see two quarterly SF 425 Federal Cash Transaction Reports.
  - One report for their “G” account
  - One report for their “P” account
- Each SF 425 must be submitted or a hold will be placed on the Division of Payment Management (DPM) account.

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Unique Document Number Schema

- All HHS agencies required to adopt a unique Document Number Schema for ARRA awards.
  - For NIH, core schema remains intact; except the last character will be “Z” for initial awards.
    - Example: Grant Number= 1 R01 AI123456-01; ARRA Doc # = RAI123456Z
  - Transfers (T-7s): Transfer “competitive segment” for ARRA grants will be denoted with “Y”, “X” or “W” when applicable.

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Administrative Supplements & Competing Revisions

- Accommodated the “separation” and accountability required by ARRA while maintaining a programmatic connection to the parent grant
  - ARRA T-3 budget/projects periods reflect that of the T-3 only and not the parent
  - ARRA T-3s issued in FY2009 provided for a single budget/project period up to 24 months
  - Most ARRA T-3s issued in FY2010 will be no more than a 12-month budget/project period
  - Specific information on ARRA additional funding must be included in annual progress report of the parent grant

15 **More at:** http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-080.html

Administrative Supplements & Competing Revisions (cont.)

- No "co-mingling" of ARRA T-3 and parent grant $$$ allowed (assuming parent grant funded with regular appropriation $$$)
  - Separate institution accounts and PMS drawdowns
  - No rebudgeting between parent and ARRA T-3
  - No carryover of ARRA T-3 balances into the parent
  - If an ARRA award includes a commitment for an ARRA-funded future year in FY2010, grantees will be able to carryover from the FY2009 budget period into FY2010.
  - No carryover allowed between ARRA funding budget periods and budget periods funded by non-ARRA fund
- Separate Financial & Closeout Reports Required
- Separate Targeted/Planned Enrollment and Inclusion Enrollment table for each clinical research protocol funded with ARRA funds and NIH Appropriations funds

16 **More at:** http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-080.html

Unique Business Processes: Modified Carryover Authorities

Grant Number	Document Number	Notes
5 R01 AI123456-04	RAI123456A	Non-ARRA Funded
2 R01 AI123456-05	RAI123456Z	ARRA Funded
5 R01 AI123456-06	RAI123456Z	ARRA Funded
2 R01 AI123456-07	RAI123456B	Non-ARRA Funded

- -04 Yr funds **CANNOT** be carried forward into -05; -04 year financially closed
- -05 Yr funds **CAN** be carried forward into -06
- -06 Yr funds **CANNOT** be carried forward into -07
- -04 Yr funds **CANNOT** be carried forward into -07

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ARRA Reminder Notices

- See reminders for spending and no-cost extensions for ARRA awards: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-067.html
  - Spending should be timely and expeditious and in accordance with expected pace of research
  - Standard NIH Terms of Award apply in addition to ARRA specific terms.
  - Grantee has authority to extend project period end dates up to 12 months. (This is separate from the non-ARRA parent for Type 3 awards.)
    - Additional (prior approval) extensions will only be considered in limited circumstances

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ARRA Reminders

- Supplements
  - Scientific/Program progress should be addressed separately in the annual progress report (Type 5); if no T-5 address in final progress report
  - Special progress reporting for Summer Experience program
  - Separate closeout documents are required for each supplement and competitive revision
  - Special financial closeout requirements for grants with multiple ARRA-funded supplements

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New Tools to Search NIH Funding RePORT

- Reports, data and analyses website (RePORT) released in 2008 and expanded in 2009 with addition of RCDC data (Research, Condition and Disease Categorization process)
- Replaces the former Award Information and Data web page and provides:
  - Quick access to "Frequently Requested Reports", FAQs;
  - Efficient search tools for locating data and reports
  - Links to funding estimates for certain research areas, conditions, and diseases.
  - Includes ARRA-specific data queries

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More at: http://report.nih.gov

New Tools to Search NIH Funding RePORTER

- Broader Research Portfolio Online Reporting Tool Expenditures and Result (RePORTER)
  - Replaces CRISP. Combines NIH project databases and funding records, PubMed abstracts, full-text articles from PubMed Central, and information from the U.S. Patent and Trademark Office with a robust search engine, allowing users to locate descriptions and funding details on NIH-funded projects along with research results.

