




Research Integrity

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Financial Conflict of Interest



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What is a Financial Conflict of Interest (FCOI)?

A **significant financial interest** (SFI) that could **directly** and **significantly** affect the **design, conduct, or reporting** of PHS funded research. This determination will be made by a **Designated Official** (DO) at your institution.

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FCOI Regulations

- * 42 CFR Part 50 Subpart F (grants and cooperative agreements)
http://www.access.gpo.gov/nara/cfr/waisidx_05/42cfr50_05.html
- * 45 CFR Part 94 (contracts)
http://www.access.gpo.gov/nara/cfr/waisidx_05/45cfr94_05.html

These regulations became effective October 1, 1995

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Intent of the Regulations To Promote Objectivity in Research

Institutions **must** establish standards to ensure there is no reasonable expectation that the **design, conduct, or reporting** of PHS funded research is biased by a conflicting financial interest of an Investigator

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Objectivity in Research

- * Protects research subjects
- * Preserves public trust in research
- * Protects reputation of institution and researcher
- * Protects integrity of scientific data

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Applicability of FCOI Regulations

To be applicable, three elements must exist:

- 1) A grant or cooperative agreement funded by the **Public Health Service** (PHS)
- 2) **Research** - A systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research (includes basic, applied research, and product development)
- 3) **Investigator**

(Note: The regulations do not apply to Phase I SBIR or STTR projects)

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Important Definitions 45 CFR Part 50, Sec 603

Investigator – Principal Investigator (PI) and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding

The term "Investigator" includes the Investigator's spouse and dependent children

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Definition of Investigator

Let's Clarify:

An investigator is not just the Principal Investigator conducting the PHS sponsored research. It can be...

Anyone (i.e., key personnel, lab technicians, etc.) that is involved in the design, conduct, or reporting of the PHS sponsored research

Remember these regulations also apply to an investigator's spouse and dependent children

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Significant Financial Interest (SFI)

"Anything of Monetary Value"

Exclusions:

- Salary at the applicant institution
- Ownership interests in the institution, if the institution is an applicant under the **SBIR** program
- Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities
- Income from service on advisory committees for public or non-profits entities
- An equity interest **under \$10,000** in value **AND** represents **less than 5%** ownership in a single entity
- Salary, royalties, or other payments that over the next twelve months are expected to be **less than \$10,000**

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Significant Financial Interest Matrix

Equity Interest	Greater than \$10K in value	Less than \$10K in value
Greater than 5% ownership in single entity	SFI	SFI
Less than 5% ownership in single entity	SFI	Not an SFI

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Key Requirements 42 CFR Part 50

Sec. 50.604 (a)

- Maintain an appropriate written and enforced policy
- Inform each investigator of the policy, reporting responsibilities, and the regulations (i.e., 42 CFR Part 50)

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Key Requirements 42 CFR Part 50

Sec. 50.604 (a)

If the Institution carries out the PHS-funded research through subgrantees, contractors, or collaborators, the Institution must:

- * Take reasonable steps to ensure that the subrecipients comply with the regulation by either having them:
 - Comply with the prime grantee's FCOI policy; or
 - Provide assurances to the prime grantee that they have a program in place that will allow them to comply with the regulation

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Key Requirements 42 CFR Part 50.604

- * **(b)**: Designate an official (**DO**) to solicit and review **financial disclosure statements** from each investigator planning to participate in PHS-funded research
- * **(c) (1)**: Require that at the time an application is submitted to PHS that the Investigator has submitted to the **DO** a listing of known **SFIs**
- * **(c) (2)**: **Financial disclosures** must be updated during the period of award, either annually or as new reportable **SFIs** are obtained

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What is a Financial Disclosure Statement?

A listing of Investigators' **SFIs** (and those of his/her spouse and dependent children):

- (i) that would reasonably appear to be affected by the research for which PHS funding is sought; **and**
- (ii) in entities whose financial interests would reasonably appear to be affected by the research (e.g., stocks)

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SFI Versus FCOI

Remember...

