

Wellesley College

Investigator Significant Financial Interest Disclosure Policy for Sponsored Projects

INTRODUCTION

These guidelines define Wellesley College policy and procedures regarding conflicts of interest in relationship to all externally sponsored projects. The purpose of the guidelines is to protect the credibility and integrity of the College's faculty and staff so that public trust and confidence in the College's sponsored activities are ensured.

This policy governing financial conflict of interest applies to all Investigators who are responsible for the design, conduct, or reporting of sponsored projects, or proposals for external funding. The Provost and Dean of the College ("Provost") is responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the Provost is implemented. Violation of any part of this policy may also constitute cause for disciplinary or other administrative action pursuant to College policy.

CONFLICT OF INTEREST:

A potential Conflict of Interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the College, such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation and not on the character or actions of the individual. This policy is predicated on the expectation that Investigators should conduct their affairs so as to avoid or minimize conflicts of interest, and must respond appropriately when conflicts of interest arise. To that end, this policy informs faculty and staff about situations that generate conflicts of interest related to research and sponsored projects, provides mechanisms for Investigators and the College to manage those conflicts of interest that arise, and describes situations that are prohibited. Every Investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an Investigator should discuss the situation with the Provost.

DEFINITIONS

Family means any member of the Investigator's immediate family, specifically, any dependent children and spouse or domestic partner.

Financial Conflict of Interest means a Significant Financial Interest that the College reasonably determines could directly and significantly affect the design, conduct or reporting of sponsored projects.

Institutional responsibilities means the Investigator's responsibilities associated with his or her College appointment or position, such as research, teaching, clinical activities, administration, and institutional, internal and external professional committee service.

Investigator means any individual who is responsible for the design, conduct, or reporting of sponsored projects or proposals for external funding. This definition is not limited to those titled or budgeted as principal investigator or co-investigator on a particular proposal, and may include postdoctoral associates, senior scientists, or graduate students. The definition may also include collaborators or consultants as appropriate.

Public Health Service or *PHS* means the Public Health Service of the U.S. Department of Health and Human Services, and any components of PHS to which the authority of PHS may be delegated. The components of PHS include, but are not limited to **National Institutes of Health**, the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Federal Occupational Health, Food and Drug

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Administration, Health Resources and Services Administration, Indian Health Service, and Substance Abuse and Mental Health Services Administration.

Significant Financial Interest means

- 1) any of the following financial interests held by the Investigator or the Investigator's Family that reasonably appear to be related to the Investigator's Institutional Responsibilities:
 - a. If with a publicly traded entity: salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works) and any equity interest (e.g., stocks, stock options, or other ownership interests) when the aggregate value during the 12 month period preceding or as of the date of disclosure, exceeds \$5,000;
 - b. If with a non-publicly traded entity:
 - i. any salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works) when the aggregate amount received during the 12 month period preceding the disclosure exceeds \$5,000; or
 - ii. equity interest of any value held at any point during the 12 month period preceding or as of the date of disclosure;
 - c. Income related to intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) not reimbursed through the College.
- 2) travel undertaken by the Investigator and related to his or her Institutional Responsibilities which is sponsored or reimbursed by an entity other than U.S. Federal, state or local governmental agencies, U.S. institutions of higher education, research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers when the aggregate value of such travel exceeds \$5,000. This includes travel that is paid on behalf of the Investigator rather than reimbursed. If the exact monetary value is not readily available, reasonable estimates should be used to determine if the travel qualifies as a Significant Financial Interest.

Significant Financial Interest excludes:

- 1) salary, royalties, or other remuneration from the College;
- 2) income from the authorship of academic or scholarly works;
- 3) income from seminars, lectures, or teaching engagements sponsored by or from advisory committees or review panels for U.S. Federal, state or local governmental agencies; U.S. institutions of higher education; U.S. research institutes affiliated with institutions of higher education, academic teaching hospitals, and medical centers; or
- 4) equity interests or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions made in these vehicles; or
- 5) travel reimbursed by the College, regardless of the source of funds.

DISCLOSURE REQUIREMENTS:

All Investigators are required to disclose to the College on an initial, annual, and ad hoc basis any Significant Financial Interests that would reasonably appear to be affected by the activities funded or proposed for funding; or in entities whose financial interests would reasonably appear to be affected by such activities. The Provost is responsible for the distribution, receipt, processing, review and retention of disclosure forms and designates the Office for Sponsored Research and the WCW Grant & Contract Services Office to administer the disclosure process.

PHS (includes NIH) Investigators – responsible for the design, conduct, or reporting of PHS sponsored research, or proposals for such funding – must disclose **all Significant Financial Interests** to the College on an initial, annual, and ad hoc basis. Under PHS regulations, it is the College, rather than the investigator, that must determine whether a significant financial interest or entity in which the SFI is held would reasonably appear to be affected by the research funded or proposed for funding.

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Regardless of the minimum disclosure requirements, the Investigator, in his or her own best interest, is encouraged to disclose any other 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.

a) Initial Disclosures

Prior to entering into sponsored projects or applications for sponsored projects, the Investigator must submit to the Provost or designee a disclosure of his or her Significant Financial Interests as described above. The College will not submit a proposal on behalf of the Investigator(s) unless the Investigator(s) have submitted such disclosures.

b) Annual and Ad Hoc Disclosures

All disclosures must be updated by investigators while they remain engaged with externally sponsored projects or proposals for such funding, either on an annual basis or as new reportable Significant Financial Interests are discovered or acquired.

