

The University of Pennsylvania Policy on Conflicts of Interest Related to Research was recently modified, as reprinted in full below. Changes were implemented for the purpose of including additional perspectives in discussions conducted by the Conflict of Interest Standing Committee, which is advisory to the Vice Provost for Research. As a result of the changes, the Committee may now include voting member(s) drawn from the community external to the University, and voting abstention rules were modified slightly as to faculty in the same department when the Committee member is part of a very large department with many divisions. These changes do not significantly impact the goals or operations of the Committee and are intended to enrich the Committee's discussions. The Tri-Chairs of the Faculty Senate were notified of the anticipated changes on July 20, 2017 and the changes became effective August 14, 2017.

—Dawn A. Bonnell, Vice Provost for Research

## University of Pennsylvania Policy on Conflicts of Interest Related to Research

Originally effective August 24, 2012; effective as updated August 14, 2017

### Introduction

As an institution committed to academic excellence, innovative research, and the highest quality clinical care, the University of Pennsylvania consistently generates new knowledge with the potential to link theory with practice in ways that enhance and transform our society. Penn's dedication to excellence, discovery, and collaboration lead our faculty, students, and staff to opportunities for engaging the world around us.

We support an environment in which faculty and staff are able to pursue teaching, research, and patient care responsibilities in ways that enrich their work and further the University's mission. Faculty involvement with external entities—in academia, government, the nonprofit sector, and industry—offers many positive benefits consistent with the University's goals, including the practical application of new scientific discoveries and the ability to obtain research funding.

We must recognize, however, that these opportunities also introduce the potential for conflicts of interest that could affect one's responsibilities and activities as a member of the Penn community. Involvement with external entities may create the risk that these relationships could bias the work performed by our faculty. Identifying, understanding, and responding to conflicts of interest are of primary importance to protecting the credibility and objectivity of our work, the professional reputations of our faculty and staff, and respect for the role of the University as educator, care-giver, and researcher.

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 to control their ability to create bias and to maintain integrity, credibility, and respect for the work of Penn researchers.

This policy is applicable to all research being conducted under the University's auspices, regardless of whether the research is externally or internally funded, including proposals and applications made by University researchers to external sponsors, protocols submitted to the University's Institutional Review Board or Institutional Animal Care and Use Committee, research funded by the University's Centers and Institutes, material transfer agreements, nonmonetary collaborative agreements, and similar types of research agreements.

### I. Definitions

As used in this policy, the following terms shall have the meaning ascribed to them below:

**Clinical trial** shall have the same meaning as prescribed from time to time by the World Health Organization.<sup>1</sup>

**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.<sup>2</sup>

**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, the University, the University of Pennsylvania Health System, 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, or persons having such other relationships to the *Investigator* as the *Institutional official* may determine from time to time.

<sup>1</sup> As of the date of this policy, the WHO definition reads:

... a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials.

<sup>2</sup> Engaging in a trial includes, but is not limited to, serving as a Principal Investigator, Co-Investigator, regulatory sponsor/IND holder or in any other role responsible for the design, conduct, or reporting of the trial (including reporting results to the FDA); performing any other subject-related activity specific to the trial, such as the recruitment, selection, or enrollment of subjects, obtaining informed consent, providing subject treatment and care specific to the trial, or performing study procedures; or collecting, analyzing, or interpreting data.

**FCOI report** means the University's report of a financial conflict of interest required by law or otherwise by agreement to be made to a research sponsor or other oversight agency.

**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.

**Financial conflict of interest (FCOI)** means a *Significant financial interest* that could directly and significantly affect the design, conduct, or reporting of the *Research*.

**Financial interest** means anything of monetary value, whether or not the value is readily ascertainable.

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

**Research** means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., of a diagnostic test or drug).

**Senior/key personnel** means the project director or principal investigator and any other person identified as senior/key personnel by the University in a grant application, progress report, or any other report submitted to the sponsor related to the *Research*.

