

# **Financial Conflict of Interest (FCOI) Office of Extramural Research (OER) National Institutes of Health (NIH)**

## **Welcome**

Welcome to the National Institutes of Health (NIH) Office of Extramural Research (OER) Financial Conflict of Interest (FCOI) tutorial. This tutorial may be used as a reference guide for FCOI policies or you may view the tutorial in its entirety and complete the section review questions in order to receive a certificate of completion.

## **Introduction**

This tutorial reviews the main requirements of and the responsibilities for compliance with the 2011 revised Federal regulation on Financial Conflict of Interest (FCOI) for grants or cooperative agreements at [42 CFR Part 50 Subpart F](#), Promoting Objectivity in Research. The tutorial does not cover the provisions of the FCOI contract regulation provided at [45 CFR Part 94](#), Responsible Prospective Contractors. Inquiries related to contracts can be directed to [fcoicontracts@mail.nih.gov](mailto:fcoicontracts@mail.nih.gov).

The FCOI regulation promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct or reporting of research funded under NIH grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest. Institutions are required to implement policies and procedures consistent with the regulation; such policies and procedures can reflect institutional priorities and culture so long as they are in full compliance with the requirements of the regulation. Accordingly, this tutorial is designed to support institutional training programs regarding the implementation of the revised FCOI regulation for NIH grants and cooperative agreements.

In addition, although the regulation applies to other funding components within the Public Health Service (PHS), this tutorial refers only to the NIH.

In this tutorial, the terms:

- "regulation or FCOI regulation" refers to 42 CFR Part 50 Subpart F, Promoting Objectivity in Research, which applies to both grants and cooperative agreements;
- "disclosure" refers to the Investigator's disclosure of Significant Financial Interests (SFI) to their Institution; and
- "report" refers to the Institution's report of identified FCOIs to the NIH.

This tutorial highlights the key Federal requirements for which the Investigator (through the Institution's implementation of the regulation), the Institution, and the NIH are accountable under the regulation; however, it is not intended in any way to substitute for the comprehensive review and implementation of all regulatory requirements.

Additional FCOI information related to grants and cooperative agreements is available at <http://grants.nih.gov/grants/policy/coi/index.htm>.

## **What are the most significant differences between the 1995 regulation and the 2011 revised regulation?**

The 2011 revised regulation includes comprehensive changes, focusing on these areas in particular:

- Definition of Significant Financial Interest (SFI)
- Extent of Investigators' disclosure of information to Institutions regarding their SFIs;
- Institutions' management of identified Financial Conflicts of Interest (FCOI)
- Information reported to the PHS funding component (e.g., NIH);
- Information made accessible to the public (i.e., Institutions' FCOI policy and FCOIs of Senior/Key personnel); and
- Investigator training.

## **Purpose**

### **What is the purpose of the FCOI regulation?**

Consistent with [42 CFR 50.601](#), the FCOI regulation was established to promote 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 FCOIs.

The NIH is committed to safeguarding the public's trust in Federally-supported research that is conducted with the highest scientific and ethical standards.

## **Applicability**

### **Who and what is covered by this regulation?**

As explained at [42 CFR 50.602](#), Institutions and Investigators must comply with the regulation:

- **Institution**: The regulation applies to any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that applies for or that receives NIH research funding by means of a grant or cooperative agreement. In those few cases where an individual, rather than an Institution, is applying for or receives NIH research funding, NIH will make case-by-case determinations on the steps to be taken, consistent with the regulation, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from an FCOI of the individual.

- **Investigator:** Through an Institution's implementation of the regulation, the regulation applies to each Investigator who is planning to participate in, or is participating in NIH-funded research.

In the regulation at [42 CFR 50.603](#), "Investigator" is defined as the Project Director or Principal Investigator (PD/PI) 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, including persons who are subgrantees, contractors, consortium participants, collaborators, or consultants. Although this definition may seem broad, the concern was that limiting the definition by titles or other designations would increase the risk that an FCOI with NIH-funded research would not be identified and thus not be managed appropriately.

