



Research Regulation at the NIH

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National Institutes of Health



National Institutes of Health
Office of Extramural Research

WINNING
the
FUTURE

NIH: Steward of Biomedical & Behavioral Research for the Nation



NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems...

...and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.



Understanding the Dual Nature of NIH



NIH **is** an institution
(Intramural Research)

- Approx. 6,000 scientists
- Approx. 11% of NIH's budget



NIH **supports** institutions & people
(Extramural Research)

- >2,500 institutions
- >400,000 scientists & research personnel
- Approx. 70,000 applications and 40,000 awards annually
- Approx. 81% of the NIH budget

Grants Process Overview

Planning, Writing, & Submitting

- Applicant often begins writing application several months prior to application due date
- Applicant organization submits most applications to NIH through the Federal portal, Grants.gov

Receipt & Referral (Months 1-3)

- Applications compliant with NIH policies are assigned for review by the Division of Receipt and Referral in the Center of Scientific Review
- CSR assigns application to an NIH Institute/Center (IC) and a Scientific Review Group (SRG)

Peer Review (Months 4-8)

- Initial level of review by SRG members for scientific merit
- Impact scores & summary statement available to Principal Investigator on eRA Commons
- Second level of review by advisory council/board

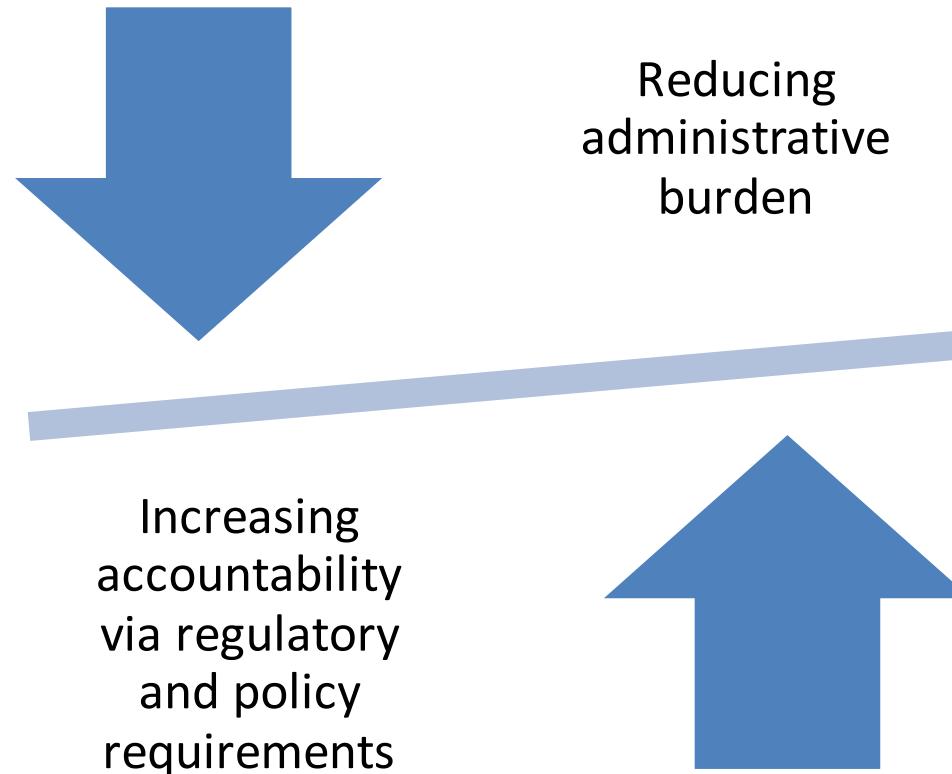
Award (Months 9-10)

- Pre-award process: IC grants management staff conducts final administrative review and negotiates award
- NIH IC director makes funding decision. IC staff issues and sends Notice of award to applicant institution/organization

Post-Award Management (ongoing)

- Conduct of research
- Administrative and fiscal monitoring, reporting, and compliance.