**Significant financial interest (SFI)** means one or more of the following of the *Investigator* (or the *Investigator's Family member*) that reasonably appear to be related to the *Investigator's Institutional responsibilities*:

- (i) With regard to any publicly traded *Outside organization*, an *SFI* exists if the value of any remuneration received from the *Outside organization* in the 12 months preceding the disclosure plus the value of any equity interest in the *Outside organization* as of the date of disclosure, when aggregated, exceeds \$5,000. Remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); 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;
- (ii) With regard to any non-publicly traded *Outside organization*, an *SFI* exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or if the *Investigator* or *Family member* holds any equity interest (e.g., stock, stock option, or other ownership interest);
- (iii) Intellectual property rights and interests (e.g., patents, copyrights) not assigned to the University, upon receipt of any income related to such rights and interests;
- (iv) *Clinical trial intellectual property* rights (and royalties or other remuneration, if any, paid with respect to such rights); or
- (v) Any *Fiduciary role* in an *Outside organization*.

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 that 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. Moreover, 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*.

Notwithstanding the foregoing, unless arising from the *Investigator's Clinical trial intellectual property*, *SFI* does not include:

- salary, royalties, or other remuneration paid by the University to the *Investigator* if the *Investigator* is currently employed or otherwise appointed by the University;
- rights in intellectual property assigned to the University, including the right to participate in the University's royalties or in the University's equity pool if the equity interest is held and controlled by the University under the *Patent and Tangible Research Property Policies and Procedures of the University of Pennsylvania*, as amended from time to time;
- equity in or income from investment vehicles, such as mutual funds and retirement accounts, as long as the *Investigator* does not directly control the investment decisions made in these vehicles; or
- income from seminars, lectures, or teaching engagements sponsored by, or income from service on advisory committees or review panels for, an *Excluded payer*.

## II. Investigator's Duty to Disclose Significant Financial Interests and Travel

**Disclosure of significant financial interests:** At least annually, each *Investigator* must submit to designated offices at his or her School a disclosure of *Significant financial interests (SFI)* and such other information as the *Institutional official* or the *Investigator's* School shall require. This disclosure must be updated at the time of submission of a proposal for sponsored *Research*,<sup>3</sup> upon submission of a protocol, upon being added (in a capacity that meets the definition of *Investigator*) to an ongoing *Research* project, and also within 30 days of the *Investigator's* discovering or acquiring a new *SFI*. The means and format of the disclosure will be prescribed by the School and University from time to time and communicated to the University research community<sup>4</sup>. In addition to the disclosure of *SFIs*, the *Investigator* must provide requested information to assist in the assessment of whether any of the *Investigator's SFIs* are related to the *Investigator's Research*.

**Disclosure of travel:** *Investigators* who are funded or proposed to be funded by the Public Health Service or other sponsor designated from time to time by the University, must also disclose the occurrence of any reimbursed or sponsored travel (i.e., travel which is paid on behalf of the *Investigator* and not reimbursed to the *Investigator* so that the exact monetary value may not be readily available), related to the *Investigator's Institutional responsibilities* during the previous 12 months, other than travel reimbursed or sponsored by an *Excluded payer*. Travel disclosures must include the purpose of the trip, the identity of the trip's sponsor or organizer, the trip's origin and destination, and the duration of the trip. In addition, the University or *Investigator's* School may request other information about the trip as necessary to evaluate whether the travel may constitute a *Financial conflict of interest (FCOI)*.

<sup>3</sup> This includes proposals to transfer existing awards from another institution in connection with the commencement of an *Investigator's* employment by the University.

<sup>4</sup> As of the time of preparation of this policy, 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.

**III. Assessment of Disclosures**

**Review by the School:** Each School shall appoint a Conflict of Interest (COI) Office/Officer to review disclosures of *SFIs* and, where applicable, travel, and the *Investigator's* assessment of relatedness of *SFIs* to the *Research* in which the *Investigator* engages or proposes to engage. The School COI Office/Officer shall review the disclosures and reasonably determine whether any of the disclosed *SFIs* or travel payments could be affected by the *Research* or are in an entity whose *Financial interest* could be affected by the *Research*. The determination of relatedness to the *Research* will be made based on both the *Investigator's* assessment of relatedness and on other facts reasonably deemed relevant by the COI Office/Officer or the *Institutional official*.

