

# Office of the Vice Provost for Research

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## University of Pennsylvania Policy on Conflicts of Interest related to Research (FCOI Policy)<sup>1</sup> Overview

### Policy on Conflicts of Interest Related to Research

For several years, the University had two relevant policies pertaining to disclosure, assessment and management of *Investigators'* personal financial interests related to research. In 2011, federal regulation mandated significant changes to those policies. The University has recently developed a single uniform policy which not only reflects the new regulatory requirements, but also seeks to integrate and simplify certain aspects of the two previous policies. This unified policy – which supersedes the prior policies – defines the obligations of *Investigators* in Penn's research community and governs *Investigators'* financial interests / relationships related to their research, regardless of funding source. A summary of key policy provisions follows; however, *Investigators* engaged in research are responsible for reviewing the complete policy referenced above prior to participating in research at Penn.

**Purpose.** The purpose of this policy is to set forth the framework for identifying, evaluating, and managing financial conflicts of interest related to University research activities in order to minimize the risk of bias and to maintain integrity, credibility and respect for the work of Penn researchers.

**Applicability.** This policy is applicable to all research being conducted under the University's auspices, regardless of whether the research is externally or internally funded.

### **Disclosure Requirements<sup>2 3</sup>**

Each *Investigator* must disclose the following *Significant financial interests (SFIs)* (and those of his/her *Family members*) that reasonably appear to be related to the Investigator's *Institutional responsibilities*:

- For a public *Outside organization*: remuneration for the 12 months preceding the date of the disclosure plus the value of current equity that when aggregated exceed \$5,000
- For a non-publicly traded *Outside organization*: any equity (regardless of value) and remuneration for the 12 months preceding the date of the disclosure exceeding \$5,000
- Income from intellectual property rights not assigned to Penn
- Any *Clinical trial intellectual property*, whether or not assigned to Penn
- Any *Fiduciary Role*

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<sup>1</sup>The acronym FCOI (for Financial Conflict of Interest) reflects the policy's overall focus on the identification, evaluation and management of financial conflicts of interests.

<sup>2</sup>It is anticipated that the full implementation of the disclosure procedures in this policy will occur in stages, as necessary software and other resources are deployed to help support this process. Initial emphasis will be to first assure compliance with federal regulation and thereafter additional procedures will be phased in. The University will provide notice from time to time to its research community to advise of the specific means by which to submit disclosures.

<sup>3</sup>Defined terms are italicized with selected definitions provided at the end of the overview.

*Investigators* must disclose their *SFIs* at the time of proposal submission, annually, when added as an *Investigator* to an ongoing Public Health Service (PHS) project, and prior to participation in any PHS-funded research. *Investigators* are also required to timely update (within 30 days) their disclosures in the event of acquiring new *SFIs* or changes in their previously reported *SFIs*.

*Investigators* participating in research funded by the PHS must also disclose travel reimbursed or paid on the *Investigator's* behalf within the most recent 12 months, other than by an *Excluded Payer*.

A *financial interest* is related to an *Investigator's Institutional responsibilities* if, for example, it arises from extramural activities that derive from the *Investigator's* professional standing or are within that *Investigator's* expertise in his or her professional field(s) of discipline, such as consulting, serving on a scientific advisory board, providing continuing professional education services, or serving as an expert witness for an *Outside organization* that, to the best of the *Investigator's* knowledge, conducts or seeks to conduct business related to the *Investigator's* field of discipline. In addition, equity in, or serving in a fiduciary role for, an *Outside organization* that, to the best of the *Investigator's* knowledge, conducts or seeks to conduct business related to the *Investigator's* field of discipline, is related to the *Investigator's Institutional responsibilities*.

**Assessment of Disclosures.** Each School will appoint an FCOI Office / Officer to review *SFI* disclosures and the *Investigator's* assessment of the relationship of the *SFIs* to the *Investigator's* research to determine which *SFIs* (if any) are related to the research. A determination of relatedness will be made based on the *Investigator's* assessment and/or on other facts deemed relevant by the School. If the School determines that one or more disclosed *SFIs* or travel relates to the research, the School shall direct the *Investigator* to submit information regarding those related *SFIs* to the University's Office of the Vice Provost for Research (OVPR) using such means of disclosure as prescribed by the OVPR (presently, the Financial Interest Disclosure Electronic System or FIDES).

