
Disclosure of Significant Financial Interests and Obligations Guidance

For Public Health Service (PHS)/National Institutes of Health (NIH) supported applications or contract proposals, whether new or continuing research, information on "**Significant Financial Interests**" that would reasonably appear to be affected by the research must be disclosed to the Institution's designated official(s) by **any Investigator responsible for the design, conduct or reporting of PHS -supported research before** an application is submitted to the funding agency.

Prior to award, the institution must manage, reduce, or eliminate any conflicts of financial interests, i.e., those that could directly and significantly affect the design, conduct or reporting of the research.

When an Investigator, through the University, carries out PHS funded research through a subrecipient, the University as the awardee Institution will take reasonable steps to ensure that any subrecipient Investigator complies with RF/SUNY policy.

Before spending funds for PHS-supported research, an Institution shall ensure public accessibility of information on certain Significant Financial Conflicts of Interest (FCOI) that the Institution has determined are related to the PHS-funded research and are FCOI, via a publicly accessible website **or** by a written response to any requestor within 5 days of the request.

Quick Start

I have/am applying for PHS/NIH-sponsored research. In a nutshell, what do I need to do?

Investigators must do **two** things:

- 1- [Complete the required FCOI training](#)
- 2- [Submit Significant Financial Interests and Obligations Disclosure](#)

Required FCOI Training F.A.Q.s

Who is required to take the FCOI training?

PHS/NIH Investigators are required to complete this training for compliance with PHS

regulations. However, any University at Albany personnel who wishes to complete this training module may do so.

How do I complete the FCOI training?

The University at Albany offers an on-line FCOI training program through the CITI Program. Please follow the instructions below. Contact the Office of Regulatory Research Compliance, ORRC@albany.edu or 518-442-9050, if you require assistance.

Go to the CITI website at: <https://www.citiprogram.org/default.asp>

- A- If you have **never logged into CITI previously**, follow the registration instructions. PLEASE NOTE: When choosing an institution to affiliate with, Choose, “SUNY - University at Albany” --Do not choose Albany State University.) When you are asked to Select Curriculum, scroll down to: “**Question 4- Would you like to take the Conflict of Interest mini-course?**” Choose “Yes”, and continue to the learner modules.
- B- If **you have already previously registered for other CITI training** (e.g., human subjects/IRB training, etc.), after you log in, under your “SUNY – University at Albany” course(s), choose the link to “Add a course or update your learner groups”, scroll down to: “**Question 4 Would you like to take the Conflict of Interest mini-course?**” Choose “Yes”, and continue. The modules will be added to your learner modules.

How long will it take to complete the training?

The training modules should take 15-20 minutes to complete.

Is a refresher (re-certification) required?

Yes. The CITI course completion certificate is valid for four years. Once completed, training is required once every four years thereafter, and immediately under designated circumstances

How to I provide proof of my disclosure(s) when applying for PHS sponsored research?

At the time of application for PHS Funds, Investigator must **upload PDF copy(ies) of CITI FCOI training completion report(s) into Coeus as “Institutional Attachments.”**

Significant Financial Interests and Obligations Disclosure Form F.A.Q.s

Who must submit a Disclosure?

PHS requires that each investigator planning to participate PHS-funded research to disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) (i) that would reasonably appear to be affected by the research or educational activities funded or proposed for funding by PHS; or (ii) could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

- ◆ **PHS definition of "Investigator"** -- project director or principal investigator and any other person, including a student or post-doctoral fellow, 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. With respect to financial interests, "Investigator" includes the Investigator's spouse and dependent children ("Related Party").

Which Disclosure Form(s) am I required to complete?

Please complete the [PHS Disclosure of Significant Financial Interests and Obligations](#). It is a two-part form:

- 1- All PHS investigators must complete and submit **Part I**.
- 2- If an investigator answers "Yes" to any of the questions on Part I, **only then** must the investigator complete and submit **Part II**.

When do I submit the Disclosure Form?

Submission of the Significant Financial Interests and Obligations Disclosure form is required:

- a. At the time of application for funds,
- b. Annually thereafter during the period of the award, and
- c. Within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest.

I am not sure what I am required to report. What does PHS consider a "Significant Financial Interest of Obligation"?

