



Assuring Objectivity in Research: Financial Conflict of Interest

June 2013

Sally Rockey, PhD
Deputy Director for Extramural Research
National Institutes of Health



National Institutes of Health
Office of Extramural Research

Relationships between Academic Investigators and Industry are Important

- The public benefits when academic researchers collaborate with industry to develop innovative products that promote individual and public health
- Academic researchers do most of the basic research that underpins much of the advances in medicine.
- Industry often builds on that basic research to develop therapeutic drugs and devices. Therefore, it is essential not to stifle these relationships.

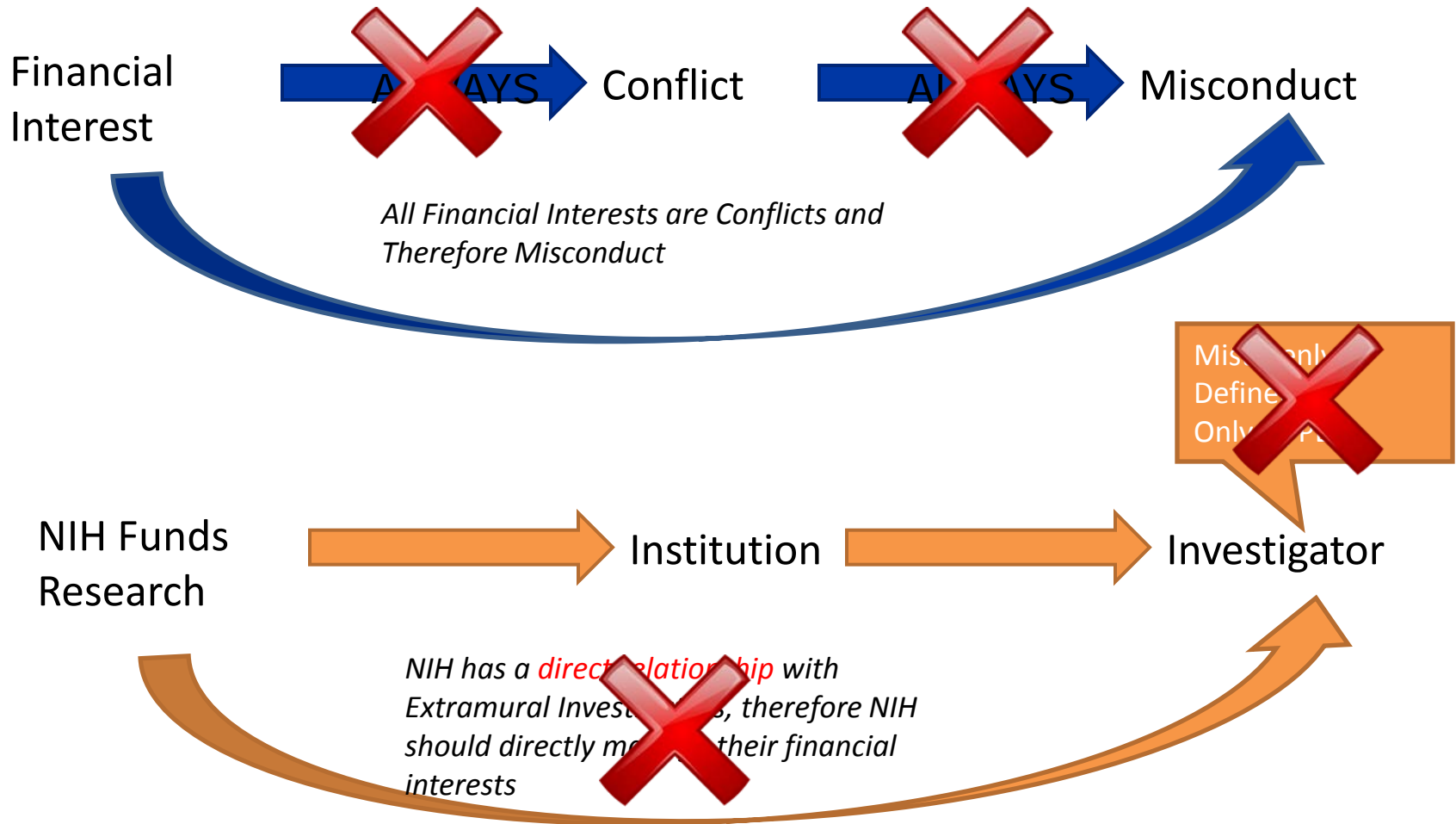


Maintaining Objectivity in Research is Equally Important

- Preserves the public trust
- Promotes integrity of:
 - Institution
 - Investigator
 - Data
 - HHS/NIH
- Provides transparency
- Therefore, in 1995 HHS published regulations to promote objectivity in research.



Common Misconceptions



Financial Conflict of Interest (FCOI) Regulations

- HHS is the only agency that has regulations governing financial conflicts of interest of extramural investigators
- First promulgated in 1995, revised in 2011 (implemented in August 2012) with the same basic framework
- 42 CFR Part 50 Subpart F (PHS-funded grants and cooperative agreements)
- 45 CFR Part 94 (PHS-funded contracts)



FEDERAL REGISTER

Vol. 76 Thursday,
No. 165 August 25, 2011

Part IV

Department of Health and Human Services

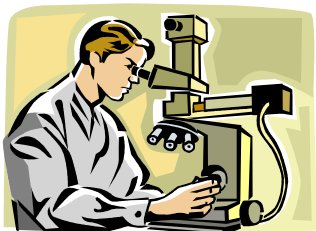
42 CFR Part 50
45 CFR Part 94
Responsibility of Applicants for Promoting Objectivity in Research for Which
Public Health Service Funding Is Sought and Responsible Prospective
Contractors; Final Rule

These regulations promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.



