

Financial Conflict of Interest Policy

Applicable to Research Proposals Submitted to Government Agencies

Investigator Financial Disclosure Policy

When an investigator involved in research has significant financial interests in a company, organization, or institution external to the College, or receives compensation, funding, or other assistance from entities external to the College that can be affected by the investigator's research, there is the potential for the creation of a conflict of interest or the appearance of a conflict. As a result, federal regulations require that institutions applying for research grants from federal agencies maintain a policy on conflicts of interest and require that investigators disclose any potential conflicts of interest to the College when applying for support for their research. The objective of this Policy and the federal regulations on which it is based is to promote "objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under [federal grants] will be biased by any conflicting financial interest of an Investigator" (defined below). 45 CFR § 50.601.

Definitions:

The following definitions apply to this policy:

Research – means a systematic investigation designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and product development. The term includes any such activity for which research funding is available from a federal agency.

Investigator – means the principal investigator, co-principal investigator(s) and any other person at the College who is responsible for the design, conduct, or reporting of research or educational activities.

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:
 - i. 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); and
- **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;

- ii. 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
 - iii. **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 will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

3. The term significant financial interest **does not include** the following types of financial interests:
 - o salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights;
 - o any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or forprofit organization;
 - o 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;
 - o 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
 - o 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.

Investigator Obligations:

To comply with federal law, federal regulations, and the College's Conflict of Interest Policy, Investigators must take the following steps when submitting research proposals:

- Complete and submit the Financial Interest Disclosure Form (available on the Provost's Office website; <http://www.swarthmore.edu/academics/provosts-office/handbooks.xml>) to the College that lists the Investigator's known Significant Financial Interests (1) that would reasonably appear to be affected by the research; and (2) that are in entities whose financial interests would reasonably appear to be affected by the research. Investigators with no Significant Financial Interests to disclose should also complete the Form and indicate the lack of Significant Financial Interests therein. Forms must be submitted to the College in advance of submission of applications for research grants to federal agencies.
- Update their Disclosure Forms annually or within 30 days of obtaining a new reportable Significant Financial Interest.

The Financial Interest Disclosure Form should be submitted to the Provost. If, upon review of the form, there appears to be a potential conflict, the Provost will, along with the department chair/laboratory director, review the potential conflict of interest and initiate steps to manage or eliminate the conflict(s) if appropriate.

Except to the extent required by law and federal regulations, the information disclosed will be kept confidential. You should know, however, that the College is required to report the existence of real or potential conflicts of interest to certain federal agencies. Specifically, the NIH (PHS) requires institutions to report to the PHS the existence of any conflicting interests and to assure that the interest has been managed, reduced or eliminated. NSF requires that only conflicts that have not been managed, reduced or eliminated prior to the expenditure of funds under an award be reported to NSF.

Institution's Obligations

Training

Institutions must train investigators: (A) prior to engaging in any research related to any PHS-funded grant or contract; (B) and at least every four years; (C) and immediately if: the Institution revises its FCOI policies in a way that affects the requirement of Investigators or if an investigator moves to a new Institution or an Institution finds that an Investigator is not in compliance with the regulations or with the Institution's financial conflict of interest policy or management plan.

Policy Creation

Federal agencies require Swarthmore to take a number of steps to ensure the discovery and elimination of any conflicts of interest in research programs. First, the College is required to develop, maintain, and enforce a policy on conflicts of interest. To this end, the College has developed the foregoing policy, appointed individuals to review Financial Disclosure Forms, and created mechanisms for enforcement.

In order to manage, reduce or eliminate potential conflicts, the College is required to institute a management plan. The College also may take any of the following steps:

- public disclosure of Significant Financial Interests
- monitoring of research by independent reviewers
- modification of the research plan to avoid conflicts of interest
- disqualification of Investigators from the portion of the funded research that could create conflicts of interest
- require divestiture of Significant Financial Interests
- require severance of relationships that create conflicts of interest.

