Financial Conflict of Interest

2011 Revised Regulation
FCOI Webinar for Grantees
Provided by the National Institutes of Health

November 30, 2011

FCOI: What You Need to Know

- Financial Conflict of Interest (FCOI) 2011 Revised Regulation
- Key Definitions
- Overview of Other Changes
- Grantee Institution Responsibilities
- Noncompliance
- Submitting FCOI Reports to NIH
- NIH Responsibilities
- Resources
- Q&A Panel

Have Questions During the Presentations?

- Submit questions electronically during the webinar.
- Questions will be answered following the presentations, as time allows.

FCOI 2011 Revised Regulation

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Deputy Director for Extramural Research
National Institutes of Health

Financial Conflict of Interest (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

2011 Revised FCOI Regulation

- Revised regulations on:
  - *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought*
  - *Responsible Prospective Contractors*
- Published in Federal Register on August 25, 2011
- Implementation by August 24, 2012
- Applies to each Notice of Award issued subsequent to compliance dates of final rule

2011 Revised FCOI Regulation

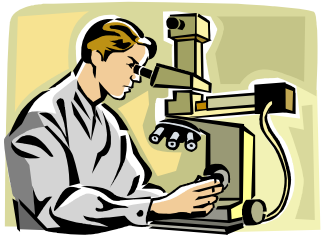
- In the interim, Institutions should:
  - Comply with 1995 regulations;
  - Revise policies;
  - Establish procedures for compliance;
  - Train Investigators; and
  - Continue to report FCOIs to NIH.

- Institutions that implement the regulation prior to August 24, 2012 signify their compliance by making the institutional FCOI policy publicly accessible.

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.

FCOI Regulations Framework



Investigator

Disclosure of SFI
Compliance with Institutional Policy

Institutional Policy
Implementation
Evaluation of SFI
Identification of FCOI
Management

Institution

Compliance with Regulations
Reporting to NIH

NIH

Oversight

PHS regulation 42 CFR Part 50, Subpart F and 45 CFR Part 94

Who is Covered?

- Each Institution that applies for or receives PHS/NIH grants or cooperative agreements for research
  - Domestic, foreign, public, private (not Federal)
- 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

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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.

Significant Financial Interest (SFI)

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a *significant financial interest* 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 disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

Significant Financial Interest (SFI)

(ii) With regard to any non-publicly traded entity, a *significant financial interest* 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 the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Significant Financial Interest (SFI)

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities, provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by excluded sources provided in regulation.

SFI Exclusions

- Salary royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution;
- Intellectual Property Rights assigned to the Institution and agreements to share in royalties related to such rights;
- Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization;

SFI Exclusions

- 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 research institute that is affiliated with an Institution of higher education; or

- Income from service on advisory committees or review panels for a federal, state or local government agency, Institution of higher education as defied at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

Financial Conflict of Interest (FCOI)

An SFI that could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

Senior/Key Personnel

Senior/key personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under the regulation.

Note: Different definition than the NIH Grants Policy Statement

Overview of Other Changes

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Science Policy Advisor to the NIH Deputy Director for Extramural Research

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. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request.

Prior to the expenditure of funds, make certain information concerning FCOIs held by senior/key personnel via a publicly accessible, via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the regulation.

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

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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:
Investigator Disclosure of SFIs

- **At time of Application**: Require that each Investigator, including subrecipient Investigators, if applicable, planning to participate in PHS/NIH-funded research to disclose to the designated official(s) at time of application.
- **Annually**: Require each Investigator, including subrecipient Investigator, if applicable, to submit an updated disclosure of SFI at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award.
- **Within 30 days**: Require each Investigator, including subrecipient Investigator, if applicable, who is participating in the NIH-funded research to submit an updated disclosure of SFI within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

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: FCOI Reporting

- Provide initial and ongoing FCOI reports to NIH:
  - Prior to the expenditure of funds
  - During the period of award
    - Within 60 days of identifying a new FCOI
  - Annually
    - Report on the status of FCOI and any changes in management plan
    - Due at same time as when grantee submits annual progress report, including multi-year progress report, or at time of extension
- All FCOI reports are submitted to NIH through the eRA Commons FCOI Module.

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.

Institutional Responsibilities:
Public Accessibility of FCOIs

- Prior to expenditure of funds, make certain information concerning FCOIs held by senior/key personnel publicly accessible via a Web site or provide written response within five business days of a request.
  - Update the website annually and within 60 days of identifying any new FCOIs when posting FCOIs to website
  - Retain information for three years

Institutional Responsibilities:
Public Accessibility of FCOIs

- Information to be made publicly available includes the following:
  - Investigator's name;
  - Investigator's title and role with respect to the research project;
  - Name of the entity in which the SFI is held;
  - Nature of the SFI; and
  - Approximate dollar value of the SFI (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through references to public prices or other reasonable measures of fair market value.

