

## Public Health Service (PHS) Funded Research

The PHS regulations on Objectivity in Research are designed to promote objectivity by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of PHS Research Activities will be free from bias resulting from any Investigator's Financial Conflicts of Interest. At UWM, PHS objectivity in research requirements are addressed in the [FCOI in PHS Funded Research Policy](#). For PIs, co-investigators, and key personnel on PHS-funded awards, there are additional steps required including,

Significant Financial Interest Disclosure (SFID) submission

Federal Conflict of Interest Training (FCOI) completion

Application of Management Plans (completed with assistance from the Research Conflict of Interest Committee and the Office of Research)

### Definitions

**Financial Conflict(s) of Interest (FCOI):** A Significant Financial Interest that could directly and significantly affect the design, conduct or reporting of PHS Research Activity.

**Investigator:** The Principal Investigator or project director and any other person regardless of title or position who is responsible for the design, conduct or reporting of research proposed for funding or funded by PHS. This includes, but is not limited to, Key Personnel named on a proposal budget.

**PHS-Funded Research:** Research funded by Public Health Service entities (which include the National Institutes of Health (NIH), the Centers for Disease Control (CDC), and others, [listed here](#)), as well as non- federal agencies which also follow PHS FCOI regulations (such as those [listed here](#)).

**Significant Financial Interest (SFI):** Anything of monetary value that meets the PHS thresholds (see [Significant Financial Interest Disclosure](#) below) for reporting received by the Investigator and, except for travel, received by the Investigator's spouse and dependent children for the following categories and reasonably appears to be related to or is in the same field of expertise as the Investigator's Institutional Responsibilities.

**Significant Financial Interest Disclosure (SFID):** The required form to indicate whether or not there is an SFI. If the form is positive, this includes review and approval by Department, School/College, and Office of Research approvers as necessary.

### FCOI Training

#### Who Needs to Complete FCOI Training

UWM requires all Investigators engaged in PHS-funded research to receive training in financial conflicts of interest.

#### What Needs to be Completed

The FCOI course is a three-module course addressing Financial Conflicts of Interest, Conflicts of Commitment and Conscience, and Institutional Responsibilities As They Affect Investigators.

#### When FCOI Training Must Be Completed

FCOI Training must be completed every four years or, per federal guidelines, when changes to the UWM's FCOI policies change in a manner that affects Investigator requirements. The UWM Office of Sponsored Programs

(OSP) will check an Investigator’s FCOI training status each time they begin the setup of an award account with PHS-funded research on which an Investigator is PI or senior/key personnel. Notification will be sent via email to ensure FCOI training is up-to-date. Spending on new and non-competing PHS funded award accounts will not be permitted until FCOI training of all senior/key personnel is complete.

**How to Complete FCOI Training**

The course is available at [the CITI website](#). Select University of Wisconsin – Milwaukee from the dropdown menu. Then go to Choose Courses, Add a Course, and select Financial Conflicts of Interest (FCOI).

For questions about FCOI training, please contact the [RCOI Committee Administrator](#).

**Significant Financial Interest Disclosure**

**Who Needs to Fill Out an SFID**

Anyone who is an Investigator on a PHS-Funded Research application must complete an SFID prior to submission of the proposal. Anyone who is an Investigator on PHS-Funded Research must complete an SFID prior to award set-up, and every year thereafter that they are on PHS-Funded Research.

