

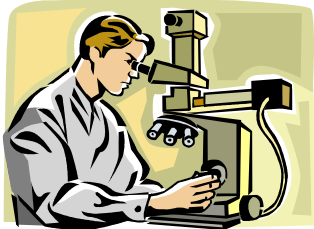


Extramural Financial Conflict of Interest (FCOI)

Joseph Ellis, Director
Office of Policy for Extramural
Research Administration
December 4, 2009



The Current Regulation



Investigator

**Disclosure
Compliance**

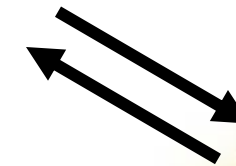


**Compliance
(including accurate
& timely reporting)**

**Institutional Policy
Implementation
Management
Oversight**



Institution



NIH



Oversight

PHS regulation Grants: 42 CFR Part 50, Subpart F &
Contracts: 45 CFR, pt. 94
1995





Advanced Notice of Proposed Rulemaking

- Asked for public comment on whether the FCOI regulation should be amended in the following six broad areas:
 - I. Expanding the scope of the regulation and disclosure of interests
 - II. Definition of “significant financial interest” (SFI)
 - III. Identification and management of conflicts by Institutions
 - IV. Assuring Institutional compliance
 - V. Requiring Institutions to provide additional information
 - VI. Defining Institutional conflict of interest



- 5/09 Advance Notice of Proposed Rulemaking (ANPRM) posted in Federal Register.
 - Comments received through 7/7/09
- NIH now considering comments and drafting proposed changes to the regulation.
 - Anticipate issuing a Notice of Proposed Rule Making (NPRM) within next few months
 - Will publish in the Federal Register for public comment
 - Final Rule anticipated in summer/fall CY2010