



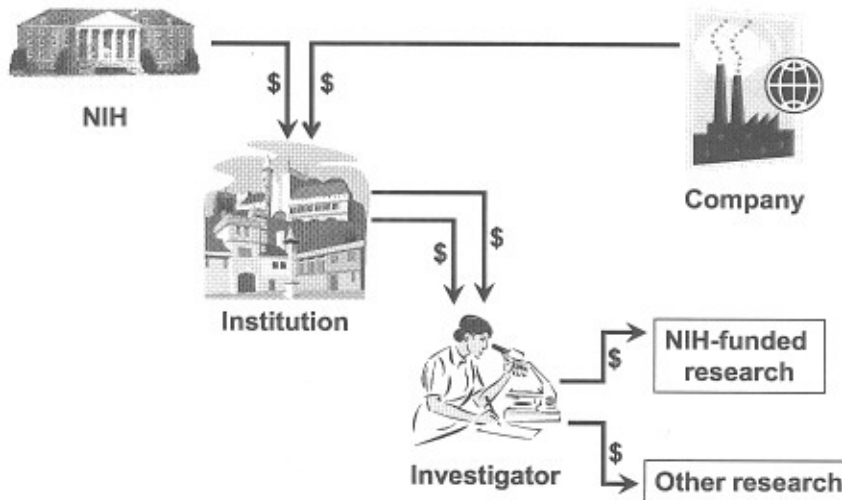
Assuring Objectivity in Research: NIH and Financial Conflict of Interest

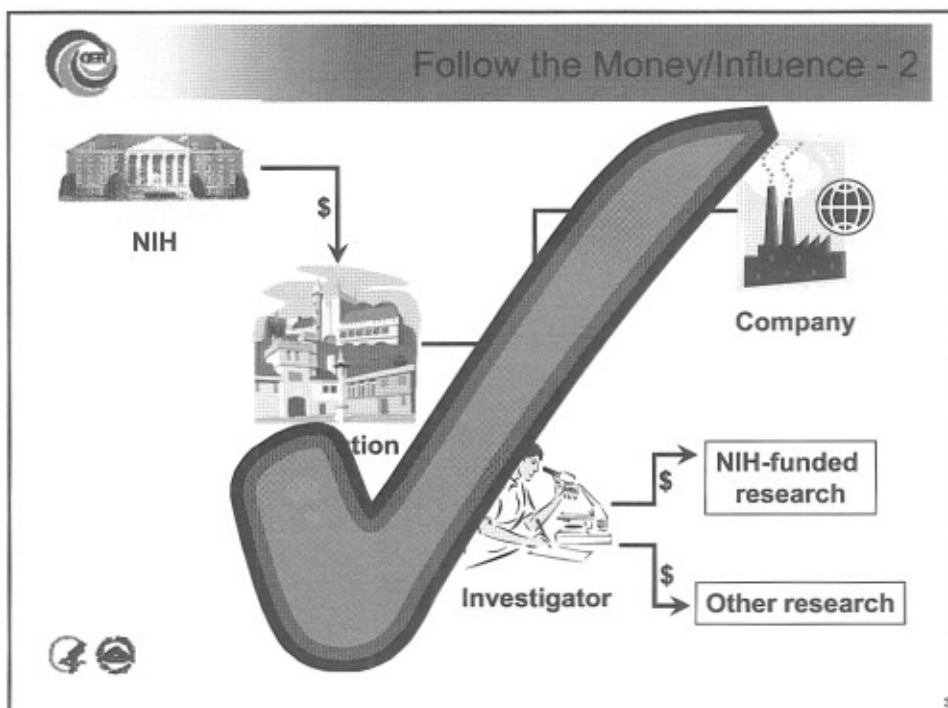
Sally Rockey, Ph.D.
Acting Deputy Director for Extramural Research,
National Institutes of Health


Presented to ACD
05 December, 2008




Follow the Money/Influence - 1






 What is the Purpose of the Regulation?

- This regulation is aimed at ensuring that the design, conduct, or reporting of research funded under NIH grants and cooperative agreements will not be biased by any conflicting financial interest of the Investigators responsible for the research.





4



Summary of FCOI Reporting Requirements

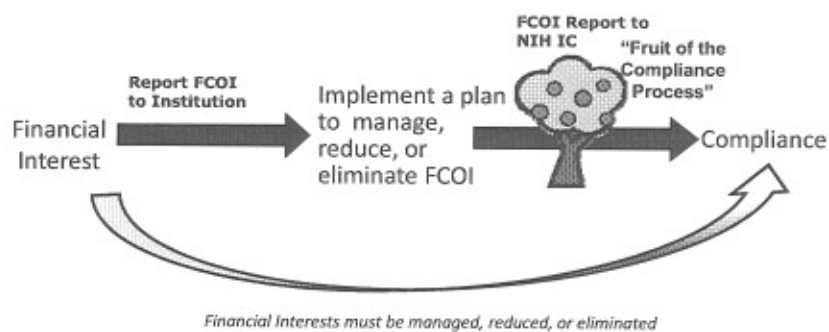
1. At the time of application: Investigators must submit known significant financial interests to the Institution. ***** The PI determines if the FI is related to NIH supported research *****
2. Prior to the expenditure of funds: The Institution must report an identified financial conflict of interest to the NIH and assure that it has been managed, reduced, or eliminated.
3. FCOI identified after the initial report: The Institution must report to the NIH within 60 days of identification and assure that it has been managed, reduced, or eliminated.