...while increasing accountability



Examples of Regulatory and Policy Requirements and Their Sources

Federal-wide

- Uniform Guidance: effort reporting and indirect cost negotiation (OMB); other financial reporting and activities
- Animal Welfare Act
- Occupational Safety and Health Act of 1970 - Laboratory safety
- System for award management (SAM) registration (formerly CCR)
- Research performance progress report (RPPR)
- Close-out reports
- Responsible Conduct of Research Training
- Intellectual property policy; Bayh Dole
- United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern

DHHS

- Financial conflict of interest regulation
- Sub-projects financials
- Human subjects/Common Rule
- PHS policy on human care and use of lab animals
- FDAAA
- Research misconduct reporting/investigation policy

NIH

- Inclusion of women and minorities as subjects in clinical research
- Public access policy
- Data and resource sharing policy
- NIH policy on clinical trial registration and results reporting
- NIH guidelines for research involving recombinant or synthetic nucleic acid molecules
- Peer review regulations
- Invention reporting
- Single IRB policy
- Application requirements

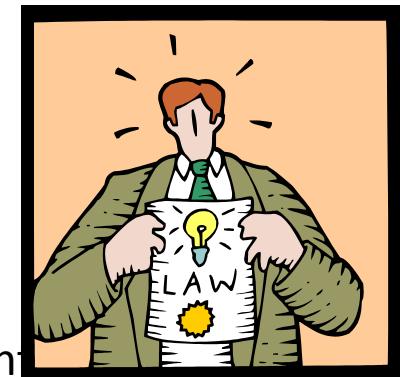


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Legislative Mandates in Effect for FY 2015

- NIH Notice: NOT-OD-14-053; Released February 10, 2014
- Statutory provisions that limit the use of funds on NIH grant, cooperative agreement, and contract awards for FY2015.
- **FY 2014 Legislative Mandates that remain in effect:**
 - (1) Salary Limitation (Section 203)
 - (2) Gun Control (Section 217)
 - (3) Anti-Lobbying (Section 503)
 - (4) Acknowledgment of Federal Funding (Section 505)
 - (5) Restriction on Abortions (Section 506)
 - (6) Exceptions to Restriction on Abortions (Section 507)
 - (7) Ban on Funding Human Embryo Research (Section 508)
 - (8) Limitation on Use of Funds for Promotion of Legalization of Controlled Substances (Section 509)
 - (9) Dissemination of False or Misleading Information (Section 515(b))
 - (10) Restriction on Distribution of Sterile Needles (Section 522)
 - (11) Public Access to Scholarly Publications (Section 527)
 - (12) Restriction of Pornography on Computer Networks (Section 526)
- **Additional Legislative Mandate in effect for FY 2015:**
 - (13) Compliance with Guidance on the Spread of the Ebola Virus for Applicable Grants (603)



Legislative Mandates (examples)

Gun Control

“None of the funds made available in this title may be used, in whole or in part, to advocate or promote gun control.”

Public Access to Scholarly Publications

“Each Federal agency, or in the case of an agency with multiple bureaus, each bureau (or operating division) funded under this Act that has research and development expenditures in excess of \$100,000,000 per year shall develop a Federal research public access policy that provides for – (1) the submission to the agency, agency bureau, or designated entity acting on behalf of the agency, a machine-readable version of the author’s final peer-reviewed manuscripts that have been accepted for publication in peer-reviewed journals describing research supported, in whole or in part, from funding by the Federal Government; (2) free online public access to such final peer-reviewed manuscripts or published versions not later than 12 months after the official date of publication; and (3) compliance with all relevant copyright laws.”

Restriction of Pornography on Computer Networks

“None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.”