The regulation does not apply to Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) Programs Phase I applications/awards.

As indicated by the definition of "Research" at [42 CFR 50.603](#), the regulation applies to basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug) authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

## Key Definitions

Among the definitions listed at [42 CFR 50.603](#) are eight key definitions that you must know in order to understand the FCOI regulation. They are Institution, Investigator, Institutional Responsibilities, Financial Interest, Financial Conflict of Interest, Manage, Senior/key Personnel, and Significant Financial Interest.

**Institution** refers to any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for or that receives NIH research funding

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

**Institutional responsibilities** means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution, including, but not limited to, 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** means anything of monetary value, whether or not the value is readily ascertainable.

**Financial Conflict of Interest (FCOI)** means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

**Manage** means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

**Senior/Key Personnel** means the Project Director/Principal Investigator (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 NIH by the Institution under the regulation.

**Significant Financial Interest (SFI)** is defined by the regulation as:

(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;

(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.

(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 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including 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; 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, 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.

## End of Section Review - Multiple Choice

Who is considered an Investigator under the 2011 revised FCOI regulation?  
Pick one correct answer.

- A) The project director/principal investigator and any other persons identified by the project director/principal investigator.
- B) The project director/principal Investigator and other senior key personnel listed in the grant application or progress report.
- C) The project director/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 reporting of research funded by the NIH, which may include, for example, collaborators or consultants.

C is the correct answer.

## Overview of Responsibilities

### Investigator, Institution, and National Institutes of Health (NIH)

The regulation promotes the objectivity of NIH-funded research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by NIH grants and cooperative agreements will be free from bias resulting from Investigator FCOIs. The Investigator, Institution and the NIH all have responsibilities under the regulation.

**Investigator:** Through implementation of the FCOI regulation by the Institution, an Investigator is responsible for complying with the Institution's FCOI policies and procedures, completing training on FCOI, and for disclosing the required information to the Institution whether the Investigator is planning to participate in or is participating in NIH-funded research. The Investigator is required to disclose to the Institution's designated official(s) his/her SFIs (and those of the Investigator's spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities. The Investigator must disclose the SFIs as follows:

- (1) No later than at the time of application for NIH-funded research;
- (2) Within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; and

- (3) At least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.

**Institution:** The Institution is responsible for maintaining an up-to-date, written, enforced FCOI policy that complies with the regulation and making the policy publicly accessible. Additional responsibilities include, but are not limited to:

- Soliciting and reviewing disclosures of Investigators' SFIs that are reasonably related to an Investigator's institutional responsibilities;
- Determining whether an Investigator's SFI is related to the NIH-funded research and, if so related, whether the SFI is a FCOI (SFI that could directly and significantly affect the design, conduct or reporting of the NIH-funded research);
- Developing and implementing management plans, as needed to manage FCOIs for awardee Investigators and subrecipient Investigators, if applicable;
- Submitting initial and annual FCOI reports to the NIH in accordance with the regulation;
- Completing retrospective reviews when there is noncompliance with the Institution's policy or the FCOI regulation and updating any previously submitted FCOI report, if required after the retrospective review is complete;
- Submitting mitigation reports when bias is found in NIH-supported research as a result of the finding from a retrospective review.

**NIH:** NIH is responsible for education and outreach, oversight and compliance.

## **Investigator Responsibilities**

### **Who is considered an Investigator for the purpose of this regulation?**

Under [42 CFR 50.603](#), "Investigator" refers to the PD/PI 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, including persons who are subgrantees, contractors, consortium participants, collaborators, or consultants.

Note that these responsibilities are not limited to the PD/Pis or Senior/Key Personnel but rather, apply to all individuals who are responsible for the design, conduct or reporting of research.

Questions regarding applicability of the FCOI regulation to particular individuals should be addressed in your Institution's policy and procedures and questions should be referred to your Institution's designated official(s).

