

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 Research, Interests, and Activities (RIA) system relevant financial interests/relationships, including *Significant Financial Interests* or *SFIs*.

If you are an *Investigator* (defined as any individual responsible for the design, conduct, or reporting of research, regardless of title or position) on a proposal or IRB protocol, regardless as to the source of research funding, you must submit an Outside Interests and Activities disclosure in RIA prior to participating in the research, as well as at other times throughout the life of the project or study (e.g., at least once per year and within 30 days of acquiring a new SFI). 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 complete a research relatedness assessment, also in RIA. An SFI is "related" to research if the research could affect the value of the SFI, or if the SFI is in an entity that could be affected by the research. *Note:* RIA has replaced the FIDES disclosure system, which will remain accessible only as a reference and in read-only mode (i.e., disclosures can no longer be made in FIDES as of March 18, 2024).

See [RIA Support Page](#) for more information.

FCOI Review Process

Once you have completed your primary disclosure and any necessary research relatedness assessments in RIA, your school will determine whether any disclosed SFIs are "related" to the research and will require review by the Research Integrity Office (RIO) within the Office of the Vice Provost for Research. RIO Staff will determine whether your participation may be administratively reviewed or will require review by the faculty-based Conflict of Interest Standing Committee (CISC).

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, research-related disclosures that include the following *SFIs* are referred to the 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* (as defined by the World Health Organization).

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 RIA disclosure, 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- and PCORI-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 email coi@pobox.upenn.edu