



University City Science Center Financial Conflict of Interest Policy

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University City Science Center Financial Conflict of Interest Policy

I. General Science Center Policy

Objectivity in our work is of paramount importance to the University City Science Center, (Science Center.) It is equally important that we avoid even the appearance of a conflict of interest. Therefore, the Science Center requires disclosure of any actual or perceived conflict of interest to protect the integrity and credibility of the Science Center and its employees, so that public trust and confidence is ensured.

An actual or perceived conflict of interest occurs when there is, or could appear to be a divergence between one's private interests and his/her obligations to the Science Center such that an independent observer might reasonably question whether the individual's actions or decisions are determined by considerations of personal gain on the part of the individual (or members of his/her immediate family) that may relate to Science Center programs, research, use of facilities, or use of external or internal funds.

Any employee who has, or appears to have, a financial conflict of interest must submit a written disclosure to the Science Center Vice President, Government and Capital Engagement. In the event the Vice President of Government and Capital Engagement is acting as the Principal Investigator on an award, disclosure will be made to Science Center General Council and/or the Science Center CEO. The disclosure statement should be submitted as soon as the situation arises. Disclosure is a key factor in protecting the Science Center and one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

II. Policy Applicable to Public Health Service/National Institutes of Health Funding

A. PURPOSE

The 2011 revised regulation, "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought" (<https://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>) seeks to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under Public Health Services (PHS) grants or cooperative agreements, including those awarded by the National Institutes of Health (NIH), will be free from bias resulting from an investigator's financial conflicts of interest.

This policy is designed to ensure that the Science Center is in full compliance with federal regulations when applying for or receiving PHS funding, as put forth in the National Institutes of Health guidelines (see <https://grants.nih.gov/grants/policy/coi/index.htm>).

This policy applies to all Investigators (as defined by the policy) who are involved with PHS-funded research by means of a grant or cooperative agreement, including research funded by NIH.

B. DEFINITIONS

As used in this policy:

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

Financial interest means anything of monetary value, whether the value is readily ascertainable.

Institutional Official means the individual within the Science Center who has been designated to solicit and review disclosures from Investigators of significant financial interests related to the Investigator's institutional responsibilities. For the purposes of this policy, the Institutional Official will be the Vice President, Government and Capital Engagement, General Council, or Science Center CEO.

Institutional responsibilities mean an Investigator's professional responsibilities on behalf of the Science Center, and as defined by the Science Center in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, and institutional committee memberships.

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 funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

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

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

Significant financial interest means:

1. 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:
 1. Regarding 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;

2. 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
 3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
2. 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; provided, however, that 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 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. This disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with this policy, the Institutional Official will determine if further information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes an FCOI with the PHS-funded research.

Significant financial interest does **NOT** include the following types of financial interests:

1. Salary, royalties, or other remuneration paid by the Science Center to the Investigator if the Investigator is currently employed or otherwise appointed by the Science Center, including intellectual property rights assigned to the Science Center and agreements to share in royalties related to such rights;
2. 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;
3. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency of the United States, a United States 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 a United States Institution of higher education; or

4. Income from service on advisory committees or review panels for 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.

C. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

All Investigators are required to disclose to the Science Center's Institutional Official the Investigator's Significant Financial Interests (and those of the Investigator's spouse and dependent children) on an annual and ad hoc basis, as described below, using the attached Significant Financial Interest Disclosure Form. Investigators should submit the completed form together with supporting documentation in a sealed envelope marked confidential to the Science Center's Institutional Official.

All Investigators who are participating in PHS-funded research are required to submit an updated disclosure of significant financial interests at least annually, to the Science Center's Institutional Official, during the period of the award.

In addition to the annual disclosure, Investigators must make disclosures in the following situations:

- *New applications for funding:* All Investigators who are planning to participate in the PHS-funded research must disclose to the Science Center's Institutional Official the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) before the application is submitted.
- *New significant financial interests:* All Investigators must submit an updated disclosure of significant financial interests to the Science Center's Institutional Official within thirty days of acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
- *Travel:* Investigators also must disclose the occurrence of any reimbursed or sponsored travel, as defined above under the term "Significant financial interest." This disclosure must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Science Center's Institutional Official will determine if further information is needed, including a determination or disclosure of monetary value, to determine whether the travel constitutes a FCOI.

D. REVIEW OF FINANCIAL DISCLOSURES

If a Significant Financial Interest Disclosure Form reveals a Significant Financial Interest, as defined above, the Science Center's Institutional Official shall promptly review the form, together with supporting documentation, to decide whether it constitutes a FCOI. A FCOI exists when the Institutional Official reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research. The Science Center may involve the Investigator in the Institutional Official's determination of whether a significant financial interest is related to the PHS-funded research.

