

# Financial Conflict Of Interest (FCOI)

## Office of Extramural Research (OER)

### National Institutes of Health (NIH)

#### Welcome

This tutorial reviews the requirements of and the responsibilities for compliance with the Federal regulation on Financial Conflict of Interests (FCOI). Institutions are expected to implement policies and procedures that reflect Institutional priorities and cultures, so long as these policies address the requirements of the regulation. Accordingly, this tutorial is designed to augment, rather than replace, Institutional training programs.

#### Additional Information

This tutorial reviews the requirements of and the responsibilities for compliance with the Federal regulation on Financial Conflict of Interests (FCOI), specifically Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F for grants or cooperative agreements and Title 45 CFR Part 94 for research contracts. These documents are available at the following websites:

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2009298b4a29f6706dd67eab8247368d&rgn=div6&view=text&node=42:1.0.1.4.20.6&idno=42>

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=2009298b4a29f6706dd67eab8247368d&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>

In this tutorial, the term

- "regulation or FCOI regulation" refers to that regulation which applies to both grants and contracts;
- "disclosure" refers to the Investigator's disclosure of financial interests to the Institution; and
- "report" refers to the Institution's report of identified FCOIs to the NIH.

This tutorial will help you understand the requirements for which the NIH, the Institution, and the Investigator, through the Institution's implementation of the regulation, are accountable under the regulation.

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

The FCOI regulation promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under NIH grants, cooperative agreements, or contracts will be biased by an Investigator's conflicting financial interests.

#### Definitions

A *Financial Conflict of Interest (FCOI)* exists when the Institutional designated official(s) reasonably determines that a Significant Financial Interest (defined below) could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

*HHS* refers to the U.S. Department of Health and Human Services, a Federal Department of which NIH is an agency.

*Institution* refers to any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is the direct and primary recipient of NIH grant funds or that submits a proposal for a research contract whether in response to a solicitation from the NIH or otherwise, and is accountable to NIH for the performance of the project/contract, the appropriate expenditure of grant/contract funds by all parties, and all other obligations of the grantee/awardee, such as compliance with the terms and conditions of NIH grant/contract awards, including FCOI.

*Investigator* refers to the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the NIH or proposed for such funding, including Investigators working for subgrantees/contractors/subcontractors/collaborators. The term Investigator includes the Investigator's spouse and dependent children.

*NIH* is the National Institutes of Health, a Federal Agency whose mission is to improve the health of the people of the United States. NIH is a part of the Public Health Service, which is part of the U.S. Department of Health and Human Services.

An *NIH awarding component* is the Institute and/or Center of the NIH that funds the research that is subject to this regulation.

*Research* is a systematic investigation designed to develop or contribute to generalized knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research and product development. As used in this context, the term includes any such activity for which research funding is available from the NIH through a grant, cooperative agreement, or contract.

*Significant Financial Interest* is defined by the regulation as anything of monetary value, including but not limited to:

- salary or other payments for services (e.g., consulting fees or honoraria);
- equity interests (e.g., stocks, stock options, or other ownership interests);
- intellectual property rights (e.g., patents, copyrights, and royalties from such rights).
- Significant Financial Interest does not include:
- salary, royalties, or other remuneration from the Institution;
- any ownership interests in the Institution, if the Institution is an applicant under the SBIR or STTR Programs;
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- income from service on advisory committees or review panels for public or nonprofit entities;

Significant Financial Interest also does not include:

- an equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both the following tests: 1) does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value and 2) does not represent more than a five percent ownership interest in any single entity; or

- salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months are not expected to exceed \$10,000.

*Small Business Innovation Research (SBIR)* an award designed to support projects from small businesses ultimately having commercial viability.