**Review by the Institutional official:** The *Institutional official* is responsible to make the ultimate determination regarding whether a related *SFI* constitutes an *FCOI* and, if so, whether the *FCOI* is amenable to management. If the School COI Office/Officer determines that one or more disclosed *SFIs* or travel relate 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 from time to time and communicated to the University's research community. The University may utilize several forms of review to reasonably determine *FCOIs*. The type of review to be utilized and review standards may be prescribed from time to time through guidance from the *Institutional official* based generally upon the nature and value of the disclosed interests, as well as other factors.

**Recommendations by the Conflict of Interest Standing Committee:** A Conflict of Interest Standing Committee (CISC) shall serve in an advisory capacity to the *Institutional official*, providing recommendations related to whether an *SFI* constitutes an *FCOI*, whether the *FCOI* is manageable, and if so, the management plan. The primary scope of inquiry of the CISC is to review matters involving *SFIs* and their potential to affect the objectivity of specific *Research*. Matters involving other types of conflicts of interest (*e.g.*, procurement, conflict of commitment) will be referred to the Schools and/or other University offices, depending on the nature of the conflict.

The CISC will consist of approximately 10-20 members (or such number of members as the *Institutional official* may determine from time to time) of the standing faculty appointed by the *Institutional official*. Efforts will be made to have faculty representation on the CISC reflective of the volume of disclosures submitted by each School. In addition, the *Institutional official* may from time to time appoint one or more member(s) drawn from the community external to the University. The external member(s) shall comply with the same standards of conduct and duties applicable to participation by University-affiliated members of the CISC relative to their participation on the committee. Only appointed CISC members who are faculty and the external member(s), if any, shall have voting rights in CISC decisions. *Ex-officio*, non-voting members will include the Associate Vice Provost for Research; Associate Vice Provost Office of Research Services; the Associate Vice Provost for Research and Executive Director, Penn Center for Innovation; the Director, Human Research Protections;<sup>5</sup> and an attorney from the Office of the General Counsel. Other non-voting participants may be appointed at the discretion of the *Institutional official*.

The recommendations of the CISC require approval by a majority of the voting members present during the meeting. A member may be present at a meeting either in person or by electronic means, such as telephone or internet conferencing, allowing participation in the meeting. A quorum of six voting members present, or such other quorum requirement as may be determined from time to time (and applied prospectively) by the *Institutional official*, is required for a meeting. A CISC voting member shall not vote on a particular case if: the case involves a member of the same departmental division, or if the department has no divisions or fewer than six divisions, the same department; the CISC member has a personal in-

terest because of inter-departmental relationships, such as collaboration with the faculty member whose case is under consideration; or the CISC member has a financial or other relevant interest related to the case under discussion. Disclosure of any of the above conditions must be made by the CISC member prior to the beginning of the discussion. The Chair has discretion to request that a CISC member not participate in a discussion based on the above conditions.

In general, the following types of *SFIs* related to *Research* will be reviewed by the CISC, as they are likely to constitute an *FCOI* unless there are factors that would reasonably prevent any direct or significant effect on the design, conduct, or reporting of the *Research*:

- (i) Equity in a privately held *Outside organization* that is actively conducting or seeking to conduct business related to the *Research*;<sup>7</sup>
- (ii) Equity with a value greater than \$50,000 or greater than 5% ownership in a publicly traded *Outside organization* that is actively conducting or seeking to conduct business related to the *Research*;
- (iii) Payments greater than \$25,000 in the preceding 12 months from an *Outside organization*;
- (iv) *Fiduciary role* on behalf of an *Outside organization* that is actively conducting or seeking to conduct business related to the *Research*;
- (v) Intellectual property interest (not assigned to the University or other *Excluded payer*) if any income has been received from such intellectual property interest in the preceding 12 months; or
- (vi) *Clinical trial intellectual property*.

The *Institutional official* may also choose to submit for CISC review other types of *SFIs* not listed above or instances where an *Investigator* has more than one type of *SFI* related to the *Research*.

Prior to commencement of a *Research* project, review and assessment of *FCOIs* shall be conducted within the timeframes required by law or otherwise by agreement with the sponsor and, where applicable, shall be concluded prior to the expenditure of funds from the sponsor. During an ongoing *Research* project, should an *Investigator* who is new to the project disclose an *SFI* or should a current *Investigator* disclose a new *SFI*, the disclosure will be reviewed in the manner described above to determine whether the *SFI* relates to the *Research* and constitutes an *FCOI*.

