

---

*The primary objective of conflict of interest review is to protect the integrity of research. Financial interests with entities outside USF are not inherently unethical, illegal or wrong. However, these interests must be managed to ensure the objectivity of the research and teaching process, the safety of research participants, and the reputations of our researchers and of USF itself. This training module provides guidance regarding Investigators' responsibilities under the USF Financial Conflict of Interest Policy (No. 0-309).*



## Financial Conflict of Interest (FCOI) Training for Investigators

### Applicability

When USF employees or students participate as an [Investigator](#) in a [USF Research Project](#), they are subject to the [USF Financial Conflict of Interest \(FCOI\) Policy 0-309](#). The policy has specific requirements for [Federally-Funded Investigators](#) (including research funded by [PHS and Certain Federal Agencies, Foundations, or Extramural Sponsors](#) that have adopted the [PHS Objectivity in Research Rule](#)).



**Not sure if your study is funded by a PHS component?**

[Click here.](#)

## Disclosure Requirements:

**Federally-Funded Investigators** are required to disclose whether they or their [Immediate Family](#) member have a [Significant Financial Interest \(SFI\)](#) that reasonably appears to be related to their [Institutional Responsibilities](#). Such disclosures must be made via the ARC portal by completing an [eCOI Interest Inventory](#) periodically as follows:

- 1) **At Proposal** (i.e., prior to the submission of the proposal); and
- 2) **At Notice of Award** (i.e., confirm or update existing disclosure's accuracy);
- 3) **Within thirty (30) days of discovering or acquiring a new SFI**; and
- 4) **Annually** during the [Period of the Award](#).



**Subrecipient Investigators** subject to USF's FCOI Policy are required to disclose whether they or their Immediate Family members have a SFI that is directly related to their work under their Subrecipient Agreement. Subrecipient disclosure requirements only apply to projects funded in whole or in part by the National Science Foundation (NSF) or PHS and Certain Federal Agencies, Foundations, or Extramural Sponsors that have adopted the PHS Objectivity in Research Rule.



## What constitutes a Significant Financial Interest (SFI)?

Any one or more of the following seven types of financial interests that you or your Immediate Family members have would be considered a "[Significant Financial Interest](#)" under the USF FCOI Policy:

1) **Financial interests exceeding \$5000 in publicly-traded entities.**



How is this value calculated? Add the value of any [Remuneration](#) received within the past 12 months to the value of any equity interest as of the date of the disclosure (i.e., remuneration + equity). If this value exceeds \$5000, then you have an SFI, unless an exclusion applies.

2) **Remuneration exceeding \$5000 from a non-publicly traded entity**, received within the past 12 months.

3) **Any equity interest in a non-publicly traded entity.**

4) **A proprietary interest**, e.g. patents, copyrights, royalties, licensing fees, etc.

5) **Role as director, officer, partner, trustee or member of board of directors** (with or without compensation).

6) **Paid authorships** including ghostwriting.

7) **Reimbursed or sponsored travel** (PHS-Funded Investigators only)



Investigators must disclose **all** SFIs related to their Institutional Responsibilities; whereas, Subrecipients must only disclose SFIs directly related to their work under the subcontract.

### ***The following are not SFIs:***

*If received from an Exempt Organization, reimbursement or sponsorship of travel, income from service on advisory committees or review panels, seminars, lectures, or teaching engagements.*

*An Exempt Organization is a federal, state, or local government agency, a U.S. institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with a U.S. institution of higher education.*

*Any salary or other remuneration you receive from USF as a USF employee or appointee, with the exception of any income you receive from shared royalties related to intellectual property rights assigned to USF.*

*Income from investment vehicles, such as mutual funds and retirement accounts, as long as you do not control the investment decisions made in those vehicles, such as mutual funds and retirement accounts.*



## FCOI Training Requirements

All Federally-Funded Investigators and Subrecipient Investigators bound by the USF FCOI Policy must periodically complete training, referred to as “FCOI Training”, as follows:

### Key Points to know...



#### When Submitting Federally-Funded Proposals:

All Investigators must complete an Interest Inventory in the ARC system *prior to* submitting the proposal.

*Note: Per USF policy, proposals will not be submitted without Interest Inventories for each Investigator named on the proposal.*



#### At Notice of Award:

Confirm the accuracy of each [Interest Inventory](#) prior to receiving funding for the project.



