
INVESTIGATOR CONFLICT OF INTEREST POLICY

Category: Research
Responsible Office: VP for Research and Economic Development
Responsible Executive: Research Foundation Operations Manager

Date Established: 9/17/09
Date Last Revised: 09/11/18

Summary

Investigators must disclose their and their immediate family members significant obligations, significant financial interests, and sponsored travel that is related to their institutional responsibilities. This provides the reasonable expectation that the design, conduct, or reporting of research by UB faculty, students, or staff will not be biased.

Policy

POLICY STATEMENT

The University at Buffalo (UB, university) is committed to promoting objectivity in research and to maintaining high ethical standards to ensure that the design, conduct, and reporting of research is not biased by the financial interests of individuals acting on behalf of UB. The responsibilities and obligations of investigators to the university must be clearly separated from their personal financial interests and obligations.

Investigators may not have any significant interest or engage in any outside activity which results in unmanaged or unmitigated conflicts of interest. Therefore, each investigator must disclose his or her significant financial interests and any non-university significant obligations including those of his or her immediate family members in order to ensure that the design, conduct, and reporting of research or other activity is free of bias.

Investigator Disclosure

Investigators must submit a disclosure statement that includes information pertaining to their significant financial interests (SFIs) and any sponsored travel related to their institutional responsibilities:

- At the time of application for funds or prior to the activation of the award, whichever occurs first
- Prior to submitting human subject protocols for review by an Institutional Review Board (IRB)
- Any time a funded or unfunded human research study is proposed
- Annually thereafter during the period of the study
- Within 30 days of discovering or acquiring a new SFI

Training

Financial conflict of interest (FCOI) training is required for all investigators engaged in human subject research activities. FCOI training is required for each investigator involved in U.S. Public Health Service (PHS) funded research and other funded research when required by the sponsor. Required FCOI training must be completed as follows:

- Prior to engaging in the research and at least once every four years
- Immediately when:
 - An investigator is new to UB
 - An investigator is noncompliant with this policy or with a management plan developed for the investigator
 - This policy is revised in a manner that affects the responsibilities of the investigator

Requirements for Sub-recipients

When funding from the Public Health Service (PHS) or other sponsors is sub-allocated to another institution, sub-recipients must comply with PHS regulations. Sub-recipients must certify in the subcontract that their policy complies with PHS FCOI regulations. If the sub-recipient does not have a policy that complies with PHS regulations, the subcontract must state that the sub-recipient will comply with UB policy. The subcontract must include the time period during which the sub-recipient must provide all necessary information for evaluation of SFIs.

BACKGROUND

The University at Buffalo community (faculty, staff, students, and fellows) are committed to meeting the highest ethical standards and preserving public trust by promoting objectivity in their teaching, research, and public service missions. As part of this commitment, all members share an obligation to protect UB's mission and reputation from being compromised by private interests and to operate in compliance with policies of various federal funding agencies.

This policy is consistent with the revised federal regulation on *Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors*, New York State *Public Officers Law Code of Ethics*, and The Research Foundation of State University of New York *Code of Conduct*.

APPLICABILITY

This policy applies to all investigators who apply for, receive, plan to participate in, or are participating in sponsored projects (e.g., grants, contracts, cooperative agreements) and participate in human subjects research (funded and unfunded).

DEFINITIONS

Conflict of Interest (COI) - an interest that has the potential to compromise or bias the professional judgment or objectivity of the holder of the interest, or has the appearance of having the potential to compromise or bias the holder of the interest. A COI may exist when an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise.

A COI may be financial, general, or of commitment:

Financial conflict of interest (FCOI) may arise when an employee or an immediate family member has the potential for financial gain through outside activity and such outside activity is related to his or her job responsibility.

General COI may arise in situations where an employee uses or attempts to use his or her position to obtain personal gain or privileges for himself, herself, or an immediate family member.

Conflicts of commitment arise when outside professional activities or other significant commitments, obligations, or responsibilities interfere with an employee's primary job responsibilities.

Conflict of Interest (COI) Committee - a committee established to evaluate potential conflict of interest situations, develop management plans and assist with monitoring compliance, and serve as a resource for members of the university community.

Conflict of Interest Officer (COI Officer) - the individual assigned responsibility for reviewing and managing potential university conflicts of interest. The COI Officer supports the Conflict of Interest (COI) Committee and determines whether potential conflicts are referred to the COI Committee.

Disclosure Statement – includes information related to an investigator's significant financial interests and non-university significant obligations.

Equity Interest - any stock, stock option, or other ownership interest as determined through reference to public prices or other reasonable measures of fair market value.

Financial Conflict of Interest (FCOI) - exists when an investigator's significant financial interest, external obligation, or sponsored travel could directly and significantly affect the design, conduct, or reporting of research or creative activity. SFIs that could directly and significantly affect the design, conduct, or reporting of funded research are considered an FCOI.

Immediate Family Members - includes an individual's spouse or domestic partner or person in a civil union or similar relationship, dependent children, or any other family members residing in the same household.

Institutional Responsibilities - an individual's professional obligations on behalf of UB, which include, but are not limited to, activities such as research, teaching, professional practice, institutional committee memberships, and service on review boards.

Investigator - a project director, principal investigator, or any other person (including subcontractors, collaborators, or consultants), regardless of title or position, responsible for the design, conduct, or reporting of sponsored projects.

Management Plan - an action plan that will reduce or eliminate an FCOI, prevent or mitigate the harm that could arise from the conflict, and to the extent possible, ensure that the design, conduct, and reporting of research or other activity is free of bias.

Outside Activity - any activity outside of UB employment including:

- Ownership or investment in any outside business or enterprise
- Serving as a director, officer, partner, consultant, broker, agent, or representative of any outside enterprise
- Outside professional activity or other activity
- Other employment

Public Health Services (PHS) - a branch of the U.S. Department of Health and Human Service (HHS), and components of the PHS including but not limited to the: Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Substance Abuse and Mental Health Services Administration (SAMHSA).

Remuneration - includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).

Royalty – cash, equity, or other value received by UB as consideration for license of rights to UB intellectual property.

Significant Financial Interest (SFI) - a financial interest consisting of one or more of the following interests of the investigator (or those of the investigator's immediate family members) that reasonably appears to be related to the investigator's institutional responsibilities:

- With regard to any publicly traded entity, 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 if, when aggregated, exceeds \$5,000
- With regard to any non-publicly traded entity, the value of any remuneration received from the entity in the twelve months preceding the disclosure if, when aggregated, exceeds \$5,000, or when the investigator or his or her immediate family members hold any equity interest (e.g., stock, stock option, or other ownership interest)
- Intellectual property rights and interests (e.g., patents, copyrights), and royalty from such rights, upon receipt of income related to such rights and interest; royalty is included except when received by the investigator from State University of New York (SUNY) or the Research Foundation (RF) if the investigator is currently employed or otherwise appointed by the university
- Income received from foreign entities for seminars, lectures, teaching engagements, or service on advisory committees or review panels
- Sponsored travel

SFI Exclusions

The following types of financial interests are excluded from the definition of significant financial interest:

- Salary, royalty, or other remuneration paid to an investigator by the university (State, RF, University at Buffalo Foundation (UBF)), if the investigator is currently employed or otherwise appointed by the university

- Intellectual property rights assigned to SUNY or the RF and agreements to share in royalty related to such rights
- 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
- Income received from U.S. based organizations for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education

Significant Obligation - positions held by an individual or his or her immediate family members as an officer, trustee, director, employee, or consultant of an outside entity whether or not the entity is for profit and whether or not the position is paid, that would reasonably appear to affect the individual's institutional responsibilities.

Sponsored Project - any externally funded research, training, evaluative testing, or public service project directed by UB faculty or staff as part of their university work that requires the university to perform a specified program or deliver a specified product.

Sponsored Travel - travel related to an investigator's institutional responsibilities that is paid by a non-UB entity on behalf of the investigator, and not reimbursed to the investigator so that the exact monetary value may not be readily available.

RESPONSIBILITIES

Investigators

- Complete a disclosure statement:
 - At the time of application for funds or prior to the activation of the award, whichever occurs first
 - Prior to submitting human subject protocols for review by an Institutional Review Board (IRB)
 - Annually thereafter
 - Within 30 days of discovering or acquiring a new SFI
- Complete FCOI training for human subjects research, PHS funded awards, or when required by the sponsor.
- Disclose FCOIs in public presentations or publication of research results.

Deans, Vice Presidents

- Conduct the initial review of disclosure statements.
- Review the SFI with the investigator to determine whether the SFI constitutes, or may constitute, an FCOI.
- Develop a draft management plan when an FCOI is clearly present, in consultation with the investigator, to manage or eliminate the FCOI or report the FCOI to the COI Officer for further review and possible action by the COI Committee.
- Consult with the COI Officer when the existence of an FCOI is possible but not definitive.

Conflict of Interest (COI) Officer

- Review all potential and actual FCOIs. Contact investigator and dean's office to gather all relevant information.
- Refer FCOIs or potential FCOIs to the COI committee, as appropriate.
- Complete a retrospective review of the investigator's activities within 120 days of determining an FCOI was not disclosed or managed.
 - If bias is found, for PHS awards, notify the PHS awarding component through eRA Commons and submit a mitigation report; for all other funding sources, notify the awarding agency as appropriate.
- Maintain records of all investigator disclosures of FCOIs, the review of and response to such disclosures, actions taken, and retrospective reviews, if applicable.
- Provide a written response to requests for information about an FCOI related to PHS funded research within five (5) business days of receipt of the request.
- Maintain the disclosure statements, management plans, and all associated correspondence related to the requirements of this policy.

Conflict of Interest Committee

- Review and accept or modify management plans, as appropriate.
- Determine if the sponsored award should be declined if all parties cannot agree to a management plan.

Sponsored Projects Services (SPS)

- Include a certification in all applications stating that UB will comply with the FCOI regulations for PHS funding or when required by the sponsor.
- Review records to determine that investigator disclosures have been submitted and reviewed prior to activating an award.
- Require all investigators to complete FCOI training prior to releasing any funds when required by the sponsor.

Contact Information

Contact	Phone	Email
Office of the Vice President for Research and Economic Development	716-829-3978	coiofficer@buffalo.edu

Related Information

University Links

Conflict of Interest – File Your Disclosure

<http://www.buffalo.edu/research/research-services/compliance/coi/file-your-disclosure.html>

Office of Research Compliance

<http://www.buffalo.edu/research/about-us/units/ORC.html>

Research and Economic Development - Compliance Training

<http://www.buffalo.edu/research/research-services/training/compliance-training.html>

Vice President for Research and Economic Development

<http://www.buffalo.edu/research.html>

Related Links

New York State Ethics Laws and Regulations

<https://jcope.ny.gov/ethics-laws-and-regulations>

New York State Joint Commission on Public Ethics

<https://jcope.ny.gov/>

Research Foundation Code of Conduct (Approved 1/23/12; Revised 1/15/13 and 2/5/14):

http://www.rfsuny.org/media/RFSUNY/Policies/code_of_conduct.pdf

Research Foundation Conflict of Interest Policy

http://www.rfsuny.org/media/RFSUNY/Policies/conflict_of_interest_policy_pol.htm

Research Foundation Employee Handbook:

<http://www.rfsuny.org/media/RFSUNY/Documents/HR/Employee-Handbook.pdf>

Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-109.html>

State University of New York Conflict of Interest Policy (Document 6001)

http://www.suny.edu/sunypp/documents.cfm?doc_id=527

State University of New York Extra Service for Professional Staff Policy, Document 8800

http://www.suny.edu/sunypp/documents.cfm?doc_id=419

State University of New York Patents, Inventions, and Copyright Policy:
http://www.suny.edu/sunypp/documents.cfm?doc_id=88

History

September 2018 Full review. Updated the policy to:

- Require investigator disclosure for funded and unfunded human study research
- Use the term “royalty” consistent with the SUNY *Patents, Inventions, and Copyright Policy*

Presidential Approval

Signed by President Satish K. Tripathi

11/15/12
