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## INVESTIGATOR CONFLICT OF INTEREST

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

**Date Established:** 9/17/09  
**Date Last Revised:** 11/15/12  
**Date Posted to Library:** 11/20/12

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### Summary

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

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### Policy

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#### BACKGROUND

The University at Buffalo (UB, University) 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*.

#### POLICY STATEMENT

The University at Buffalo 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 interest or engage in any outside activity which results in unmanaged or unmitigated conflicts of interest. Therefore, each investigator must disclose his/her significant financial interests and any non-university significant obligations including those of his/her immediate family members in order to ensure that the design, conduct, and reporting of research or other activity is free of bias.

## Disclosures

Each investigator is required to complete the *Investigator Disclosure Statement* at the time of applying for funded research or prior to the release of grant funds, whichever occurs first, annually thereafter, and within 30 days of discovering or acquiring a new significant financial interest (SFI).

## Training

Financial conflict of interest (FCOI) training is recommended for all investigators engaged in sponsored 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 PHS Subrecipients

When funding from the PHS is sub-allocated to another institution, the subrecipient must comply with all PHS Regulations. Subrecipients must certify in the written agreement that their policy complies with PHS FCOI Regulations. If the subrecipient does not have a policy that complies with PHS Regulations, the written agreement must state that the subrecipient will comply with UB's Policy.

## 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).

## 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/her job responsibility.

General COI may arise in situations where an employee uses or attempts to use his/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.

**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.

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

**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 Income** - includes any royalty income, licensing income, or other proceeds (e.g., payments linked to product sales or other usage and milestone payments), or the written contractual right to receive future royalties, licensing income or other proceeds, directly or indirectly, under a pending or issued patent, license, copyright, or other property right.

**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/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 royalties from such rights, upon receipt of income related to such rights and interest; royalties are 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, royalties, 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 royalties 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/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 an *Investigator 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 during the period of the funded award
  - within 30 days of discovering or acquiring a new SFI.
- Complete FCOI training for PHS funded awards, or when required by the sponsor.
- Disclose FCOIs in public presentations or publication of research results.

### Deans and Vice Presidents

- Conduct initial review of *Investigator Disclosure Statements*.
- When an investigator discloses any SFI, review with investigator to determine whether the SFI constitutes, or may constitute, an FCOI.
- If an FCOI is clearly present, develop a draft management plan 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.
- If the existence of an FCOI is possible but not definitive, forward to the COI Officer for review and possible action by the COI Committee.

### COI Officer

- Review all potential and actual FCOIs. Contact investigator and dean's office to gather all relevant information.
- When appropriate, refer FCOIs or potential FCOIs to the COI committee.
- Within 120 days of determining an FCOI was not disclosed or managed, complete a retrospective review of the investigator's activities.
  - 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.
- As the University's office of record, maintain the *Investigator Disclosure Statements*, management plans, and all associated correspondence related to the requirements of this Policy.

#### **Conflict of Interest Committee**

- When appropriate, review and accept or modify management plans.
- If all parties cannot agree to a management plan, the COI Committee may determine that the sponsored award should be declined.

#### **Sponsored Projects Services (SPS)**

- For PHS funding, or when required by the sponsor, include a certification in all applications stating that UB will comply with the FCOI regulations.
- Ensure that investigator disclosures have been submitted and reviewed prior to activating an award.
- When required by the sponsor, ensure all investigators have completed FCOI training prior to releasing any funds.

## **PROCEDURE**

#### **Submission of Disclosure**

Investigators must submit an *Investigator Disclosure Statement* that includes information pertaining to their 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)
- annually thereafter during the period of the funded award
- within 30 days of discovering or acquiring a new SFI.

#### **Review of Disclosures**

- The responsible dean or vice president will conduct the initial review of the *Investigator Disclosure Statements* to determine if there is an actual or potential FCOI.
- If the dean or vice president identifies an actual or potential FCOI, he/she will draft a management plan in conjunction with the investigator and forward to the COI Officer.
- If the dean or vice president is unable to determine if an FCOI exists, the SFI should be referred to the COI Officer.
- The COI Officer will review all actual or potential FCOIs and draft management plans, and when appropriate, refer the matter to the COI Committee.
- The COI Committee will accept or modify management plans and is responsible for all final decisions related to FCOIs.
- When required, the COI Officer will communicate FCOIs and management plans to funding agencies.