*Small Business Technology Transfer (STTR)* is a program under the Small Business Innovation Research Program designed to foster technological innovations through cooperative efforts between small business and research institutions. The STTR grants are awarded for projects having potential for commercialization

## What is the purpose of the FCOI regulation?

The FCOI regulation was established to promote objectivity in research by setting requirements to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under NIH grants, cooperative agreements, or contracts will be biased by any conflicting financial interest of an Investigator.

## Why is it important to comply with the regulation?

Complying with the regulation ensures that potential conflicts are disclosed to the Institution, and that the Institution manages, reduces, or eliminates FCOIs and reports them to the NIH so that the research is unbiased, and the public trust is preserved.

## Who is covered by this regulation?

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 to NIH for grants or cooperative agreements for research or submits a proposal for a research contract whether in response to a solicitation or otherwise.

**Investigator:** Through an Institution's implementation of the regulation, the regulation applies to Investigators participating in NIH-funded research. In the regulation, "Investigator" refers to the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the NIH or proposed for such funding, including Investigators working for sub-grantees/contractors/subcontractors/ collaborators. The regulation's definition of Investigator includes the Investigator's spouse and dependent children. The regulation's definition of Investigator is very broad. An Institution that limits the definition of "Investigator" by titles or other designations increases the risk that an unidentified FCOI may compromise the research enterprise.

The regulation does not apply to applications for Phase I support under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs.

## Pop Quiz - Multiple Choice

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

A) The Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the NIH or proposed for such funding, including Investigators working for sub-grantees/contractors/subcontractors/collaborators, as well as the Investigator's spouse and dependent children.

- B) The Principal Investigator and other key personnel listed on the grant or contract.
- C) The Principal Investigator and his/her spouse and dependent children.

A is the correct answer.

## Overview of Responsibilities

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

The regulation promotes the objectivity of NIH-funded research by ensuring the research is not biased by an Investigator's conflicting financial interests. The NIH, the Institution, and the Investigator all have responsibilities under the regulation.

NIH: NIH is responsible for oversight and compliance.

Institution: The Institution is responsible for complying with the regulation, including developing, maintaining and communicating a written and enforced FCOI policy and for the following:

- collecting financial disclosures of participating investigators' Significant Financial Interests 1) that would reasonably appear to be affected by the research for which the NIH funding is sought and 2) in entities whose financial interests would reasonably appear to be affected by the research;
- determining which disclosures are FCOIs;
- managing, reducing, or eliminating these FCOIs; and
- reporting FCOIs to the NIH.

Investigator: Through implementation of the FCOI regulation by the Institution, a participating Investigator is responsible for complying with the Institution's policies and procedures and for disclosing the required information to the Institution.

## NIH Responsibilities

The NIH oversees compliance with the regulation by reviewing all Institutional reports of FCOI. The NIH may at any time request additional information regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias and may inquire into the Institutional procedures and actions regarding FCOIs in research funded by the NIH, including a requirement for submission, or review on site, of all records pertinent to compliance with the regulation.

NIH has an ongoing program of activities to promote and enhance compliance that includes site visits to discuss and review FCOI policies of Institutions.

In addition, NIH conducts education and outreach activities to promote compliance with the regulation. More information about these activities as they relate to grants and cooperative agreements can be located at <http://grants.nih.gov/grants/policy/coi/index.htm>.

Please be aware that an Institution may have more stringent FCOI policy requirements than those set forth in the regulation.

## What happens after a conflict is reported to NIH?

NIH reviews the reported FCOIs to determine if additional information is needed. After considering the additional information provided, the NIH may decide that further action is needed to assure the objectivity of the research, or that the Institution has not managed,

reduced, or eliminated the FCOI in accordance with the regulation. The NIH may determine that suspension of funding is necessary until the matter is resolved.

### **Special Requirement**

The regulation specifically requires that in any case in which it is determined that a funded clinical research project 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 conflicting interest that was not disclosed or managed as required by the regulation, the Institution must require the Investigator(s) involved to disclose the conflicting interest in each public presentation of the results of the research.

