

Office of the Vice Provost for Research

The FCOI Core Program Components– Disclosure, Review and Management

Italicized terms in the following summary are defined in the [University of Pennsylvania Policy on Conflicts of Interest related to Research](#) (the FCOI Policy).

Disclosure

Under Penn’s FCOI policy, you may be required to disclose in the Financial Interest Disclosure Electronic System (FIDES) certain, relevant financial interests / relationships, *Significant Financial Interests* or *SFIs*.

Disclosures related to PHS proposals. If you are an *Investigator* (individual responsible for the design, conduct or reporting of research, regardless of title or position) on a proposal funded / to be funded by the PHS, disclosure may involve a two-step process. *Investigators* must submit a Financial Interest and Travel Statement (PHS-FITS) to their Schools prior to participating in PHS-funded research and at other times throughout the life of the award. Depending on the nature and value of financial interests disclosed and whether such interests are determined by your School to be related to the research, *Investigators* may be required to provide a more detailed disclosure in FIDES. If your research does not involve PHS funding, you may disclose your financial interests directly in FIDES.

See, [FCOI Disclosure in FIDES](#) and [Special Disclosure Process for PHS-funded Projects](#)

FCOI Review Process for FIDES eDisclosures

- **Screening**

When an eDisclosure is received by the Office of the Vice Provost for Research (OVPR), it is reviewed by staff for completeness. You will be contacted via e-mail or telephone if staff need additional information or require clarification in order to review your eDisclosure.

A *Financial Conflict of Interest (FCOI)* is an *SFI* that could directly and significantly affect the design, conduct, or reporting of the research. The University may utilize several forms of review to reasonably determine whether an *FCOI* exists. Generally, eDisclosures that report the following *SFIs* are referred to the Conflict of Interest Standing Committee (CISC) for review and management recommendations:

- A *Fiduciary role* on behalf of an *Outside Organization* and/or equity in a privately held *Outside Organization*;
- Equity with a value > \$50,000 or > 5% ownership in a publicly traded *Outside Organization* if such entity is actively conducting or seeking to conduct business related to the research;
- Payments > \$25,000 in the preceding 12 months from an *Outside Organization*;
- *Intellectual property interests* (not assigned to Penn or other *Excluded Payers*) if any income has been received from such IP interest in the preceding 12 months;

- *Any interest in Intellectual Property* that is the subject of a copyright, issued patent, or a patent application (regardless of its licensure or option status and whether or not assigned to Penn) if it is being tested, evaluated, or developed in, or if its commercial value could be affected by, a *Clinical Trial*.

In addition, other types of *SFIs* or instances where an *Investigator* has more than one type of *SFI* related to the research may be referred to the CISC for review.

- **CISC - Review and Recommendation**

The CISC, which consists of members of the standing faculty and non-voting *ex officio* members, advises the Vice Provost for Research as to whether disclosed *SFIs* are related to the research and constitute *FCOIs* which must be managed, reduced or eliminated. At each meeting, a CISC member presents a summary of information reported in the eDisclosure, relevant information about the research, and any supplemental information. The recommendations of the CISC require approval by a majority of the voting members present during the meeting.

- **Standard Management Options**

Whether or not submitted for CISC review, an *SFI* may be found to constitute an *FCOI* requiring management (including elimination of the *SFI*, where appropriate) as a condition to the *Investigator's* participation in the research. The CISC has discretion to recommend a variety of management requirements, depending on the type and amount of the *SFI*, the nature of the research, the role of the *Investigator*, and other factors. These options include:

- Limitations on an *Investigator's* financial interests
- Required disclosures in all publications and presentations, to study participants in the informed consent for the study, and to all the investigators, research personnel, students, trainees and others working on this research
- Compliance with additional Penn and School policies, including disclosure, review and approval of consulting or other personal service agreements and assurance that any scope of work for such agreements remains in all respects separate from and subordinate to the *Investigator's* responsibilities as a Penn faculty member and employee
- Specific restrictions or conditions on the *Investigator's* role in the research (e.g., appointment of a co-PI; limitation on involvement in subject selection, recruitment, data analysis); changes in the study design (e.g., blinding)
- Continuing reporting obligations
- Other requirements

- **Final Determination**

The Vice Provost for Research makes the final determination regarding whether disclosed *SFIs* constitute *FCOIs* which must be managed, reduced or eliminated, and if management is recommended, determines the required elements of the management plan. The determination will be communicated in writing to the *Investigator* and other University personnel as appropriate. The *Investigator* will have the opportunity to review the management plan and

must provide written confirmation to the OVPR of his or her acceptance of the obligation to abide by the plan.

The *Investigator* is required to annually certify that there have been no changes in his/her financial interests relevant to the specific research since last reported to the OVPR and that s/he is in compliance with all aspects of the management plan then in effect. In addition, the *Investigator* is expected to cooperate with any additional monitoring of compliance with the management plan.

An executed management plan is required in order for the ORS to spend awarded funds. For human subjects research, the participation of any Investigator with an FCOI is subject to the IRB's review and approval.

Federal or Sponsor FCOI Reporting Requirements

OVPR staff will prepare, if applicable, *FCOI reports* required by the research sponsor or oversight agency that will contain information required by law or otherwise by the sponsor.

Requests from the Public Regarding FCOI Information

To the extent required by law or otherwise by the research award, the University will make available to the public certain information regarding *FCOIs* of *Senior/Key personnel* affiliated with the University. In the case of PHS-funded research, such information shall remain available for at least three years from the date that the information was most recently updated.

For questions regarding FCOI, please contact Rich L. Shellenberger Jr., FCOI Program Coordinator, at (215) 898-3603 or by e-mail at coi@pobox.upenn.edu