**IV. Determination and Management of FCOI**

Whether or not submitted for review by the CISC, an *SFI* may be found by the *Institutional official* to constitute an *FCOI* and may be subjected to a requirement that the *FCOI* be managed (including elimination of the *Financial interest*, where appropriate) as a condition to the *Investigator's* participation in the *Research* to which it is related. The determination of whether an *FCOI*, including an *FCOI* involving a *Clinical trial*, is manageable without elimination of the *Financial interest* should take into account relevant factors such as the nature and design of the *Research*; the magnitude and nature of the *Financial interest*; the extent to which the *Financial interest* could be influenced by the *Research*; the uniqueness of the *Investigator's* position with respect to the study (for example, whether safety or other factors will be diminished if the *Investigator* does not participate); whether the interest is amenable to management; and in addition, with respect to *Clinical trials*, the degree of risk to human subjects, the role of the *Investigator* in the study, and the degree of the *Investigator's* influence upon the recruitment and enrollment of subjects or the results of the study.

**Management plan:** Where appropriate, a plan to manage the *FCOI* may be developed and recommended to the *Institutional official*. The *Institutional official* will have the authority to accept, modify, or reject the recommendations or to refer the *FCOI* to the CISC for additional consideration. The *Institutional official* will communicate the findings and elements of the management plan to the *Investigator* and other University personnel as appropriate. The *Investigator* will be granted the opportunity to review the management plan and must acknowledge in writing his or her acceptance of the obligation to abide by the plan.

<sup>5</sup> The foregoing titles may be changed from time to time.

**Reconsideration:** If the *Investigator* objects to the terms of the management plan, the *Investigator* may submit promptly<sup>6</sup> to the *Institutional official* a written request for reconsideration, specifying the basis for the objection. The *Institutional official* has discretion to refer the matter back to the CISC for further review and recommendations, but is not required to do so. The *Institutional official* also has the option to consult with the relevant School officials. If the *Investigator* is not satisfied with the decision of the *Institutional official* after such reconsideration, the *Investigator* may appeal to the Provost, whose determination is final.

**Reporting:** Once the management plan has been finalized, OVPR staff will prepare, if applicable, *FCOI reports* required to be submitted to the research sponsor or oversight agency. The *FCOI reports* shall contain information required by law or otherwise by the sponsor.<sup>7</sup> The *Investigator* should be aware that information pertaining to *FCOIs* may be disclosed to sponsors or oversight agencies and, in some cases, to the public and may contain such details as the value and nature of the *Financial interest* and elements of the management plan.

**Monitoring:** Establishment of a management plan also initiates responsibility for monitoring compliance with the plan until the completion of the *Research* project. As part of finalizing the management plan, the OVPR, *Investigator's* School or other designee will establish an ongoing monitoring program to ensure compliance with requirements of the management plan.

#### V. Investigator's Obligation to Complete Training

As part of the responsibility for participating in *Research* at the University, *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. *Investigators* new to the University shall undergo training promptly after commencement of employment. In addition, each *Investigator* must undergo training within a reasonable period of time following any substantive change to this policy that affects the requirements for *Investigators*, and must be retrained if it is determined that the *Investigator* has not complied with this policy or with a management plan related to his or her activities. Training shall include a description of this policy, the *Investigator's* disclosure responsibilities, an overview of the relevant Public Health Service regulation, and such other topics as the *Institutional official* shall determine from time to time.

#### VI. Investigator's General Obligation to Cooperate

The *Investigator* is required to cooperate fully with the University in all aspects of the administration of this policy. This includes, among other things, providing all information as required to allow the University to understand and assess the *Investigator's* disclosure of *SFI* and the relatedness of the *SFI* to the *Investigator's Research*, assisting in the conduct of retrospective reviews where appropriate, and responding promptly and appropriately to implementation and monitoring of management and mitigation plans or corrective action.