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

### **Pop Quiz - Multiple Choice**

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

A) Request additional information regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias.

B) Inquire into the Institutional procedures and actions regarding FCOIs in research funded by the NIH.

C) After its review of information and records, may determine that suspension of funding is necessary until the matter is resolved.

D) All of the above.

E) None of the above.

D is the correct answer.

### **Pop Quiz Review**

Let's try that again. What action may the NIH take under this regulation?

After reviewing information and records, the NIH may determine that suspension of funding is necessary until the matter is resolved.

Inquire into the Institutional procedures and actions regarding FCOIs in research funded by the NIH.

Request additional information regarding all conflicting interests identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias.

The answer is all of the above.

### **Institutional Responsibilities**

An Institution refers to any domestic or foreign, public or private, entity or organization (excluding a Federal agency) applying for NIH grants and cooperative agreements for research or submitting a proposal for a research contract whether in response to a solicitation or otherwise.

The Regulation requires that the Institution:

- Create and maintain a written and enforced policy stating the procedures for implementing the regulation.
- Inform each Investigator of the FCOI regulation, of the Institution's FCOI policy, and of the Investigator's disclosure responsibilities under the regulation and the policy.

If the Institution carries out the NIH-funded research through subgrantees/contractors/subcontractors/collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulation either by requiring those Investigators to comply with the Institution's policy or by requiring the Investigator's entity to provide assurances to the Institution that will allow the Institution to comply with the regulation. Please see 42 CFR Section 50.604(a) for grants and cooperative agreements and 45 CFR Part 94.4(a) for contracts. With respect to grants or cooperative agreements, this arrangement should be defined in a formal written agreement with each consortium participant. Please see the NIH Grants Policy Statement at [http://grants.nih.gov/grants/policy/nihgps\\_2003/NIHGPS\\_Part12.htm#\\_Toc54600259](http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part12.htm#_Toc54600259).

- Designate an institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- Provide guidelines to the designated official(s) to identify FCOIs.
- Proceed with appropriate actions to manage, reduce, or eliminate any FCOIs.
- Maintain records of all financial disclosures and all actions taken by the Institution with respect to each FCOI as follows: (1) in the case of grants or cooperative agreements, for at least three years from the date of submission of the final expenditures report, or where applicable, from other dates specified in 45 CFR 74.53(b) for different situations; (2) in the case of research contracts, for three years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7.
- Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- Certify, in each application for funding to which the regulation applies, that the Institution has a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH.
- By the time of application, require that each Investigator who is planning to participate in the research has submitted to the Institutional designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children) 1) that would reasonably appear to be affected by the research for which funding is sought; and 2) in entities whose financial interest would reasonably appear to be affected by the research.
- Report the existence of any FCOI to the NIH accurately and in a timely manner as required by the regulation:
  - Prior to the Institution's expenditure of any funds under the award, the Institution must report to the NIH the existence of an FCOI (but not the nature of the interest or other details) found by the Institution and assure that the conflicting interest has been managed, reduced, or eliminated.

- For any FCOI that the Institution identifies subsequent to the Institution's initial report under the award, the Institution must report the FCOI and manage, reduce, or eliminate it, at least on an interim basis, within 60 days of that identification.
- Agree to make information available upon request to the NIH regarding all FCOIs identified by the Institution and how those conflicting interests have been managed, reduced, or eliminated.

### **What are the requirements for an Institution's written and enforced policy?**

It is the responsibility of the Institution to identify and manage, reduce, or eliminate any FCOIs.

An Institution may administer its policy through whichever office or structure it chooses, as long as the requirements of the regulation are met.

If the Institution carries out the NIH-funded research through subgrantees/contractors/subcontractors/collaborators, the Institution must take reasonable steps to ensure that Investigators working for these entities comply with the regulation, either by requiring those Investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulation.

