Addendum to the Policy on Conflicts of Interest and Commitment Pertaining to Sponsored Projects

Conflicts of Interest and Commitment Pertaining to PHS Sponsored Projects

INTRODUCTION

This policy addresses actual and potential Employee conflicts of interest and commitment pertaining to Sponsored Projects that involve funding from U.S. Public Health Service agencies\(^1\). It is written in response to the requirements placed on the University by the Public Health Service policy (42 CFR 50, Subpart F, effective August 24, 2012). This policy becomes effective on August 24, 2012.

PURPOSE OF POLICY

The University and its Employees are committed to conducting themselves and University activities in accordance with the highest standards of integrity and ethics, and in compliance with applicable state and federal laws related to conflict of interest and objectivity in scholarly projects. It is the purpose of this policy to set forth the principles for identifying the potential for conflicts and the procedures for reviewing and addressing actual and potential conflicts to assure that they do not improperly affect University research and other sponsored activities. In addition, the intent of this policy is to assist faculty and other employees to more effectively manage real or potential conflicts of interest and commitment. By reporting and managing conflicts from the start, the University and employee can work together to prevent outcomes that may be harmful to either the employee or the University at large.

APPLICABILITY

This policy applies to faculty members and other Employees when, on behalf of the University, they are responsible for or in a position to influence the design, conduct, or reporting of research that involves funding from Public Health Service agencies.

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\(^1\) Agencies within the Public Health Service
- Administration for Children and Families (ACF)
- Administration on Aging (AoA)
- Agency for Healthcare Research and Quality (AHRQ)
- Agency for Toxic Substances and Disease Registry (ATSDR)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare & Medicaid Services (CMS)
- Federal Occupational Health (FOH)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration (SAMHSA)
DEFINITIONS

Associated Entity means any trust, organization, or enterprise over which the Employee, alone or together with an Immediate Family member, exercises a controlling interest.

Business means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other nongovernmental legal entity organized for profit, nonprofit, or charitable purposes.

Business Interest means holding any Executive Position or membership on a board regardless of compensation.

Employee means: (1) any person possessing either a full-time or part-time appointment at the University, including faculty and staff; and (2) Employees, students, and other individuals, whether salaried or not salaried, who on behalf of the University are responsible for, or in a position to influence the design, conduct, or reporting of the research or other scholarly activity. For the purposes of this policy, the term “Employee” is interchangeable with “Investigator” as used in the PHS policy.

Executive Position means any position that includes responsibilities for a significant segment of the operation or management of a business.

Immediate Family means the Employee’s spouse or domestic partner and dependent children.

Significant Financial Interest (SFI) means a financial interest meeting one or more of the four criteria outlined in the section of this policy captioned “Conflict of Interest.”

Sponsored Agreement means a contract, grant, cooperative agreement, or any other document that binds the University to terms and conditions and provides funding from Public Health Service agencies.

PHS Sponsored Project. means research, training, and instructional projects involving funds, materials, or other consideration from Public Health Service agencies under agreements that bind the University and/or an affiliated institution to one or more of the following:

1. A line of scholarly or scientific inquiry specified to a substantial level of detail;
2. A line-item budget;
3. Financial reporting;
4. External audit;
5. The return of unexpended funds to the sponsor at the conclusion of the project; or,
6. The disposition of either tangible or intangible properties that may result from the activity.
POLICY

The University and its Employees often benefit from Employees’ participation in both public and private outside activities. The University has no interest in unreasonably interfering with Employees’ legitimate outside interests. University Employees, in turn, have an obligation to ensure that their outside obligations, financial interests, and activities do not conflict or interfere with their commitment to conduct University research and other sponsored activity without improper influence, and to disclose to the University all actual or potential conflicts of interest.

A research university promotes the public good by fostering the transfer of knowledge gained through university research and scholarship to the private sector. A conflict of interest exists in any situation in which a faculty member has an outside interest that might affect, or appear to affect, his or her judgment in carrying out University responsibilities. Professional external activities conducted by a faculty member should improve effectiveness as a teacher or contributor to scholarly attainments, or should in some manner serve the interests of the University or of the University community. External activities must not distract significantly from a faculty member’s primary responsibilities and must not require such extensive absence as to cause the faculty member to neglect course obligations or to become unavailable to students and colleagues. External activities should be of such nature and conducted in such manner that they bring credit to the University, and must not compromise any intellectual property owned by the University.