**What Needs to Be Reported on an SFID**

According to federal regulations and UWM policy, the following interests of an Investigator, or an Investigator's spouse or dependent children, constitute an SFI:

***PUBLICLY TRADED ENTITIES***

<b><i>REPORTABLE</i></b>	<b><i>NON-REPORTABLE</i></b>
The value of remuneration received from an entity in the twelve months preceding disclosure, in combination with the value of any equity interest in the company as of the date of disclosure, <b>exceeds \$5,000</b>	Remuneration received in the twelve months preceding disclosure, in combination with the value of any equity interest in the company as of the date of disclosure <b>does not</b> exceed \$5000

***NON-PUBLICLY TRADED ENTITIES***

<b><i>REPORTABLE</i></b>	<b><i>NON-REPORTABLE</i></b>
The value of any remuneration received from an entity in the twelve months preceding disclosure <b>exceeds \$5,000</b>	Remuneration received in the twelve months preceding disclosure <b>does not</b> exceed \$5000

***EQUITY INTEREST IN A COMPANY***

<b><i>REPORTABLE</i></b>	<b><i>NON-REPORTABLE</i></b>
Income from intellectual property rights received during the previous twelve months that <b>exceeds \$5,000</b>	Royalty income from intellectual property that arose from University employment and that was assigned to UWM Research Foundation
Service in positions with fiduciary responsibility, including executive positions, senior management positions, or memberships on boards of directors	Service in positions with no fiduciary responsibility or remuneration

## TRAVEL

<b>REPORTABLE</b>	<b>NON-REPORTABLE</b>
All reimbursed and sponsored travel over the last twelve-month period	Non-reimbursed travel (i.e. personal travel)
New travel within 30 days of the start of the travel event reimbursed made by an outside entity to cover expenses paid by a PHS funded Investigator as part of a travel event	Travel reimbursed by a federal, state, or local U.S. government agency, a U.S. institution of higher education, a U.S. academic teaching hospital, a U. S. medical center, a research institute affiliated with a U.S. institution of higher education, or travel covered through UWM's e-Reimbursement system

### When Does an SFID Need to Be Completed

Anyone who is an Investigator on a PHS-Funded Research application must complete an SFID prior to submission of the proposal. Anyone who is an Investigator on PHS-Funded Research must complete an SFID prior to award set-up, and every year thereafter that they are on PHS-Funded Research.

### How to Complete an SFID

Investigators who are submitting an application for or have received an award for PHS-Funded Research and do not have a completed SFID within the last 12 months should complete one in the [SFID portal](#). If any assistance with the portal is needed, Investigators should contact the [RCOI Committee Administrator](#).

### SFID Approval

Investigators who do not have an SFI to report will have their SFID forwarded to the RCOI Committee for review. Investigators who do have an SFI to report will have the SFID routed to their Chair, Dean, and the Vice Provost of Research to approve and to give insight into whether or not it might be a conflict of interest. Once signed by all of the approvers, the SFID is forwarded to the RCOI Committee administrator for review.

### Approver Training

Chairs and Deans who approve SFID Forms are required to complete the FCOI Approvers course in CITI. The FCOI approver course is a four-module course addressing Financial Conflicts of Interest, Conflicts of Commitment and Conscience, and Institutional Responsibilities As They Affect Investigators, and Institutional Conflicts of Interest.

### RCOI Committee Review of SFID

The RCOI Committee administrator will review all SFID forms as they are completed, determining if there is a nexus between an Investigator's research and the reported interest and if so, if it is or appears to be a conflict of interest.

If there is or appears to be a conflict, the RCOI Committee administrator works with the Researcher to implement a management plan that specifies actions that have been, or will be, taken to manage the financial conflict of interest and report the management plan to the PHS agency affected.

## **SFI and Non-Compliance Reporting to PHS**

UWM is required to monitor Investigator compliance with management plans and provide reports on FCOIs and instances of bias to PHS. If the RCOI Committee finds noncompliance because an Investigator has failed to disclose a reportable outside financial interest or failed to comply with a management plan, the RCOI Committee may impose the following sanctions:

- Require the Investigator to complete additional training
- Withhold research funding
- Conduct a retrospective review
- Report the noncompliance to the PHS awarding component and Dean or other supervisor

If an Investigator with PHS-Funded Research does not report a Significant Financial Interest in a timely manner, UWM needs to review the SFI to determine if there is a conflict of interest, and if a conflict of interest is found, complete a retrospective review.