	Laws/Regulations/Policies	Efforts to Streamline/Reduce Burden (NIH, FDP, RBM)
Administrative Burdens: Burdens directly related to obtaining research support and complying with Federal terms and conditions of award; these burdens results from are associated with research activities funded by Federal Agencies.		
Grant Activities		
Grant and Progress Report Writing and Submission	<ul style="list-style-type: none"> PL106-107 (Federal Financial Assistance Management Improvement Act), 1999 Digital Accountability and Transparency Act (DATA Act; S.994), 2014 Federal Funding Accountability and Transparency Act (FFATA), 2006 Division F Section 217 of PL 111-8 (Omnibus Appropriations Act, 2009): implemented by NIH Public Access Policy OSTP memorandum on Increasing Access to the Results of Federally Funded Scientific Research (aka “Holdren memo”), 2013 	<ul style="list-style-type: none"> Just-in-Time procedures Modular budgets Streamlined noncompeting award process eRA Commons Application Submission System & Interface for Submission Tracking (ASSIST) My NCBI Science Experts Network Curriculum Vitae (SciENcv) Research Performance Progress Report (RPPR) Application resubmission policy (NOT-OD-14-074)
Peer Review	<ul style="list-style-type: none"> Section 492 of the Public Health Service Act “Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects” (42 CFR Part 52h) 	<ul style="list-style-type: none"> Enhancing Peer Review Initiative Peer review surveys (“Continuous Review of Peer Review”) Alternative review platforms (e.g., Internet Assisted Review)
Patent/Copyright	Bayh-Dole Act	<ul style="list-style-type: none"> iEdison Electronic submission of Final Invention Statement via eRA Commons
Intellectual Property		

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<i>Grant Activities</i>		
Financial Conflicts of Interest	<ul style="list-style-type: none"> • PHS/HHS 42 C.F.R. Part 50, Subpart F • 45 C.F.R. Part 94 	<ul style="list-style-type: none"> • Electronic submission of Financial Conflict of Interest Reports via eRA Commons • FDP Clearinghouse of educational institutions and other entities in compliance with FCOI rules and regulations
Clinical Trial Registration & Results Reporting	<ul style="list-style-type: none"> • Food and Drug Administration Amendments Act of 2007 (FDAAA) Title VIII 	<ul style="list-style-type: none"> • Notice of Proposed Rulemaking on Clinical Trials Registration and Results Submission (published for a 90 day comment period in the Federal Register on November 21, 2014); see NOT-OD-15-018 • Draft NIH Policy on Dissemination of NIH-funded Clinical Trial Information; see NOT-OD-15-019

	Laws/Regulations/Policies	Efforts to Streamline/Reduce Burden (NIH, FDP, RBM)
<i>Financial Responsibilities</i>		
Budget Transfers/Spending Authority		<ul style="list-style-type: none"> • OMB Circular A-21 <ul style="list-style-type: none"> • NIH Implementation of Uniform Guidance (consolidation/alignment of cost principles) in the Grants Policy Statement (NOT-OD-15-065)
Cost Accounting		
Cost Sharing		<ul style="list-style-type: none"> • Not applicable as NIH does not require cost-sharing
Monitoring Budget		<ul style="list-style-type: none"> • Just-In-Time procedures • Modular budgets • Electronic submission of Federal Financial Report via eRA Commons • NIH Implementation of Uniform Guidance (consolidation/alignment of cost principles) in the Grants Policy Statement
Subcontracting and Collaboration	<ul style="list-style-type: none"> • Title 41 of CFR 	Implementation of FDP sub-award template
<i>Personnel Management</i>		
Personnel Hiring and Management		<ul style="list-style-type: none"> • NIH Implementation of Uniform Guidance in the Grants Policy Statement <ul style="list-style-type: none"> • admin charges as direct costs • new effort reporting guidelines • NIH participation with FDP on Project Certification Demonstration

Research Burdens: Activities inherent to conducting research, imposed on regardless of the source of support, and generally implemented by each institution individually

Laboratory Activities

Safety Planning, Training, and Monitoring		<ul style="list-style-type: none">• Training resources available on NIH website
Chemical Inventory Management	• Occupational Safety and Health Act of 1970	<ul style="list-style-type: none">• Resources on chemical safety available on NIH website
Laboratory Security Oversight		