The regulation requires that each Institution must maintain a written, enforced policy on conflict of interest that conforms to the following requirements:

- Complies with the regulation;
- Informs each Investigator of the Institution's policy as well as the FCOI regulation;
- Informs each Investigator of his or her disclosure responsibilities; and
- Provides adequate guidelines for enforcement mechanisms and sanctions where appropriate.

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

The Institution must establish a procedure to solicit and review financial disclosure statements from each Investigator who is planning to participate in the NIH-funded research. The financial disclosures should include a listing of the Investigator's Significant Financial Interests (as well as those of his/her spouse and dependent children) 1) that would reasonably appear to be affected by the research for which NIH funding is sought and 2) in entities whose financial interests would reasonably appear to be affected by the research.

After reviewing the financial disclosure, the responsible Institutional official(s) must determine whether an FCOI exists; and if so, what actions should be taken by the Institution to manage, reduce or eliminate such a conflict.

An FCOI exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of NIH-funded research.

### **What information must the Institution provide to the NIH and when?**

At the time of the application, the Institution certifies that it has a written and enforced administrative process to identify and manage, reduce, or eliminate conflicting financial interests with respect to all research projects for which it seeks funding from the NIH.

Prior to spending any funds under an award, the Institution must report to the NIH the existence of any identified FCOI and assure that the FCOI has been managed, reduced, or eliminated in accordance with the regulation.

The regulation does not require the Institution to report to designated NIH officials the nature or other details of a reported FCOI; however, the Institution is required to make information available, upon request, to the NIH regarding all FCOIs identified by the Institution and how those interests have been managed, reduced, or eliminated to protect the research from bias.

During the period of award, the Institution must ensure that all financial disclosures are updated either on an annual basis or as new Significant Financial Interests are obtained 1) that would reasonably appear to be affected by the NIH research; and 2) in entities whose financial interests would reasonably appear to be affected by the research.

When an FCOI is identified after the initial report, the Institution must report it to the NIH and the FCOI be managed, reduced, or eliminated, on at least an interim basis, within 60 days of the identification.

For grants and cooperative agreements, FCOI reports should be sent to the appropriate Chief Grants Management Officer of the NIH funding Institute/Center [http://grants.nih.gov/grants/stafflist\\_gmos.htm](http://grants.nih.gov/grants/stafflist_gmos.htm). For contracts, reports should be sent to the appropriate Director, Office of Acquisitions [http://oamp.od.nih.gov/AcquisitionOffices/chief\\_cos1.asp](http://oamp.od.nih.gov/AcquisitionOffices/chief_cos1.asp).

The Institution's report should include the following information:

- Grant or contract number, as appropriate,
- Principal Investigator or contact Principal Investigator if the grant/contract is awarded under the Multiple PI Model,
- Investigator with the FCOI, and
- Specify whether the conflict has been managed, reduced, or eliminated.

### **What should be done in the event that non-compliance with the Institution's FCOI Policy results in bias?**

In the event that an Investigator's failure to comply with the Institution's FCOI policy has biased the design, conduct, or reporting of the NIH-funded research, the Institution must promptly notify the NIH awarding component of the corrective action taken or to be taken. The NIH will review the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions on how to maintain appropriate objectivity in the funded project.

### **Pop Quiz - 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) Both A and B.
- D) Neither A nor B.

C is the correct answer.



## Investigator Responsibilities

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

“Investigator” refers to the Principal Investigator and any other person who is responsible for the design, conduct, or reporting of research funded by the NIH or proposed for such funding, including Investigators working for subgrantees/contractors/subcontractors/collaborators. The term Investigator includes the Investigator’s spouse and dependent children.

Note that these responsibilities are not limited to the Principal Investigator or 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 Institutional 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;
- Submitting to the Institutional designated official(s) by the time of application, a list of his/her known Significant Financial Interests (and those of his/her spouse and dependent children) 1) that would reasonably appear to be affected by the NIH research; and 2) in entities whose financial interests would reasonably appear to be affected by the research;
- During the period of award, updating all financial disclosures to the Institution according to its policy, either on an annual basis or as new Significant Financial Interests are obtained 1) that would reasonably appear to be affected by the NIH research; and 2) in entities whose financial interests would reasonably appear to be affected by the research.