Conflict of Interest

In those circumstances in which the University is engaged in or intends to engage in a PHS Sponsored Project, or has subcontracted or intends to subcontract a part of the work under one of the University’s Sponsored Projects, a conflict of interest may occur when an Employee, members of the Employee’s Immediate Family, or an Associated Entity has a Business Interest in a Business whose purpose or activities are similar or related to the work to be conducted under the PHS Sponsored Project, or when the Employee has an SFI in such Business. An SFI is defined as a financial interest meeting one or more of the following criteria:

1. With regard to any publicly traded entity, an SFI exists if the value of any remuneration received by the Employee (or the Employer’s spouse or dependent children) 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. Remuneration includes salary and any payments 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, an SFI 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 Employee (or the Employee’s spouse or dependent children) holds any equity interest (e.g. stock, stock
option, or other ownership interest).

3. Intellectual property rights and interests (e.g. patents, copyrights), upon receipt of income related to such rights and interests.

4. Travel reimbursement or sponsored travel (i.e. that which is paid on behalf of the Employee and not reimbursed to the Employee), related to the Employee’s institutional responsibilities, provided, however, that this disclosure does not apply to travel reimbursement or sponsored travel paid by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, or a research institute that is affiliated with an institution of higher education.

Conflict of Commitment
It is the policy of the University that all regular faculty members are expected to devote their primary professional time, and energy to their teaching, research and other scholarly works, service on University committees, advising students, performance of necessary administrative duties, and, where applicable, patient care. Although a specific work-week is not defined for faculty members, it is expected that such a position constitutes a full-time obligation and that, with the exceptions explicitly permitted by University policies on external activities, they will not engage in other employment. Accordingly, external activities must be arranged so as not to interfere with the primary commitments.

External activities conducted by a faculty member should be of such nature as to improve effectiveness as a teacher or contribute to scholarly attainments, or should in some manner serve the interests of the University or of the community. External activities must not distract significantly from primary responsibilities and must not require such extensive absence as to cause the faculty member to neglect teaching, advising, research and/or service obligations. External activities must be of such nature and conducted in such manner that they not compromise any intellectual property owned by the University.

Specific requirements for Employees serving in non-faculty positions can be found in University Policy 1-100-010, Professional Standards and Business Conduct – General Policy.

Guidance on external affiliations for faculty members can be found in the University Statutes, which state in part, “Non-teaching professional service outside the University shall not interfere with the fulfillment of faculty responsibilities and shall not exceed the equivalent of one day per week. For any work of a continuing or regular nature, annual approval by the Provost is required.”

Employees whose appointments are less than full-time are expected to devote professional time, and energy to their teaching, research, patient care, and/or administrative activities, in accordance with their agreed-upon time commitments.
In no event should a faculty member engage his/her students as employees on personal consulting agreements or in connection with other personal business, including performance of duties related to any Business Interest or SFI.

University resources, including facilities, personnel, equipment, letterhead, seals, or confidential information, must not be used, except in a purely incidental way, in connection with such personal business, or for any other purposes that are unrelated to the education, research, scholarship, and public service missions of the University. All non-university external affiliations are to be performed strictly as a personal matter using personal or non-university resources. In addition, employees may not provide preferential access to research results, materials or products generated from University teaching or research activities, or to university-owned equipment to an external entity for personal financial gain.