Animal Subjects

IACUC Protocols, Personnel and Student Training, and Compliance Issues	<ul style="list-style-type: none">• Animal Welfare Act (7 U.S.C. 2131 et seq.) of 1966• Public Law 99-158, "Animals in Research" (1985)• PHS Policy on Humane Care and Use of Laboratory Animals	<ul style="list-style-type: none">• Greater autonomy within local IACUCs (NOT-OD-14-063)• Just-in-Time process: IACUC approvals needed for awards only; not required for application submission• Update to PHS Policy on Humane Care and Use of Laboratory Animals (NOT-OD-15-079)
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Human Subjects

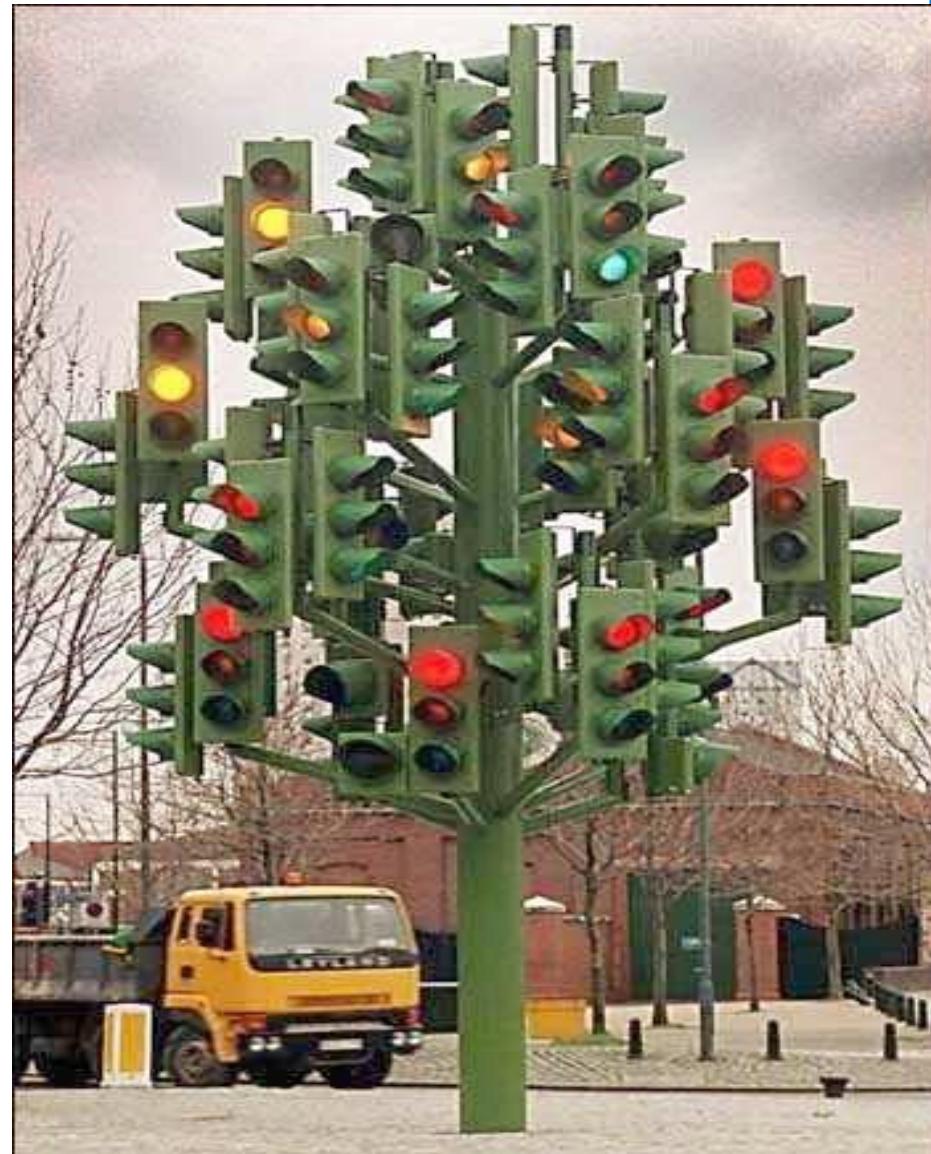
IRB Protocol Approval, Personnel and Student Training, and Compliance Issues	<ul style="list-style-type: none">• "The Common Rule" HHS 45 CFR part 46 (1991; revised 2009)	<ul style="list-style-type: none">• Use of Single IRB for Multi-Site Research (December 2014 RFI) (NOT-OD-15-026)• Consistent with ANPRM• NIH offers a free tutorial on Protecting Human Research Participants that institutions may elect to use to fulfill requirement for education in the protection of human subjects
HIPAA Compliance	<ul style="list-style-type: none">• "The Common Rule" HHS 45 CFR part 46	