Subgrantees

Subgrantees who are not employed by or otherwise affiliated with the College must be in compliance with this Policy. They can comply in two ways:

- A subgrantee may have his or her conflicts resolved through the Swarthmore College process for identifying and resolving financial conflicts of interest; or,
- If the subgrantee is employed by an institution that has enacted a financial conflict of interest policy that is in compliance with applicable federal regulations, including 42 CFR § 50.604, the subgrantee's employer may provide assurances that any conflicts related to the project under consideration have been managed, reduced or eliminated pursuant to the employer's policy.

The appropriate assurances can be provided by having the subgrantee's employer complete the subgrantee form (available on the Provost's Office web site (<http://www.swarthmore.edu/academics/provosts-office/handbooks.xml>) If the subgrantee chooses to comply through providing assurances, the assurance form must be submitted with the Investigator's conflict-of-interest form. If the subgrantee is not employed by an institution that has enacted a policy in compliance with applicable federal rules and regulations, he or she must submit to Swarthmore College Financial Conflict of Interest Policy and follow Swarthmore College's instructions for managing, reducing or otherwise eliminating any conflicts.

There must be a written agreement between Swarthmore College and the subgrantee to establish which of the two methods of compliance is in effect. If it is the first method, then the agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the College sufficient to enable it to comply with its responsibilities. If it is the second method, then the agreement shall specify time period(s) for the subgrantee to report all identified financial conflicts of interest to Swarthmore College sufficient to enable it to provide timely financial conflict of interest reports to any of the Public Health Services. Institutions must report subrecipient financial conflicts of interest prior to the expenditure of funds for a grant or 60 days after the receipt of new significant financial interests.

Reporting Obligations

Swarthmore College is required to certify in each application for research funding from federal agencies the existence of this Policy and to identify any existing conflicts of interest and assure that they have been managed, reduced or eliminated. The College also must report any conflicting interests to the appropriate federal agency before expending any grant funds. In

addition, if any conflicts of interest become apparent after the initial report to the relevant federal agency, the College is required to report the existence of such a conflict within 60 days of its identification. The College will comply with federal agency requests to make information available about any conflicts of interest and how they have been managed, reduced, or eliminated.

Once a financial conflict of interest is identified, the College has an obligation to create a management plan for that financial conflict of interest. When the College reports to the federal agency about the conflicting interest, it must include enough information about the management plan so the agency can understand the conflict and assess the management plan. This includes informing the agency of the entity that is in conflict. If a conflict exists that was not timely disclosed by an Investigator or was not previously reviewed by the College, the College must implement a management plan that shall specify the actions that have been taken and will be taken to manage such conflicts going forward.

Should a financial conflict of interest not be identified or managed in a timely manner, then the College will enlist an independent expert in the investigator's field to lead a retrospective review to determine whether funded research was biased in its design, conduct, or reporting; and, the College will report this financial conflict of interest as well as any mitigation report on bias to the awarding component.

Record Retention

Federal regulations require the College to maintain records of all financial disclosures and all actions taken by the College for a minimum of three (3) years from the date of submission of the final expenditure report at the completion of the grant, or if any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, until all such actions have been resolved and final action taken.

Sanctions

Federal regulations require the College to impose sanctions or take other administrative actions where appropriate. Swarthmore maintains the right to impose sanctions on Investigators for failure to disclose Significant Financial Interests and for failure to abide by this Policy. Sanctions may include restrictions on future submission of research proposals and other disciplinary actions up to and including dismissal as described in the *Handbook for Instructional Staff*, section III-A-13. Institutional sanctions can travel with the Investigator upon his transfer to another Institution.

Transparency

The College will respond within five business days to any request for information on financial conflicts of interest disclosed by and still held by any of its investigators. This information will be available for at least three years since it was most recently updated. At a minimum, this information will include: 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.

Requests for this information are to be made to the Provost, whose contact information can be found through the College web site.

Applicable Federal Regulations and Policies:

Investigators or Supervisors who wish to learn more about the federal regulations governing conflicts of interest can take advantage of the applicable sections of the NIH Regulations, the NSF Proposal and Award Policies and Procedures Guide, and the Tutorial from NIH on Compliance with Federal Regulations on Conflicts of Interest.

If you have any questions about the College's conflict of interest policy, please contact the Office of the Provost at 610/328-8319.

Effective Date of this Policy: August 24, 2012