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More at: http://projectreporter.nih.gov/reporter.cfm

NIH Priority 2010

- **Identifying and Attracting New Biomedical Researchers**
  - Assistance to New and Early Stage Investigators (ESIs)
  - NIH commits to identify ESIs so appropriate consideration of their career stage can be applied during review and award selection.
- ESIs are identified by data in Personal Profile section of 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-09-034.html.

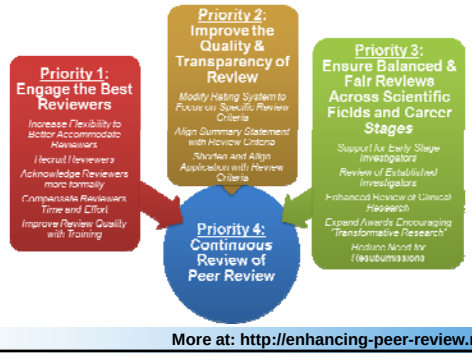
22 More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html

NIH OFFICE OF EXTRAMURAL RESEARCH

New Scientific and Grants Management Policies

OPERA

Enhancing Peer Review: Summary of Recommendations



24 More at: http://enhancing-peer-review.nih.gov

Priorities and Goals Implemented Thus Far

- Phase-out of A2 resubmission applications
- New and early stage investigator policies
- Continuous submission process for study section members expanded to include NIH Advisory Group members
- Enhanced peer review criteria
- New 1-9 scoring system
- Scoring of individual review criteria
- Templates for structured reviewer critiques
- Score order review
- Clustered review of new and ESI investigator R01 applications

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More at: http://enhancing-peer-review.nih.gov

Restructured Applications and Instructions

- Implementation of goal: *Align the structure and content of applications with review criteria, and shorten the length of applications*
- Three sections of application instructions revised:
  - Research Plan
  - Biographical Sketch
  - Resources and Facilities
- Shorter Page Limits
- *For additional information see NIH Guide Notice NOT-OD-09-149 issued 09/16/09. (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-149.html)

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More at: http://enhancing-peer-review.nih.gov

Research Plan Changes

- New **Research Strategy** section replaces 3 sections of the current Plan
  - Background and Significance,
  - Preliminary Studies/Progress Report
  - Research Design and Methods
- **Research Strategy** has 3 subsections:
  - **Significance**
  - **Innovation**
  - **Approach**
    - Progress report for renewal/revision applications
    - Preliminary studies for new applications (can be placed anywhere in the Research Strategy Section)

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More at: http://enhancing-peer-review.nih.gov

Biographical Sketch Changes

- *Personal Statement:* Tell us why your experience and qualifications make you particularly well-suited for your role in the project
  - Does not apply to participating faculty on Ts
- *Publications:* Include no more than 15, and make selections based on recency, importance to the field, and/or relevance to the application
- *Page limit remains at 4*

28 More at: http://enhancing-peer-review.nih.gov

Facilities and Resource Changes

- Provide a description of how the scientific environment will contribute to the probability of success of the project
- For ESIs describe the institutional investment in the success of the investigator
- In Select Agent Section of Research Plan describe the biocontainment resources available at all performance sites

29 More at: http://enhancing-peer-review.nih.gov

Shorter Page Limits

Introduction Except Intro to Resubmission for Ts, K12, and R25	1 page
Specific Aims	1 page
Research Strategy R03, R13/U13, R21, R36, R41, R43, Fs, SC2, SC3	6 pages
Research Strategy R01, single project U01, R10, R15, R18, U18, R21/R33, R24, R33, R34, U34, R42, R44, DP3, G08, G11, G13, UH2, UH3, SC1	12 pages
Candidate Information + Research Strategy Career Development Awards (Ks, except K12)	12 pages
Research Training Program Plan Including NRSA (Ts), K12 and R25	25 pages