For additional information, see [FCOI Disclosures in FIDES](#) and [Special Disclosure Process for PHS-funded Projects](#)

**Determination of a Financial Conflict of Interest (FCOI).** 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 *SFI* related to the research is an *FCOI*, including review by the Conflict of Interest Standing Committee (CISC), depending on the nature and value of the disclosed financial interests, as well as other factors.

**Management of FCOIs, including FCOIs Involving Clinical Trials.** An *SFI* found to constitute an *FCOI* may be subject to a management plan as a condition to the *Investigator's* participation in the research. The determination of whether an *FCOI* is manageable, including an *FCOI* involving a *Clinical Trial*, should take into account relevant factors, including but not limited to, the

uniqueness of the *Investigator's* position with respect to the study, the nature and design of the research and the magnitude and nature of the *financial interest*. With respect to *Clinical Trials*, other relevant factors include the degree of risk to human subjects, the role of the *Investigator* in the study, the study's design, and the degree of the *Investigator's* influence upon the recruitment/ enrollment of subjects and/or the results of the study.

**Training.** *Investigators* must receive training from the University related to research-related *FCOI* prior to engaging in research at the University and at least every four years thereafter.

**Requests from the Public Regarding FCOI Information.** To the extent required by law (e.g., PHS regulations) or otherwise by the terms and conditions of a research award, in response to a written request for information related to *FCOIs* held by *senior/key personnel* of the particular research project specified in the request, the University will provide required information to the requestor.

**Other Policy Provisions.** In addition to the foregoing, the *FCOI* Policy includes other provisions as required by law, research sponsors and/or the University. These include *FCOI* disclosure and reporting requirements for sub-awards, the reporting of *FCOIs* to research sponsors (e.g., PHS agencies), as well as provisions to address noncompliance with the *FCOI* Policy.

### **Selected Definitions**

***Clinical trial*** shall have the same meaning as prescribed from time to time by the World Health Organization.

***Clinical trial intellectual property*** means an *Investigator's* interest in intellectual property that is the subject of a copyright, issued patent, or a patent application (regardless of whether the intellectual property has been patented, licensed, or assigned to the University) if such intellectual property is being tested, evaluated, or developed in, or if its commercial value could be affected by, the *Clinical trial* in which the *Investigator* is engaged or proposes to engage.

***Excluded payer*** means a Federal, state, or local government agency, a United States institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. By way of example, Children's Hospital of Philadelphia, the Philadelphia Veterans Affairs Medical Center, the Howard Hughes Medical Institute, and Wistar Institute are *Excluded payers*.

***Family member*** means an *Investigator's* spouse or dependent child. From to time, the *Institutional official* may amend the definition of *Family member* and notify the University research community prior to the effective date of such change.

***Fiduciary role*** means membership on the governing board of an entity, including service on its board of directors, or having a position of authority or responsibility to act in the best interest of the entity, including being an officer, manager, partner, or limited liability company member with management responsibility.

***Institutional official means*** the Vice Provost for Research or such other person as the Provost appoints from time to time as the individual within the University responsible to oversee the University's compliance with conflict of interest regulations and policies.

***Institutional responsibilities*** means an *Investigator's* professional or employment-related responsibilities on behalf of the University or any of its Schools, which may include research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

***Investigator*** means the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, whether externally or internally funded, or proposed for such funding, which may include, for example, collaborators or consultants.

***Outside organization*** means any organization other than the University or University of Pennsylvania Health System or its corporately-owned entities (e.g., Clinical Care Associates and Clinical Practices of the University of Pennsylvania), and other than an *Excluded payer*.

#### **Related Penn Policies**

- [Patent and Tangible Research Property Policies and Procedures of the University of Pennsylvania](#)
- [Consulting and Outside Activities Policies and Procedures of the University of Pennsylvania](#)
- [Guidance on the Revised Patent Policy with Regard to Consulting](#)
- [Policy Relating to Copyrights and Commitment of Effort for Faculty](#)

For questions regarding FCOI, please contact Richard Shellenberger, FCOI Program Coordinator, at (215) 898-3603 or by e-mail at [coi@pobox.upenn.edu](mailto:coi@pobox.upenn.edu)