

**Pittsburg State University  
Office of Research Administration and Compliance  
Financial Conflict of Interest Policy/Procedure**

**POLICY/PROCEDURE:** Disclosure of Significant Business or Financial Interests That May Represent Conflicts of Interest

**DATE:** April 20, 2022

**PURPOSE:** The purpose of this Policy/Procedure is to ensure that faculty and staff are aware of and remain free from conflicts of interest that may arise as a result of interaction with the public and private sectors.

**REVIEW:** This Policy/Procedure will be reviewed in August of even-numbered years by the Chief Compliance Officer (CCO) with substantive revisions presented to the General Counsel (GC).

**POLICY/PROCEDURE**

**1. Overview**

Pittsburg State University (PSU, university) encourages its employees to interact with business, industry, state and federal agencies to facilitate professional development and as an important component of its research, instructional, and service activities. The university and its employees also are committed to conducting themselves and their activities in a manner consistent with the highest standards of integrity and ethics.

Federal regulations require that institutions have policies and procedures in place to ensure that employees disclose any significant financial interests and conflicts of commitment that may represent an actual or potential conflict of interest in relationship to externally sponsored projects. Therefore, this document articulates the general university regulations and procedures regarding conflicts of interest, which serve to protect the credibility and the integrity of the university's faculty and staff, as well as the institution, so that public trust and confidence in its sponsored activities are not compromised in any way. Further, the National Institutes of Health (NIH) requires that institutions promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from investigator financial conflicts of interest (FCOI). Therefore, this document provides specific reference to unique requirements for employees who are planning to participate in, or are participating in, PHS research funding received as a grant or cooperative agreement.

This policy is not limited in application to PHS-funded research. Rather, this policy applies broadly to research performed at, or on behalf of PSU, without regard to whether the research has external funding and, if externally funded, regardless of the funding source. Additionally, it establishes the process for the management and reporting of financial conflicts of interest in research and conflicts of interest in general.

It is the goal of PSU to provide a transparent system of disclosure of its employees' activities, external to the university, which might otherwise raise concerns about conflicts of commitment. The procedure

provides the institutional responsibilities to protect the credibility and reputation of the university and its faculty and staff when those employees are engaged in external activities, ensures compliance with state ethics laws and Kansas Board of Regents Policies and Regulations, and addresses conflicts between external professional and non-professional activities and university responsibilities.

The potential for conflict arises because of the nature and scope of activities engaged in by the university and its employees. The university assumes that potential for conflicts will occur regularly in the normal conduct of activities. However, it is essential that any significant potential for conflicts be disclosed and reviewed by the university. After disclosure, the university can then make an informed judgment about a particular case and require appropriate oversight, limitations, or prohibitions on the activity. Employees may not engage in activities in which an actual unmanageable conflict of interest occurs. In addition to issues addressed in these regulations, there may be ethical considerations that are distinct and separate from conflict of interest questions. FCOI under this policy shall be managed by the Office of Research Administration and Compliance (ORAC).

## **2. Applicability**

This policy applies to all employees of PSU and to persons who are contractors, consortium participants, collaborators, or consultants who are planning to participate in, or are participating in, PHS and other external research funding received as a grant or cooperative agreement.

## **3. For All PSU Employees and Collaborative Individuals Participating in or Planning to Participate in Funding Received as a Grant or Cooperative Agreement from Public Health Services or Other External Research Funding**

### **a. Definitions**

- (1) **Investigator:** The principal investigator, co-principal investigator, project director, and any other person at PSU, or its contractors, collaborators, or consultants regardless of title or position, who are responsible for the design, conduct, or reporting of research or educational activities that are funded or proposed for funding by the Public Health Services (PHS) or any other external entity. Usually these will be the individuals whose names appear on the Proposal Approval Routing Form. The definition of investigator includes the investigator's family members, defined as a spouse and dependent relatives or household members. These definitions align with those in the Kansas Board of Regents Policy Manual, Chapter 12, Commitment of Time, Conflict of Interest, Consulting and Other Employment regarding conflicts of interest.
- (2) **Senior/Key Personnel:** The Principal Investigator or any other person identified as senior or key personnel by the university in a grant application, award, or contract or in any progress report, or any other report submitted to the PHS or other external funding agency.
- (3) **Significant Business or Financial Interest means:**
  - (a) A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent relatives or household members) that reasonably appears to be related to the investigator's institutional responsibilities:
    - 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;

- 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
- With regard to any entity, a significant financial interest exists if the investigator (or the investigator's spouse or dependent children) has received income related to any intellectual property during the twelve months preceding the date of the FCOI disclosure and/or reasonably anticipated to be received in the twelve months following the date of the FCOI disclosure which, when aggregated with other financial interests in the entity, exceeds \$5,000.

