Financial Conflict of Interest

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What You Need to Know

- Geisinger's Current Financial Conflict of Interest (FCOI) Policy
- FCOI 2011 Revised Regulation
- Key Definitions
- Overview of Other Changes
- Grantee Institution Responsibilities
- NIH Responsibilities

Geisinger's Current FCOI Policy

- 09.100 - Conflicts of Interest Policy for Employees and 14.400 - Policy for Investigator Conflicts of Interest in Research require the following:
  - Disclosure of **all** financial interests
  - Completion of the Annual Conflict of Interest Questionnaire
  - Submission of any material changes in financial interests during the course of the year.

FCOI 2011 REVISED REGULATION

FCOI Regulation

- 42 CFR Part 50 Subpart F (grants and cooperative agreements)

- 45 CFR Part 94 (contracts)

  Initial Regulation effective 10-1-95

  - http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm

  Revised Final Rule published on 8-25-11

  - http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf

What is the Purpose of the Regulation?

This regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

Who is Covered?

- Each Institution that applies for or receives PHS/NIH grants or cooperative agreements for research
- Any Investigator, as defined by the regulation, planning to participate in or participating in the research
- When an individual, rather than an Institution, is applying for or receives PHS/NIH research funding
- SBIR/STTR Phase II applicants/awardees
  (Phase I SBIR/STTRs are exempt)

KEY DEFINITIONS

Investigator

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the NIH, or proposed for such funding, which may include, for example, collaborators or consultants.

Investigator’s Institutional Responsibilities

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Financial Interest

A Financial Interest includes anything of monetary value, whether or not the value is readily ascertainable.

Financial Interest

- The term, Financial Interest, **does not** include the following:
  - Salary, royalties, or other Remuneration paid by Geisinger to Investigators employed or appointed by Geisinger, including:
    - Intellectual property rights assigned to Geisinger and agreements to share in royalties related to such rights;
    - Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles;
    - Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a not-for-profit Research institute; or
    - Income from service on advisory committees or review panels for an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a not-for-profit Research institute.

Significant Financial Interest (SFI)

- Any Financial Interest that consists of one or more of the following interests of the Investigator (and Family) that reasonably appears to be related to the Investigator's Institutional Responsibilities:
  - For a **publicly traded Entity**: SFI exists if the value of any Remuneration received from the Entity in the twelve months preceding the disclosure and the value of any equity interest in the Entity as of the date of the disclosure, when aggregated, exceeds $5,000;
  - For a **non-publicly traded Entity**: SFI exists if the value of **any** Remuneration received from the Entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000 or when the Investigator (or Family) holds any equity interest (e.g., stock, stock option or ownership interest)in such Entity, regardless of the amount; or
  - Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests received from an Interested Business.

OVERVIEW OF OTHER CHANGES

Investigator Disclosure

1995 REGULATION:

Only SFIs related to NIH-funded research as determined by the Investigator

2011 REVISED REGULATION:

SFIs include financial interests that are related to an Investigator's institutional responsibilities

Institutions are responsible for determining whether SFI relates to NIH-funded research and if it is an FCOI

Public Accessibility

1995 REGULATION:

No requirement

2011 REVISED REGULATION:

Make FCOI policy available via a publically assessable web site.

Certain information regarding financial conflicts of interests with PHS funded research must be available on a publically available website or by written request within five business days.

Management of FCOI

1995 REGULATION:

Manner of compliance with regulation not specified (manage, reduce or eliminate are indicated as options)

2011 REVISED REGULATION:

For all identified FCOIs, Institutions must develop and implement a management plan (may include reduction or elimination of the SFI)

FCOI Reporting

1995 REGULATION:

Prior to the Institution's expenditure of any funds under the award

Within 60 days for any interest that the Institution identifies as conflicting subsequent to the Institution’s initial report under the award

2011 REVISED REGULATION:

Current requirements, plus annual updates on any previously-identified FCOI for the duration of the research project (including during an extension with or without funds)

Noncompliance

1995 REGULATION:

No requirement

2011 REVISED REGULATION:

The Institution shall, within 120 days of the Institution's determination of non compliance, complete a retrospective review of the investigator's activities and the NIH-funded research project to determine if there was bias in the design, conduct, or reporting of such research. Institution is required to document the retrospective review.

A Mitigation Report required if bias is found.

Scope

1995 REGULATION:

Does not cover Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Phase I applications

2011 REVISED REGULATION:

No changes, continues to exclude SBIR/STTR Phase I applications/awards

Subrecipients

1995 REGULATION:

Institutions must take reasonable steps to ensure that Investigators working for subrecipients comply with the regulation

2011 REVISED REGULATION:

Clarifies by requiring the Institution to incorporate language as part of a written agreement with the subrecipient terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators and include a time period to meet disclosure requirements, if applicable, and FCOI reporting requirements to the awardee Institution.

Investigator Training

1995 REGULATION:

No requirement

2011 REVISED REGULATION:

FCOI training required. Each Investigator must complete training prior to engaging in research related to any NIH-funded grant and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to an Institution
- An Institution finds an Investigator noncompliant with Institution's FCOI policy or management plan.

HHS/NIH Authority

1995 REGULATION:

The HHS may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in NIH-funded research

2011 REVISED REGULATION:

Clarifies that HHS authority applies before, during, or after an award with regard to any Investigator disclosure of financial interests, regardless of whether or not the disclosure resulted in the Institution's determination of an FCOI.

AT THE GRANTEE INSTITUTION

(a.k.a. Geisinger)

Institutional Responsibilities

- Institutions must establish standards that provide a reasonable expectation that the design, conduct, and reporting of NIH-funded research will be free from bias resulting from Investigator financial conflicts of interest.