#### During the Period of Award:

Update your Interest Inventory in the ARC system. New Investigator(s) must submit an Interest Inventory prior to their participation on the project.

- 1) **Prior to engaging in a USF Research Project funded by a federal agency** or by an organization which has adopted the PHS regulation for objectivity in research; and
- 2) **At least every three years** during the Period of the Award; and
- 3) **Immediately**, when any of the following circumstances apply:
  - a. USF revises the USF FCOI Policy or its associated procedures in any manner that affects Investigator requirements; or
  - b. An Investigator is new to USF; or
  - c. USF finds that an Investigator is not in compliance with the USF FCOI Policy or an [FCOI Management Plan](#).



**What happens to your SFI disclosures?** USF will review your Interest Inventory and determine whether or not any disclosed SFIs could *directly and significantly* affect the design, conduct, or reporting of your USF Research Project. Such SFIs are considered a Financial Conflict of Interest (FCOI) and require development and implementation of a FCOI Management Plan. Pursuant to federal regulations, USF is obliged to report FCOIs related to PHS-funded projects to the appropriate funding agency and to monitor these FCOIs to ensure adherence to the FCOI Management Plan.

**Public Disclosure of FCOI Information for PHS-Funded Research.** PHS regulations require that the following information be publically available upon request: name, title, and role of the person with the FCOI; name of the entity/interest in which the SFI is held; the nature and approximate dollar value or range of the SFI, or a statement that the value cannot be readily determined.

### **What happens if SFIs are not disclosed or other noncompliance with the USF FCOI Policy is found?**

Whenever USF identifies a SFI that should have been disclosed, discovers that a management plan is not being followed, or otherwise finds noncompliance with the FCOI Policy for a PHS-Funded project, PHS regulations require USF to perform a [Retrospective Review](#) to determine whether any portion of the research was biased in the design, conduct, or reporting of such research prior to the discovery of the noncompliance. If bias is found, USF must submit a [Mitigation Report](#) to the funding agency. For projects funded by other federal agencies, USF will comply with required reporting. The USF Conflict of Interest Committee may make a determination of noncompliance regardless of funding source.

Noncompliance may result in one or more of the following:

- Disciplinary action under any applicable USF regulation, policy, or collective bargaining agreement.
- Termination of your current awards.
- Inability for you to receive future awards.
- Inability for USF to receive future awards.



## FCOI Training Glossary of Terms

### **Investigator:**

Means the project director or principal investigator and any other person (faculty, staff, students, and collaborators or consultants outside of USF), regardless of title or position, who is responsible for the design, conduct, or reporting of a USF Research Project. "Design, conduct or reporting" includes, but is not limited to:

- Designing, conducting, and/or directing a USF Research Project.
- Applying, on behalf of USF, for grants or awards to perform the USF Research Project.
- Serving as the principal investigator/program director, co-investigator, or sub-investigator.
- Enrolling research subjects (including obtaining informed consent, if applicable) or making decisions related to eligibility for enrollment.
- Analyzing, reporting, presenting or publishing research data.

All key personnel listed on a submission for the USF Research Project to the USF Institutional Research Board (IRB) or any other institutional review board, the USF Institutional Animal Care and Use Committee (IACUC), or the applicable Sponsored Research office are Investigators. Also, any Investigator working on a USF Research Project as a sub-grantee, contractor, or collaborator via a subcontract, sub-award, or other agreement is an Investigator for purposes of this definition.

### **USF Research Project:**

Any systematic investigation (i.e., the gathering and analysis of information), including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, whether or not it is made available to the general public, involving a USF employee, student, or other person where USF is responsible for the oversight and/or administration of the activity. Activities that contribute to generalizable knowledge are those that include, but are not limited to, the following:

- attempt to make comparisons or draw conclusions from the gathered data;
- attempt to reach for generalizable principles of historical or social development;
- seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes;
- create general explanations about what has happened in the past; or
- predict the future.

### **USF Financial Conflict of Interest Policy 0-309:**

This policy can be found at the following URL: <https://usf.app.box.com/v/usfpolicy0-309>

### **Federally-Funded Investigator:**

An Investigator who seeks or receives funding from a federal agency.

### **Funded by Public Health Service (PHS) or Certain Federal Agencies, Foundations, or Extramural Sponsors:**

A USF Research Project where the awarding component is an organizational unit of the Public Health Service (PHS) or one of the sponsors that has adopted the PHS Objectivity in Research Rule. This definition will be expanded as needed to comply with the official requirements imposed by additional federal agencies and extramural sponsors.