Review of Disclosures

Each Employee participating in a PHS Sponsored Project who is responsible for or in a position to influence the design, conduct, or reporting of research or other scholarly activity must disclose whether or not he or she has external affiliations that may constitute a conflict. In addition to the annual disclosure required of faculty, a disclosure must be completed prior to the University’s submission of the PHS Sponsored Project proposal. The disclosure shall be submitted on the form approved from time to time by the Office for Research Integrity and Compliance, and shall be sent to the Office for Sponsored Programs. The disclosure shall be updated annually as well as within 30 days of the discovery of the existence of an SFI. Positive disclosures will be reviewed by the Conflict of Interest Review Committee, consisting of the Vice Provost for Research; the Director, Office for Sponsored Programs; the Director, Office for Research Integrity and Compliance; the Director, Office for Technology Transfer and Licensing; and the University General Counsel. Additional members may be added on an ad hoc basis as deemed appropriate by the Vice Provost for Research.

The Director, Office for Research Integrity and Compliance is hereby named the Designated Official responsible for screening positive disclosures. The purpose of the screening is to determine which SFIs are related to PHS-funded awards, and whether an SFI could directly and significantly affect the design, conduct, and reporting of a PHS-funded award. The Designated Official shall determine which disclosures need to be forwarded to the Conflict of Interest Committee for further review and action.

The Conflict Review Committee, in accordance with its procedures, will review all positive disclosures in order to assure adherence to relevant University policies as may be outlined from time to time in such relevant documents as The University Statutes, the Policies and Procedures Manual, the Faculty Handbook, the Intellectual Property Policy, the Research and Projects Policy, and other University documents the Conflict Review Committee may deem appropriate. Positive disclosures by faculty of conflicts of commitment will be reviewed with the appropriate Dean to ensure the disclosed conflict is consistent with the faculty member’s annual disclosure. In conducting its review the Conflict Review Committee shall:

1. Consider the nature and extent of the actual or potential conflict of interest or commitment in the relationship of the Employee and the external organization;
2. Give special consideration to the terms and conditions of PHS Sponsored Project agreements that may mitigate or complicate the given situation;

3. Consult with and obtain additional information from the Employee as either the Conflict Review Committee or the Employee feel may be helpful in resolving actual or potential conflicts; and

4. Act in a timely manner so as not to delay unduly the conduct of the PHS Sponsored Project. Following its review the Conflict Review Committee may take one of the following actions:
   a. Accept the PHS Sponsored Project award and notify the sponsor as may be required by sponsor policy.
   b. Decline the PHS Sponsored Project award.
   c. Accept the PHS Sponsored Project subject to suitable modifications in either the PHS Sponsored Project Agreement or the Business Interest or Significant Financial Interest of the Employee or Employee’s Immediate Family. This will be accomplished through the development of a written conflict of interest management plan. The management plan must be signed by the Designated Official and the Investigator. The management plan shall be monitored by the Designated Official to ensure that compliance is maintained. An Investigator’s failure to comply with the terms of a management plan must be addressed in a Corrective Action Plan and reported to the sponsor.

In the event an SFI is not disclosed in a timely manner by an Investigator or discovery is made of an SFI not previously reviewed by the Conflict of Interest Committee, all subsequent reviews, determinations, and management plans must be completed within 60 days of the discovery of the SFI.

If the Employee is dissatisfied with the Conflict Review Committee’s conclusion, the Employee may appeal to the Provost who will consult with the Employee and the Conflict Review Committee as the Provost deems necessary and appropriate to the particular circumstance. The decision of the Provost shall be final.

Violations of this policy, such as willful concealment of Business Interests or Significant Financial Interest or a Conflict of Commitment, or failure to abide by a conflict of interest management plan, may result in sanctions being imposed upon the violating individual. The Conflict Review Committee will review allegations of violations and will make recommendations regarding the imposition of sanctions to the Provost. The decision of the Provost with regard to the imposition of sanctions shall be final.

The Office for Sponsored Programs shall maintain the records pertaining to each disclosure in strict confidence. Access to such records will be limited to the Employee, the Conflict Review Committee, the Provost, and others who have a legal right to review the records.
Certain sponsors, particularly federal agencies, may have requirements that differ from this policy particularly with regard to the timing and frequency of faculty disclosures. In the case of any discrepancies, the sponsor’s requirements will generally prevail.

**Reporting Requirements to Sponsoring Agencies**

When a Financial Conflict of Interest (FCOI) has been identified, the Office for Sponsored Programs will report the following information to the PHS sponsor prior to the expenditure of award funds and updated annually.

