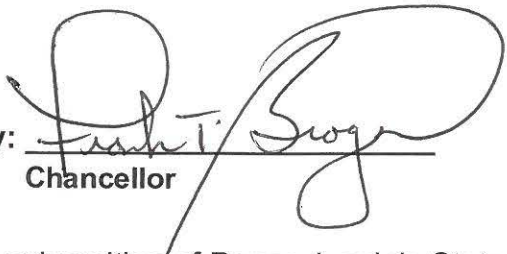


**Office of the Chancellor
Pennsylvania's State System of Higher Education
Procedure/Standard Number 2016-22**

Management of Financial Conflict of Interest (FCOI)

Approved by:  Date 3/3/16
Chancellor

History: The universities of Pennsylvania's State System of Higher Education (System) have been utilizing a framework for managing and mitigating financial conflicts of interest in research, education, and service activities, as outlined in the 2008 document, "Model Policy for Management of Conflicts of Interest at PASSHE Universities." This procedure/standard supersedes that document and provides updated requirements in accordance with federal regulations.

Related Documents: Model Policy for Management of Conflicts of Interest at PASSHE Universities, December 2008; Board of Governors' Policy 2012-01, *Conflict of Interest*.

Key Words/Categories: Sponsored Research, Conflict of interest

Additional References: *Uniform Administrative Requirements, Cost Principals, and Audit Requirements for Federal Awards*, published by the federal Office of Management and Budget (OMB) at 2 C.F.R., Chapter II, Part 200.

Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought, published by the federal Department of Health and Human Services at 42 CFR Part 50, Subpart F.

I. Purpose

Conducting high quality research and instructional activities is integral to the primary mission of State System member universities. Active participation by faculty and other employees in external activities that enhance their professional skills or constitute public service can be beneficial to the university as well as the individual.

The purpose of this procedure/standard is to provide the members of the academic community with a framework to promote quality and objectivity in research by establishing standards to ensure that the design, conduct or reporting of research or sponsored projects will not be biased by any conflicting financial interests of an investigator.

The procedure/standard provides a framework to manage, reduce or eliminate financial conflicts of interest in research, education, and service activities. This procedure/standard protects the credibility and integrity of faculty and staff, so that public trust and confidence in the sponsored activities are ensured. It is also intended that any such action be in accordance

with applicable federal and state law as well as collective bargaining agreements. The procedure/standard is issued under the authority of Act 188, Section 20-2005-A (7).

II. Scope

This procedure/standard applies to all university employees defined as an investigator. In accordance with federal regulations, each university has a responsibility to manage, reduce, or eliminate any actual or potential financial conflicts of interest that may be presented by a significant financial interest of an investigator. Thus, the university requires that investigators disclose any significant financial interest that may present an actual or potential financial conflict of interest with a sponsored project.

III. Definitions

Business Enterprise or Entity: Any person or entity or organization, or any combination thereof. A business entity includes, but is not limited to, a sole proprietorship, partnership, association, joint venture, corporation, firm, trust, foundation, or other organization or entity used in carrying out a business, including parent organizations of such entities or any other arrangement in which an entity operates through a subsidiary.

Collective Bargaining Agreement (CBA): The agreements between the Association of Pennsylvania College and University Faculties (APSCUF) and the Pennsylvania State System of Higher Education (System) or any other applicable CBA covering System employees.

Financial Conflict of Interest: A significant financial interest that the university reasonably determines could directly affect the design, conduct, or reporting of research.

Financial Interest: Anything of monetary value, whether or not the value is readily ascertainable.

Immediate Family: Spouse and dependent children of the investigator.

Intellectual Property: Any term used to describe the patents, copyrights, mask work protection, trade secrets, and plant variety protection certificates, which cover, or pertain to, inventions.

Institution: A university or any other entity or organization that is applying for or receives external funding.

Institutional Official: The institutional official may be the university provost or official designees. A committee may assist with this function at the discretion of the university provost. The institutional official determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. The institutional official shall determine what conditions or restrictions, if any, should be imposed by the institution to manage actual or potential conflicts of interest arising from disclosed significant financial interests.