## **What does the regulation require the Investigator to do?**

Through the implementation of the FCOI regulation by the Institution, the Investigator is responsible for:

- Following the Institution's FCOI policies and procedures, which may be more restrictive than the FCOI regulation;
- Completing FCOI training prior to engaging in NIH-funded research and thereafter, every four years and immediately when any of the following circumstances apply:
  - (i) the Institution revises its FCOI policies and procedures in any manner that affects the requirements of Investigators;
  - (ii) an Investigator is new to an Institution; or
  - (iii) an Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or management plan;
- Submitting to the Institution's designated official(s) prior to the expenditure of NIH funds, a listing of his/her known SFIs (and those of his/her spouse and dependent children):
  - (i) that reasonably appear to be related to the Investigator's institutional responsibilities; and
  - (ii) any reimbursed or sponsored travel related to the Investigator's institutional responsibilities as required in the regulation (see definition of SFI provided in [42 CFR Part 50.603](#)).
- During the period of award, updating all financial disclosures to the Institution according to its policy, either on an annual basis or within 30 days of the acquisition or discovery of new SFIs.

## **What financial interests need to be disclosed and when?**

The FCOI regulation covers all financial interests of monetary value, whether or not the value is readily ascertainable. Investigators are required to disclose their SFIs (and those of the Investigator's spouse and dependent children) that reasonably appear to be Investigator's institutional responsibilities

- (1) No later than at the time of application for NIH-funded research;
- (2) Within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI; and
- (3) At least annually, in accordance with the specific time period prescribed by the Institution, during the period of award.

Because an Institution's FCOI policy may be more stringent than the FCOI regulation, the Investigator should consult the Institution's FCOI policy to determine what financial interests should be disclosed and when.

### **What about assets held by an Investigator's spouse and dependent children?**

The calculation of interests that should be disclosed includes the aggregated amounts, values and holdings of financial interests of the Investigator and his/her spouse and dependent children.

### **Is the Investigator required to disclose interests in mutual funds?**

The 2011 revised regulation does not require the disclosure of 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. Please refer to your Institution's FCOI policy for disclosure requirements for mutual funds since the Institution's policy may be more restrictive.

### **Is the Investigator required to disclose stock and stock options?**

Please refer to your Institution's FCOI policy. Stock option assets are to be reported by the time an application for funding is submitted, and then reported annually or as new stocks are obtained, in the same manner as all other assets. The documentation needed to determine the value of a stock option is defined by the Institution.

### **Which financial interests do not need to be disclosed?**

Please note that the Institution may have a policy with additional requirements beyond the FCOI regulation's (minimum) requirements. Investigators should consult the Institution's FCOI policy and with the Institution's designated official(s), as needed.

The FCOI regulation does not require Investigators to disclose the following financial interests:

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

### **End of Section Review - Multiple Choice**

Please indicate whether the following statement is true or false.

The term "Significant Financial Interest" (SFI) includes an equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children exceeds \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, or represents more than five percent ownership interest in any single entity.

- A) True
- B) False

The statement is false.

### **Institutional Responsibilities**

An Institution is defined at [42 CFR 50.603](#) as any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, NIH research funding.

The regulation requires that the Institution:

- Create and maintain an up-to-date written and enforced policy that complies with the regulation.
- Make the Institution's FCOI policy publicly available via a publicly accessible Web site or make the written policy available to any requestor within five business days of a request if the Institution does not have any current presence on a publicly accessible Web site.
- Inform each Investigator of the FCOI regulation, the Institution's FCOI policy, and of the Investigator's disclosure responsibilities that meet or exceed the regulatory requirements.
- Require each Investigator to complete training on the Institution's policy, the Investigator's responsibilities to disclose SFIs and of the regulation prior to engaging in research related to any NIH-funded grant or cooperative agreement at least every four years and immediately when any of the following circumstances apply:
  - The Institution revises its FCOI policies and procedures in any manner that affects the requirements of Investigators;
  - An Investigator is new to an Institution; or