## Management of Conflicts

Real or apparent FCOIs are addressed through a management plan designed to remove bias or the perception of bias. Examples of conditions or restrictions that the management plan may include are:

- public disclosure of the SFI
- monitoring of research by independent reviewers
- modification of the research plan
- disqualification from participation in the portion of the research that would be affected by the SFI
- divesture of the SFI
- severance of relationships that create actual or potential conflicts
- removal of the investigator as the principal investigator
- additional remedies specific to the conduct of research involving human subjects, including but not limited to, disclosure of the FCOI in the consent process, or removal of the investigator's ability to recruit research subjects
- decline the sponsored award.

## Reporting Requirements

FCOI reports will be submitted to the funding agency in accordance with the agency's requirements.

In cases where the FCOI is related to PHS funded awards, FCOI reports must be submitted to PHS as follows:

- prior to expenditure of PHS funds (if an FCOI is eliminated prior to any expenditures, a report should not be submitted)
- within sixty (60) days of identification of an FCOI for an investigator who is newly participating in the project
- within sixty (60) days for new or newly identified FCOIs for existing investigators
- annually, to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project
- upon completion of a retrospective review, when necessary to update a previously submitted report.

FCOI reports must include:

- grant number
- principal investigator name
- name of investigator with the FCOI
- name of entity with which the investigator has the FCOI
- nature of the FCOI (e.g., equity, consulting fees, travel reimbursement, sponsored travel, and/or honoraria)
- value of the financial interest, or a statement that the value cannot be readily determined
- description of how the financial interest relates to the PHS, or other sponsor's, funded research and the basis for the determination that the financial interest conflicts with such research
- key elements of the related management plan, including:
  - the conflicted investigator's role and principle duties related to 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 compliance
- other information as needed.

### **Late Identification of an FCOI and Retrospective Review**

Within sixty (60) days of identifying that an SFI was either not disclosed, or not timely reviewed during an ongoing funded research project, the COI Officer will review the SFI and determine if it is related to funded research and if an FCOI exists. If an FCOI is determined to exist, the COI Committee will develop a management plan that specifies the actions that have been, and will be, taken to manage the FCOI going forward.

In addition, within 120 days of determining an FCOI exists, the COI Officer will complete a retrospective review of the investigator's activities and the funded research project to determine if there was bias in the design, conduct, or reporting of such research results. The retrospective review must be documented and should include:

- the award number and title
- principal investigator (PI) name or primary contact if multiple PIs
- name of the investigator with the FCOI and the name of the entity with whom the investigator has the FCOI
- reason for the retrospective review
- detailed methodology used for the review
- findings and conclusions
- if appropriate, an updated FCOI report.

If bias is found through the retrospective review of a PHS funded award, the COI Officer will notify the PHS awarding component promptly through the eRA Commons and submit a mitigation report that includes:

- the key elements documented in the retrospective review
- description of the impact of the bias on the research project
- plan of action to eliminate or mitigate the effect of the bias
- the extent of harm done including supporting data, if available.

If PHS decides that a particular FCOI will bias the objectivity of research, PHS may impose special award conditions, suspend funding or impose other enforcement mechanisms until the matter is resolved.

When PHS determines that a clinical research project with the purpose of evaluating the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an investigator with an FCOI that was not managed or reported by the University as required, the investigator must disclose the FCOI in each public presentation of results and submit an addendum to previously published results.

If bias is found through the retrospective review of any non-PHS funded award, the COI Officer will notify the awarding agency in accordance with sponsor guidelines.



### Requirements for Subrecipients

When PHS or other sponsor funding requires, subrecipients must comply with PHS Regulations. Subrecipients must certify in the subcontract that their policy complies with PHS FCOI Regulations. If the subrecipient does not have a policy that complies with PHS Regulations, the subcontract must state that the subrecipient will comply with UB's Policy. The subcontract will also include the time periods in which the subrecipient must provide all necessary information for evaluation of SFIs.