#### VII. Public Accessibility

This policy will be made available to the public via posting on the University's website. In addition, to the extent required by law or otherwise by the terms and conditions of a *Research* award or as otherwise determined by the *Institutional official*, the University will make available to the public certain information regarding *FCOIs* of *Senior/key personnel* affiliated with the University (and to the extent reported to the University, *Senior/key personnel* at other institutions). In response to a written request submitted to the OVPR for information related to *FCOIs* held at the time of the request by *Senior/key personnel* of the particular *Re-*

*search* project specified in the request, the University will, within five business days, provide as to *Senior/key personnel* with *FCOI* related to such project: the *Investigator's* title and role with respect to the *Research* project; the name of the entity in which the *SFI* is held; the nature of the *SFI*; and the approximate value of the *Financial interest* reported in ranges (\$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000) or a statement that the interest is one whose value cannot be readily determined through reference to reasonable measures of fair market value.

The written request to the University must identify the project in sufficient detail to permit identification of the specific grant or contract.<sup>8</sup>

In lieu of response to individual requests as described above, the *Institutional official* may in the future determine to employ postings on the University's website as the means of communication of information regarding *FCOIs* of *Senior/key personnel* to the public. In the event that the website is used for that purpose, the website will contain the information described above and shall be updated with the frequency and maintained for the periods required by law.

#### VIII. Response to Non-compliance

**Review of untimely disclosures:** Should the University identify an *SFI* that, for any reason, was not disclosed by an *Investigator* within the required timeline or was not previously reviewed by the University during an ongoing *Research* project, the *Investigator's* School and the University will, within 60 days where required by law or by the terms of the *Research* award and in any event promptly as the circumstances allow, perform their respective responsibilities to review the *SFI*, determine whether it is related to the *Research* project, and determine whether an *FCOI* exists. If the *Institutional official* determines that the *SFI* constitutes an *FCOI*, the University shall implement a management plan describing the actions that have been and will be taken to manage the *FCOI*.

**Retrospective review and mitigation:** In addition, if an *FCOI* (including *FCOIs* of subrecipients) is not identified or managed within the designated timeframe for any reason, where required by law or by the terms of the *Research* award or otherwise as may be appropriate in the view of the *Investigator's* School or the University, the University shall direct the School (or subrecipient, as applicable) to conduct in consultation with the University a retrospective review of the *Investigator's* activities and the *Research* project to determine whether any portion of the *Research* conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such *Research*. This retrospective review shall be completed within 120 days of the determination of non-compliance where required by law or by the terms of the *Research* award and in any event promptly as the circumstances allow.

Documentation of a required retrospective review will include the project number; project title; project director/principal investigator or contract project director/principal investigator; name of the *Investigator* with the *FCOI*; name of the entity with which the *Investigator* has an *FCOI*; the reason(s) for conducting the retrospective review; detailed description of the methodology used for the retrospective review; and the findings and conclusions of the review.

As appropriate, the University will provide an updated *FCOI report*, specifying actions that will be taken to manage the financial conflict of interest going forward. If the retrospective review finds bias related to the *Research* project, the University will notify the research sponsor as appropriate. As required by law or agreement or as otherwise appropriate, this notification shall include a mitigation report including the key elements documented in the retrospective review above, a description of the impact of the bias on the *Research* project, and the University's plan for eliminating or mitigating the effect of the bias.

<sup>8</sup> Requests must be submitted in writing to the Office of the Vice Provost for Research, Attention FCOI Request Department, 1 College Hall Room 118, Philadelphia, PA 19104-6303. FCOI information required to be furnished under this section shall remain available for the period required by applicable law.

<sup>6</sup> The request for reconsideration must be made with sufficient time to allow the University to respond to the objection and comply in a timely manner with reporting requirements under applicable law.

<sup>7</sup> Current Public Health Service regulation requires that such reports be made prior to the expenditure of funds, within 60 days of identifying a new *FCOI* for an existing *Investigator* or appointing a new *Investigator* with an *FCOI* to the *Research* project, at least annually and in conjunction with progress reports or renewals, or when necessary to update a previously submitted report.

**Sanctions for violation:** If it is suspected that an *Investigator* has violated this policy, the *Institutional official*, in conjunction with the applicable Deans and other administrative officials of the University, will make appropriate inquiry regarding the matter. If after such inquiry a violation is found, suitable corrective action may be taken. Such action may include the initiation of proceedings under other University policies, including the University's *Procedures Governing Sanctions Against Members of the Faculty* and relevant Human Resources policies.

