

# New PHS Rule of Financial Conflicts of Interest in Research

November 10, 2011

"The public trust in what we do is just essential, and we cannot afford to take any chances with the integrity of the research process." — Dr. Francis Collins, Director, NIH

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# New PHS Rule on FCOI in Research

Fight On

We believe that strengthening the existing regulations on managing financial conflicts of interest is key to assuring the public that NIH and the institutions we support are taking a rigorous approach to managing the essential relationships between the government, federally-funded research institutions, and the private sector.

-per NIH website

<http://grants.nih.gov/grants/policy/coi/index.htm>

# Timeline - Revisions to NIH FCOI Regulations

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**May, 2009:** NIH issues an Advance Notice of Proposed Rule Making (ANPR), proposing to overhaul 1995 federal regulation governing the identification, disclosure, and management of financial conflicts of interest (FCOI) related to research (42 CFR Part 50)

**May, 2010:** NIH issues its Proposed Rule, incorporating feedback from research community.

**November, 2010:** Research community awaits the issuance of the Final Rule.

**June, 2011:** OMB announces that review of rule is delayed indefinitely

**August 25, 2011:** Final Rule announced

**August 24, 2012:** Final Rule goes into effect

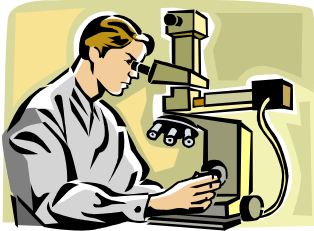
# Major Changes in Rule



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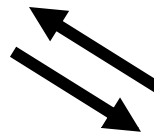
- Requires annual reporting plus transactional reporting of all significant financial interests related to professional responsibilities on behalf of the institution including, but not limited to, activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as IRBs and safety monitoring boards.
- Shifts burden of determining whether a financial interest constitutes a conflict from the individual to the institution.

# FCOI Regulations Framework



Investigator

Disclosure of SFI  
Compliance with Institutional Policy

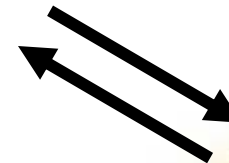


Institutional Policy  
Implementation  
Evaluation of SFI  
Identification of FCOI  
Management



Institution

Compliance with Regulations  
Reporting to NIH



Oversight

NIH



# Major Changes (cont.)



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- Requires new PHS investigator training in COI, and repeated training at least every 4 years.
- All COIs related to PHS funding must be reported to sponsor and updated annually.
- COI information related to PHS funding must be made accessible to the public, either by request or through a publicly available website.

## Other Changes in Rule



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- Changes reporting threshold to \$5,000 from \$10,000, and reporting threshold to \$0 for private equity and certain travel reimbursements. Some classes of income become reportable, including book publishing, which were not in the past.
- Various new definitions are provided.
- Administrative procedures are required for mitigation of conflicts, and review of completed research, when they are not disclosed on time.

# New PHS Rule on COI in Research



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## Elements Remaining Constant

- No significant changes in how conflicts are managed and how committees function for review of conflicts. Rules do not set a “rebuttable presumption” standard against conflicted human subjects research.
- No mandate for an institutional conflict of interest policy.



## Effects on USC



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- Annual disclosures will be required from PHS funded investigators or those proposing PHS research, along with updates to reflect changes.
- Responsibility on University to connect financial interests with research.
- Likely increase in COIs that need to be managed and monitored.
- New software will be needed for disclosure and management of COIs.
- Implementation of training programs.
- Revisions required to current COI in research policy.

# Efforts to Prepare



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- Taskforce working on revising policy
  - Streamlining policy
  - Updating to reflect rule requirements
  - Creating a class of COIs that will be managed administratively
- Electronic disclosure systems being evaluated
  - Online disclosure
  - Incorporate other types of disclosure (RWI, Conflict of Commitment)

# Resources



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- NIH FCOI Web Site
  - <http://grants.nih.gov/grants/policy/coi/>
  - Contains FAQs, Summary of Major Changes, etc
- Link to webinar for NIH grantees and administrators on Wednesday, November 30, 2011 from 11:00 a.m. to 12:00 noon PST  
[http://grants.nih.gov/grants/policy/coi/fcoi\\_webinar\\_20111130.htm](http://grants.nih.gov/grants/policy/coi/fcoi_webinar_20111130.htm)
- More to Come on Policy, Tool and Rollout