Institutional Responsibilities: The investigator's professional responsibilities on behalf of the institution, which may include, for example, activities such as research, research consultation, teaching, advising, professional practice, institutional committee memberships,

and service on panels such as institutional review boards or data and safety monitoring boards.

Investigator: The principal investigator, co-principal investigator(s), project director, and any other person at the university who is responsible for the design, conduct, or reporting of research or educational activities funded by or proposed for funding by a sponsor.

PHS: Public Health Service of the United States (U.S.) Department of Health and Human Services (HHS), and any component of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component: The organizational unit of the PHS that funds the research.

Potential Financial Conflict of Interest: Any outside activity, commitment, or interest that may reasonably give the appearance of adversely affecting, compromising, or being incompatible with the institutional responsibilities of the investigator.

Research: A systematic investigation, study or experiment designed to develop or contribute to generalized knowledge. The term encompasses basic and applied research and product development. The term includes any such activity for which funding is available from a sponsor through a grant or cooperative agreement.

Resolution Plan: An action plan agreed to by the university and the investigator, outlining the steps that must be taken by the investigator and/or the university to manage or eliminate a potential financial conflict of interest situation.

Significant Financial Interest: A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent children) that reasonably appears to be related to the investigator's institutional responsibilities:

- (a) With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, 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;
- (b) With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the investigator (or the investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- (c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (d) For PHS-funded projects, investigators also must disclose the occurrence of any

reimbursed or sponsored travel (i.e., that 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 their institutional responsibilities. However, this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Exclusions from this definition:

- (a) Salary, royalties, or other remuneration paid by the institution to the investigator if the investigator is currently employed or otherwise appointed by the institution;
- (b) Intellectual property rights assigned to the institution and agreements to share in royalties related to such rights;
- (c) Any ownership interest in the institution held by the investigator, if the institution is a commercial or for-profit organization;
- (d) 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;
- (e) Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
- (f) Income from service on advisory committees or review panels for a federal, state or local government agency, institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

Sponsor: Any non-university entity providing partial or full support of research or scholarly activity performed by university members utilizing university resources.

Uniform Guidance: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, published by the federal Office of Management and Budget (OMB) at 2 C.F.R., Chapter II, Part 200. Specifically subsection 200.112 and subsection 200.113.

University: any member university of the Pennsylvania State System of Higher Education.

IV. Procedures

It will be the university's procedure/standard that all investigators disclose any significant financial interest, and those of their immediate family, that may present an actual or potential financial conflict of interest.

1. Disclosure Requirements

All investigators are required to disclose their outside financial interests to the institution prior to the time of application, annually, and an ad hoc basis, as described below. The institutional official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

a. Disclosures at Application

With sponsored projects, all investigators specifically named in a proposal are required to report and disclose any potential financial conflict of interest prior to submission of the proposal to the funding agency. The university reserves the right to not process grant proposals and applications if all required disclosures are not submitted. Each investigator is required to disclose any significant financial interests, and those of their immediate family.

Individual federal sponsors may have unique and additional disclosure requirements as published in requests for proposals, or similar invitations, and/or award terms and conditions. All investigators and university personnel shall comply with such requirements.

b. Annual Disclosures

All investigators must disclose their significant financial interests to the institution on an annual basis.

c. Ad hoc Disclosures

In addition to disclosure prior to application and annual disclosure, certain situations require ad hoc disclosure. All investigators must disclose any significant financial interest they acquire during the course of the year, within thirty (30) days of discovering or acquiring the significant financial interest. All new investigators must disclose their significant financial interest within thirty (30) days of their initial appointment to the sponsor-funded project.

d. Review of Disclosures

A disclosed significant financial interest will be reviewed by the institutional official for a determination of whether it constitutes a financial conflict of interest. A financial conflict of interest exists when the institutional official reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. If the institutional official determines there is a financial conflict of interest, a resolution plan shall be established that details steps that must be taken to manage, reduce, or eliminate the financial conflict of interest. The resolution plan must be determined prior to the expenditure of funds under the funded project. To address complex situations, oversight committees may be established by the institutional official to periodically review ongoing activity, to monitor the conduct of the activity, and to otherwise oversee compliance with the resolution plan.