Continuing Challenges

- Competing needs to reduce burden, yet increase transparency and accountability
- Multiple tiers of laws, regulations, and policies that may guide the entire government or a specific department, agency, or area of research
- Variability in institutional policies for implementation and oversight
- Ever-changing landscape of scientific discovery and technological advances

....a lot of information to take in at once....

Questions?



Supplementary Slides



NIH National Institutes of Health
Office of Extramural Research

Federal-Wide Streamlining Efforts

- **PL106-107**, signed into law in 1999
(Federal Financial Assistance Management Improvement Act)

- Workgroups formed to focus on pre-award, post-award, audit issues.

- Workgroups implemented:

- Grants management line of business—consolidating grants management systems across Federal agencies
- Grants.gov
- Standards for funding opportunity announcements
- Common forms
- Required use of “E-FIND”
- Increased A-133 audit threshold from \$300,000 to \$500,000
- Common rule on non-procurement, suspension, and debarment
- Title 2 of the CFR as the central location for OMB grants guidance



Grants Streamlining Activities Under P.L. 106-107



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Digital Accountability and Transparency Act (DATA Act; S.994)



Purpose:

- Expand the Federal Funding Accountability and Transparency Act of 2006 by disclosing direct federal agency expenditures and linking federal contract, loan, and grant spending information to federal programs to enable taxpayers and policy makers to track federal spending more effectively;
- Establish government-wide data standards for financial data and provide consistent, reliable, and searchable government-wide spending data that is displayed accurately for taxpayers and policy makers on USASpending.gov;
- Simplify reporting for entities receiving federal funds by streamlining reporting requirements and reducing compliance costs while improving transparency;
- Improve the quality of data submitted to USASpending.gov by holding federal agencies accountable for the completeness and accuracy of the data submitted; and
- Apply approaches developed by the Recovery Accountability and Transparency Board to spending across the federal government



Administration Directives for Scientific Data

- OSTP memorandum on *Increasing Access to the Results of Federally Funded Scientific Research* (aka “Holdren memo”) (February 2013)
 - All science agencies must increase access to federally funded scientific data
 - Require all investigators to develop data management/sharing plans by end of 2015
- OMB policy on *Open Data Policy-Managing Information as an Asset* (“M-13-13”) (May 2013)
 - Requires agencies to make administrative and scientific data publicly available

Food and Drug Administration Amendments Act of 2007 (FDAAA) Title VIII

- Applies to public & private sector
- Covers trials of FDA-regulated:
 - Drugs and biologics (except phase 1)
 - Services (except small feasibility studies)
 - Pediatric post-market surveillance studies of devices required by FDA
- Requires trial registration before 21st day after enrollment begins
- Requires submission of summary results of trials of approved products
- Includes enforcement provisions:
 - Notices of non-compliance
 - Withholding of NIH/HHS grant funds
 - Civil monetary penalties up to \$10,000/day (FDA)



FDAAA Compliance Provisions

- FDA authorized to levy monetary penalties
- NIH *must* verify submission of information before releasing any remaining funds for a grant or funds for a future grant
- Grant and progress report forms must certify information has been submitted
- NIH must provide responsible parties with notice of non-compliance
- Non-compliance must be made public through ClinicalTrials.gov