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Restructured Application Forms/Instructions **must** be used for due dates after **January 25, 2010**

- To implement changes for Peer Review initiative new SF 424 R&R application packages were posted in December, along with new Parent Announcements, and updated active FOAs
- Resubmissions must use new application forms and instructions (and shorter page limits)
- Amended NIH Policy on submission of late grant application materials prior to initial peer review (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-070.html)
  - Page limits for supplemental information
  - Must have concurrence of Authorized Organization Representative

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More at: http://enhancing-peer-review.nih.gov

Training Applications

- Transitioned to electronic submission 1/25/10.
- Revised Responsible Conduct of Research Plan
  - NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research.
  - Effective 1/25/2010 for new and renewal applications
  - Effective 1/1/2011 for progress reports

32 **More RCR at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html**

Training Applications and Awards

- Assurance and Reporting
  - Applies only to doctoral degree granting institutions receiving: D43, TU2, T15, T32, T37, T90, U2R, U90, and U54/TL1
  - Assurance that institution will disclose to doctoral applicants:
    - % of students admitted who attained a doctoral degree
    - Average time until receipt of doctoral degree
  - Report same info to NIH on Table 12A of Institutional Research Training Data Tables of renewal applications and progress reports beginning 10/01/2009
- Mandatory use of xTrain beginning January 1, 2011, for all Statements of Appointment (PHS 2271) and Termination Notices (PHS 416-7). See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-072.html

33 **More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-141.html**

Federal Financial Report SF-425

- Effective 1/1/10 NIH grantees are to report cash transaction data via the Payment Management System (PMS) using the FFR cash transaction data elements
- Additional information and training available on the Division of Payment Management website: **http://www.dpm.psc.gov/**.
- Transition of FSR data to FFR is on hold
  - Grantees should continue to use eFSR system until further notice.

34 More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-038.html

NIH Guidelines on Human Stem Cell Research – 7/7/09

- Established criteria for NIH review of Human Embryonic Stem Cells (hESCs) to be included in new Registry as eligible for use in NIH funding
- Centralize processes and procedures for NIH reviews of hESCs
- Organizations submitting information about hESCs for potential inclusion in the Registry must use NIH Form 2890 (web-based form)

35 More at: http://stemcells.nih.gov

NIH hESC Registry

- First 13 lines approved 12/2/09, 51 lines are currently approved
- Grantees may only use lines listed on new Registry
- Old cell lines are **not** grandfathered into the new Registry
- Applicants should review approved hESCs
  - If any of the approved lines are appropriate, cite Registry number in application/correspondence (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-020.html)
  - If no approved lines are appropriate, include statement that one from the Registry will be used (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-123.html)

36 More at: http://grants.nih.gov/stem_cells/registry/current.htm

NIH hESC Registry

- Grantees must notify NIH of change in hESC in Progress report
- If award RESTRICTED from hESC research until registered cell lines identified, AOR must notify IC of which hESCs from Registry will be used. If proposed hESCs appropriate, restriction will be lifted via revised NOA.

37 More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-020.html

Revised Progress Report

- Use required as of 10/01/2009 (eSNAP updated 10/2009)
- Policy changes:
  - All Personnel Report (PD/PIs & all > 1 person month)
    - See FAQs http://grants.nih.gov/grants/funding/all_personnel_report_faq.htm
  - Provide Commons ID for postdocs
  - Assurance for Institutions with Awards for Grad Student Training for Doctoral Degrees
  - Describe any change to innovative potential (peer review initiative change)
  - Biosketch (peer review initiative change)
  - New question regarding hESC change

More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-139.html and
38 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-150.html

eRA Commons ID Required for Postdocs on Progress Reports

- All Personnel Report implemented as part of Progress Report (effective 10/01/2009)
- Report those in a postdoctoral role for one person month or more
- Provide Commons ID for postdocs

Note for Commons Account Administrators: *help your postdocs establish eRA Commons accounts using the new Commons Postdoctoral role*

39 More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-140.html

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.