- An Institution finds that an Investigator is not in compliance with the Institution's FCOI policy or management plan.
- Designate an institutional official(s) to solicit and review disclosures of SFIs from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.
- Require each Investigator who is planning to participate in, or is participating in, the NIH-funded research to disclose to the Institution's designated official(s) the Investigator's SFIs (and those of the Investigator's spouse and dependent children) no later than at the time of application for NIH-funded research.
- Require each Investigator who is participating in the NIH-funded research to submit an updated disclosure of SFIs at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution, pursuant to [50.604\(e\)\(2\)](#) of the regulation, or in a subsequent disclosure of SFIs, and shall include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).
- Require each Investigator who is participating in the NIH-funded research to submit an updated disclosure of SFIs within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.
- Provide guidelines consistent with the regulation for the designated institutional official(s) to determine whether an Investigator's SFI is related to NIH-funded research and, if so related, whether the SFI is an FCOI.
- Take the necessary actions to manage FCOIs, including any financial conflicts of a subrecipient Investigator pursuant to [50.604\(c\)](#) of the regulation. Management of an identified FCOI requires development and implementation of a management plan.
- Complete and document a retrospective review if necessary and, if bias is found, develop and submit a mitigation report, pursuant to [50.605\(a\)](#) and [50.605\(b\)\(2\)](#).
- Provide initial and annual (i.e., ongoing) FCOI reports to the NIH through the eRA Commons FCOI Module, as required.
- Make information concerning identified FCOIs held by senior/key personnel publicly accessible consistent with the regulation and maintain public accessibility of the information for three years from the date the information was most recently updated. Make such information available prior to the expenditure of funds and update the information at least annually and within 60 days of a newly identified FCOI.
- Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, or response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of an FCOI), and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from

the date the final expenditures report is submitted to the NIH or, where applicable, from other dates specified in [45 CFR 74.53\(b\)](#) and [92.42\(b\)](#) for different situations.

- Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- Agree to make information available promptly upon request to the NIH relating to any Investigator disclosure of financial interests 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.

### **What are the responsibilities related to Subrecipients?**

If the Institution carries out the NIH-funded research through a subrecipient (e.g., subcontractor or consortium members) the awardee Institution must take reasonable steps to ensure that any subrecipient Investigator complies with the regulation, consistent with [42 CFR 50.604](#), as follows:

Incorporate 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.

- If the subrecipient's FCOI policy applies to subrecipient Investigators, the subrecipient shall certify as part of the agreement that its policy complies with the regulation. If the subrecipient cannot provide the certification, the agreement shall state that subrecipient Investigators are subject to the FCOI policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;
- If the subrecipient's FCOI policy applies to subrecipient Investigators, the agreement shall specify time period(s) for the subrecipient to report all identified FCOIs to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the NIH through the eRA Commons FCOI Module.
- If the subrecipient Investigator is subject to the awardee Institution's FCOI policy, the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply with its review, management, and reporting obligations under the regulation. The awardee Institution will submit any FCOI reports for subrecipient Investigators to the NIH through the eRA Commons FCOI Module.

In all cases, the awardee Institution is responsible for reporting all identified FCOIs for subrecipient investigators to the NIH through the eRA Commons FCOI Module.

### **What are the requirements for making an Institution's FCOI policy publicly accessible?**

An Institution is required to make its FCOI policy publicly available via a publicly accessible 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. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the NIH award, the requirement to post the information on that Web site will apply within 30 calendar days.

When the Institution posts its FCOI policy or otherwise makes the policy publicly accessible, it signifies that the Institution applying for or receiving NIH funding from a grant or cooperative agreement that is covered by the 2011 revised regulation is in full compliance with all the regulatory requirements. The Institution must be in compliance with the 2011 revised regulation no later than August 24, 2012.