2. Reporting Requirements

A significant financial interest shall be reported to a sponsor, based on the applicable regulations. Various federal sponsors may have unique and additional reporting requirements as approved. All investigators and university personnel shall comply with any such requirements.

3. Record Retention

Financial conflict of interest related records shall be retained by the university per the sponsor's terms. The university will exert reasonable efforts to keep records secure. Sponsors have the right to review records pertaining to their awards. Investigators will be informed of any records requests from a federal sponsor.

4. Sanctions for Noncompliance

In the event that an investigator is found to have violated this procedure/standard or the terms of the resolution plan, the institutional official will recommend sanctions, which may include disciplinary action in accordance with the applicable CBA or existing university rule or regulation. If the violation results in a collateral proceeding under university policies regarding misconduct in research, then the institutional official shall defer a decision on sanctions until the misconduct in research process is completed. The institutional official's recommendation on sanctions shall be presented to the investigator's dean or division administrator. The institutional official shall then present recommendations to the president for enforcement of any disciplinary action, in accordance with the applicable CBA.

In addition, the university shall follow federal regulations regarding the notification of the sponsoring agency in the event that an investigator has failed to comply with this procedure/standard or the terms of the resolution plan. The sponsor may take its own action, as it deems appropriate, including the suspension of funding for the investigator until the matter is resolved, or in more severe cases, suspension or debarment from all federal grants for a period of time specified by federal policy or regulation.

Specifically for PHS-funded research, whenever a financial conflict of interest is not identified or managed in a timely manner, including failure by the investigator to disclose a significant financial interest, failure by the institution to review or manage a financial conflict of interest, or failure to comply with the resolution plan, the institution shall, within 120 days of the determination of noncompliance, complete a retrospective review of the investigator's activities and the project to determine bias in the design, conduct or reporting of such research.

If results of the retrospective review warrant, the university will update any previously submitted report to the PHS awarding component. If bias is found through retrospective review, the university will notify the PHS awarding component promptly and submit a mitigation report in accordance with the PHS regulation.

In any case in which the U.S. Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted or reported by an investigator with a financial conflict of interest that was not managed or reported by the institution as required by the regulation, the institution shall require the investigator to disclose the financial conflict of interest in each public presentation of the results of the research, and to request an addendum to previously published presentations.

5. Investigator Training for PHS-Funded Research Projects

Each investigator must complete training prior to engaging in research funded by a PHS awarding component, and at least every four years thereafter. They must also complete training if: this procedure/standard is revised in a manner that affects requirements of investigators; an investigator is new to the PHS-funded research project; and/or an investigator is not in compliance with the procedure/standard or resolution plan.

6. Public Accessibility for PHS-Funded Research Projects

Prior to the expenditure of any funds under a PHS-funded research project, the university will make publically accessible, via a written response to any requestor within five business days of a request, information concerning any significant financial interest that meets the following criteria: the significant financial interest was disclosed and is still held by the investigator; a determination has been made that the significant financial interest is related to the PHS-funded research; and, a determination has been made that the significant financial interest is a financial conflict of interest. The information to be made available shall be consistent with the requirements of the PHS regulations, and shall be retained for at least three years from the date the information was last updated.

7. Compliance of Subrecipients

Collaborators, subgrantees and subcontractors from other institutions are required to either comply with this procedure/standard or provide certification that their institutions comply with federal regulations regarding investigator significant financial Interest disclosure and that their portion of the project complies with their institutional policies. When applicable, via a written agreement, the university will establish whether the subrecipient will follow the procedure/standard of the university or the procedure/standard of the subrecipient. When applicable, the subrecipient must report financial conflicts of interest to the university in sufficient time to allow the university to report to the sponsor.