### Public Accessibility Requirements for Funded Awards

The COI Officer will provide a written response to requests for information about an FCOI related to PHS funded research and other funded research when required by sponsor policy, within five (5) business days of receipt of the request. The response should include the: investigator's name, title, and role with respect to the project; name of the entity in which the SFI is held; nature of the SFI and the approximate dollar value of the SFI.

### Certification with PHS Applications

Sponsored Projects Services (SPS) will include a certification in all applications for PHS funding, and when required by other funding agencies, stating that UB will comply with PHS regulations.

### Documentation

The COI Officer will maintain records of all investigator disclosures of FCOIs, the review of and response to such disclosures, all actions taken, and retrospective reviews, if applicable, for at least three years from the date of submission of the final expenditure report for the sponsored research.

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## Contact Information

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## Related Information

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### Documents:

SUNY Conflict of Interest Policy (Document No. 6001): [http://www.suny.edu/sunypp/documents.cfm?doc\\_id=527](http://www.suny.edu/sunypp/documents.cfm?doc_id=527)

SUNY Extra Service for Professional Staff: [http://www.suny.edu/sunypp/documents.cfm?doc\\_id=419](http://www.suny.edu/sunypp/documents.cfm?doc_id=419)

SUNY Outside Activities of University Policy Makers: [http://www.suny.edu/sunypp/documents.cfm?doc\\_id=547](http://www.suny.edu/sunypp/documents.cfm?doc_id=547)

The Research Foundation of the State University of New York ("RF") Conflict of Interest Policy (Board of Directors Resolution 95-5): [https://portal.rfsuny.org/portal/page/portal/Intellectual\\_property/Policies/mupol006.htm](https://portal.rfsuny.org/portal/page/portal/Intellectual_property/Policies/mupol006.htm)

RF Code of Conduct (Approved January 23, 2012):

[https://portal.rfsuny.org/portal/page/portal/The\\_Research\\_Foundation\\_of](https://portal.rfsuny.org/portal/page/portal/The_Research_Foundation_of)

[SUNY/home/Working\\_at\\_the\\_RF/corporate\\_ethics\\_values/corp\\_ethics\\_policies/code\\_of\\_conduct.pdf](https://portal.rfsuny.org/portal/page/portal/The_Research_Foundation_of_SUNY/home/Working_at_the_RF/corporate_ethics_values/corp_ethics_policies/code_of_conduct.pdf)

RF Employee Handbook: [http://hr.buffalo.edu/files/phatfile/Employee\\_Handbook.pdf](http://hr.buffalo.edu/files/phatfile/Employee_Handbook.pdf)

NIH Guide Notice (August 23, 2011): <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-109.html>

Patents and Inventions Policy of State University of New York:

[https://portal.rfsuny.org/portal/page/portal/Intellectual\\_property/Policies/mupol001.htm](https://portal.rfsuny.org/portal/page/portal/Intellectual_property/Policies/mupol001.htm)

Patents, Inventions, and Copyright Policy: [http://www.suny.edu/sunypp/documents.cfm?doc\\_id=88](http://www.suny.edu/sunypp/documents.cfm?doc_id=88)  
Computer Software Policy: [http://www.suny.edu/sunypp/documents.cfm?doc\\_id=408](http://www.suny.edu/sunypp/documents.cfm?doc_id=408)  
SUNY Extra Service for Professional Staff: [http://www.suny.edu/sunypp/documents.cfm?doc\\_id=419](http://www.suny.edu/sunypp/documents.cfm?doc_id=419)  
Conflicts Scenarios: <https://confluence.itec.suny.edu/confluence/display/rfcpg/Conflict+of+Interest+Scenarios>  
Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors:  
[http://grants.nih.gov/grants/policy/coi/fcoi\\_final\\_rule.pdf](http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf)  
Public Officers Law:  
<http://www.jcope.ny.gov/about/ethc/PUBLIC%20OFFICERS%20LAW%2074.pdf>

**Forms:**

Investigator Disclosure Statement:  
<https://www.coiriskmanager.com/sunybuffalo>  
Outside Activity Report form for University Policy Makers:  
<http://www.jcope.ny.gov/forms/ethc/Outside%20Activity%20Report%20JCOPE.pdf>

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**Presidential Approval**

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*Signed by President Satish K. Tripathi*

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*11/15/12*

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