
INSTITUTIONAL CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH POLICY

Category: Research
Responsible Office: VP for Research and Economic Development
Responsible Executive: VP for Research and Economic Development

Date Established: 3/25/13
Date Last Revised: 09/11/18

Summary

The University at Buffalo recognizes its obligation to protect the rights and welfare of human subject research participants and to ensure research integrity. Accordingly, all significant institutional conflicts of interest in human subjects research require disclosure, evaluation, and management or elimination.

Policy

POLICY STATEMENT

The University at Buffalo (UB, University) strives to ensure that its research, teaching, public service, and other activities are not compromised or perceived as biased by business and financial considerations. The breadth of university activities and the variety of its relationships may lead to an actual or perceived institutional conflict of interest that must be resolved appropriately.

Potential institutional conflicts of interest (ICOI) must be identified promptly and managed or eliminated before any contract, sponsored project, dedicated gift, or transaction is executed; any contractual relationship is initiated; or any action is taken that might be influenced or appear to be influenced by the conflict of interest.

An ICOI may occur in human subjects research when a significant business and financial interest of UB affects or appears to affect the design, conduct, reporting, review, or oversight of human subjects research. ICOIs are of significant concern when they create the potential for inappropriate influence over a human subjects research project, particularly to the integrity of the research and the safety and care of subjects enrolled in the research. All potential ICOIs in human subjects research require disclosure, evaluation, and either management or elimination.

Potential Conflicts

An ICOI may exist in human subjects research when:

- UB receives or might reasonably be expected to receive significant royalty from the sale of a product covered by any patent, license or copyright, whether issued or pending, held by State University of New York (SUNY) or Research Foundation (RF) and is proposed to be used in human subjects research projects at UB
- UB holds or proposes to hold, directly or indirectly, significant equity interests of any amount (or entitlement to the same), in research sponsors of human subjects research projects, whether such research sponsor is public or non-public, through its technology licensing activities or investments related to such activities
- UB has received substantial gifts (including gifts in kind) from a potential commercial sponsor of human subjects research or a company that owns or controls products being studied or tested in human subjects research

- Covered individuals with direct responsibility for human subjects research (and their immediate family members), hold a significant financial interest in, consults for, serves on the board of, or is otherwise expected to act for the benefit of an entity that has a significant financial interest in human subjects research

Disclosure By Covered Individuals

Covered individuals with direct responsibility for human subjects research are required to complete a disclosure statement annually, and within 30 days of discovering or acquiring a new significant financial interest (SFI) that includes information pertaining to the following SFIs of the covered individual and their immediate family members:

- A controlling interest
- Ownership of more than 10 percent of the voting interest
- Ownership of more than 10 percent of the fair market value
- Service as a member of the board of directors or other governing body, including a trustee or advisory director
- Service as an officer
- Service as an employee

Disclosure By the University

Semi-annually, the following offices will report to the COI Officer:

- UB Technology Transfer Office will report invention disclosures, licensing arrangements, and patents
- University at Buffalo Foundation (UBF) will report substantial gifts

Reporting Concerns of Potential Conflicts

An individual who has concerns about the permissibility of any relationship or activity on the part of the university or its personnel involving an external relationship should promptly consult the COI Officer. If, after examination of the situation, the COI Officer determines that a potential ICOI exists or poses significant potential for public perception of an ICOI, the COI Officer will refer the matter to the Conflict of Interest Committee (COI Committee). The COI Committee will review the matter and recommend a plan to manage or eliminate the potential ICOI.

Protection from Retaliation

Employees making good faith reports of suspected conflicts of interest are protected from retaliation. Acts of retaliation or reprisal against an individual for reporting in good faith a potential ICOI is a violation of this policy.

APPLICABILITY

This policy applies to all university personnel with direct responsibility for human subjects research including administrators, faculty, and staff (covered individuals), who are in a position to make decisions, including those delegated such authority, for all university entities.