5



FCOI Report: Fruit of the Compliance Process



6



Potential Issues: Investigator

- Disclosure
 - Does not correctly identify Significant Financial Interests
 - Does not fully disclose those interests to his/her Institution
- Compliance
 - Fails to comply with management plan put in place by Institution after an FCOI is identified



7



Potential Issues: Institution

- Policy issues
 - Institutional policy does not comply with the regulation
 - Officials do not follow the policy consistently
- FCOI Identification
 - SFIs are not correctly identified as conflicts
- FCOI management
 - Mitigation strategy is not sufficient to manage, reduce or eliminate conflict
 - Implementation of management plan is not enforced
- Reporting to the NIH
 - FCOI is identified and managed, reduced or eliminated but not reported to the NIH or not reported in a timely manner



8



NIH Role

- NIH may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in NIH-funded research, including a requirement for submission of, or review on site, all records pertinent to compliance.
- NIH may decide that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict in accordance with requirements.
- If necessary, NIH may suspend funding until the matter is resolved.



9



NIH Responsibilities Now

- Program of FCOI oversight for many years
- NIH has undertaken vigorous internal review of processes for extramural FCOI oversight
- Examined numerous cases of alleged FCOI in extramural community
 - Congressional inquiries
 - Press
 - NIH-identified cases
- Embarked on extensive communication, outreach and training



10



Cases

- In the past year
 - 20 cases (including 1 yesterday)
 - All received in depth review
 - 6 currently under review
 - 13 of 20 compliant with reg
 - Disclosures OK
 - SFI did not relate to NIH support
 - If it did management plan in place
 - Funding received by institution not investigator
 - Only minor policy issues
 - 2 identified and FCOI and managed but did not report
 - One policy had to reiterate definition of "investigator"
 - One management plan strengthened
 - Others no findings at all
 - 1 serious issues of institutional noncompliance - Emory



11



What is the Proper Role of NIH and its Supported Institutions when Dealing with FCOI?

- NIH has oversight
 - Institutions manage
- Is there enough oversight and enough management?
 - Who should manage financial interests?
 - **Should the regulation be changed to strengthen NIH oversight and Institutions' management?**



12



ADVANCED NOTICE OF PROPOSED RULE MAKING

ANPRM



13



ANPRM – What is it?

- Not a draft of “new” regulation
- Formal RFI process to gain input on potential changes to regulation
- Subsequently (and potentially) an NPRM and then Final Rule



14



Topics covered in ANPRM

1. Expanding the scope of the regulation and disclosure of interests
Should NIH require Investigators to disclose all financial interests related to their Institutional responsibilities when they receive an NIH award?
2. Definition of "significant financial interest" (SFI)
 - Should the current exemptions be maintained?
 - If so, are current de minimus levels reasonable? Should they be the same for all types of research?
 - If not, which exemptions should be reconsidered?
3. Identification and management of conflicts by Institutions
 - For research involving human participants, should Investigators who are involved in participant selection, the informed consent process, and clinical management of a trial, be prohibited from having a Significant Financial Interest in any company whose interests could be affected by their research or clinical trial? If so, what special circumstances – such as limited availability of specially qualified Investigators – may justify waiving this condition?



15



Topics covered in ANPRM (con't)

4. Assuring Institutional compliance
Should independent confirmation of an Institution's compliance with the regulation be required? What would this look like?
5. Requiring Institutions to provide additional information
Should Institutions be required to submit to the PHS funding component additional information on any identified conflict?
6. Defining Institutional conflict of interest
How would Institutional conflict of interest be defined?
What would an Institutional conflict of interest policy address in order to assure the PHS of objectivity in research?



16



Advanced Notice of Proposed Rule Making (ANPRM) on FCOI Regulation

- Began developing in July
- House language in yet unpassed 2008 appropriation bill directing NIH to publish an ANPRM
- August 2008: Sent to Department
- September 2008: revised and resubmitted to based on comments
- November 2008: revised and resubmitted to Secretary based on comments
- Maximum 60 days for OMB clearance after HHS approval



17



NIH Training in FCOI

- NIH FCOI Tutorial
 - Launched Aug 2008
 - Web-based and interactive
 - Clear explanation of regulations
- NIH Extramural Staff Training in FCOI
 - Mandatory for all NIH Extramural Staff with responsibilities for program portfolios, including program administrators and grants management staff.
 - Two dates (Nov 18 and 21) plus videocast archived
 - Nov 18: 456 registered; Nov 21: 458 preregistered



18