A **SFI** is not always a **FCOI**. A **FCOI** exists when the **DO** reasonably determines that a **SFI** could directly and significantly affect the **design, conduct, or reporting** of the PHS funded research

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Key Requirements 42 CFR Part 50.604

(g) (2): **Prior** to the Institution's **expenditure of any funds** under the award, the Institution will **report** to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest) found by the institution and assure that the interest has been **managed, reduced, or eliminated...**

(for any interest identified after the initial report, report its existence and assure that the interest will be managed, reduced, or eliminated, at least on an interim basis, **within 60 days** of that identification)

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Summary of Reporting Requirements

1. **At the time of application**, the Investigator must submit a listing of **SFIs**
2. **Prior to the expenditure of any funds** the Institution must report a **FCOI** to the NIH and assure that it was managed, reduced, or eliminated
3. Any other **FCOI identified after an initial report** should be reported and managed, reduced, or eliminated within **60 days**

(Institution must maintain records of all financial disclosures and all actions taken regarding each conflict of interest for at least three years from the date of submission of the final expenditure report...)

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Ways to Manage, Reduce or Eliminate Conflicts

42 CFR Part 50.605 (a) (1) – (6)

- * Public **disclosure** of SFIs
- * **Monitor** of research by independent reviewers
- * **Modification** of research plan
- * **Divestiture** of SFIs
- * **Severance** of **relationships** that create actual or potential conflicts

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PCSVs and TSRs

Proactive Compliance Site Visits and Targeted Site Reviews

PCSVs – To assess the level of understanding of certain Federal/NIH Requirements (37 grantees visited since FY 00)

- * Roles and Responsibilities
- * Training and Education
- * Financial Management
- * Financial Conflict of Interest
- * Invention and Patent Reporting
- * Administering and Overseeing Clinical Research

TSRs – **New NIH initiative**

- * Determine if Federal financial conflict of interest regulations are fully and correctly implemented (8 completed since FY 05)

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Some Things to Consider

Do you have an effective FCOI program?

- * Do you have a written policy?
- * Is it enforced?
- * Do you have guidelines for determining if a FCOI exists?
- * Do you have procedures for managing, reducing, or elimination a FCOI? Are they applied consistently to all cases?

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Some Things to Consider

How are Investigators informed of the need to comply with the FCOI regulations?

- * Do you have an effective training program?

Who is responsible for:

- * Managing the reporting process and maintaining records?
- * Determining if a FCOI exists?
- * Reporting a FCOI to the NIH?
- * Developing a plan to manage, reduce, or eliminate a FCOI?
- * Ensuring compliance with a management plan?

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Areas of Concern

- * Interpretation of the definition Investigator
- * FCOIs not reported to NIH
- * Subrecipient noncompliance
- * Policies are not specific to the PHS regulation
- * Compliance program ineffective
 - * Lack of attention by administration
 - * Program not adequately designed
 - * Lack of effective training
 - * Poorly designed financial disclosure forms
 - * Lack of adequate oversight
 - * Inconsistent handling of FCOI cases

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Suggestions for Improving Your Institutional Policy

- * Provide a link to the PHS regulations
- * Identify a contact point for FCOI issues
- * Define roles/responsibilities
- * Define terms used in the PHS regulations
- * Establish guidelines for Institutional Officials to use in determining the existence of a FCOI
- * State requirement for reporting a FCOI to NIH
- * Include examples of when a FCOI may or may not exist

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Compliance in Action

Centralized database:

- Provides FCOI policies, forms (with instructions), and training resources
- Electronically solicits financial disclosures
- Electronically receives and tracks submission of disclosure forms
- Stores copies of disclosure forms for review
- Tracks management plans (audits to monitor compliance)

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Compliance in Action

- Mandatory centralized training
- Involve Investigators in developing management plans
- Establishment of a FCOI committee
- Distribute case studies or sample management plans (templates) to ensure consistency and promote fairness and efficiency
- Management setting a positive example

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Questions?

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Research Integrity



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What is *Research Integrity*?

- ▶ Individual scientist's commitment to:
 - Intellectual honesty in proposing, performing, reporting, and reviewing research;
 - Personal responsibility for
 - Your actions;
 - Practices that characterize responsible conduct of research.
- ▶ Institutional commitment to:
 - Environment that promotes responsible conduct by individuals;
 - Provision of policies, processes, procedures to monitor and evaluate, and improve the environment.

From: 2002 IOM Report on Integrity in Scientific Research 29

What is *Responsible Conduct of Research*?