Disclosures of financial interests must include, at a minimum, the identity of the external entity, the nature of the financial interest, and the value of the financial interest. Disclosures of reimbursed or sponsored travel must include, at a minimum, the purpose of the trip, the identity of the external entity sponsoring or reimbursing the travel, the destination, the duration, and, the monetary or estimated value. The Provost will determine if additional information is needed (e.g., the role of the Investigator in the sponsored project) to determine whether the financial interest constitutes a Financial Conflict of Interest with the Investigator's project.

REVIEW AND DECISION OF THE PROVOST OR DESIGNEE

Disclosure forms will be reviewed promptly by the Provost or designee for a determination of whether it presents a Financial Conflict of Interest. If a Financial Conflict of Interest exists, the Provost will take action to eliminate, reduce, or manage the conflict, as appropriate. The Provost may consult other members of the College community, including the Investigator or other faculty or staff familiar with the project and/or with the Financial Conflict of Interest regulations for guidance in specific cases, or in the application of the policy to particular situations.

A Financial Conflict of Interest will exist when the Provost or designee determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of externally-supported research or other sponsored activity. If the Provost determines that there is a Financial Conflict of Interest that can be managed, he or she must require and approve a written management plan before any related project activity goes forward. The affected Investigator is responsible for developing and submitting a proposed management plan, in consultation with the Provost or designee.

To address complex situations, oversight committees may be established by the Provost to periodically review the ongoing activity, to monitor the conduct of the activity (including use of students and postdoctoral appointees), to ensure open and timely dissemination of results, and to otherwise oversee compliance with the management plan.

REPORTING TO SPONSORS

Should any reported conflict or non-compliance require reporting to a Federal agency or other external sponsor, the Provost or designee will report in accordance with that sponsor's regulations. If the funding is made available to Wellesley College from a prime awardee, such reporting shall be made available to the prime awardee such that they may fulfill their reporting obligations to the sponsor.

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INVESTIGATOR NON-COMPLIANCE

a) Disciplinary Action

In the event of an Investigator's failure to comply with this Policy, the Provost may suspend all relevant activities or take other disciplinary action until the matter is resolved or other action deemed appropriate by the Provost is implemented.

The Provost's decision to impose sanctions on an Investigator because of failure to comply with this Policy, or failure to comply with the decision of the Provost, will be described in a written explanation of the decision to the investigator, and, where applicable, the IRB.

b) Retrospective Review

In addition, if the Provost determines that a Financial Conflict of Interest was not identified or managed in a timely manner, including but not limited to an Investigator's failure to disclose a Significant Financial Interest that is determined to be a Financial Conflict of Interest, or failure by an Investigator to materially comply with a management plan for a Financial Conflict of Interest, the Provost or designee will complete a retrospective review of the Investigator's activities and the project to determine whether the activity conducted during the period of non-compliance was biased in the design, conduct or reporting of the sponsored project.

Documentation of the retrospective review shall include the project number, project title, PI, name of Investigator with the Financial Conflict of Interest, name of the entity with which the Investigator has the Financial Conflict of Interest, reason(s) for the retrospective review, detailed methodology used for the retrospective review, and findings and conclusions of the review.

The Provost or designee will update any previously submitted report to the sponsoring agency or the prime awardee relating to the project, specifying the actions that will be taken to manage the Financial Conflict of Interest going forward. If bias is found, the report will include a mitigation report in accordance with sponsor regulations, including a description of the impact of the bias on the project and the plan of action to eliminate or mitigate the effect of the bias.

TRAINING REQUIREMENTS

All Investigators must review this policy annually.

a) PHS (Includes NIH) Investigators

Each PHS Investigator must complete training on this Policy prior to engaging in PHS sponsored activity or proposals, and at least every four years thereafter. In the event that this Policy is substantively amended in a manner that affects the requirements of PHS Investigators, the PHS Investigators must complete training on this Policy within a reasonable period of time as determined by the Provost.

b) All Investigators

If it is determined that the Investigator has not complied with this policy or with a management plan related to their activities, the Investigator must complete training on this Policy within a reasonable period of time as determined by the Provost.

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RECORD RETENTION

The Office for Sponsored Research and the WCW Grant & Contract Services Office will retain all disclosure forms, conflict management plans, and related documents for a period of seven years, or three years from the date of the final closeout of any related award, whichever is longer.

CONFIDENTIALITY

To the extent permitted by law, all disclosure forms, conflict management plans, and related information will be confidential. However, the Institution may make such information available to an agency funding research or other activity of the Investigator or to a requestor of information concerning financial conflict of interest related to external funding, if requested or required. If the Institution is requested to provide disclosure forms, conflict management plans, and related information to an outside entity, the Investigator will be informed of this disclosure.

PUBLIC ACCESSIBILITY

The Institution will provide information regarding any currently held Significant Financial Interest that has been determined to be a Financial Conflict of Interest under this policy to any requestor within five business days of the request. The information to be made available shall be consistent with the requirements of sponsor policy.

REGULATORY AUTHORITY

In accordance with Federal regulations, specifically Department of Health and Human Services regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and the National Science Foundation (NSF) Investigator Financial Disclosure Policy (NSF 60 FR 35820), the College has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an Investigator. These regulations promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research and other sponsored activities performed under external grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.