

# *Financial COI Regulations – NIH Final Rule*

**FRSWG**

**October 28,2011**



# Financial Conflict of Interest

- The NIH is committed to preserving the public's trust that the research supported by us is conducted without bias and with the highest scientific and ethical standards. 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.

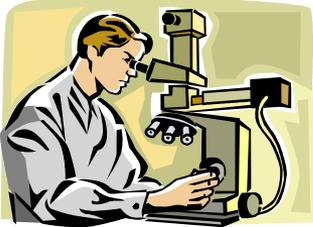
*"The public trust in what we do is just essential, and we cannot afford to take any chances with the integrity of the research process."*

*— Dr. Francis Collins, Director, NIH*

# Revised FCOI Regulations

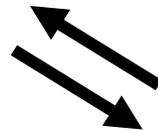
- Revising the regulations on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*
- Federal Register published August 25, 2011
  - <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>
- **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

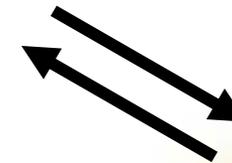


Institutional Policy  
Implementation  
Evaluation of SFI  
Identification of FCOI  
Management



Institution

Compliance with Regulations  
Reporting to NIH



Oversight

NIH



## *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

- 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.
  - Reimbursed or sponsored travel unless reimbursed/sponsored by gov't agency or institution of higher education
- 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 (cont'd)

- 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; **dollar ranges permissible**.
    - **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**.

# *How will HSC Comply*

- New Disclosure Statement Of Financial Interests And Outside Professional Activities
  - To consolidate new NIH standards with UNM and HSC standards
  - Reduce COI disclosure to a single form
  - COI Committee C has prepared initial draft and will finalize disclosure
- Ready for approval by Chancellor Jan 2012
- Launch use of new form to conform to new policy Feb 2012
- Develop online training module on Learning Central by Jan 31, 2012
- All research faculty complete training and certification to meet new standards by August 2012 deadline

# Resources

- Mailbox for inquiries
  - [FCOICompliance@mail.nih.gov](mailto:FCOICompliance@mail.nih.gov)
- OER FCOI Web Site
  - <http://grants.nih.gov/grants/policy/coi/>
  - (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-121.html>)
  - FAQs posted on 9/30/2011. See NIH Guide Notice NOT-11-121

*Questions?*