Noncompliance

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Assistant Grants Compliance Officer
Division of Grants Compliance and Oversight
Office of Extramural Research

Institutional Responsibilities:
Retrospective Review

- Whenever an FCOI is not identified or managed in a timely manner, including failure by the Investigator to disclose an SFI, failure by the Institution to review or manage an FCOI, or failure to comply with the management plan, the institution shall within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the project to determine bias in the design, conduct or reporting of such research.

- Notify NIH promptly and submit a Mitigation Report when bias is found.

Institutional Responsibilities:
Retrospective Review

- Documentation of the key elements of a retrospective review:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the Investigator with the FCOI;
- Name of the entity with which the Investigator has an FCOI;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings and conclusions of the review.

If results of the retrospective review warrant, update previously submitted FCOI report

Institutional Responsibilities:
Mitigation Report

- If bias is found through retrospective review, notify the NIH Awarding Component promptly (through the eRA Commons) and submit a Mitigation Report.

- Mitigation Report
  - Key elements documented in retrospective review
  - Description of the impact of the bias on the research project
  - Plan of action(s) to eliminate or mitigate the effect of the bias

- Thereafter, submit FCOI reports annually.

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.

Submitting FCOI Reports to NIH

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Division of Grants Compliance and Oversight
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FCOI Reporting

- Electronic Research Administration (eRA) Commons FCOI Module
  - Reporting tool for submitting FCOI reports for grants and cooperative agreements
  - Existing reporting tool is being enhanced

Note: FCOI reports for NIH-funded research contracts should be sent to the NIH Office of Acquisition Management and Policy at fcoicontracts@mail.nih.gov.

eRA Commons FCOI Module:
FCOI Reporting Tool

- **System allows institutions to:**
  - Initiate and send FCOI Reports to NIH electronically through the eRA Commons FCOI Module
  - Revise or update a previously submitted FCOI report (future enhancement)
  - Submit a Mitigation Report when bias is found (future enhancement)
  - Search previously created records
  - Edit a previously submitted record
  - Respond to a request for additional information
  - Rescind a previously submitted record
  - View history of actions

- To prepare, Institutional Signing Officials must assign FCOI roles to users in eRA Commons.

- More information on the FCOI Module can be found at http://era.nih.gov/services_for_applicants/other/fcoi.cfm

eRA Commons FCOI Module:
Future Enhancements

- Enhancements to the existing FCOI Module are forthcoming to accommodate additional FCOI reporting requirements.

- After Institution implements the 2011 regulatory requirements, additional FCOI information must be provided as an attachment to the existing Module if the submission occurs prior to the release of the revised FCOI Module.

REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE

Report	Content	Required when?
Initial FCOI Report	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan.	(1) Prior to expenditure of funds (2) Within 60 days of any subsequently identified FCOI
Annual FCOI Report	Status of FCOI and Changes to Management Plan	Annual report due at same time as when submitting annual progress report or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward.	After completion of retrospective review, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings and Conclusion.	When bias is found as a result of a retrospective review.

At the NIH

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NIH Responsibilities

- If the failure of an Investigator to comply with the Institution's FCOI policy or FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the Institution shall promptly notify the NIH of the corrective action taken or to be taken.
- NIH may determine that corrective action is needed and may include directions to the Institution on how to maintain appropriate objectivity in NIH-funded research.
- NIH may require Institutions employing such an Investigator to enforce any applicable corrective actions prior to award or when the transfer of a grant involves such an Investigator.

NIH Responsibilities

- NIH may inquire at any time before, during or after award into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a FCOI.
- Institutions are required to submit, or permit on site review of, all records pertinent to compliance with the regulation.
- NIH will maintain confidentiality of all records of financial interest.
- If NIH decides that a particular FCOI will bias the objectivity of research, NIH may impose special award conditions, suspend funding or impose other enforcement mechanisms until the matter is resolved.

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.

Resources and Q&A Panel

Moderator: Joe Ellis

Director
Office of Policy for Extramural Research
Office of Extramural Research

Information/Resources

- Mailbox for inquiries
  - FCOICompliance@mail.nih.gov

- OER FCOI Web Site
  - http://grants.nih.gov/grants/policy/coi/
  - FAQs posted on 9/30/2011. See NIH Guide Notice NOT-11-121 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-121.html

Questions?

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