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

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

The FCOI regulation requires the Investigator to disclose to the Institution by the time the application is submitted to the NIH all known Significant Financial Interests are obtained that 1) would reasonably appear to be affected by the NIH research; and 2) in entities whose financial interests would reasonably appear to be affected by the research.

The term “Significant Financial Interest” is defined by the regulation as anything of monetary value, including but not limited to:

- salary or other payments for services (e.g., consulting fees or honoraria);
- equity interests (e.g., stocks, stock options, or other ownership interests);
- intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

The term "Significant Financial Interest" does **not** include:

- salary, royalties, or other remuneration from the Institution;
- any ownership interests in the Institution, if the Institution is an applicant under the SBIR Program;
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- income from service on advisory committees or review panels for public or nonprofit entities;
- an equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both the following tests: 1) does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and 2) does not represent more than a five percent ownership interest in any single entity; or
- salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months are not expected to exceed \$10,000.

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

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

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

An interest in a pooled fund such as a diversified mutual fund may be sufficiently remote that it would not reasonably be expected to create a FCOI for an Investigator funded by the NIH. However, disclosure of such interests should be guided by your Institution's policies.

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

Stock option assets that constitute a Significant Financial Interest should be disclosed annually or as new stocks are obtained according to the Institution's policy, in the same manner as any Significant Financial Interest. The documentation needed to determine the value of a stock option is defined by the Institution.

#### **Are blind trusts required to be disclosed?**

Investigators should consult the Institution's policy on this question. Institutions may determine that the research will not be affected by qualified blind trust assets not known to the Investigator that are managed by an independent fiduciary. Because such assets would not be known to an Investigator, they could not directly and significantly affect the design, conduct or reporting of the research. Of course, an Investigator is aware of the assets originally placed in the trust at the time of its formation and would be required to disclose any such assets that constitute Significant Financial Interests that would reasonably appear to be affected by research funded by the NIH and in entities that would reasonably appear to be affected by the research. Only new assets purchased with the proceeds from the original assets would be unknown to the Investigator.

## Are foreign investments (e.g., shares in a foreign corporation) covered by the financial disclosure requirement?

Yes, if the investments constitute Significant Financial Interests 1) that would reasonably appear to be affected by the NIH research; and 2) in entities whose financial interests would reasonably appear to be affected by the research.

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

Please note that the Institution may have a broader policy with additional requirements beyond the FCOI regulation's requirements. Investigators should consult the Institution's policy and with appropriate Institutional designated official(s).

The FCOI regulation does not require that Investigators disclose an equity interest that when aggregated for the Investigator and his/her spouse and dependent children, does not exceed \$10,000 in value and does not represent more than five percent ownership in any single entity. Salary, royalties or other payments that when aggregated for the investigator and his/her spouse and dependent children over the next twelve months are not expected to exceed \$10,000 are also excluded from the disclosure requirements.

Salary, royalties, or other remuneration from your Institution are not included in the regulation's financial disclosure requirements.

Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities and income from service on advisory committees or review panels for public or nonprofit entities do not need to be disclosed under the regulation.

## Pop Quiz - True/False

Please indicate whether the following statement is true or false.

The term "Significant Financial Interest" 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.

The statement is true.

## In Closing

It is vitally important that we - the NIH, Institutions, and Investigators - work together to ensure 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 assure that research is unbiased and will maintain the public's trust in the research endeavor. The future of the entire research enterprise depends on the actions that we take today.

In case of questions about a potential conflict and how to ensure 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 web site that may be helpful in answering questions related to grants and cooperative agreements <http://grants.nih.gov/grants/policy/coi/index.htm>.