### **What are the requirements for making information on FCOI of Senior/Key Personnel publicly accessible (see regulatory definition of Senior/Key Personnel at [42 CFR 50.603](#))?**

Per [42 CFR 50.605](#), prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response within five business days of a request, of information concerning any Significant Financial Interest disclosed to the Institution that meets the following three criteria:

- (A) The SFI was disclosed and is still held by the Senior/Key Personnel for the NIH-funded research project identified by the Institution in the grant application, progress report, or any other required report submitted to the NIH;
- (B) The Institution determines that the SFI is related to the NIH-funded research; and
- (C) The Institution determines that the SFI is an FCOI.

The information that the Institution makes available via a publicly accessible Web site or written response shall include, at a minimum, the following:

- a. Investigator's name;
- b. Investigator's title and role with respect to the research project;
- c. Name of the entity in which the SFI is held;
- d. Nature of the SFI (e.g., equity, consulting fees, travel reimbursement, honoraria, etc.); and
- e. 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 reference to public prices or other reasonable measures of fair market value.

## **Who is required to disclose financial interests?**

Under the 2011 revised regulation, and through its implementation by the Institution, each Investigator (see Key Definitions) who is planning to participate in, or who is participating in, NIH-funded research, is required to disclose to the official(s) designated by the Institution a listing of SFIs (and those of his/her spouse and dependent children) that reasonably appear to be related to the Investigator's institutional responsibilities and any reimbursed or sponsored travel related to the Investigator's institutional responsibilities as prescribed in the regulation (see definition of SFI at [42 CFR 50.603](#)).

## **What are the responsibilities of the Institution's designated official(s) to review and address FCOI?**

The Institution must establish guidelines consistent with the regulation for the Institution's designated official(s) to solicit and review disclosures of SF s from each Investigator who is planning to participate in, or is participating in, the NIH-funded research. After reviewing the financial disclosure, the designated official(s) must determine whether the Investigator's SFI is related to NIH-funded research, and if so, whether an FCOI exists. If an FCOI exists, the designated official(s) must take such actions as necessary to manage the FCOI, including any financial conflicts of subrecipient Investigators, if applicable.

An SFI is related to NIH-funded research when the Institution, through its designated official(s), reasonably determines that the SFI: could be affected by the NIH-funded research; or the SFI is in an entity whose financial interests could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a SFI is related to the NIH-funded research.

An FCOI exists when the Institution, through its designated official(s), reasonably determines that an SFI could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

## **When must the Institution provide information to the NIH and what must be provided?**

- At the time of the application, the Institution provides a certification that it:
  1. Has in effect an up-to-date, written, and enforced administrative process to identify and manage FCOIs with respect to all research projects for which funding is sought or received from the NIH;
  2. Shall promote and enforce Investigator compliance with the regulatory requirements including those pertaining to disclosure of SFIs;
  3. Shall manage any FCOI and provide initial and annual (e.g., ongoing) FCOI reports to the NIH (e.g., through the eRA Commons FCOI Module) consistent with the regulation;
  4. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of,

or response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of an FCOI; and

5. Shall fully comply with the requirements of the regulation.

- Prior to spending any funds under an NIH award: The Institution must submit an FCOI report to the NIH through the eRA Commons FCOI Module for any identified FCOI of each Investigator and manage the FCOI. If the FCOI is eliminated prior to the submission of the initial report, no FCOI report is required. In addition, the Institution must submit an FCOI report for any FCOI(s) identified for subrecipient Investigators, if applicable.
- Within sixty (60) days (FCOI identified during ongoing NIH-funded project): The Institution must submit an FCOI report through the eRA Commons FCOI Module within sixty (60) days for any SFI that the Institution identifies as an FCOI subsequent to the Institution's initial FCOI report during an ongoing NIH-funded research project (e.g., FCOI exists for an Investigator who is newly participating in the project or for an existing Investigator who discloses a new SFI to the Institution during the period of award). The Institution shall within sixty days: review the disclosure of SFI; determine whether it is related to the research; and, if so, implement on at least an interim basis, a management plan that shall specify the actions that have been and will be, taken to manage such FCOI; and submit the FCOI report to the NIH.
- Within sixty (60) days of the Investigator's disclosure of an SFI that was not disclosed in a timely manner by the Investigator or if the Institution fails to review a previously existing SFI during an ongoing NIH-funded project, the Institution's designated official(s) shall:

Review the SFI; determine whether it is related to the NIH-funded research; and determine whether an FCOI exists. If an FCOI exists, the Institution must implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such FCOI going forward and submit an FCOI report to the NIH. In addition to the FCOI report, the Institution must, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the period of noncompliance, was biased in the design, conduct, or reporting of such research.

Based on the results of the retrospective review, if appropriate, update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward.

- Promptly notify NIH when bias is found in the design, conduct or reporting of NIH-funded research: The Institution must promptly notify NIH and submit a mitigation report if bias is found during the retrospective review. The mitigation report must include the key elements documented in the retrospective review and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effects of the bias. Thereafter, the Institution will submit FCOI reports annually.

- Annually for any FCOI previously reported by the Institution with regard to an ongoing NIH-funded research project: For any FCOI previously reported, the Institution shall provide an annual FCOI report that addresses the status of the FCOI and any changes to the management plan. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. The Institution shall provide annual FCOI reports to the NIH for the duration of the project period (including extensions with or without funds) at the same time as when the Institution is required to submit the annual progress report or at the time of project extension.

For grants and cooperative agreements, all FCOI reports, including revised FCOI reports and mitigation reports must be submitted through the electronic Research Administration (eRA) Commons FCOI Module. See the eRA systems support information provided on eRA's home page at <http://era.nih.gov/> for additional information on the FCOI Module.

### **What is the minimal information that the Institution must be included in an FCOI report to the NIH?**

1. Project number;
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
3. Name of the Investigator with the FCOI;
4. Name of the entity with which the Investigator has an FCOI;
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. Value of the financial interest (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 reference to public prices or other reasonable measures of fair market value;
7. A description of how the financial interest relates to the NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research;
8. A description of the key elements of the Institution's management plan, including:
  - a) Role and principal duties of the conflicted Investigator in the research project;
  - b) Conditions of the management plan;
  - c) How the management plan is designed to safeguard objectivity in the research project;
  - d) Confirmation of the Investigator's agreement to the management plan;
  - e) How the management plan will be monitored to ensure Investigator compliance; and
  - f) Other information as needed.

### **What actions should be taken in the event that an Investigator fails to comply with the Institution's FCOI policy or management plan?**

Each Institution must establish adequate enforcement mechanisms, provide for employee sanctions, and other administrative action, where appropriate. The Institution may determine the nature of the enforcement mechanisms and sanctions.

If an Investigator fails to comply with an Institution's FCOI policy or a FCOI management plan, the Institution shall complete within 120 days of determining noncompliance a retrospective review of the Investigator's activities and the NIH-funded research project, document the Institution's methodology of reviewing the SFI(s), and document the Institution's determination as to whether any NIH-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research.

If bias is found, the Institution shall submit a mitigation report to the NIH, in accordance with [42 CFR 50.605\(b\)\(3\)](#), that shall address the impact of the bias on the research project and the actions the Institution has taken to mitigate the bias. Depending on the nature of the FCOI, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date that the FCOI is identified and the completion of the Institution's retrospective review, in accordance with [42 CFR 50.605\(a\)\(3\)](#) and [42 CFR 50.605\(b\)\(3\)](#).

The 2011 revised regulation further requires that if the NIH determines that one of its funded clinical research projects 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, 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.

### **What should be done in the event an Investigator's non-compliance with the Institution's FCOI policy or management plan results in bias?**

Consistent with [42 CFR 50.606](#), if the failure of an Investigator to comply with an Institution's FCOI policy or an 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.

The NIH will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to promote and maintain appropriate objectivity in the NIH-funded research project.

NIH may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to an NIH award or when the transfer of an NIH grant(s) involves such an Investigator.

