

Document: Investigator Financial Conflict of Interest Policy

Type: Policy

This policy applies to all awards administered by The Research Foundation for SUNY at SUNY Polytechnic Institute and applies to all Investigators who apply for, receive, plan to participate in or are participating in sponsored research.

Background

SUNY Polytechnic Institute is committed to promoting objectivity in research and to maintaining high ethical standards to ensure that the design, conduct, and reporting of research is not biased by the financial interests of investigators. The responsibilities and obligations of investigators as they relate to the University must be clearly separate from their personal financial interests and obligations.

Investigators must disclose their and their immediate family members significant financial interests and non-university significant obligations to ensure that the design, conduct and reporting of sponsored program activity will not be biased.

Definitions

Investigator - The Project Director, Principal Investigator, Co-Principal Investigators and all other key person(s) who are responsible for the design, conduct, or reporting of externally or internally supported activities. Individuals who do not make independent decisions regarding the design, conduct, or reporting of the activity in question, and only work on or are engaged in the activity *do not* meet the definition of an investigator.

Conflict of Interest - when an Investigator is, or may be, in a position to influence activities or decisions in ways that could lead to personal gain for the Investigator or the Investigator's family, or give an improper advantage to third parties in their dealings with the University. Conflicts may also arise when Investigators have outside obligations of any kind that are in substantial conflict with the Investigator's responsibilities or the public interest.

Significant Financial Interest (SFI) - a financial interest consisting of one or more of the following interests of the Investigator (or those of the Investigator's immediate family members) that reasonably appears to be related to the Investigator's responsibilities:

- with regard to any publicly traded entity, 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 if, when aggregated, exceeds \$5,000
- with regard to any non-publicly traded entity, the value of any remuneration received from the entity in the twelve months preceding the disclosure if, when aggregated, exceeds \$5,000, *or* when the Investigator or his/her immediate family members hold any equity interest (e.g., stock, stock option, or other ownership interest)
- intellectual property rights and interests (e.g., patents, copyrights), and royalties from such rights, upon receipt of income related to such rights and interest;
- income received from foreign entities for seminars, lectures, teaching engagements, or service on advisory committees or review panels
- reimbursed or sponsored travel (e.g. travel paid on behalf of the investigator).

SFI Exclusions - The following types of financial interests are excluded from the definition of significant financial interest:

- salary, royalties, or other remuneration paid by SUNY, The Research Foundation for SUNY, if the Investigator is currently employed or otherwise appointed by SUNY or the RF;
- intellectual property rights assigned to SUNY or the RF 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 received from U.S. based organizations for seminars, lectures, teaching engagements, or service on advisory committees or review panels 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.

Financial Conflict of Interest (FCOI) - Exists when an Investigator's SFI, external obligation, or sponsored travel could directly and significantly affect the design, conduct, or reporting of research or creative activity. SFIs that could directly and significantly affect the design, conduct, or reporting of funded research are considered an FCOI.

Policy and Procedures

As part of its commitment to promoting objectivity in research, and consistent with federal regulations, Research Foundation policy, and the requirements of external agencies, SUNY Polytechnic Institute has formulated this policy to identify and address potential, actual and apparent conflicts of interest.

Disclosures

Real and apparent FCOI may arise from any number and type of external commitments and financial interests. Investigators are **required** to report fully and accurately all external commitments and financial interests they hold, as well as the commitments and interests of their spouse, domestic partner and dependent child(ren).

Investigators must complete and submit an *Investigator Disclosure Statement*:

- at the time of application for funds or prior to the activation of an award, dependent on sponsor requirements;
- annually thereafter during the period of a funded award;
- when required by the sponsor or by the terms and conditions of an award; and
- within 30 days of discovering or acquiring a new SFI, or when an existing SFI materially changes.

The Institutional Official will review the disclosure statement and determine whether an Investigator's SFI is related to his or her research or sponsored programs activities and, if so, whether the SFI constitutes a conflict of interest.

A SFI is related to research or sponsored programs activities when the Institutional Official reasonably determines that the SFI could be affected by the research or sponsored program activity, or is in an entity whose financial interest could be affected by the research or sponsored program activity.

Conflict Resolution and Management

Conflicts of Interest shall be avoided, resolved, or managed, as needed, pursuant to applicable regulations, policies and procedures on conflicts of interest. Any University employee may request advice about a potential conflict of interest from the Institutional Official.

If the Institutional Official determines that a disclosure constitutes an FCOI, a Conflict Management Plan shall be developed and implemented. The plan is designed to remove the bias, or the reasonable perception of bias. Real and apparent FCOI often can be managed, in whole or in part, by:

- public disclosure of the implicated external commitments and financial interests, specifically to journal publishers, granting agencies, conference organizers, audiences at presentations, colleagues, collaborators, and students;
- monitoring by independent reviewers of the related research and/or of the student participation;
- modification of the research plan;
- disqualification from participation in all or a portion of the research project;
- removal of the investigator as the principal investigator or the appointment of a co-investigator;
- declination of the sponsored award.

Special attention is paid when research personnel have academic oversight responsibilities for undergraduates, graduate students, or postdoctoral associates who are working on projects that are funded by, or conducted in collaboration with, an external entity in which the research personnel have a financial interest.

The Investigator must provide concurrence and certification for compliance with the Conflict Management Plan prior to participating in the research or sponsored activity. Should an Investigator fail to concur with the recommended Conflict Management Plan, he/she may transmit comments to the Vice President for Research (VPR) within ten business days from receipt of the Institutional Official's decision. In such a case, the VPR will review the case (which may include seeking the advice of appropriate impartial experts and holding discussions with the Investigator and/or Institutional Official, for example) and will render a judgment within twenty business days of the time that the Institutional Official's initial determination is made known to the Investigator.

The Institutional Official shall be charged with the monitoring of the Conflict Management Plan.

Training

Financial conflict of interest (FCOI) training is recommended for all Investigators engaged in sponsored research activities. FCOI training is **required** for each Investigator involved in U.S. Public Health Service (PHS) funded research and other funded research when required by the sponsor. SUNY Polytechnic Institute uses CITI for COI Training.

Required FCOI training must be completed:

- prior to engaging in the research and at least once every four years thereafter;
- when an Investigator is noncompliant with this Policy or when a management plan developed for the Investigator

Requirements for PHS Subrecipients

When funding from the PHS is sub-allocated to another institution, the subrecipient must comply with all PHS Regulations. Subrecipients must certify in the written agreement that their policy complies with PHS FCOI Regulations. If the subrecipient does not have a policy that complies with PHS Regulations, the written agreement must state that the subrecipient will comply with SUNY Polytechnic Institute's Policy, as stated in this document.

Policy Compliance

Persons subject to this policy are required to report fully and accurately their external commitments and financial interests and to comply with any plans developed to manage their real or apparent FCOI. Failure to comply with this policy may result in:

- a hold being placed on the establishment of all new awards;
- a hold being placed on the expenditure of all sponsored and institutional funds;
- institutional approval not being given for the submission of any new proposals to external sponsors; and/or

- no internal financial support being provided for investigator initiated projects

Contact

Any questions regarding this information should be directed to the Institutional Official, Scott Bateman, at sbateman@sunypoly.edu.