Extramural Financial Conflict of Interest (FCOI)

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December 4, 2009
The Current Regulation

Disclosure Compliance

Institutional Policy Implementation Management Oversight

Compliance (including accurate & timely reporting)

Investigator

Institution

NIH

Oversight

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
Rulemaking

• 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