Trial Types *NOT* Covered by FDAAA

- Phase 1 trials of FDA-regulated drugs and biologics
- Small feasibility device studies
- Pediatric post-market surveillance studies that are not required by FDA
- Trials of interventions that are not regulated by FDA, e.g., behavioral trials, surgical trials
- Observational studies (i.e., where usual/standard of care interventions are assigned by clinician in the course of care)

We need all NIH-funded clinical trials posting results

Draft NIH Policy: *Dissemination of NIH-funded Clinical Trial Information*

- Expects registration and results submission to ClinicalTrials.gov for all NIH clinical trials regardless of
 - Phase
 - Type of intervention
 - Whether they are subject to FDAAA
- Same timelines as FDAAA
 - Registration not later than 21 days after enrollment
 - Submission of results one year after the completion date



Clinical Trial Registration & Results Reporting

- ***Notice of Proposed Rulemaking*** on Clinical Trials Registration and Results Submission published for a 90 day comment period in the *Federal Register* on November 21, 2014.
 - Comments to Docket No. NIH-2011-0003 at
<http://www.regulations.gov>
- ***Draft NIH Policy*** on Dissemination of NIH-funded Clinical Trial Information published for a 90-day comment period in the *NIH Guide for Grants and Contracts* on November 19, 2014.



New Biographical Sketch (Biosketch) Format in NIH Applications

- See Guide Notice: NOT-OD-15-032
- Required for applications submitted for due dates on or after May 25, 2015
- The new format allow researchers to:
 - Describe the magnitude and significance of their scientific contributions (including publications)
 - Provide more detailed information about their research experience in the context of the proposed project
- Science Experts Network Curriculum Vitae (SciENcv) will allow you to enter your biographical data once and convert it into biosketches that can be used for NIH or NSF grant applications and annual progress reports.





ASSURING OBJECTIVITY IN RESEARCH: FINANCIAL CONFLICT OF INTEREST

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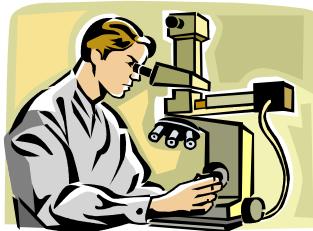


Definitions

- **Significant Financial Interest (SFI)** is a financial interest of the investigator (and those of the investigator's spouse and dependent children) that
 - (1) reasonably appears to be related to the investigator's institutional responsibilities (the investigator's professional responsibilities on behalf of the institution) and
 - (2) consists of one or more of the interests identified as a SFI in the regulations. This includes anything of monetary value, such as (but not limited to):
 - Salary or other payments for services (e.g., consulting fees or honoraria)
 - Equity interests (e.g., stocks, stock options or other ownership interests)
 - Intellectual property rights (e.g., patents, copyrights and royalties from such rights)
- **Financial Conflict of Interest (FCOI)** is an investigator's SFI that the institution determines could directly and significantly affect the design, conduct, or reporting of PHS-funded research.



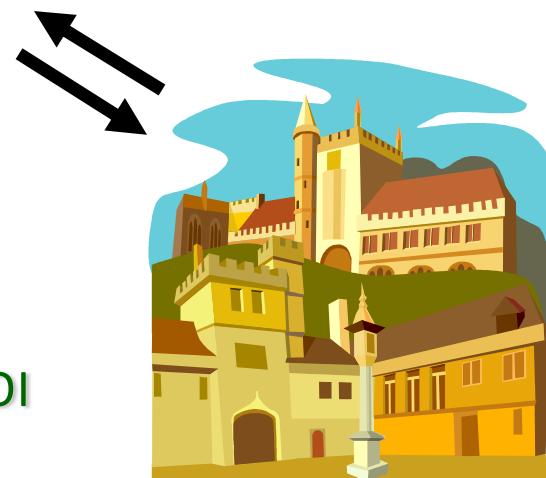
FCOI Regulations Framework



Investigator

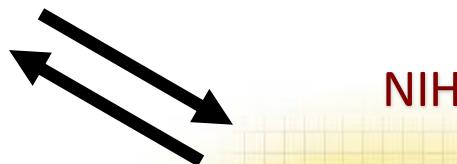
Disclosure of SFI
Compliance with Institutional Policy

