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## INVESTIGATOR DISCLOSURE POLICY

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**Category:** Research  
**Responsible Office:** Office of the Vice President for Research  
**Responsible Executive:** Vice President for Research

**Date Established:** 9/17/09  
**Date Last Revised:** -  
**Date Posted to Library:** 9/18/09

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### Summary

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To ensure compliance with federal and state regulations, the University at Buffalo requires an Investigator to disclose his/her financial interests and non-university obligations and the financial interests and non-university obligations of his/her domestic partner and dependent children by completing and submitting an annual disclosure statement.

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### Policy

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#### POLICY STATEMENT

Members of the University community, in pursuing UB educational, research, and public service missions, must meet high ethical standards and minimize the risks of conflict between private interests and the public interests the University serves.

The responsibilities and obligations of Investigators to the University must be clearly separated from their personal financial interests and their personal obligations to others. Prudent stewardship of public resources requires protecting University research, educational, and public service missions from being compromised by conflicts of interest and the appearance of conflicts of interest.

To meet these objectives and to ensure compliance with federal regulations (Department of Health and Human Services, Food and Drug Administration, National Science Foundation) as well as state regulations, UB requires an Investigator to disclose his/her financial interests and non-university obligations and the financial interests and non-university obligations of his/her domestic partner and dependent children by completing and submitting the [Annual Disclosure of Significant Financial Interests and Significant Obligations](#).

This Policy sets forth requirements and guidelines for:

1. disclosure of outside financial interests and obligations by Investigators at UB who engage in sponsored programs funded by any external entity and/or funded internally through specified internal programs;
2. review of Investigator disclosures by designated University officials; and
3. identifying, reporting, and resolving conflicts of interest.

#### Disclosure and Review of Disclosures

1. The Annual Disclosure of Significant Financial Interests and Significant Obligations will serve as the mechanism for disclosing financial interests and obligations by all Investigators at the University.
2. Disclosure statements (Annual Disclosure of Significant Financial Interests and Significant Obligations) must be submitted to the cognizant dean(s) or cognizant vice

- president(s) not later than the time applications for external and selected types of internal support are submitted by the University or prior to acceptance of an award made without prior submission of a proposal. Disclosure statements may also be submitted at any other time, but must be updated whenever significant financial interests or obligations change during the period of the proposal and the performance period of the award.
3. To ensure compliance with this policy, each proposal for external or selected types of internal support must be accompanied by a list of all Investigators.
  4. The cognizant dean(s) or cognizant vice president(s) shall be the University's designated officials responsible for reviewing Investigator financial disclosure statements in the context of each proposal and/or award and for determining whether a conflict of interest or appearance of conflict of interest exists, and shall determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce, or eliminate such conflicts. Cognizant deans and cognizant vice presidents have primary responsibility for assisting investigators to identify areas of potential concern and, whenever possible, for instituting remedies that permit affected research, creative activity, or public service activity to proceed. Remedies instituted by cognizant deans and cognizant vice presidents to manage, reduce, or eliminate conflicts of interest shall be in writing, signed by all affected parties, and a copy shall be forwarded to the Vice President for Research (VPR).
  5. All applications for external support submitted by the University and for selected types of internal support must be accompanied by written certification by the cognizant dean or cognizant vice president that the appropriate disclosure form has been submitted. Applications for support of a University program, project, activity, or service will not be submitted to an outside party, unsolicited support will not be accepted by the University, and selected University internal support will not be awarded unless accompanied by the cognizant dean or cognizant vice president's certification that the appropriate disclosures have been made.
  6. In instances where a cognizant dean or cognizant vice president is an Investigator on an application for external or selected types of internal support, the VPR shall be responsible for reviewing financial disclosure statements, determining whether a conflict of interest exists, and shall determine what conditions or restrictions, if any, should be imposed by the University to manage, reduce, or eliminate such conflicts.
  7. On receipt of a grant award, the Office of Sponsored Projects Services shall request that the cognizant dean's or cognizant vice president's office (or their delegate) certify that no conflict of interest or conflict of obligation exists, or that any such conflict has been resolved. No funds for externally or selected types of internally funded projects may be expended until all conflicts of interest have been managed, reduced, or eliminated.
  8. The VPR shall report to the appropriate funding source any instance where an Investigator participating in funded research or creative activity has not complied with this Policy, and the specific corrective measures taken by the University.
  9. The review of financial disclosure forms requires all participants to exercise the utmost discretion. To the maximum extent permitted by federal and state law and by University policy, all elements of this process are to be treated as strictly confidential. The purpose of confidentiality is to assure that the integrity of the research and the privacy of the Investigator as well as the interests of the University are protected at all times.