- (b) Investigators who are planning to participate in PHS and other externally-funded research must disclose their reimbursed or sponsored travel related to their institutional responsibilities for which the aggregate amount exceeds \$5,000 in value from a single entity over the previous twelve-month period. Reimbursed or sponsored travel includes 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. 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 as defined in [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. Disclosure shall be made to the employee's supervisor and will include the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The supervisor will forward the disclosure to the CCO who will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with PHS and other externally-funded research. Once investigators have made their initial disclosure, they are required to update their disclosures within 30 days of acquiring reimbursed or sponsored travel that exceeds \$5,000 in value from a single entity over the previous twelve-month period. These reimbursements apply to the investigator and his/her spouse and dependent relatives.
- (c) The term significant financial interest does not include the following types of financial interests: salary, royalties, or other remuneration paid by PSU to the investigator if the investigator is currently employed or otherwise appointed by PSU, including intellectual property rights assigned to PSU and agreements to share in royalties related to such rights; 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; income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an

institution of higher education as defined in [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 income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education as defined in [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.

- (4) Unit Head: Dean, department chair, executive director, director, assistant/associate vice president or vice president.
- (5) Designated Official: Dean of a college or school, an executive, or vice president not in charge of an academic unit. In some cases, the unit head and the designated official will be the same person.
- (6) Entity: Any domestic or foreign, public or private, organization (excluding a federal agency) from which an investigator (and spouse and dependent relatives or household members) receives remuneration or in which any person has an ownership or equity interest.
- (7) COIC: Conflict of Interest Committee. Members of this committee are appointed by the President and include the General Counsel (GC), Director of Internal Audit (DIA) and the Assistant Controller (AC).

b. Procedure

(1) Training

All employees and other individuals planning to act as investigators must complete training regarding FCOI prior to engaging in research related to PHS and other externally-funded grant and at least every four years, and immediately when any of the following circumstances apply:

- (a) PSU revises its FCOI policies or procedures in any manner that affects the requirements of investigators;
- (b) An investigator is new to PSU; or
- (c) PSU finds that an investigator is not in compliance with PSU's FCOI policy or management plan.

Appropriate training is provided through Collaborative Institutional Training Initiative (CITI) <https://www.citiprogram.org/index.cfm?pageID=14>. To identify appropriate training and submit training records, an investigator should contact [grants@pittstate.edu](mailto:grants@pittstate.edu).

(2) Annual Disclosure

All employees and other individuals holding or planning to submit for PHS and other external funding within the academic year shall disclose to their supervisor, by October 1 of each year, the following significant business or financial interests, including interests of their spouse and dependent relatives or household members:

- (a) Any significant business or financial interest that would reasonably appear to be related to the investigator's institutional responsibilities; or
- (b) Any significant business or financial interest in an entity whose business or financial interest would reasonably appear to be related to the investigator's institutional responsibilities.
- (c) Any significant business or financial interest that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
- (d) Any significant business or financial interest in an entity whose business or financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

The annual disclosures shall include any information that was not disclosed initially to PSU or in a subsequent disclosure of significant financial interests (e.g., any FCOI identified on a PHS and other externally-funded project that was transferred from another institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

Each investigator who is participating in the PHS or other externally-funded research shall submit an updated disclosure of significant financial interests within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Employees planning to act as investigators who have no significant business or financial interests as described above shall submit a certification to that effect.

Employees who do not hold external funding as of October 1 of each year and subsequently apply for such funding shall complete the disclosure process outlined above prior to submission of their funding proposal(s), if they have not already done so.

The preceding provisions shall apply to all key personnel (as defined above) on all PHS and any other externally-funded projects.

Annual disclosures and any updates to disclosures shall be completed and sent to [grants@pittstate.edu](mailto:grants@pittstate.edu) for review. Requests for approval of outside employment may also be sent to [grants@pittstate.edu](mailto:grants@pittstate.edu) and will be reviewed and managed by the unit head and the CCO.

