

Research Conflict of Interest Policy

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| Farmingdale State College | Approved By: | The Cabinet |
| | Effective Date: | March 20, 2018 |
| | Supersedes issue of: | None |
| | Category: | Research Administration |
| | Contact: | Director of Research Administration Director of Sponsored Program Development |

Background

Faculty and staff of Farmingdale State College (FSC) and the Research Foundation (RF) are encouraged to foster an atmosphere of academic freedom by promoting the open and timely exchange of scholarly knowledge. In keeping with this obligation, they are also required to avoid conflicts of interest.

The intent of this policy is to remove bias or the perception of bias from the research process by identifying and managing any financial conflicts of interest.

The policy defines an “Investigator” as any individual (including non-FSC collaborators and volunteers) participating in the design, conduct, or reporting of an externally funded project or human subjects research as defined and governed by the campus Institutional Review Board (IRB). Investigators are required to make full disclosure of all existing significant obligations and financial interests in the following circumstances:

- Through the Annual Disclosure process;
- Prior to the submission of a proposal for external funding to a sponsor; and
- Within 30 days of an event that would change the disclosure on file.

FSC uses the Pre-Award and Compliance System (PACS) Conflict of Interest module as the system of record for tracking conflict of interest disclosures. PACS also provides the platform for investigators to submit their disclosures or follow up on initiated certifications.

Annual Disclosure Process

Investigators must submit an annual “Disclosure Statement of Significant Obligations, Significant Financial Interests, and Sponsored Travel.”

Investigators should file their disclosure as soon as possible and no later than November 1st of each year. The disclosure year extends until October 31 of the following year.

Disclosure Review

No review or action is required or conducted if the disclosure certification submitted by an investigator contains no reported information.

Disclosure certifications that do contain reported information are subject to review by the Office of Sponsored Programs and Research Administration (OSPRA) and the Vice President for Administration and Finance.

For disclosures requiring review, the Director of Sponsored Program Development will review financial disclosures, determine whether a potential conflict of interest exists, and determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflict of interest.

What should be disclosed?

Investigators should disclose outside entities with which they or an immediate family (spouse and dependent children) have a business relationship outside of FSC. Outside entities include companies, service providers, non-government organizations (NGOs), foundations, competitors, non-competitors, and any other for-profit or not-for-profit entities (hereinafter called "companies") with which you or an immediate family member had a business relationship in the previous 12 months, or with which you or an immediate family member anticipate a relationship within this calendar year. A business relationship is defined as an association between individuals or companies for commercial purposes which may be governed by contracts or agreements and may involve remuneration of some kind.

Payments or Remuneration - The following is a non-exclusive list of payments that you must disclose:

- Payments from all non-institutional sources, whether or not you received an IRS Form 1099, W-2, or K-1, except as noted in the Exclusions below.
- Any payment or promise of payment of any kind to you or an immediate family member, either in currency or in-kind, for any purpose, whether or not you believe the purpose or the payment is related to your employment at this institution, except as noted in Exclusions, below.
- Payments or promises of payment from a company that has licensed or has options to license any intellectual property (patents, inventions, copyrights, trademarks) either directly or through any other entity, where such intellectual property was developed by you or an immediate family member.
- Any payments made to a company on your behalf. For example, you are part of an organized consulting group that receives payment for your work, that consulting group and the companies that paid you through the consulting group are to be disclosed.

- Payments from any corporate sponsor that pass through an intermediary should be attributed to the corporate sponsor. For example, a pharmaceutical company hires a public relations firm to arrange seminars in support of the pharmaceutical company's product. You or an immediate family member speak at a seminar and receive compensation. The payments should be attributed to the pharmaceutical company regardless of which company's name appears on the check you receive or anticipate receiving).

Equity holdings or ownership - You are required to disclose shares of stock you or an immediate family member own, including options, warrants, or promises of such, etc., whether the company is privately or publicly held.

While you **do not** need to disclose any and all equity holdings which may be part of a savings, investment or retirement strategy, the following is a non-exclusive list of ownership or equity holdings that you must disclose:

- Pharmaceutical, biotechnology, medical device, or other companies related to research conducted on the campus.
- Start-up companies, regardless of their relationship with the College
- Companies that, to your knowledge, provide any tangible items to this institution, including equipment, office, medical or computer supplies, furniture, etc., regardless of cost.
- Companies that, to your knowledge, provide services or other intangibles to FSC, including but not limited to medical services, housekeeping, laundry, landscaping, information technology, consulting, accounting, etc., regardless of cost.

Significant Obligations – You are required to disclose any unpaid positions such as officer, trustee, director, consultant, advisor, adjunct professor that you or an immediate family member hold, regardless of their relationship to the College.

Exclusions - The following exclusions apply to payments made to or ownership by you or an immediate family member. These excluded items need not be disclosed:

- 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, 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 an Institution of higher education; or

- Income from service on advisory committees or review panels for a federal, state or local government agency, 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 an Institution of higher education.

Threshold Determination

In terms of sponsored activity, a conflict of interest exists when the College reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the sponsored research or educational activities.

Conditions or restrictions that might be imposed to manage, reduce, or eliminate conflicts of interest include, but are not limited to: public disclosure of significant financial interests; monitoring of research by independent reviewers; modification of the research plan; disqualification from participation in the portion of the research that would be affected by significant financial interests; divestiture of significant financial interests; or severance of relationships that create conflicts.

Prior to expenditure of any research funding, the College will inform the sponsor of any identified conflicting financial interests and will provide assurance that the interest has been managed, reduced, or eliminated in accordance with the regulations. As required, information as to how conflicts have been handled will be made available to the sponsor upon request. Subsequently identified conflicts will be reported to the sponsor within 60 days of such identification, along with mitigating strategies.