10. When and as required by an external sponsor and prior to the expenditure of any funds, the VPR will report to the sponsor the existence of a conflict of interest (but not the nature of the interest or any other details) and provide assurance that the conflict has been managed, reduced, or eliminated, and if a conflict is identified subsequent to receiving an award, a report to the sponsor will be made and the conflicting interest will be managed, reduced, or eliminated, at least on an interim basis, within sixty (60) days of identification.
11. The VPR shall inform all sponsoring entities of cases in which the University is unable to satisfactorily manage a conflict of interest.
12. The University will maintain all disclosures and records of actions taken to resolve conflicts of interest for three (3) years after the termination or completion of the award to which they relate, or until after the resolution of any state or federal government action involving those records, whichever is later. Maintenance of these materials will be the responsibility of the cognizant deans and cognizant vice presidents.

### **Remedies**

Any or all of the following conditions or restrictions may be applied to manage, reduce, or eliminate actual or potential conflicts of interest:

- Public disclosure of significant financial interests;
- Monitoring of the project or activity by independent reviewers;
- Modification of the project or activity plan;
- Disqualification from participation in the portion of the externally funded project or activity that would be affected by the significant financial interests or significant obligations;
- Divestiture of significant financial interests;
- Severance of relationships or significant obligations that create actual or potential conflicts.

If the University is unable to resolve a conflict of interest, it may decline to perform the activity in question.

### **Waivers**

With the exception of activities sponsored by the United States Public Health Service (PHS), the cognizant dean or cognizant vice president may recommend in writing to the VPR that an activity go forward without imposing conditions or restrictions if the dean or vice president determines that imposing such conditions or restrictions would be ineffective and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare. Research, training or educational activity in question may not commence until a final decision has been made in writing by the VPR.

### **Appeal**

Should an Investigator disagree with the cognizant dean's finding in determining that an actual or potential conflict of interest exists, or disagree with the proposed remedy, the investigator may appeal to the Associate Vice President for Research (AVPR) within ten (10) working days of the dean's or vice president's decision. The AVPR will review the case, seek the advice of the Advisory Panel on Responsible Conduct, and render a judgment within ten (10) working days of receipt of the appeal. No expenditures for external and selected types of internal support of a

program, project, activity, or service may be made by the University until a final decision has been made.

When a cognizant vice president serves as the reviewer of a disclosure statement, the appeal shall be to the VPR. When the VPR serves as the reviewer of a disclosure statement (see #6 in the Disclosure & Review of Disclosures section), the appeal shall be to the Provost.

### **Compliance**

The VPR shall report promptly in writing to the Provost all cases in which an Investigator has failed to comply with the University's Investigator Disclosure Policy or the means determined to resolve a conflict of interest. In such cases, the Provost shall, at the direction of the President, institute disciplinary proceedings against an Investigator who has failed to comply with the disclosure policy.