### **End of Section Review - Multiple Choice**

How soon must an Institution report an FCOI to the NIH?

- A) Prior to the Institution's expenditure of any funds under the award.
- B) For any FCOI that the Institution identifies subsequent to the Institution's initial report under the award, within 60 days of that identification.
- C) Annually.
- D) Both A and B.
- E) Neither A nor B

F) A, B, and C.

F is the correct answer.

### **End of Section Review - Multiple Choice (cont'd)**

**What should an Institution do if an Investigator fails to disclose in a timely manner one of their Significant Financial Interests?**

- A) Upon disclosure, promptly notify the NIH.
- B) Upon disclosure, the Institution must review the SFI, determine whether it is related to the NIH-funded research, determine whether an FCOI exists, and if so, submit an FCOI report within 60 days of identification; complete, within 120 days of determining noncompliance, a retrospective review of the Investigator's research activities to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct or reporting of the research; and if so, promptly notify the NIH and submit a mitigation report to the NIH.
- C) Upon disclosure. Impose sanctions against the Investigator.
- D) Upon disclosure, promptly notify the NIH, submit an FCOI Report and management plan.
- E) A and C

B is the correct answer

## **NIH Responsibilities**

The NIH oversees and monitors the Institution's compliance with the regulation. 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 an FCOI. An Institution is required to submit, or permit on site review of, all records pertinent to compliance with the regulation to facilitate NIH's review of identified FCOI to determine if the Institution's management of an FCOI is sufficient.

### **Special Requirement for Clinical Research**

The regulation at [42 CFR 50.606](#) specifically requires that in any case in which the Department of Health and Human Services 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 a financial conflict of interest that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator(s) involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

Please remember that an Institution may have an FCOI policy that is more stringent than the regulation.

### **What happens after a Financial Conflict of Interest (FCOI) is reported to NIH?**

Generally, NIH professional and scientific staff will evaluate the information received in FCOI reports to determine if additional information may be needed and whether an Institution's actions are sufficient to manage the identified FCOI. This information is also used to monitor compliance. After considering the information provided in the FCOI report, the NIH may request additional information from the Institution. Once that information is considered, the NIH may decide that further action is needed to ensure the objectivity of the research or that the Institution has not managed the FCOI in accordance with the regulation.

If NIH decides that a particular FCOI will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the FCOI in accordance with the regulation, NIH may, consistent with the regulations and the [NIH Grants Policy Statement](#) (which provides the policy requirements that serve as the terms and conditions of all NIH grant awards), determine that imposition of special award conditions under [45 CFR 74.14](#) and [92.12](#), or suspension of funding or other enforcement action under [45 CFR 74.62](#) and [92.43](#), is necessary until the matter is resolved.

### **End of Section Review – Multiple Choice**

What action may the NIH take under this 2011 revised FCOI regulation? Pick one correct answer.

- A) Request additional information regarding all conflicting financial interests identified by the Institution and how those interests have been managed to protect the research from bias.
- B) 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.
- C) After its review of information and records, NIH may determine that imposition of special award conditions under 45 CFR 74.14 and 92.12, or suspension of funding or other enforcement action under 45 CFR 74.62 and 92.43, is necessary until the matter is resolved.
- D) All of the above.
- E) None of the above.

D is the correct answer.

### **Summary**

It is vitally important that we—the Investigators, Institutions, and NIH—work together to promote and maintain objectivity in research. Responsibilities should be fulfilled thoughtfully and in compliance with all Federal and institutional requirements. Maintaining objectivity and identifying

conflicting financial interests in research will help maintain the public's trust in the research process.

In case of questions about a potential conflict and how to promote and maintain objectivity in NIH-funded research, Investigators should consult the Institution's policy and with designated officials within their Institution. The National Institutes of Health also has information available on its Office of Extramural Research Web site that may be helpful related to grants and cooperative agreements found at <http://grants.nih.gov/grants/policy/coi/index.htm>.

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