1. Grant/Contract Number;
2. Principal Investigator;
3. Name of the Investigator identified as having the FCOI;
4. Whether the FCOI was managed, reduced, or eliminated;
5. The name of the entity with which the Investigator has a FCOI;
6. The nature of the FCOI (e.g. equity, consulting fees, travel reimbursement);
7. The amount of the financial interest in the format prescribed in the PHS policy;
8. A description of how the financial interest relates to the PHS Sponsored Project research and the basis for the University’s determination that the financial interest conflicts with such research; and,
9. The key elements of the University’s Management Plan.

Reporting by the Office for Sponsored Programs to the PHS sponsor shall also be done within 60 days of a new Investigator being engaged in the award or in the event a previously unreported FCOI is discovered.

**Public Access**

The Office for Research Integrity and Compliance shall create and maintain a database of information contained in positive disclosures. This information must be made available within 5 days of the receipt of a written request from any member of the public. The database shall be updated annually at a minimum. The information shall be maintained in the database for three years from the most recent update of the information pertaining to the project. The database shall be updated within 60 days of the receipt of a positive disclosure.

The information shall include the following information:

1. Investigator name;
2. Investigator title;
3. Investigator role on the project;
4. Name of the entity with which there is an SFI;
5. The nature of the SFI;
6. The approximate value of the SFI expressed in the following ranges:
   1. $0 - $4,999;
   2. $5,000 - $9,999;
   3. $10,000 - $19,999;
   4. Amounts between $20,000 - $100,000 expressed in $20,000 increments;
5) Amounts above $100,000 expressed in $50,000 increments;
6) Or a statement that the value cannot be readily and reasonably determined in terms dollar value or fair market value.

Mitigation Plans
If noncompliance with this Policy or the PHS regulation is identified, the Conflict of Interest Committee shall engage in a retrospective review of the circumstances and will develop a mitigation plan. The review must be completed within 120 days of the discovery of an unreported FCOI or noncompliance with the disclosure requirements or the terms of a management plan. This review does not need to be reported to the PHS sponsor. In cases in which bias is found in the research, the University must report to the PHS sponsor and will address the impact of the bias on the research project and the actions taken to eliminate or mitigate the effect of the bias.

Subrecipient Reporting
At the time of proposal, the Office for Sponsored Programs will request the proposed Subrecipient(s) to obtain a disclosure of actual and potential SFIs from each individual considered to be Subaward key personnel. Should an award be made, the Office for Sponsored Programs will negotiate with subawardees whether they will abide by this Policy or their own policies. This decision will be made a part of the Subaward agreement. The Subaward will also contain time periods designed to meet disclosure and/or reporting requirements. Subrecipients who rely on their own policies must (a) certify that it’s FCOI policy complies with applicable regulations and (b) report identified FCOI to the Office for Sponsored Programs in sufficient time to allow that office to report the FCOI to the PHS sponsor to meet the PHS reporting requirements.

If the subrecipient decides to follow this Policy, the Subaward document shall include a requirement for subrecipient investigators to submit disclosures to Boston College in a timely manner in order for the University to identify, manage, and report FCOIs to the sponsor.

Training
The Office for Research Integrity and Compliance shall establish and maintain a training mechanism designed to inform all those responsible for the design, conduct, and reporting under PHS Sponsored Projects of their responsibilities concerning conflicts of interest. The training must be taken prior to an Investigator engaging in research related to any PHS-funded awards. The training must be refreshed every four years by each individual.

For Investigators new to Boston College, the training must be taken unless the Investigator provides written evidence of having taken the training at another institution and the training is acceptable to the University.
Record Maintenance

Records pertinent to compliance with this Policy and relevant PHS regulations will be maintained for three years from the date the final expenditure report is submitted to the sponsor, or, in the event an audit is performed or claims are made against the University during the three year period, the record retention period will be extended to three years after the closure of the audit or claims. This requirement may be amended in the event of litigation, claims, financial management review, or audit occurring prior to the expiration of the three year retention period.