1. Disciplinary sanctions may include termination or alteration of the employment or academic status of persons against whom charges have been substantiated, and must be consistent with established UB and State University of New York Board of Trustees policies, and applicable collective bargaining agreements. Article 19 of the UUP Agreement shall be the sole source of University discipline for members of the UUP-represented unit.
2. Upon completion of disciplinary proceedings, the Provost or appropriate vice president shall report to the appropriate University officers or bodies, to cognizant federal agencies when federal funds are involved, and to other parties as necessary.
3. The University shall require the Investigator to include a notice, with each public presentation of research and creative activity, of conflicts of interest that were not disclosed or resolved prior to the expenditure of funds or which arose during the course of the activity.

### **Program to Inform the University Community**

All persons subject to this Policy shall be informed of its contents as well as understand the meaning of conflict of interest. To those ends, the VPR will ensure that all unit heads receive a copy of this Policy with instructions that copies be made available to all its members (faculty, administrators, students, staff, and fellows). Each unit head shall make his or her members aware of the Investigator Disclosure Policy on an annual basis and provide a copy of the Policy to new members as soon as possible after the start of their association with the unit. The VPR shall determine whether there are members of the University who would not be covered by such a distribution procedure and ensure that those individuals also receive a copy of the Policy. Any failure of this distribution process should not be construed as relieving any individual member of the University of obligations under this Policy for Investigator Disclosure.

### **Review and Evaluation**

This Policy shall be periodically reviewed by the University to determine if it is working as intended and if any modifications are needed. This review and evaluation should occur every two (2) years, unless circumstances warrant review in a shorter period of time.

## **BACKGROUND**

The University at Buffalo (UB) as a community and as a public institution of higher learning is committed to performing the highest quality research and creative activity. In meeting this

commitment, the University encourages interaction of its faculty, administrators, students, staff and fellows with the public and private sectors as an important component of its educational, research, and public service missions. External funding through grants, contracts, and gifts from public and private sources is necessary to provide essential support for University activities.

Professional interactions with public agencies, private businesses, non-profit organizations, and individuals advance the University's ability to provide research and educational opportunities for our students, to contribute to the economic well being of our community, and to add to our store of knowledge and understanding. Similarly, technology transfer in the form of patents, licensing agreements, and consulting opportunities for University members are important means of meeting the needs of society and fostering the welfare of the citizens of the State of New York.

## APPLICABILITY

This Policy applies to all external and specified internal support for University research programs, projects, activities, and services, solicited and unsolicited.

## DEFINITIONS

**Advisory Panel on Responsible Conduct** - serves in an advisory capacity to the VPR on allegations of misconduct and issues arising from the Investigator Disclosure Policy. The Panel consists of one faculty member from each decanal unit, one member from the University Libraries, one member nominated by the Chair of the Faculty Senate, and the VPR who also serves as Chair of the Panel.

**Conflict of Interest** - A conflict of interest exists when a designated official at UB reasonably determines that a significant financial interest of an Investigator or a significant external obligation of an Investigator could directly and significantly affect the design, conduct, or reporting of research or creative activity.

A conflict of interest in the conduct of externally and selected internally supported activities may take several forms, but typically arises when an Investigator at the University is, or may be, in a position to influence activities or University decisions in ways that could lead to personal gain for the Investigator or the Investigator's immediate family (domestic partner and dependent children), or give an improper advantage to third parties in their dealings with the University or the State. Conflicts may also arise when Investigators have outside obligations of any kind which are in substantial conflict with the Investigator's University responsibilities or the public interest. The potential for conflicts of interest may arise from specific actions taken by Investigators, or by the nature of positions they hold in and outside the University, or by the financial interests they or their immediate family hold.

For example, a conflict of interest can result when:

1. A significant financial interest of an Investigator would reasonably be expected to be affected by the design, conduct, or reporting by the Investigator of a University research, educational, or public service activity;
2. An Investigator has a significant non-University obligation to an individual or entity that provides support for a University research, educational, or public service activity involving the Investigator; or

3. An Investigator has a non-University obligation to an individual or an entity to which the University provides support through an agreement to perform a program project, activity, or service involving the Investigator.

