

# 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

## Disclosure Requirements:

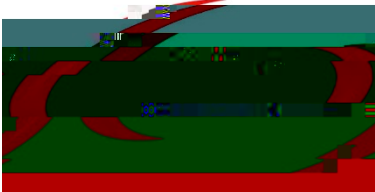
Federally -Funded Investigators are required to disclose whether they or their [Immediate Family](#) member have a [Significant Financial Interest \(SFI\)](#) that reasonably appears to be related to their [Institutional Responsibilities](#). Such disclosures must be made via the ARC portal by completing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

- 1) At Proposal (i.e., prior to the submission of the proposal)

## 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 USFFCOI Policy :

- 1) Financial interests exceeding \$5000 in publicly-traded entities.
- 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 (PHSFunded Investigators only)



### 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



What happens to your SFI disclosures? USF will review your In

## 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:

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O \$SSO\LQJ RQUSFHDQWV or awards to perform the USF Research Project.

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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

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 PHSFunded 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).





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).