Subcontractors from commercial firms need not make a certification, except when the prime award is from PHS. PHS requires a certification from any subcontractor, including commercial firms, stating that it is in compliance with federal policies regarding investigator significant financial interest disclosure and that its portion of the project is in compliance with their company policies.

V. Effective Date: March 3, 2016

Sources:

1. Pennsylvania's State System of Higher Education, Conflict of Interest Model Procedure/standard, December 2008
2. Federal Demonstration Partnership, Model Financial Conflict of Interest Procedure/standard, 2012
3. Indiana University of Pennsylvania, Procedure/standard for Financial Conflict of Interest in University Research, 2012
4. Kutztown University of Pennsylvania, Policy ACA-068, Financial Conflict of Interest Policy
5. Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F, Promoting Objectivity in Research, 2011
6. NIH, Checklist for Procedure/standard Development Related to the 2011 Revised Financial Conflict of Interest Regulation, Promoting Objectivity in Research, 2011
7. NIH, Financial Conflict of Interest Presentation, June 2012
8. OMB Uniform Administrative Requirements, Cost Principals, and Audit Requirements for Federal Awards, 2 C.F.R., Chapter II, Part 200

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Supplemental Resources

Suggested Conflict of Interest Policy for Use by Subrecipients of HHS/PHS funding, Federal Demonstration Partnership, National Academies:
http://sites.nationalacademies.org/pqa/fdp/pqa_061001 select link to FDP Model Policy

Sample Financial Interest Report for University or Subrecipient Use, Federal Demonstration Partnership National Academies:
http://sites.nationalacademies.org/pqa/fdp/pqa_061001, select link to FDP Model Report Form. Attached.

Financial Interests Report

(Submitted pursuant to the requirements of the institution name here Conflict of Interest policy)

Name: _____

I am reporting on activities: for the year _____
 as an addendum to my most recent report

<input type="checkbox"/> yes	<input type="checkbox"/> no	1. Compensation (including travel expenses). Have you or a member of your family received compensation from a for-profit entity for activities such as consulting, expert witness, advisory board membership, and the like? If yes, furnish information on an additional page.
<input type="checkbox"/> yes	<input type="checkbox"/> no	2. Equity. Do you or a member of your family own stock or hold stock options with a publicly-traded or privately-owned entity? If yes, furnish information on an additional page.
<input type="checkbox"/> yes	<input type="checkbox"/> no	3. Role. Do you or a member of your family serve as a director, trustee, officer or other key employee in a for-profit corporation, partnership, business, or other entity outside of the <u>institution name here</u> ? If yes, furnish information on an additional page.
<input type="checkbox"/> yes	<input type="checkbox"/> no	4. Intellectual Property. Do you or a member of your family have rights to and/or receive royalties from intellectual property (including, patents copyrights and trademarks but excluding academic or scholarly works) licensed to and/or owned by a for-profit entity? Do NOT include intellectual property owned or managed by the <u>institution name here</u> . If yes, furnish information on an additional page.

Certification:

I have read and understand the institution name here's policy on Conflict of Interest and have completed this report to the best of knowledge and belief. If required, I will comply with any conditions or restrictions imposed by the institution name here to manage any real or perceived conflicts. Should my outside financial or managerial interests, or those of my family, change in a way that results in different answers to any of the questions asked in this report, I agree to submit a revision.

(Date)

(Signature)

Additional page(s) attached

Financial Interests Report - additional page

Addition to Financial Interests Report of: _____

Reporting for self family member:
name: _____
relationship: _____

Name of External Entity: _____

Address of External Entity: _____

Type of external relationship: (check all that apply)

<input type="checkbox"/>	Consultant
<input type="checkbox"/>	Speaker
<input type="checkbox"/>	Advisory Board or Committee
<input type="checkbox"/>	Equity Holdings
<input type="checkbox"/>	Governing Board or Officer
<input type="checkbox"/>	Intellectual Property Rights
<input type="checkbox"/>	Royalty Income
<input type="checkbox"/>	Other (describe below)

Amount of compensation or financial interest in reporting period: \$ _____

If travel paid by entity:

Destination _____

Amount \$ _____

Comments or explanatory information: