

RESEARCH

Effective Date: August 24, 2012

Date Revised: July 1, 2015

Supersedes: N/A

Related Policies: Code of Ethical Conduct; Faculty Conflict of Commitment and Interest Policy; Professional Standards and Business Conduct Policy

Responsible

Office/Department: Office of Research Administration and Finance

Keywords: Principal Investigator; Financial Conflict of Interest; Significant Financial Interest; Public Health Service

Policy on Financial Conflict of Interest Related to Research

I. Purpose and Scope

This policy is designed to promote objectivity in research, to assist in the identification of potential and actual conflicts of interest, and to support compliance with government regulations applicable to financial conflicts of interest. The policy implements the requirements of certain federal regulations, specifically "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought" (42 C.F.R. Part 50, Subpart F) and "Responsible Prospective Contractors" (45 C.F.R. Part 94), and applies to all projects funded, directly or indirectly through a subaward from another organization, by the Public Health Service of the U.S. Department of Health and Human Services (PHS), including all PHS agencies, other than Phase One SBIR or STTR awards. It also applies to research funded by other agencies or foundations that use PHS Financial Conflict of Interest regulations in their award terms.

These PHS specific regulations supplement Northeastern University's Policy on Conflict on Commitment and Interest as stated in the Faculty Handbook.

II. Definitions

For purposes of this Policy,

Aggregate means the total of all remuneration, sponsored travel (for PHS investigators), any equity interests and all other monies from a single source.

Designated Official means either the unit chair, college Dean, or equivalent administrator (hereinafter referred to as "the Dean") and, in complex cases any member of the Northeastern University Conflict Advisory Committee

designated by the Senior Vice Provost for Research to review disclosures to determine if there is a relationship between an Investigator's Significant Financial Interest, including, for PHS Investigators, Sponsored Travel, and his or her research. The Designated Official is the individual within Northeastern

University that is ultimately responsible for the review of disclosures of Significant Financial Interests and the management of Financial Conflicts of Interest.

Equity Interests refer to stock, stock options, warrants, and other existing or contingent ownership interests in a commercial entity.

Family means an Investigator's spouse or domestic partner, and dependent children.

Northeastern University Conflict Advisory Committee means individuals responsible for reviewing and providing guidance on conflict of interest matters.

Financial Conflict of Interest means a Significant Financial Interest and, for PHS Investigators, sponsored travel, that Northeastern University reasonably determines could directly and significantly affect the design, conduct, or reporting of research.

Institutional Responsibilities means the Investigator's responsibilities associated with his or her Northeastern University appointment or position, such as teaching, scholarship, research, creative activity, service, etc., as defined in the Faculty Handbook.

Investigator means the principal investigator and any co-principal investigators for a research project. This includes, but is not limited to, the project director, principle investigator, or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Outside Professional Activities means compensated and uncompensated activities undertaken outside of an Investigator's Institutional Responsibilities.

Related Company means a commercial entity in which the Investigator, alone or in combination with his or her Family, holds a Significant Financial Interest.

Remuneration includes salary and payments for services, such as consulting fees, honoraria or paid authorship.

Senior/Key Personnel are identified in the grant application, progress report, or any other report submitted to the PHS, and include, but are not limited to, the program director/principle investigator (PD/PI) and other individuals who contribute to the scientific development or execution of a project in a substantive, measureable way, whether or not they request salaries or compensation.

Significant Financial Interest (SFI) means a financial interest or income received or held by an Investigator, alone or in combination with his or her Family (and not expressly excluded below) that reasonably appears to be related to the Investigator's institutional responsibilities. Examples of SFI that must be disclosed are:

1. Interest or income in or from a **publicly traded** entity where
 - a. the aggregate value of Remuneration **and** any equity interest exceeds \$5000 (any remuneration received during the 12 month period preceding the disclosure, or expected to

- be received in the 12 months after the disclosure; the value of any equity interests in the entity as of the date of disclosure)
- b. the entity is sponsoring any of the Investigator's research;
2. Interest or income in or from a **non-publicly traded** entity where
 - a. the aggregate value of Remuneration exceeds \$5000 (any remuneration received during the 12 month period preceding the disclosure, or expected to be received in the 12 months after the disclosure;) **or** when any equity Interests are held
 3. Interest in the form of income related to intellectual property rights and interests paid by an entity other than Northeastern University
 4. Travel related to Institutional responsibilities not reimbursed or sponsored by Northeastern University, including but not limited to travel sponsored by international universities, corporate sponsors, foundations e.g. American Cancer Society, American Heart Association, etc.
 5. Phase II SBIR/STTR applications

Significant Financial Interest does NOT include:

1. Remuneration or Royalties paid by Northeastern University to the Investigator;
2. Remuneration from authorship of academic or scholarly works;
3. Remuneration and sponsored/reimbursed travel related to 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. institutes of higher education; U.S. research institutes affiliated with institutes of higher education, academic teaching hospitals, and medical centers;
4. Equity Interests in or income from investment vehicles, such as mutual funds and retirement accounts, so long as the Investigator does not directly control the investment decisions for these vehicles.
5. Phase I SBIR/STTR applications

Sponsored Travel, for PHS Investigators, refers to travel expenses paid to or on behalf of an Investigator by a single entity in a twelve-month period; and to travel reimbursed or paid on behalf of an Investigator's Family member by a single entity within a twelve-month period *if* such travel reasonably appears to be related to the Investigator's Institutional responsibilities.

III. Policy

DISCLOSURE REQUIREMENTS

Full and prompt disclosure is critical to Northeastern University's ability to identify, manage, and eliminate Financial Conflicts of Interest. There are three types of disclosures:

1. Annual Disclosures. Investigators who come within this Policy must disclose their Significant Financial Interests to Northeastern University on an annual basis, in addition to their annual disclosure of information with respect to conflicts of commitment and interest as prescribed in the Faculty Handbook.

2. Proposal-related Disclosures. Prior to submitting a proposal for funding, the Principal Investigators identified in the proposal and, if requested by the Senior Vice Provost for Research or the Designated Official, other Investigators associated with the proposal must disclose whether the Investigator's Significant Financial Interests and how they may be related to the Investigator's Institutional Responsibilities. If there is a potential relationship, the Investigator must file a full disclosure with additional information regarding the relationship of the project to the Related Company prior to submission of the proposal to the sponsor.
3. Ad hoc Disclosures.
 - a. An Investigator must disclose on an ad hoc basis any new Significant Financial Interest within 30 days following the date on which the Significant Financial Interest is acquired or arises. This 30 day requirement is specific to the PHS regulations.
 - b. An Investigator must disclose on an ad hoc basis his or her Significant Financial Interests prior to the Investigator commencing participation in any research project the Investigator is joining.

TRAVEL DISCLOSURES

In addition to the disclosures required by Northeastern University Policy, PHS regulations require Investigators to disclose to Northeastern University any Sponsored Travel undertaken by the Investigator related to his or her Institutional Responsibilities, and for such sponsored Travel to be included in the Aggregate value of an investigator's financial interests, in determining whether those rise to the level of Significant Financial Interest.

Travel disclosures must be made if travel is reimbursed or sponsored by an organization other than:

- Northeastern University
- U.S. Federal, state or local governmental agencies
- U.S. Institutions of higher education
- Research institutes affiliated with Institutes of higher education, and
- Academic teaching hospitals and medical centers.

Such disclosures must be made by the Investigator within 30 days following reimbursement or within 30 days following the completion of the trip if the organization or entity funds the travel directly. The travel disclosure must include at a minimum, the purpose of the trip, the identity of the organization or entity funding the travel, the destination, and the duration of the trip (usually measured in days). The Designated Official will determine if additional information is needed to determine whether the travel constitutes a Financial Conflict of Interest.

Limitations on Outside Professional Activities

Northeastern encourages faculty to become involved in the transfer of knowledge from the University into the commercial marketplace. It is appropriate for the University to facilitate the transfer of the knowledge gained through academic research to applications which can benefit the general population. Moreover, experience gained by faculty in the course of outside professional activities can enhance their teaching and research or scholarship within the University. But the process of technology transfer can create the potential for conflicts of commitment and/or interest, particularly when there is opportunity for personal gain on the part of the faculty. The intent of this provision of the policy is to minimize

potential conflicts and to provide means of managing them when they arise. An implicit assumption underlying the University's "Policy on Faculty Outside Professional Activities" is that such outside professional activities are a privilege and not a right and must not detract from a faculty member's full-time obligation to his or her University duties. When any outside activity detracts from the conduct of University duties, a conflict of commitment will result. Even activities such as pro bono work, government service in the public interest, and any outside employment unrelated to the faculty member's University responsibilities should be managed so they do not take precedence over a faculty member's primary commitment to the University.

Outside professional activities can also generate conflicts of interest regardless of the time involved. For example, direction of a program of research or scholarship at another institution that could be conducted appropriately at Northeastern as part of the faculty member's normal duties can deprive Northeastern students and colleagues of the benefits of the faculty member's primary intellectual energies and valuable educational opportunities. Another example is submitting research proposals through channels other than Northeastern to support work that could be performed at Northeastern. First, the use of Northeastern resources in the course of that work is practically unavoidable. Second, it becomes difficult, if not impossible, for the University to review and reward the contributions of its faculty, staff, and students for work managed and/or conducted elsewhere. Third, the action can result in situations that place students and staff in conflicts of interest. On the other hand, the University does not intend to limit faculty from participating in multi-site training or research programs. Nor does it intend to limit the ability of faculty to do research that requires access to facilities not available at Northeastern. Weighing these considerations, normally Northeastern faculty members on active duty are prohibited from serving as principal investigators on sponsored projects submitted and managed through other institutions.

Significant management roles (those that involve supervision of the work of others and/or day-to-day responsibility for operating decisions) in private business typically are demanding both in terms of time and energy. It is unlikely that such roles can be fulfilled by the manager working only one day per week, the maximum time permitted for full-time faculty to engage in outside consulting activities. Because full-time faculty are expected to devote their primary energies and professional interests to their University obligations, they may not accept significant managerial responsibilities as part of their outside consulting activities.

Whenever faculty members are involved in research as part of their outside consulting or business activities, they must establish clear boundaries that separate their University and outside obligations, so as to avoid questions about their appropriate use of resources and attributions of the products of their work.

SUBAWARDS ISSUED BY NORTHEASTERN UNIVERSITY UNDER PHS FUNDED PRIME AWARDS

When Northeastern University issues a subaward to another organization to carry out a portion of a PHS funded project, the subawardee must comply with the PHS conflict of interest regulations. Northeastern University, therefore, will only grant subawards under PHS funded awards to institutions that have financial conflict of interest policies that comply with the PHS regulations. This requirement will be set forth in the Northeastern University subaward.

If a subawardee Investigator has a Financial Conflict of Interest, Northeastern University is responsible for reporting the Financial Conflict of Interest to the PHS on behalf of the subawardee. As a result,

subawardees must report Financial Conflicts of Interest to Northeastern University within 45 days of discovering the Financial Conflict of Interest so that Northeastern University may report it to the PHS in a timely manner. In addition, Northeastern University is required by PHS to make information regarding subawardee Financial Conflicts of Interest available to the public. Northeastern University uses the same method it uses to disclose Northeastern University Financial Conflicts of Interest and notifies the subawardee of any requests for information. Questions regarding the specifics of subawardee Financial Conflicts of Interest are directed to the subawardee.

SUBAWARDS ISSUED TO NORTHEASTERN UNIVERSITY UNDER PHS FUNDED PRIME AWARDS

When Northeastern University makes a proposal for or receives a subaward from another organization to carry out a portion of a PHS funded project, Northeastern University must comply with the PHS regulations regarding conflicts of interest. Northeastern University's Policy and these PHS regulations apply to these proposals and awards rather than the policies of the subawarding organization. Northeastern University provides reports of Financial Conflicts of Interest to the subawarding organization for reporting to PHS as specified in the PHS regulations. Reports are provided in the same form and format as Northeastern University uses in connection with its direct awards from PHS. The subawarding organization is also responsible for the public accessibility reporting (see above). The subawarding organization may choose to do so either by posting Northeastern University's report to a publicly available website or responding to written requests within 5 business days.

INVESTIGATOR NON-COMPLIANCE - RETROSPECTIVE REVIEW

In cases where a Financial Conflict of Interest is not identified or managed in a timely manner, including due to 1) failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest; 2) failure by Northeastern University to review or manage such a Financial Conflict of Interest; or 3) failure by the Investigator to comply with a Financial Conflict of Interest management plan, Northeastern University must, within 120 days of its determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research to determine whether the design, conduct, or reporting of the PHS-funded research, or any portion thereof, conducted during the period of noncompliance, was biased. Retrospective reviews will be conducted by the respective Dean's Office in consultation with Office of General Counsel and Office of Research Administration and Finance.

Northeastern University is required to document the retrospective review and report detailed findings to PHS, including at least the following key elements:

1. project number;
2. project title;
3. Principal Investigator or contact Principal Investigator if there are multiple Principal Investigators on the project;
4. name of the Investigator with the Financial Conflict of Interest;
5. name of the Entity with which the Investigator has a Financial Conflict of Interest;
6. reason(s) for the retrospective review;
7. detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. findings of the review; and
9. conclusions of the review.

Based on the results of the retrospective review, Northeastern University will update the previously submitted Financial Conflict of Interest report, if appropriate, specifying the actions that will be taken to manage the Financial Conflict of Interest. If bias is found, Northeastern University must notify PHS promptly and submit a mitigation report. The mitigation report must include, at a minimum:

1. the elements documented in the retrospective review above;
2. a description of the impact of the bias on the research; and
3. Northeastern University's plan of action or the actions taken to eliminate or mitigate the effect of the bias (e.g., extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research is salvageable).

Thereafter, Northeastern University will submit Financial Conflict of Interest reports annually, as specified under the PHS regulations. Depending on the nature of the Financial Conflict of Interest, Northeastern University may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS funded research between the date that the Financial Conflict of Interest or the Investigator's noncompliance is determined and the completion of Northeastern University's retrospective review.

TRAINING

Northeastern University must provide training regarding Northeastern University's Policy and the PHS regulations to Investigators. Investigators must complete the training prior to engaging in research related to any PHS-funded grant, and at least every four years thereafter. Investigators must also complete training immediately when (i) the Northeastern University FCOI policy is substantively amended in a manner that affects the requirements of Investigators or (ii) Northeastern University determines that the Investigator has not complied with this FCOI policy or with a management plan related to his or her research, or (iii) a PHS funded Investigator is new to Northeastern University.

Training is provided through the Collaborative Institutional Training Initiative (CITI). More information can be found at [Northeastern University's Investigator Training webpage](#).

RECORD RETENTION

The Designated Official will retain all disclosures, conflict management plans, and related documents for a period of at least seven years following submission of the final expenditure report for the applicable project to the PHS or the prime PHS awardee, unless any litigation, claim or negotiation, audit, or other action involving the records is commenced before expiration of the seven-year period, in which case, records will be retained until completion of the action and resolution of all issues.

IV. Additional Information

Northeastern University's COEUS application is being upgraded with SFI disclosure functionality. Once this system upgrade is completed, the Office of Research and Administration (ORAF) will be contacting PHS funded Investigators with additional information and training.

V. Contact Information

Office of Research Administration and Finance, 617-373-5600