If the University determines that an *Investigator* has failed to comply with this policy or an *FCOI* management plan and that the non-compliance appears to have biased the design, conduct, or reporting of the *Research*, the University shall promptly notify the research sponsor as required by law or agreement or as otherwise appropriate, of the corrective action taken or to be taken. Among other actions, in the event that the Department of Health and Human Services determines that a clinical *Research* project funded by the Public Health Service (including the National Institutes of Health) with the purpose of evaluating the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an *Investigator* with an *FCOI* that was not managed or reported by the University as required by Federal regulations, the University shall among other things require the *Investigator* involved to disclose the *FCOI* in each public presentation of the results of the *Research* and to request an addendum to previously published presentations.

## IX. Responsibilities for Research Subrecipients

If required under the terms and conditions of a sponsored *Research* project, the University will require any written subaward agreement with any organization to include terms establishing the applicable *FCOI* policy governing the subrecipient's work, whether it is the University of Pennsylvania policy or the policy of the subrecipient institution. The subrecipient will be required to provide certification that its policy is established in accord with sponsor requirements or, if unable to provide such certification, the University policy will be applicable to all subrecipient *Investigators*. (As a rule, the University will require subrecipient institutions to maintain and administer their own *FCOI* policies and will only in exceptional circumstances assume primary responsibility for directly soliciting and reviewing subrecipient personnel disclosures that enable the University to directly identify and manage identified *FCOIs* from the *SFI* disclosures of subrecipient personnel.) In addition, the written subaward agreement will establish timelines and information requirements that will allow sufficient time for the University to evaluate, as applicable, subrecipient disclosures or subrecipient *FCOI reports* in order for the University to meet any applicable sponsor reporting requirements.

## X. Record Retention

In general, records related to the identification, evaluation, and response to *FCOI* in *Research* shall be retained for three years following the date that the final *Research* expenditure report has been submitted to the research sponsor or for a longer period when specified by applicable governmental<sup>9</sup> or University requirements.

<sup>9</sup> Including where applicable, 45 CFR 74.53(b) and 92.42, and 48 CFR part 4, subpart 4.7

## XI. Oversight by the Institutional Official

The *Institutional official* is responsible for:

- communicating the expectations of the University's *FCOI* policy to the research community;
- providing access to appropriate *FCOI* training;
- designating tools and procedures for *Investigator* disclosure of *SFIs*;
- creating policies and guidelines for the determination of whether an *FCOI* exists;
- developing processes for the review of *SFI* disclosures, the evaluation of *FCOIs*, and the development and monitoring of management plans;
- establishing a process for providing *FCOI reports* to the research sponsor or other oversight agencies as appropriate;
- implementing a procedure to provide required notification to the research sponsor if bias is found in the design, conduct, or reporting of *Research* and to submit any required mitigation plan to the sponsor;
- establishing a procedure for notifying research sponsors of non-compliance with this policy as appropriate;
- establishing procedures for the maintenance of *FCOI*-related records in accordance with University and Federal record retention guidelines;
- establishing appropriate enforcement mechanisms, including actions to promote *Investigator* compliance;
- establishing procedures to implement that subrecipient agreements specify the use of University or subrecipient *FCOI* policies;
- making this policy publicly accessible; and
- establishing a process for making information related to *FCOIs* held by *Senior/key personnel* publicly available, where required, in the applicable timeframes.

These responsibilities may be delegated to other University or, in consultation with the applicable Dean, School personnel as necessary and appropriate to promote adherence with this policy and applicable sponsor guidelines.

## XII. Related Authority

This policy implements the requirements of the Public Health Service, including the National Institutes of Health as set forth in *Promoting Objectivity in Research*, 42 CFR 50, Subpart F and *Responsible Prospective Contractors*, 45 CFR 94, and describes the University's approach to meeting the requirements of other sponsors.

This policy was originally adopted as of August 24, 2012 and revised as of August 14, 2017. When originally adopted in August, 2012, the policy superseded and replaced two policies: *Financial Disclosure Policy for Research and Sponsored Projects*, February 6, 2001, *Almanac*, Volume 47, No. 21, and *Financial Disclosure and Presumptively Prohibited Conflicts for Investigators Participating in Clinical Trials*, July 17, 2007, *Almanac*, Volume 54, No. 1.