If there is a change in the reported information during the year, the investigator shall submit updated information.

Regardless of the above minimum requirements, an investigator may choose to disclose any other business, financial, or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

The CCO shall maintain records of business or financial disclosures for all externally sponsored projects submitted under this policy for three years beyond the termination or completion of

the award to which they relate, or until the resolution of any government action involving those records, whichever is longer.

The CCO shall maintain the confidentiality of disclosures to the extent possible.

(3) Certification at the Time of Proposal Submission

Prior to submitting a proposal for funding to the PHS or any other external entity, each investigator shall certify that he/she has disclosed any significant business or financial interests (including those of a spouse and dependent relatives or household members) that would 1) reasonably appear to be related to the investigator's institutional responsibilities, and 2) reasonably appear to be affected by the project for which funding is sought, and the unit head shall certify that, based on the investigator's disclosure, either (1) no conflicts of interest exist; or (2) existing conflicts will be managed, reduced to an acceptable level, or eliminated prior to expenditure of funds under the award. These certifications shall be made via the *Proposal Approval Routing Form for Sponsored Projects* and reviewed by the CCO.

(4) Review of Disclosures

The process outlined in section 3.b.(2) above is applicable.

The CCO shall review all disclosures. If the CCO determines that a conflict of interest exists, the CCO, in consultation with the COIC and unit head, shall take actions necessary to ensure that such conflicting interests will be managed, reduced to an acceptable level, or eliminated. In making this determination, the CCO may seek the advice of other university administrators. The CCO and the COIC, conjunction with the investigator and unit head, shall prepare a management plan for managing, reducing, or eliminating the conflict. This document will be signed by the investigator, unit head, and CCO. The unit head shall serve as the monitor for a management plan involving individuals in their department. If, however, the unit head has a relationship with the entity described in the management plan (for example, as a collaborator, advisor, or reviewer), then in consultation with university administration and the managed individual, the CCO and COIC may call upon another administrator, unaffiliated with the research and/or the external entity, to serve as the management plan monitor.

If the CCO determines that no conflict of interest exists, the CCO shall make a notation of such and maintain appropriate record within the ORAC. The CCO shall strive to make his/her determination within 30 days of receipt of the disclosure.

If the CCO and the investigator have not agreed upon a management plan 30 days following a determination that a conflict exists, the investigator may seek the intervention of the President.

The CCO shall maintain records of all actions taken with respect to each conflicting interest for three years beyond the termination or completion of the award to which they relate, or until the resolution of any government action involving those records, whichever is longer.

The CCO shall maintain, to the extent possible, the confidentiality of management plans.

c. External Reporting – Non-PHS Funded Research

The CCO shall be responsible for all reporting requirements to external agencies. These include the following:

- (1) The CCO will sign institutional certifications required in proposals.
- (2) The CCO will report the existence of a conflict and its management plan to the unit head and the designated official, and the management plan will be kept on file in the ORAC.
- (3) The CCO will notify the sponsoring agency in the event an employee has failed to comply with the university's policy.
- (4) The CCO will notify the sponsoring agency in the event that PSU is unable to manage a conflict of interest satisfactorily.
- (5) In the event a conflict of interest is identified after the expenditure of funds under an award, the CCO will, within 60 days of identifying the conflict (less time if required by the sponsoring agency), notify the agency of the existence of the conflict and assure that the conflict has been managed, reduced to an acceptable level, or eliminated.
- (6) Upon request from any sponsoring agency or other authorized government entity, the CCO will provide information regarding all conflicting interests identified by PSU and describe how those interests have been managed, reduced to an acceptable level, or eliminated.
- (7) In the event that an investigator fails to comply with the university's conflict of interest policy and has biased the design, conduct, or reporting of an externally funded project, the CCO will notify the agency of corrective action taken.

d. External Reporting – PHS Funded Research

The CCO shall be responsible for all reporting requirements to external agencies. These include the following:

- (1) The CCO will sign institutional certifications required in proposals.
- (2) The CCO will report the existence of a conflict and its management plan to the unit head and designated official.
- (3) For proposals to the PHS, the CCO will report to PHS the existence of a conflict, but not the details of the conflict, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI. Furthermore, whenever PSU implements a management plan in accordance with PHS policy, the CCO shall monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

Prior to expenditure of any funds under a PHS-funded research project, PSU shall provide to the PHS awarding component an FCOI report regarding any investigator's significant financial interest found by the CCO to be conflicting and ensure that PSU has implemented a management plan in accordance with this section. In cases in which the CCO identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, PSU shall not submit an FCOI report to the PHS awarding component.