"Conducting research in a way that fulfills the professional responsibilities of scientists and contributes to the perpetuation of science as a social endeavor held in high repute."

From: Nick Steneck, 2004 Presentation on "Research Integrity"

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Why think about research integrity?



University fires disgraced S. Korean scientist
Updated Thu. Feb. 9 2006 6:21 AM ET
Associated Press

Norway probes cancer doctor accused of faking data
Wed Jan 18, 2006 5:06 PM GMT

Researcher's faked data leads to lifetime ban on US grants The Scientist Volume 19 | Issue 7 | Page 58
Eric Poehlman, a well-known obesity researcher with more than 200 articles to his name, says he fabricated data in 17 applications for US federal grants and agreed to be barred for life "from seeking or receiving funding from any federal agency in the future, including all components of the Public Health Service."

What are the risks?

- ▶ Pressures
 - To receive grant support
 - To publish
 - To patent
 - To serve on committees...
- ▶ Temptation
- ▶ Biases
- ▶ Self-deception

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What are the responsibilities?

- ▶ Understand pressures
- ▶ Recognize temptation
- ▶ Acknowledge biases
- ▶ Avoid self-deception
- Process and Results must meet established standards of
 - scientific field
 - your institution

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NIH Policy

NIH and Scientific Community expect adherence to exemplary standards

- ▶ Intellectual honesty
 - Formulation,
 - Conduct,
 - Reviewing research, and
 - Reporting research results

All allegations are assessed

- ▶ Received by NIH or Office of Research Integrity, DHHS
- ▶ Related to NIH-funded research

Consistent process of cooperative interaction between NIH and ORI

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Allegation

- ▶ An instance or disclosure or other indication of possible scientific misconduct which involves NIH-supported research
- ▶ Made to:
 - Institutional Official;
 - NIH or other DHHS official; or
 - ORI
- ▶ Written or oral

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Research Misconduct

- ▶ Fabrication,
- ▶ Falsification,
- ▶ Plagiarism, or
- ▶ Significant departure from accepted practices of the research community for
 - proposing,
 - performing
 - reviewing research or
 - reporting research results
- It does not include honest error or differences of opinion about interpretation of data.

42 CFR Parts 50 and 93 – effective June 16, 2005

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Fabrication

- ▶ Making up data or results and recording or reporting them

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Falsification

- ▶ Manipulating research materials, equipment, or processes, or
- ▶ Changing or omitting data or results such that the research is not accurately represented in the research record

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Plagiarism

- ▶ The appropriation of another person's ideas, processes, results, or words without giving appropriate credit

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GOAL: Integrity in Science

Use resources

- ▶ Available from the HHS Office of Research Integrity (ORI)
<http://ori.dhhs.gov/>
- ▶ At the institution
- ▶ In the laboratory

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What can you do to promote responsible research?

- ▶ Mentor trainees
- ▶ Establish clear and consistent standards
- ▶ Set a good example
- ▶ Promote effective communication
- ▶ Provide oversight

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What should an institution do to promote responsible research?

- ▶ Promote mentoring
- ▶ Establish clear policies and guidelines
- ▶ Provide continuing educational opportunities for employees
- ▶ Emphasize the importance of communication & provide processes for resolution of disagreements
- ▶ Monitor oversight process

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What should you do if you see...

Harm to Human Subjects

- ▶ Contact IRB

Harm to animals

- ▶ Contact IACUC

Authorship disputes

Differences in interpretation of data

- ▶ Work with mentor, Dept. Chair, Dean, Ombudsman...

Research misconduct

- ▶ Act in accordance with Institution's Misconduct Policy

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What should an institution do if there is evidence of...

Harm to human research participants

- ▶ Contact OHRP

<http://ohrp.osophs.dhhs.gov/index.html>

Harm to animals

- ▶ Contact OLAW

<http://grants1.nih.gov/grants/olaw/olaw.htm>

Authorship disputes

Differences in interpretation of data

- ▶ Pursue process at your institution

Research misconduct

- ▶ Contact NIH or ORI

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What are your institution's roles and responsibilities?

- ▶ Conduct inquiry and/or investigation into allegations of research misconduct and send reports to ORI
- ▶ Comply with institutional research misconduct policy
- ▶ Protect whistleblowers

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Questions?

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