E. MANAGEMENT OF FCOI

If the Institutional Official determines that a FCOI exists, he or she must require the creation of and approve a written plan for the management of the FCOI before related research may proceed. The Investigator, in cooperation with the Science Center, shall develop and present to the Institutional Official a Conflict-of-Interest Management Plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by the Significant Financial Interest.

Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

No expenditures on PHS awards will be permitted until the Investigator has complied with the disclosure and training requirements (see below) of this policy and has agreed, in writing, to comply with any plan(s) determined to be necessary for the management of the FCOI.

The Science Center shall monitor Investigator compliance with the FCOI management plan on an ongoing basis until the completion of the PHS-funded research project.

If the Science Center identifies a FCOI and eliminates it prior to the expenditure of any PHS-awarded funds, the Science Center is not required to submit a FCOI report to the respective agency.

F. REPORTING FINANCIAL CONFLICTS OF INTEREST

(1) Sponsoring agency.

If the Institutional Official determines that any Significant Financial Interests is an FCOI, the Institutional Official shall provide to the PHS sponsoring agency an FCOI report regarding the FCOI and ensure that the Science Center has implemented a management plan in accordance with this policy. The FCOI report must be provided to the PHS sponsoring agency in accordance with its specific requirements within 60 days of the original disclosure and before any funds are expended under a PHS-funded research project, and it must include sufficient information to enable the PHS awarding agency to understand the nature and extent of the financial conflict and assess the appropriateness of the Science Center's management plan.

If PHS funding for the project comes via a subaward agreement, the FCOI report shall be made available to the prime awardee such that they may fulfill their reporting obligations to the PHS sponsoring agency.

(2) Public request.

As required by sponsoring agency regulations, information on Financial Conflicts of Interest will be made available to members of the public in response to inquiries to the Institutional Official within 5 business days of receipt of such requests.

G. SUBRECIPIENTS

If any part of PHS-funded research is conducted through a subrecipient (e.g., subcontractors or consortium members), the Science Center (i.e., awardee Institution) will take reasonable steps to ensure that any subrecipient Investigator complies with applicable federal regulations. To this end, the Science Center shall enter into a written agreement with each subrecipient that (1) includes a statement indicating whether the Science Center's or the subrecipient's institutional FCOI policy shall apply; and (2) specifies the timing for reporting of FCOIs by subrecipients to the Science Center to enable the timely review and reporting of such FCOIs in compliance with PHS requirements.

H. TRAINING

All Investigators must complete training on this policy prior to engaging in research related to any PHS-funded grant and at least every four years.

In addition, Investigators must complete training on this policy within a reasonable amount of time determined by the Institutional Official in any of the following circumstances:

- The Science Center revises its FCOI policies or procedures in a way that affects the requirements of Investigators;
- An Investigator is new to the Science Center;
- The Science Center finds that an Investigator is not in compliance with this policy or an approved FCOI management plan.

Investigators should contact the Vice President, Government and Capital Engagement to schedule training. The Vice President, Government and Capital Engagement will complete annual FCOI training and maintain updated completion records at all times.

I. NON-COMPLIANCE

(1) **Sanctions:** The Science Center requires Investigators to comply fully with this policy. Instances of deliberate breach of policy, including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms, violation of the guidelines, or failure to comply with prescribed monitoring procedures may result in sanctions being imposed upon the violating individual.

(2) **Retrospective Review:** In addition, if the Institutional Official determines that a FCOI was not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Science Center to constitute a FCOI; failure by the Science Center to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI management plan, the Science Center shall, within 120 days of the 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.

The Science Center is required to document the retrospective review; such documentation shall include the following key elements: project number; project title; name of PI; name of the Investigator with the FCOI; name of the entity with which the Investigator has a FCOI; reason(s) for the retrospective review; detailed methodology used for the retrospective review; findings of the review; and conclusions of the review.

Based on the results of the retrospective review, if appropriate, the Institutional Official shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the Science Center is required to notify the PHS sponsoring agency promptly and submit a mitigation report to the PHS sponsoring agency. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Science Center's plan of action or actions taken to eliminate or mitigate the effect of the bias.

J. RECORD MAINTENANCE

The Science Center will retain all disclosure forms, conflict management plans, and related documents for a period of three years from the date the final expenditure report is submitted to the sponsor. Access to such records will be limited to the investigator, authorized institutional officials and others who have legal right to review the records.

K. REGULATORY AUTHORITY

This policy implements the requirements of 42 C.F.R. 50, Subpart F and 45 C.F.R. 94; where there are substantive differences between this policy and the requirements, the requirements shall take precedence.

IV. Other Funding Sources

Research by any Investigator (person responsible for the design, conduct, or reporting of research or educational activities) funded or proposed for funding by a federal agency other than NSF or the PHS shall comply with that agency's policies regarding financial conflict of interest.