For any significant financial interest that the CCO identifies as conflicting subsequent to PSU's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an investigator who is new to the research project), PSU shall provide to the PHS awarding component, within 60 days, an FCOI report regarding the financial conflict of interest and ensure that PSU has implemented a management plan in accordance with this section. Pursuant to subsection (7) below, where such FCOI report involves a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed or managed by the institution, PSU also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, if bias is found, PSU is required to notify the PHS awarding component promptly and submit a mitigation report to the PHS awarding component.

- (4) Any required FCOI report shall include sufficient information to enable the PHS awarding component to understand the nature and extent of the financial conflict, and to assess the appropriateness of PSU's management plan. Elements of the FCOI report shall include, but are not necessarily limited to, the following:
- (a) Project number;
  - (b) PD/PI or contact PD/PI if a multiple PD/PI model is used;
  - (c) Name of the investigator with the financial conflict of interest;
  - (d) Name of the entity with which the investigator has a financial conflict of interest;
  - (e) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
  - (f) Value of the financial interest (dollar ranges are permissible: \$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 public prices or other reasonable measures of fair market value;
  - (g) A description of how the financial interest relates to the PHS-funded research and the basis for PSU's determination that the financial interest conflicts with such research; and
  - (h) A description of the key elements of PSU's management plan including:
    - Role and principal duties of the conflicted investigator in the research project;
    - Conditions of the management plan;
    - How the management plan is designed to safeguard objectivity in the research project;

- Confirmation of the investigator's agreement to the management plan;
- How the management plan will be monitored to ensure investigator compliance; and
- Other information as needed

For any financial conflict of interest previously reported by PSU with regard to an ongoing PHS-funded research project, PSU shall provide to the PHS awarding component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. PSU shall provide annual FCOI reports to the PHS awarding component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS awarding component.

- (5) Whenever, in the course of an ongoing PHS-funded research project, an investigator who is new to participating in the research project discloses a significant financial interest or an existing investigator discloses a new significant financial interest to PSU, the CCO shall, within 60 days (1) review the disclosure of the significant financial interest; (2) determine whether it is related to PHS-funded research; (3) determine whether a financial conflict of interest exists; and, if so, (4) implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, PSU may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS-funded research project between the date of disclosure and the completion of PSU's review.
- (6) The CCO will notify the sponsoring agency in the event an employee has failed to comply with the university's policy.
- (7) Whenever PSU identifies a significant financial interest that was not disclosed in a timely manner by an investigator or, for whatever reason, was not previously reviewed by PSU during an ongoing PHS-funded research project, the CCO shall, within 60 days (1) review the significant financial interest; (2) determine whether it is related to PHS- funded research; (3) determine whether a financial conflict of interest exists; and, if so:
  - (a) Implement, on at least an interim basis, a management plan that shall specify the actions that have been and will be taken to manage such financial conflict of interest going forward.
  - (b) In addition, whenever (1) 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 that is determined by PSU to constitute a financial conflict of interest; (2) failure by PSU to review or manage such a financial conflict of interest; or (3) failure by the investigator to comply with a financial conflict of interest management plan, PSU shall, within 120 days of PSU's determination of noncompliance, complete a retrospective review of the investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design,

conduct, or reporting of such research.

By PHS policy, PSU is required to document the retrospective review. Such documentation shall include, but not necessarily be limited to, all of the following key elements:

- Project number;
- Project title;
- PD/PI or contact PD/PI if a multiple PD/PI model is used;
- Name of the investigator with the FCOI;
- Name of the entity with which the investigator has a financial conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review

(c) Based on the results of the retrospective review, if appropriate, PSU shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, PSU is required to notify the PHS awarding component promptly and submit a mitigation report to the PHS awarding component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above, a description of the impact of the bias on the research project, and PSU's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, PSU will submit FCOI reports annually, as specified above. Depending on the nature of the financial conflict of interest, PSU may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of PSU's retrospective review.