40 **More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-036.html**

NIH Public Access Policy

- Omnibus Appropriations Act of 2009 made the Public Access Policy permanent
- New postings on Public Access website:
  - Communication and training materials for grantee institutions
  - New National Library of Medicine tool to Identify PubMed Central IDs
- Effective 8-21-2009, NIH Manuscript Submission IDs (NIHMSID) may be used to indicate compliance with Public Access Policy in applications and progress reports *for up to three months after a paper is published.* After that period, a Pub Med Central ID (PMCID) *must* be provided to demonstrate compliance. See NIH Guide Notice OD-09-136.

41 **More at: http://publicaccess.nih.gov**

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 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.***

42 **More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-023.html**

Mandatory Registration of Clinical Trials; Reporting of Results & Adverse Events

- 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.
- Adverse Events Reporting
  - Responsible Parties who submit results information-or update a record that contains results information-on or after September 27, 2009 will have to submit adverse event information in order for their submission to be accepted by the system.

43 **More at: http://prsinfo.clinicaltrials.gov/fdaaa.html**

NEW! NIH's Role on Registration & Reporting of Results in ClinicalTrials.gov

Responsible Parties are solely responsible for the content, quality and timeliness of registration and results reporting in accord with FDAAA.

Responsible Parties are required to affiliate their applicable clinical trials with their Institution's organization account or their own individual account, as appropriate. They will no longer be registered in an NIH IC organization account. NIH ICs cannot in any way substitute for the Responsible Party in fulfilling its statutory duties.

44 **More at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-147.html**

NIH OFFICE OF EXTRAMURAL RESEARCH

Highlights of New and Existing Grant Requirements

OPERA

Financial Conflict of Interest (FCOI) Regulations

- 42 CFR Part 50 Subpart F (PHS-funded grants and cooperative agreements)
- 45 CFR Part 94 (PHS-funded contracts)

The regulations went into effect on October 1, 1995

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Important FCOI Reminders: 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.

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Important FCOI Reminders: 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.

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Important FCOI Reminders: 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.

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Important FCOI Reminders

- Maintain proper documentation
  - All Financial disclosures; all actions taken by the Institution with respect to each conflicting interest
- Retain records for at least 3 years following submission of final Financial Status Report or, where applicable, from other dates specified in 45 CFR 74.53(b) for different situations.
- The FCOI regulations require that Institutions:
  - maintain an appropriate written, enforced policy on conflict of interest that complies with the regulations.
  - establish adequate enforcement mechanisms and provide for sanctions, where appropriate.

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Advanced Notice of Proposed Rulemaking (ANPRM) (5/2009)

- Requested comments on proposed amendment of Regulations governing FCOI
- Addressed various topics including:
  - Expanding scope of regulation & 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 regulations to address institutional CoI
- 78 comments received and considered; All comments posted at: http://www.regulations.gov/search/Regs/home.html#docketDetail?R=NIH-2008-0002

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Notice of Proposed Rulemaking (NPRM)

- NIH has considered comments submitted in response to the ANPRM and on behalf of the Department of Health and Human Services and the Public Health Service has prepared a NPRM which proposes changes to the regulations
- The NPRM is under review and clearance
- NPRM will be published in the Federal Register for public comment
- A Final Rule is expected to be published this year

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Resources

- OER FCOI Web Site
  - http://grants.nih.gov/grants/policy/coi/
- Frequently Asked Questions
  - http://grants.nih.gov/grants/policy/coifaq.htm
- Web-based tutorial
  - http://grants.nih.gov/grants/policy/coi/tutorial/fcoi.htm
- Mailbox for inquiries
  - FCOICompliance@mail.nih.gov

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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.

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Summary of Audit Requirements

Grantee Type	Source of Audit Requirement	Where to Submit Audit Reports
State & Local Governments	OMB Circular A-133	Federal Audit Clearinghouse 1201 E. 10th Street Jeffersonville, IN 47132 Questions: 1-800-253-0696
Colleges & Universities		
Non-Profits		
Hospitals		
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!*

- Failure to submit timely reports may affect future funding to the organization.
- Documents are due within 90 days of project period end date
  - Final Financial Status Report (must be submitted electronically)
  - Final Inventions Statement & Certification
  - Final Progress Report
- Grantees must ensure that there are no discrepancies between the final Financial Status Report (SF-269 or 269A) and the Payment Management System's Federal Financial Report (SF-425) cash transaction data elements

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NIH Centralized Processing Center

- Centralized office accepts receipt of all non-financial, paper-based closeout documents
  - Final Progress Report
  - Final Invention Statement and Certification
- If not using eRA Commons, 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 only)

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Non-Competing Continuation Progress Reports

- Failure to submit timely progress reports may affect future funding to the organization
- Annual progress reports are due two months prior to the anniversary date
- Electronic SNAP progress reports (e-SNAP) are due 45 days prior to the anniversary date
- All grantees have access to a searchable list to determine which progress reports are due at: http://era.nih.gov/userreports/pr_due.cfm

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NIH OFFICE OF EXTRAMURAL RESEARCH

Requirements and Compliance Assistance for OHRP / OLAW

OPERA

News from the Office for Human Research Protections

- New IRB registration requirement effective 7/14/2009. Note that registration does not mean OHRP has determined the IRB is in compliance with human subject regulations, 45 CFR 46.
- See OHRP IRB Registration FAQs http://www.hhs.gov/ohrp/IRBfaq.html
- Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (4/7/09)

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More at: http://www.hhs.gov/ohrp

OLAW Educational Outreach

- Instructions for Completion and Peer Review of the Vertebrate Animal Section (VAS) in NIH Grant Applications and Cooperative Agreements 3/17/10: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-027.html
- OLAW Online free quarterly webinars including sessions targeting IACUC Staff, Institutional Officials and archive of past webinars
- New FAQs
- OLAW supported Workshops: http://grants.nih.gov/grants/olaw/workshop.htm

Adobe Application Forms and Electronic Submission

Changes to electronic applications have arrived.

Electronic Submission: Update

- Jan. 25, 2010: transition to shortened and restructured applications
  - including the transition from ADOBE-FORMS-A to ADOBE-FORMS-B.
- Career Development Awards (Ks), Individual Fellowship Awards (Fs) and Training Grants (Ts and Ds) have all successfully transitioned to electronic submission
  - Ts and Ds transitioned as of Jan. 2010.
- NIH has successfully transitioned all grant programs to electronic submission, with the exception of **Complex, Multi-project Applications.**
- Accommodated new activity codes as needed.
- New eSubmission Web site to be launched this Spring.

Obtain Compatible Software

- Adobe Reader:
  - Only specific Adobe Reader versions are compatible with Grants.gov forms
- PDF conversion program:
  - Attachments **must** be converted to PDF
- Grants.gov Download Software page:
  - http://www.grants.gov/help/download_software.jsp

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Tips for Success

- Start early—allow at least 4 weeks to complete registration
  - NIH 2-week "good faith effort" for Commons registration
- Grants.gov & Commons registrations may be completed simultaneously once DUNS# is obtained
- Update CCR information yearly to keep Grants.gov credentials active
- Do not combine SO and PI roles on a single Commons Account
- If PD/PI has a Commons account, affiliate them to your organization rather than creating new account
- PIs should update their Commons profile prior to submitting an application (e.g. degree info is used to determined Early Stage Investigator eligibility)

Clicking "Submit" is not the last step.
Remember. . . if you can't view it, we can't review it!

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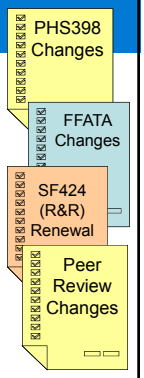
More at: http://era.nih.gov/ElectronicReceipt/avoiding_errors.htm

Sample Changes to Application Forms

- R&R SF 424 Cover
  - Added Agency Routing Identifier
  - Added SFLL or other Explanatory Documentation Attachment
- PHS 398 Cover Page Supplement
  - Removed New Investigator checkbox
- PHS 398 Career Development Award Supplemental Form
  - Accommodated changes for Enhancing Peer Review
- PHS Fellowship Supplemental Form
  - Accommodated changes for Enhancing Peer Review
  - Removed Degree Earned as collected on the Senior/Key form
- SBIR/STTR Information
  - Added Anticipated Number of personnel field



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More at: http://grants.nih.gov/grants/forms.htm

Available Resources

Resources for the transition to shortened and restructured applications can be found on these Web sites:

- **Enhancing Peer Review at NIH:**
  http://enhancing-peer-review.nih.gov/index.html
- **NIH Electronic Submission of Grant Applications:**
  http://era.nih.gov/ElectronicReceipt/index.htm

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Support

- Contact Grants.gov Contact Center for questions on form functionality or submission of the forms to Grants.gov.
- Contact eRA Help Desk at NIH for technical issues that threaten NIH's on-time receipt of your application.
  - Work with Grants.gov Contact Center to document the issue and provide the tracking number you receive from Grants.gov Contact Center to the eRA Help Desk.

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eRA Commons

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eRA Commons Enhancements: January 2010

- **Continuous Submission eligibility determined and flagged:**
  - Reviewer Address screen of a PI's Personal Profile now displays eligibility for Continuous Submission. Eligibility start and end dates are also displayed.
  - "Continuous Submission (CS) Eligible ONLY" checkbox has been added to the Manage Accounts search screen, which allows users with a Signing Official role to search only for accounts that are eligible for CS.
- **xTrain**
  - Now supports two new activity codes: **R25 and R90.**
  - Mandatory use of xTrain beginning January 1, 2011, for all Statements of Appointment (PHS 2271) and Termination Notices (PHS 416-7). See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-072.html

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Profile Maintenance

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

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NIH OFFICE OF EXTRAMURAL RESEARCH

Helpful NIH Technical Assistance Resources

OPERA

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

Available at: http://grants.nih.gov/grants/natural_disasters.htm

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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
- RePORTER - Search to analyze an Institute's portfolio of funded projects, research areas, and more http://projectreporter.nih.gov/reporter.cfm
- Grant Application Basics http://grants.nih.gov/grants/grant_basics.htm
- Intellectual Property Policy http://grants.nih.gov/grants/intell-property.htm

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NIH OER Listserv Addresses and Instructions

- Office of Biotechnology Activities (OBA):
  - https://list.nih.gov/archives/oba_news.html
- Office for 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

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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

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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

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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!

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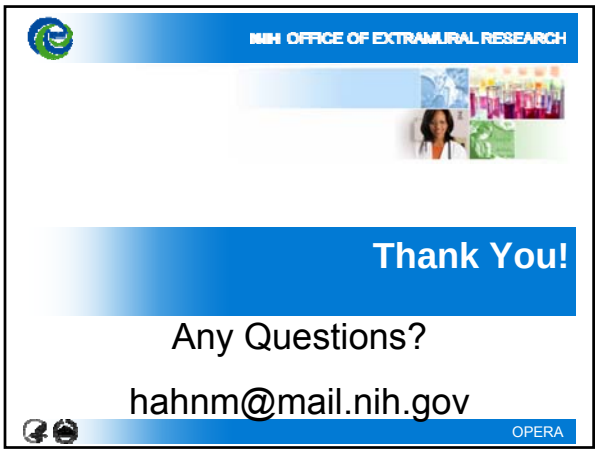
NIH OFFICE OF EXTRAMURAL RESEARCH
Thank You!
Any Questions?
hahnm@mail.nih.gov
OPERA