

Policy on Conflicts of Interest in Externally-Funded Programs, Grants or Contracts

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 agencies¹. 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).

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.

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.

Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

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

Significant Financial Interest (SFI) 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); 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. These details will include the purpose of the trip, the identity of the sponsor/organizer,

the destination, and the duration. The Director of the Office of Sponsored Programs will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests:

- i. 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;
- ii. 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;
- iii. 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
- iv. 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.

Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of \$5,000).

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 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 has a financial conflict of interest.

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, and performance of necessary administrative duties.

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, and 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.

Employees whose appointments are less than full-time are expected to devote professional time, and energy to their teaching, research 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 Bentley Research Council, and shall be sent to the Sponsored Programs Office. The disclosure shall be updated annually as well as within 30 days of the discovery of the existence of a financial conflict of interest. Positive disclosures will be reviewed by the Conflict of Interest Review Committee, consisting of the Dean of Business & Graduate School or Dean of Arts & Sciences (as appropriate); the Chair of the Institutional Review Board (IRB); the Director of Sponsored Programs; the University General Counsel; and the Executive Director of Finance (or designee). Additional members may be added on an *ad hoc* basis as deemed appropriate by the Provost and VP of Academic Affairs.

The Director, Sponsored Programs 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 Review Committee for further review and action.

The Conflict of Interest 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 University documents the Conflict of Interest 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 of Interest 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 of Interest 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 of Interest 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 Review 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 of Interest Review Committee's conclusion, the Employee may appeal to the Provost and VP for Academic Affairs who will consult with the Employee and the Conflict of Interest Review Committee as the Provost deems necessary and appropriate to the particular circumstance. The decision of the Provost and VP for Academic Affairs shall be final.

Violations of this policy, such as willful concealment of Business Interests or Significant Financial Interest, 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 of Interest Review Committee will review allegations of violations and will make recommendations regarding the imposition of sanctions to the Provost and VP for Academic Affairs. The decision of the Provost and VP for Academic Affairs with regard to the imposition of sanctions shall be final.

The Sponsored Programs Office shall maintain the records pertaining to each disclosure in strict confidence. Access to such records will be limited to the Employee, the Conflict of Interest Review Committee, the Provost and VP for Academic Affairs, 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 has been identified, the Sponsored Programs Office will report the following information to the PHS sponsor prior to the expenditure of award funds and update annually.

- a. Project Number;
- b. Principal Investigator (PI) or Contact PI if multiple PI model being used;
- c. Name of the Investigator identified as having the FCOI;
- d. The name of the entity with which the Investigator has a FCOI;
- e. The nature of the FCOI (e.g. equity, consulting fees, travel reimbursement);
- f. The amount of the financial interest in the format prescribed in the PHS policy;
- g. 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,
- h. A description of the key elements of the University's Management Plan, including:
 - Role and principal duties of the conflicted Investigator in the research project;
 - Conditions of the management plan;
 - How the management plan is designed to safeguard objectivity in the research project;
 - Confirmation of the Investigator's agreement to the management plan;
 - How the management plan will be monitored to ensure Investigator compliance; and
 - Other information as needed.

Reporting by the Sponsored Programs Office 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 Sponsored Programs Office 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 receipt of a positive disclosure.

The information shall include the following information:

- a. Investigator name;
- b. Investigator title;
- c. Investigator role on the project;
- d. Name of the entity with which there is an SFI;
- e. The nature of the SFI;
- f. 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 of dollar value or fair market value.

MITIGATION PLANS

If noncompliance with this Policy or the PHS regulation is identified, the Conflict of Interest Review 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. The University will document such review in accordance with the requirements outlined in 42 CFR § 50.605(a)(3)(ii)(B).

Based on the results of the retrospective review, if appropriate, the University shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the University will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report will include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the University's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the University will submit FCOI reports annually, as specified elsewhere in this policy. Depending on the nature of the financial conflict of interest, the University may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

SUB-RECIPIENT REPORTING

At the time of proposal, the Sponsored Programs Office 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 Sponsored Programs Office 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 its FCOI policy complies with applicable regulations and (b) report identified FCOI to the Sponsored Programs Office 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 Bentley University in a timely manner in order for the University to identify, manage, and report FCOIs to the sponsor.

TRAINING

The Sponsored Programs Office 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 Bentley University, 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.