- (8) The CCO will notify the sponsoring agency in the event that PSU is unable to manage a conflict of interest satisfactorily.
- (9) In the event a conflict of interest is identified after the expenditure of funds under an award, the CCO will, within 60 days of identifying the conflict (or in less time if required by the sponsoring agency), notify the agency of the existence of the conflict and assure that the conflict has been managed, reduced to an acceptable level, or eliminated.

- (10) Upon request from any sponsoring agency or other authorized government entity, the CCO will provide information regarding all conflicting interests identified by PSU and describe how those interests have been managed, reduced to an acceptable level, or eliminated.

In the event that an investigator fails to comply with the university's conflict of interest policy and has biased the design, conduct, or reporting of PHS-funded research, the CCO shall promptly notify the PHS awarding component of the corrective action taken or to be taken.

- (11) Prior to PSU's expenditure of any funds under a PHS-funded research project, PSU shall ensure public accessibility, via written response from the CCO to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to PSU that meets the following three criteria:

- (a) The significant financial interest was disclosed and is still held by the senior/key personnel as defined in section 3.a.(2) above;
- (b) PSU determines that the significant financial interest is related to the PHS-funded research; and
- (c) PSU determines that the significant financial interest is a financial conflict of interest.

The information that PSU makes available via written response to any requestor within five business days of a request shall include, at a minimum, the following: the investigator's name; the investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$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 public prices or other reasonable measures of fair market value.

Information concerning the significant financial interests of an individual subject to this section shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

e. Guidelines

A conflict of interest exists when the designated official reasonably determines that a significant business or financial interest could directly and significantly affect the design, conduct, or reporting of externally funded research, service, or educational activities.

- (1) Examples of manageable conflicts of interest include, but are not limited to, the following:
- (a) Situations in which the outside activity will conflict with previously established responsibilities to the university;
  - (b) Situations that might allow a university employee to influence the university's dealings with an outside organization such that personal gain for the employee or improper

- advantage for anyone is the result; and
- (c) Supervision of student research activities when research in that area might lead to financial or personal gain for the faculty member.
- (2) Examples of unacceptable conflicts of interest include, but are not limited to, the following:
- (a) Use for personal profit of unpublished information originating from university research or other confidential university sources;
- (b) Consulting under arrangements that impose obligations that conflict with the university's intellectual property policy or with the university's obligations to research sponsors or that inhibit the publication of research results obtained within the university; and
- (c) Circumstances in which a substantial body of research that could, and ordinarily would, be carried on within the university is conducted elsewhere to the disadvantage of the university and its legitimate interests.
- (3) Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate conflicts of interest include, but are not limited to:
- (a) Public disclosure of significant business or financial conflicts of interest (e.g., when presenting or publishing the research; to staff members working on the project; to the university's Institution's Institutional Review Board and Institutional Animal Care and Use Committee, etc.);
- (b) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- (c) Review of research protocol by independent reviewers;
- (d) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- (e) Modification of the research plan;
- (f) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all of the research or the portion that would be affected by the significant business or financial interests;
- (g) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (h) Severance of relationships that create conflicts.

In any case in which the 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

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reported by an investigator with an FCOI that was not managed or reported by the institution as required by the regulation, the institution shall require the investigator involved to disclose the FCOI in each publication of the results of the research and request an addendum to previously published presentations.

f. Compliance

No proposals will be submitted to PHS or any other external entity without the required certifications. If a conflict is identified, the proposal may be submitted before the management plan is implemented if the CCO, unit head and the COIC determine that the conflict can be managed or eliminated prior to the award of funds. No awarded funds will be spent until the conflict is resolved.

If breaches of the policy occur, sanctions will be imposed. Breaches include, but are not limited to, failure to file; intentionally filing an incomplete, erroneous, or misleading disclosure; failing to provide additional information as required by the CCO or unit head; or violation of terms outlined in the resolution plan. If sanctions are necessary, they will be imposed in accordance with the university's operating policies and procedures, Responding to Allegations of Research Misconduct.

The potential sanctions may include, but are not limited to, the following:

- Letter of admonition
- Suspension of award funds
- Ineligibility of the investigator for grant applications or supervision of graduate students
- Suspension, including withholding of salary
- Non-renewal of appointment
- Dismissal