Institutional Policy
Implementation
Evaluation of SFI
Identification of FCOI
Management



Institution

Compliance with Regulations
Reporting to NIH



NIH

Oversight



Major Changes to the Regulations I

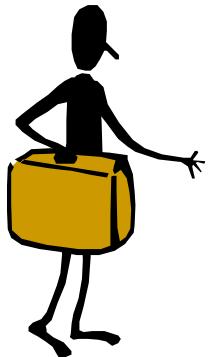
- Final Rule: “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors,” published August 25, 2011
- Significant Financial Interest (SFI)
 - Minimum threshold of \$5,000 generally applies to payments **and** equity interests
 - Includes **any** equity interest in non-publicly traded entities
 - Exclusions include income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with an Institution of higher education.
 - Excludes income from investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles.
- Investigator Disclosure
 - All SFIs related to investigators’ **institutional responsibilities**
 - Institutions responsible for determining whether SFIs relate to PHS-funded research and are financial conflicts of interest (FCOI)



Major Changes to the Regulations II

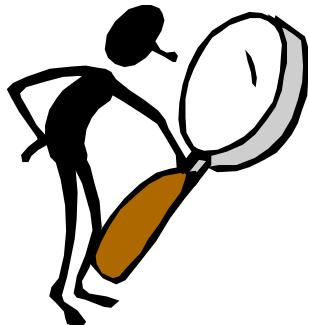
- Reporting to PHS Awarding Component (NIH)
 - Previous requirements, (grant/contract number, name of PD/PI, name of investigator with FCOI) plus:
 - **Name** of the entity with which the Investigator has a FCOI
 - **Value** of the financial interest
 - **Nature of FCOI**, e.g., equity, consulting fees, honoraria
 - A description of how the financial interest **relates** to PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research
 - Key elements of the institution's **management plan**
- Public Accessibility
 - The institution's FCOI policy must be made available via a publicly accessible web site. If the institution does not have any current presence on a publicly accessible web site, the institution shall make its written policy available to any requestor within five business days of a request.
 - Before spending funds for PHS-supported research, an Institution shall ensure public accessibility of information on certain SFIs that the institution has determined are related to the PHS-funded research and are FCOI, via a publicly accessible web site **or** by a written response to any requestor.
- Investigator Training
 - **FCOI training required** for investigators before engaging in PHS-funded research, every four years thereafter, and immediately under designated circumstances.





NIH Provides Policy Clarification: Reimbursed and Sponsored Travel and IP Rights and Interests

- NIH Guide NOT-OD-13-004 issued 10/18/2012 (travel) and FAQs E.28. - E.30. (IP rights and interests)
 - NIH clarified the following:
 - Initial disclosure includes these financial interests received over the previous 12-month period
 - \$5,000 de minimis threshold applies to both
 - How the institution may prescribe the details of travel disclosure



NIH Compliance Oversight

- Proactive Compliance Oversight Program
- NOT-OD-12-159 issued 9/21/2012
- Purpose is to assess institutional implementation and compliance with the 2011 revised FCOI regulation for grants and cooperative agreements
- Provides compliance oversight and assistance to grantees in fully developing and implementing the regulatory requirements by providing constructive feedback



FCOI Proactive Compliance Program

- Challenging policy areas for grantees:
 - Definition of senior/key personnel as it relates to public accessibility requirements
 - New reporting requirements – requirements for annual and mitigation reports
 - Monitoring management plans
- Watch website for posting of helpful observations

Resources

- Mailbox for inquiries
 - FCOICompliance@mail.nih.gov
- OER FCOI Web Site
 - <http://grants.nih.gov/grants/policy/coi/>
 - FAQs posted on 9/30/2011 and periodically updated
http://grants.nih.gov/grants/policy/coi/coi_faqs.htm
 - Checklist for Policy Development and more resources