The VP for Administration and Finance and the President will be responsible for enforcing the conflict of interest management conditions. The VP for Administration and Finance, through the Director of Sponsored Program Development, will notify sponsors, as required, if the institution finds that it is unable to satisfactorily manage a conflict of interest.

If it is determined that an investigator has biased research, the College will be responsible for the provision of sanctions in accordance with University and Board of Trustees policies and applicable collective bargaining agreements. The VP for Administration and Finance will promptly notify the sponsor, as required, of infractions and of corrective action taken or to be taken. Any campus-imposed sanctions may be in addition to any penalties that may be imposed by a cognizant Federal agency for infractions that also violate the terms or conditions of the award. The SUNY System Provost will be notified of any reports regarding conflict of interest that are forwarded to sponsors. Any apparent, or potential conflicts will be reported to RF Office of Compliance. Records of all financial disclosures and of all actions taken to resolve conflicts of interest will be maintained for at least three years beyond the termination

of the grant to which they relate, or until the resolution of any State or Federal agency action involving those records, whichever is longer.

Procedures for compliance with PHS 2011 Conflicts of Interest regulations – these procedures incorporate and supplement the FSC Conflict of Interest Policy

Farmingdale State College adheres to the *Policy on Conflicts of Interest in Public Health Service (PHS) Sponsored Programs* of the State University of New York (SUNY) and the Research Foundation of State University of New York (RF). The following specific procedure addresses the requirements under the revised regulation on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding Sought and Responsible Prospective Contractors*, published in Federal Register, vol. 76, No. 165, on August 25, 2011.

Farmingdale State College Office of Sponsored Programs and Research Administration (OSPRA) will work with investigators receiving PHS funding to ensure that all requirements under the applicable Federal regulation are met by enacting the following procedures:

1. Policy Communication

This policy, the SUNY/RF policy, and the guiding federal regulations are publicly available on the [OSP website](#).

At the onset of the grant application process, OSP will inform investigators subject to PHS regulations of their responsibilities regarding Financial Conflict of Interest (FCOI) and will request that they review the policies, applicable regulations, and instructions for completion of requirements found on the OSP website.

2. Designated Institutional Official

The Designated Institutional Official (DIO) at FSC will be the VP for Administration and Finance, through the Director of Sponsored Program Development. The DIO is responsible for reviewing all disclosures, determining whether any disclosed financial interest constitutes a conflict, and developing conflict management plans as required by this policy. The DIO may establish an *ad hoc* committee to assist with these responsibilities if necessary. **Any conflict certification submitted that contains no disclosures, does not require review.**

3. Disclosure Submission and Review

PHS investigators must complete and submit a “Disclosure Statement of Significant Obligations, Significant Financial Interests (SFI), and Sponsored Travel” through the Conflicts of Interest module in the SUNY Pre-Award and Compliance System (PACS):

- 1) Prior to submission of and application for funding to a sponsor,
- 2) Annually, by November 1st, and
- 3) Within 30 days of discovering or acquiring a new SFI

In the event that an SFI exists: If a PHS project is funded, the DIO and/or *ad hoc* committee must first determine if the SFI constitutes an FCOI. If an FCOI is present, a management plan must be developed and implemented to reduce or eliminate the conflict **before** funds can be drawn down on the award. The investigator must agree to comply with the management plan in written or recorded form. OSPRA will submit SFI and management plan information to the appropriate PHS agency within the necessary timeframe as defined by SUNY Policy 10000.

In the event that no SFI exists: the DIO's office will indicate in PACS that no SFI has been found.

4. Non-Compliance and Retrospective Review

In instances of non-compliance, the DIO will conduct a retrospective review. If bias is identified, a mitigation report will be created and managed in PACS and submitted to the PHS awarding component.

5. Required Investigator Training

All PHS investigators must complete FCOI training:

- 1) prior to engaging in research;
- 2) every four years;
- 3) Immediately, if:
 - a. Institution revises its FCOI policy that affects requirements of investigators
 - b. An investigator is new to the institution
 - c. Investigator is not in compliance with the policy or management plan

FSC utilizes the Collaborative Institutional Training Initiative (CITI) for FCOI training. CITI COI training completion certificates are fed into the PACS system nightly and will be accessible through the discloser's PACS account and within each certification.

All PIs must complete and pass this training prior to award setup. A passing grade for each module is 80%. OSPRA will verify that training is complete and up-to-date before sending a New Award Request to RF.

OSP will notify PHS Investigators of policy changes which impact Investigator requirement.

6. Subrecipients

In the event that a PHS project includes subrecipients, the DIO of the subrecipient institution must indicate in their letter of commitment that all PHS investigators have submitted updated SFI disclosure forms for review. If the project is then subsequently funded, written agreements for awards to subrecipients will incorporate terms establishing whether the SUNY FCOI Policy or the FCOI policy of the subrecipient will apply to the subrecipient's investigators. In either case, should the subrecipient identify any FCOI consistent with the PHS regulations, such conflict of interest must be reported to RF and FSC OSPRA prior to the expenditure of funds and within 45 days of identification. The FSC DIO and/or ad hoc committee must then review and create a management plan for the FCOI. OSPRA will be responsible for reporting the FCOIs to the PHS awarding agency.

7. Public Disclosure of FCOIs

Public requests for FSC FCOI information must be made in writing to the Research Foundation for SUNY FOIL Officer. Instructions and contact information may be found here: <http://www.rfsuny.org/contacts/Freedom-of-Information-Requests>

8. Recordkeeping and Reporting

OSPRA will be responsible for all recordkeeping and reporting requirements to appropriate PHS awarding agencies.