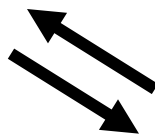
National Institutes of Health
Office of Extramural Research

FCOI Regulations Framework



Investigator

Disclosure of SFI
Compliance with Institutional Policy

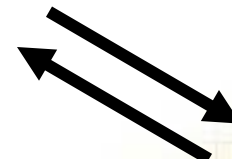


Institutional Policy
Implementation
Training
Evaluation of SFI
Identification of FCOI
Management



Institution

Compliance with Regulations
Reporting to NIH



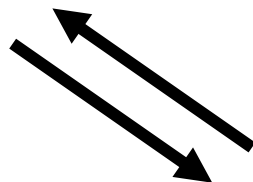
NIH



Oversight



(2010) <http://www.b-d30.org/>



FEDERAL REGISTER

Vol. 76 Thursday,
No. 165 August 25, 2011

Part IV

Department of Health and Human Services

42 CFR Part 50
45 CFR Part 94
Responsibility of Applicants for Promoting Objectivity in Research for Which
Public Health Service Funding Is Sought and Responsible Prospective
Contractors; Final Rule

[Code of Federal Regulations]
[Title 42, Volume 1, Parts 1 to 399]
[Revised as of October 1, 2000]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR50]

[Page 180-183]

TITLE 42--PUBLIC HEALTH

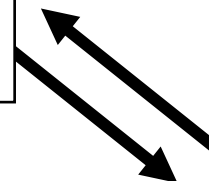
CHAPTER I--PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 50--POLICIES OF GENERAL APPLICABILITY--Table of Contents

Subpart F--Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

Authority: 42 U.S.C. 216, 289b-1, 299c-3.

Source: 60 FR 35815, July 11, 1995; 60 FR 39076, July 31, 1995,
unless otherwise noted.



NIH National Center
for Advancing
Translational Sciences

[Home](#) [Site Map](#) [Contact Us](#)

[Research](#)

[Funding & Notices](#)

[News & Events](#)

[Policy Issues](#)

[About NCATS](#)

**MAY 2013 NEWSLETTER
NOW AVAILABLE**



RESEARCH HIGHLIGHTS

Clinical and Translational Science
Learn more about clinical and translational
science activities at NCATS.

Rare Disease Research and Therapeutics
Learn more about rare disease research and