Protecting against conflicts of interest requires careful review of the following types of situations, among others:

1. Consulting arrangements or agreements between an Investigator and a business enterprise that supports or is supported by University programs involving the Investigator;
2. Consulting arrangements between an Investigator and a business enterprise that is licensed to commercialize University technologies invented by the Investigator;
3. Significant financial interests of an Investigator in a business enterprise that supports or is supported by the Investigator's University research;
4. A position held by an Investigator as consultant, officer, director, trustee, or owner of a non-University business enterprise that supports or is supported by the Investigator's University research;
5. Significant financial interests of an Investigator in a business enterprise that owns or has applied for the patent, manufacturing, or marketing rights to a drug, device, or procedure that is a subject of, or will predictably result from, the Investigator's University research;
6. Significant financial interests of an Investigator in a business enterprise that is known by the Investigator to own or have applied for patent, manufacturing, or marketing rights that can reasonably be expected to compete with a device, product, or procedure that will predictably result from the Investigator's University research.
7. Arrangements or agreements where the amount of Investigator's compensation will be affected by the outcome of the research.

Arrangements or agreements where the value of ownership interests held by the Investigator or the Investigator's immediate family will be affected by the outcome of the research.

**Investigator** - Any person who holds a University at Buffalo appointment and who is a principal investigator, co-principal investigator, or who is responsible for the design, conduct, or reporting of University programs, projects, activities, or services described in an application or prospective application for external and/or selected internal support, or in an award (excludes donations) made to the University without application.

**Significant Financial Interest** - Anything of monetary value to the Investigator or the Investigator's domestic partner and/or dependent children that would reasonably appear to be affected by work externally funded or proposed for external funding or selected types of internal funding, including but not limited to:

1. salary, royalties or other payments for services (e.g., consulting fees or honoraria) that, when aggregated for the Investigator and the Investigator's domestic partner and dependent children over the next twelve months, are expected to equal or exceed \$10,000;
2. equity interests (e.g., stocks, stock options, warrants, or other ownership interests) that meet both of the following criteria: equals or exceeds \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value and represents more than a 5% ownership interest in the single entity; and

3. intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

Examples of significant financial interests include ownership of stock, stock options, or any equity, debt, security, capital holding, salary or other remuneration, or financial consideration, or thing of value for services as an employee, consultant, officer, or board member in:

1. the entity to which the application will be submitted;
2. any entity that owns or has applied for the patent manufacturing or marketing rights to a product or procedure involved in, or which will predictably result from, the work described in the application;
3. any entity that is known by the Investigator to own or have applied for such rights in any product that can reasonably be expected to compete with the product or procedure that will predictably result from the work described in the application; or
4. any entity that will be a sub-recipient from the University of funding resulting from the application.

Significant financial interests do not include the following:

1. salary, royalties, or other remuneration paid to an Investigator by the University;
2. income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
3. income from service on advisory committees or review panels for public or nonprofit entities.

**Significant Obligation** - Significant obligations include positions held by the Investigator (or the Investigator's domestic partner and dependent children) as an officer, trustee, director, employee, or consultant of an entity whether the entity is for profit or not-for-profit and whether the position is paid or unpaid, that would reasonably appear to be affected by the work funded or proposed by the University for all external and selected types of internal funding.

**Working Days** - The days on which University offices are open.

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## Contact Information

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## Related Information

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**University Documents:**

Policy on Responsible Conduct in Intellectual and Creative Activity  
<http://www.research.buffalo.edu/policies/rescond.cfm>

**University Documents:**

Annual Disclosure of Significant Financial Interests and Significant Obligations  
[http://www.research.buffalo.edu/forms/spa/financial\\_disclosure.pdf](http://www.research.buffalo.edu/forms/spa/financial_disclosure.pdf)

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## Revision History

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December 2008	Page 1 - Added the Food and Drug Administration (FDA) to entities listed in the Policy Statement. Page 4 - Clarified language in applicability section to specify research activities.
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## Presidential Approval

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*John B. Simpson*

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John B. Simpson, President

*9/17/09*

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Date