



ASSURING OBJECTIVITY IN RESEARCH: FINANCIAL CONFLICT OF INTEREST

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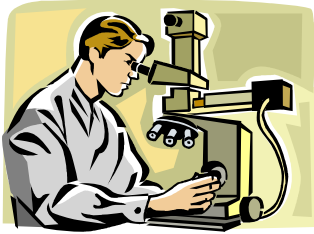


FCOI Regulations - Final Rule

- Revising the regulations on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*
- Federal Register published August 25, 2011
 - <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
(this link points to a non-HHS website which may not be accessible to all visitors)
- Implementation no later than 365 days after publication of the final rule in the Federal Register, i.e. August 24, 2012. In the interim:
 - Institutions comply with 1995 regulations
 - Institutions revise policies, establish procedures for compliance, and train Investigators
 - NIH provides training materials for extramural community and NIH staff, expands FCOI reports database
- Basic framework remains the same



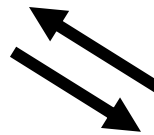
FCOI Regulations Framework



Investigator

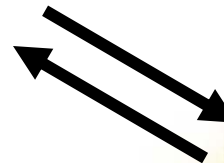
Disclosure of SFI
Compliance with Institutional Policy

Institutional Policy
Implementation
Evaluation of SFI
Identification of FCOI
Management



Institution

Compliance with Regulations
Reporting to NIH



NIH



Oversight

Major Areas Addressed in the Revised Regulations

- Definition of Significant Financial Interest (SFI)
- Extent of Investigator Disclosure
- Information Reported to PHS Awarding Component (e.g. NIH)
- Information made accessible to the public
- Investigator Training

Major Changes to the Regulations I

- Significant Financial Interest (SFI)
 - Minimum threshold of \$5,000 generally applies to payments **and/or** 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, and description of how FCOI relate to PHS-funded research
 - 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 Notice
 - 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.



Resources

- Mailbox for inquiries
 - FCOICompliance@mail.nih.gov
- OER FCOI Web Site
 - <http://grants.nih.gov/grants/policy/coi/>

New FAQs and tutorial coming soon