- Maintain an up-to-date, written, enforced policy that complies with the FCOI regulation and make available via a publicly accessible Web site.

Institutional Responsibilities:
Maintenance of Records

- Maintain records of all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of FCOI) and all actions under the Institution's policy or retrospective review, if applicable
  - for at least three years from the date of submission of the final expenditures report or, where applicable,
  - from other dates specified in 45 C.F.R. 74.53(b) and 92.42 (b) for different situations.

Institutional Responsibilities:
Application Certification

- **Certify in each application for funding that the Institution**:
  - Has in effect an up-to-date written, and enforced administrative process to identify and manage FCOIs related to all PHS research projects.
  - Shall promote and enforce Investigator compliance with the regulation pertaining to disclosure of SFIs.
  - Shall manage FCOIs and provide initial and ongoing FCOI reports to PHS/NIH.

Institutional Responsibilities:
Application Certification

- **Certify in each application for funding that the Institution**:
  - Agrees to make information available upon request relating to any Investigator disclosure of financial interest and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI.
  - Fully comply with the requirements of the regulation.

Institutional Responsibilities:
Designated Institutional Official(s)

- Designate an Institutional Official(s) to solicit & review disclosure statements from each Investigator planning to participate in, or is participating in, PHS/NIH-funded research
- Provide guidelines to identify conflicting interests related to proposed or PHS/NIH-funded research
- Designated Institutional Official(s) develop management plans that specify the actions that have been, and shall be, taken to manage FCOI

Institutional Responsibilities:
Inform Investigators

- Must inform each Investigator of the:
  - Regulation;
  - Institution's policy on FCOI; and
  - Investigator's responsibilities regarding disclosure of SFIs

Institutional Responsibilities:
Investigator Training

Institutions must require that each Investigator complete FCOI training:

- Prior to engaging in research related to any NIH funded project;
- At least every four years, and
- Immediately when any of the following circumstances apply:

  (i) Institution revises its policy in a manner that affects the investigator;

  (ii) When an investigator is new to the institution; or

  (iii) When the institution finds an Investigator is not in compliance with the Institution's policy or management plan.

Institutional Responsibilities:
Management of FCOIs

- Take necessary actions to manage FCOIs of its Investigators, including those of subrecipient Investigators
- Develop a management plan(s) and monitor compliance
- If an Institution identifies an SFI that was not disclosed or reviewed in a timely manner, the designated official(s) shall within sixty (60) days review the SFI, determine if an FCOI exists and implement an interim management plan, if needed.
- In cases of non compliance, complete a retrospective review and submit a Mitigation Report if bias is found.

Institutional Responsibilities:
Elements of an FCOI Report

- Grant number;
- PD/PI or contact PD/PI;
- Name of Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Nature of FCOI (e.g., equity, consulting fees, travel reimbursement, honoraria);
- Value of the financial interest $0-4,999; $5K-9,999; $10K-19,999; amts between $20K-100K by increments of $20K; amts above $100K by increments of $50K or a statement that a value cannot be readily determined;
- A description how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
- Key elements of the Institution's management plan.

FCOI Reporting

- Key Elements of a Management Plan include:
  - Role and principal duties of the conflicted Investigator in the research project;
  - Conditions of the management plan;
  - How the management plan is designed to safeguard objectivity in the research project;
  - Confirmation of the Investigator's agreement to the management plan;
  - How the management plan will be monitored to ensure Investigator compliance; and
  - Other information as needed.

Investigator SFI Disclosure and Institutional FCOI Reporting Requirements

Investigator Discloses known SFI(s) to the Institution	**Institution Reports identified FCOI(s) to the NIH** (Designated official(s) review the disclosures to make determinations of FCOIs and report any FCOIs to NIH.)
At time of Application	**Prior to the Expenditure of Funds**
Within 30 days of acquiring or discovering SFI	**Within 60 days of identification**
Annually at the time period prescribed by the Institution during the award period	**Annually: At the same time as when the grantee submits the annual progress report or the extension of project. Annual FCOI report is submitted through eRA Commons FCOI Module.**

Institutional Responsibilities:

Subrecipient Requirements

- Incorporate as part of a written agreement terms that establish whether the FCOI policy of the awardee Institution or that of the subrecipient will apply to subrecipient Investigators and include time periods to meet SFI disclosure, if applicable, and FCOI reporting requirements.

- Subrecipient Institutions who rely on their FCOI policy must report identified FCOIs to the awardee Institution in sufficient time to allow the awardee Institution to report the FCOI to the PHS/NIH Awarding Component (i.e., to NIH through the eRA Commons FCOI Module) to meet FCOI reporting obligations.

Summary of FCOI Noncompliance

FCOI REPORT (within 60 days)

- Whenever an Institution identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the designated official(s) shall within 60 days review and make the determination of an FCOI and report the FCOI, if it exists, to the PHS/NIH.

RETROSPECTIVE REVIEW (to determine bias)

- If an FCOI exists, complete and document a retrospective review within 120 days of the Institution's determination of noncompliance. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI going forward.

UPDATE/REVISE FCOI REPORT (following retrospective review)

- If applicable, update existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward.

REPORT (promptly after retrospective review)

- If bias is found, notify NIH promptly
- Submit a Mitigation Report through FCOI Module

ANNUAL FCOI

- Submit annual FCOI report thereafter

Institutional Responsibilities:
Enforcement

Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance.

NIH Responsibilities

In any case in which NIH determines that an NIH-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by regulation, the Institution shall require the Investigator involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

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