### **Immediate Family:**

Spouse, domestic partner, and each dependent child.

### **Significant Financial Interest:**

- I. An opportunity for the Investigator (or his/her Immediate Family) for economic gain or an external commitment that relates to, or could reasonably be affected by, the outcome of the proposed or current USF Research Project, including:
  - a. 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**.
  - b. With regard to any *non-publicly traded entity*, a Significant Financial Interest exists:
    - i. if the value of any Remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds **\$5,000**, OR
    - ii. when the Investigator (or the Investigator's Immediate Family) holds any equity interest (e.g., stock, stock option, or other ownership interest);
  - c. A position as director, officer, partner, trustee or member of board of directors of any entity related to the USF Research Project, whether or not remuneration is received for such service;

### Significant Financial Interest continued:

- d. A proprietary interest in the USF Research Project (e.g., patents, trademarks, copyrights or licensing agreements in the test article or method), and royalties of any amount from such rights, including those royalties distributed by the University. A proprietary interest is considered to be present as soon as protection is sought (e.g. upon submission of an Invention Disclosure Form to the USF Technology Transfer Office, upon filing of a patent application, etc.).
- II. For PHS-Funded Investigators only, 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 the PHS-Funded Investigator's Institutional Responsibilities. The details of the travel disclosure will include at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. USF 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.
- III. Any other financial interest or external commitment that an Investigator believes may interfere with his or her ability to oversee or participate in research without bias.

### Exclusions:

The following interests are excluded from the definition of Significant Financial Interests:

1. Salary or other Remuneration received from USF if the Investigator is currently employed or otherwise appointed by USF, with the exception of royalties distributed by the University.
2. 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, except where the value of the equity in one publicly-traded company related to the research exceeds \$50,000.
3. Income from seminars, lectures, or teaching engagements sponsored by an Exempt Organization.
4. Income from service on advisory committees or review panels for an Exempt Organization.
5. Reimbursed or sponsored travel that is reimbursed or sponsored by an Exempt Organization.  
42 CFR §50.603(1), (2), and (3).



**Exempt Organization**

A federal, state, or local government agency, an Institution of higher education as defined in 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. 42 CFR §50.603(2)

**Institutional Responsibilities:**

An Investigator's professional responsibilities on behalf of USF, including but not limited to teaching, research, research consultation, professional practice, and USF committee memberships.

**Interest Inventory:**

The disclosure to be completed in the ARC System which a Federally-Funded Investigator discloses Significant Financial Interests related to the Investigator's Institutional Responsibilities.

**Period of the Award:**

The time frame of the USF Research Project as stated in the award document, including any extensions.

**PHS Objectivity in Research Rule:**

For more information, please see: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50#subpart-F>

**Remuneration:**

Salary and any form of payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), including equity interests (e.g., stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value).

**FCOI Management Plan:**

A management plan prepared by the COI Committee in the event an Investigator is determined to have a Financial Conflict of Interest per USF Policy No. 0-309.

**Mitigation Report:**

Please see the Mitigation Report section of the USF Financial Conflict of Interest Policy 0-309. This policy can be found here: <https://usf.app.box.com/v/usfpolicy0-309>

**Retrospective Review:**

The review conducted by USF upon determining 1) that an SFI not timely disclosed or reviewed is an FCOI or 2) that a PHS-Funded Investigator has failed to comply with an FCOI Management Plan. The Retrospective Review will consist of a review of the PHS-Funded Investigator's activities and the USF Research Project Funded by PHS to determine whether any portion of the research was biased in the design, conduct, or reporting of such research prior to the identification and management of the FCOI or during the period of noncompliance of the PHS-Funded Investigator with the FCOI Management Plan. The Retrospective Review will be documented and will include, but not be limited to:

- i. Project number;
- ii. Project title;
- iii. PD/PI or contact PD/PI if a multiple PD/PI model is used;
- iv. Name of the PHS-Funded Investigator with the FCOI;
- v. Entity with which the PHS-Funded Investigator has an FCOI;
- vi. Reason(s) for the Retrospective Review;
- vii. Detailed methodology used for the Retrospective Review (e.g., methodology of the Retrospective Review process, composition of the Retrospective Review panel, documents reviewed);
- viii. Findings of the Retrospective Review (i.e., facts and observations); and
- ix. Conclusions of the Retrospective Review (i.e., determination and recommended actions).