The PHS definition of "Significant Financial Interest" (SFI) of Investigator or Related Party is one that reasonably appears to be related to the Investigator's "Institutional Responsibilities" and consists of one or more of the following:

- a. With regard to any publicly traded entity, a SFI exists if:

- i. the **value of any remuneration**¹ received from the entity in the twelve months preceding the disclosure; **and**
 - ii. the value of any **equity interest**² in the entity as of the date of disclosure, when aggregated, **exceeds \$5,000**.
- b. With regard to any non-publicly traded entity, a SFI exists if:
 - i. the **value of any remuneration** received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, **or**
 - ii. the Investigator (or a Related Party) holds any **equity interest** (e.g., stock, stock option, or other ownership interest);
- c. **Intellectual property rights and interests** (e.g., patents, copyrights), and royalties from such rights, upon receipt of income related to such rights and interests; or
- d. **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 known by the Investigator), related to the Investigator's Institutional Responsibilities, in an amount or estimated amount in excess of \$500. Excluded from this requirement is 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.

Exclusions-

- ◆ Salary, royalties, or other remuneration paid by SUNY or RF to the Investigator if the Investigator is currently employed or otherwise appointed by SUNY or the RF;
- ◆ Intellectual property rights assigned to SUNY or RF and agreements to share in royalties related to such rights;
- ◆ Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator or a Related Party does not directly control the investment decisions made in these vehicles;
- ◆ Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- ◆ Income from service on advisory committees or review panels for a federal, state or local government agency, institution of higher education as defined at 20 U.S.C.

¹ Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

² 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.

1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

- ◆ 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.

For more detailed definitions, thresholds, and guidance, please refer to [State University of New York and The Research Foundation for The State University of New York, PHS Policy on Conflicts of Interest in Public Health Service Sponsored Programs](#)

What is the definition of “Institutional Responsibilities?”

“Institutional Responsibilities” are the Investigator's professional responsibilities on behalf of SUNY and/or RF, which may include 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.

Where/to whom do I submit the Disclosure Forms (s)?

At the time of application for PHS Funds, the Investigator must submit the full disclosure via email to: Angelica Hutchinson in the Office of Sponsored Programs ahutchinson@albany.edu

How to I provide proof of my disclosure(s) when applying for PHS sponsored research?

At the time of application for PHS Funds, the Investigator must upload PDF copy(ies) as “*Institutional Attachments*” into Coeus of **PART I of the Disclosure Form(s)**.

- ◆ **Do not upload Part II of the Disclosure into your Coeus application** – even if you are required to submit Part II with your disclosure to the DIO.

Who will review my Disclosure Form(s)?

The DIO will review all FCOI submissions. If a potential FCOI is identified, the submission will be forwarded to the University’s Conflicts of Interest Committee. The Committee will review the information and assist in the development of management plan, working with the Investigator and the DIO, to mitigate significant conflicts that have been identified.

The Conflict of Interest Committee is appointed by the Vice President for Research to review financial disclosure statements for the potential of conflict of interest. The committee is composed of the Research Compliance Officer, a representative each from University/Research Foundation Human Resources office and University Counsel’s office, Office of Innovation and Technology Transfer; and representatives from the faculty. All discussions and findings shall be kept confidential to the extent possible.

What happens if a FCOI is identified?

A Financial Conflict of Interest exists when a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

For all identified FCOIs, the Conflict of Interest Committee and the DIO will work with the Investigator in the development of a management plan (which may include the reduction or elimination of the Significant Financial Interest). Examples of conditions or restrictions that a management plan might include are:

- a) Public disclosure of FCOIs;
- b) Monitoring of research by independent reviewers;
- c) Modification of the research plan;
- d) Disqualification from participation in the portion of the research that could be affected by the FCOIs;
- e) Divestiture of SFIs;
- f) Severance of relationships that create actual or potential conflicts;
- g) Removal of Investigator as Principal Investigator/Project Director; and
- h) Additional remedies specific to the conduct of research involving human subjects, including but not limited to, disclosure in the consent process of the Investigator's FCOI, and removal of the Investigator's ability to recruit research subjects.

The FCOI and the management plan will be reported to PHS for all identified FCOI's. The DIO will monitor compliance with the applicable management plan. Such monitoring will be documented and maintained in accordance with the PHS Regulations.

Questions?

FCOI Disclosure Questions, contact: Adrienne Bonilla, Esq., Assistant Vice President and Director, Office of Regulatory Research Compliance, abonilla@albany.edu

COEUS upload issues and general questions, contact: Tamar Sayer, Assistant Director, Office for Sponsored Programs, tsayer@albany.edu.