DEFINITIONS

Covered Individuals – Persons with direct responsibility for human subjects research who have, or have been delegated, the authority to make decisions on behalf of the university including, but not limited to:

- President
- Provost
- Vice President for Research and Economic Development
- University official identified in federal-wide assurance for the protection of human research subjects
- Deans, department chairs, and directors

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

Institutional Conflict of Interest (ICOI) – exists where a business and financial relationship between the university and an external entity compromises the integrity of institutional decision-making. Conflicts may arise in situations:

- When covered individuals who act on behalf of the university have personal business and significant financial interests that may be affected by their administrative decisions; in these situations, an individual's business and financial relationship also implicates the university's interests
- Where the university enters into a business and financial relationship at the institutional level with an external entity that may bring significant financial gain to the university or any of its units, such as:
 - intellectual property rights owned by SUNY or RF which has been licensed to an outside entity in exchange for equity royalties or other forms of financial remuneration
 - public or private equity held by the university in an outside entity that is a sponsor of human subjects research overseen by the Institutional Review Board (IRB)
 - stock or other equity holdings included as part of a SUNY or RF investment and endowment portfolio
 - money or other non-monetary resources provided to SUNY or RF by an external entity or individual

An ICOI may involve any university activity carried out in the pursuit of the university's mission. Of significant concern are conflicts that create the potential for inappropriate influence over human subjects research, particularly to the safety and care of subjects enrolled in the research and the integrity of the research.

Principal Investigator (PI) - a UB faculty or staff member who bears responsibility for the intellectual leadership of a project. The PI accepts overall responsibility for directing the research, financial oversight, and compliance with relevant university policies and sponsor terms and conditions.

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

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

- Controlling interest
- Ownership of more than 10 percent of the voting interest
- Ownership of more than 10 percent of the fair market value
- Service as a member of the board of directors or other governing body, including a trustee or advisory director
- Service as an officer
- Service as an employee

RESPONSIBILITY

Conflict of Interest Committee

- Draft an ICOC management plan in conjunction with the COI Officer.

Conflict of Interest Officer

- Develop a list of UB business and financial interests and provide it to the IRB.
- Review disclosure statements submitted by covered individuals and protocols submitted by the IRB to determine if an actual or potential ICOI exists.
- Draft an ICOI management plan in conjunction with the COI Committee.
- Document the review of all SFIs, potential ICOIs, and draft ICOI management plans.
- Provide documentation of all ICOI reviews and draft ICOI management plans to the IRB for approval.

Covered Individuals

- Submit a disclosure statement that includes information pertaining to their SFIs annually, and within 30 days of discovering or acquiring a new SFI.
- Review and if appropriate, agree to the draft ICOI management plan prepared by the COI Officer and COI Committee.

Institutional Review Board

- Review all protocols to determine if the project's sponsor is included on the UB business and financial interests list. Forward any project found on the business and financial interests list to the COI Officer.
- Review all protocols to determine if the results of the study could affect the financial interests of UB, thus presenting a potential conflict. Forward potential conflicts to the COI Officer.
- Review and approve ICOI management plans to protect human subjects and research integrity.

Principal Investigator

- Review and if appropriate, agree to the draft ICOI management plan prepared by the COI Officer and COI Committee.

Technology Transfer Office

- Report invention disclosures, licensing arrangements, and patents to the COI Officer.

University at Buffalo Foundation

- Report all substantial gifts received by the university to the COI Officer.

Contact Information

Contact	Phone	Email
Conflict of Interest Officer	716-829-3978	COIOfficer@buffalo.edu

Related Information

University Links

Investigator Conflict of Interest Policy

<http://www.buffalo.edu/administrative-services/policy1/ub-policy-lib/investigator-conflict-interest.html>

Human Research - Institutional Review Board

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

Institutional Review Board – Policies and Procedures Toolkit

<http://www.buffalo.edu/research/research-services/compliance/irb/policies-procedures-toolkit.html>

Human Research Protection Program Policies and Procedures Manual

<http://www.research.buffalo.edu/forms/hs/ubsop.pdf>

Research Compliance – Reporting Significant Financial Obligations

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

Research Compliance – Conflict of Interest – File Your Disclosure

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

Royalty Distribution Policy

<http://www.buffalo.edu/administrative-services/policy1/ub-policy-lib/royalty-distribution.html>

Vice President for Research and Economic Development

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

Related Links

Department of Health & Human Services – Office for Human Research Protections - <http://www.hhs.gov/ohrp/humansubjects/index.html>

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: <ul style="list-style-type: none"> • Require disclosure of significant financial interest for all human subjects research, both funded and non-funded • Use the term “royalty” consistent with the SUNY <i>Patents, Inventions, and Copyright Policy</i>
----------------	--

Presidential Approval

Signed by President Satish K. Tripathi

3/25/13

Satish K. Tripathi, President

Date