INSTITUTIONAL CONFLICTS OF INTEREST IN HUMAN SUBJECTS RESEARCH

Summary

The University at Buffalo (UB) recognizes its obligation to protect the rights and welfare of human subject research participants and to ensure research integrity. Accordingly, all potential 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 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.

An ICOI may exist in human subjects research when:

- UB receives or might reasonably be expected to receive royalty income 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)/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, 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 financial interest in sponsored 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% of the voting interest
- ownership of more than 10% 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

The following offices will report semi-annually to the COI Officer:

- Office of Science, Technology Transfer and Economic Outreach (STOR) will report invention disclosures, licensing arrangements, and patents
- University at Buffalo Foundation (UBF) will report substantial gifts.

Areas of Potential Conflicts

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. An ICOI exists when:

- UB receives or might reasonably be expected to receive royalty income from the sale of a product covered by any patent, license, or copyright, whether issued or pending, held by SUNY/RF and is proposed to be used in human subjects research projects at UB
- UB holds or proposes to hold, directly or indirectly, any 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 (or 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 financial interest in sponsored human subjects research.

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. Such conflicts may arise in situations:
- when covered individuals who act on behalf of the University have personal business and 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 financial gain to the University or any of its units, such as:
  - intellectual property rights owned by SUNY/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 SUNY/RF’s investment and endowment portfolio

money or other non-monetary resources provided to SUNY/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.

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% of the voting interest
- ownership of more than 10% 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

- In conjunction with the COI Officer, draft an ICOI management plan.

Conflict of Interest Officer

- Using the semi-annual reports submitted by STOR and UBF, develop a list of UB’s 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.
- In conjunction with the COI Committee, draft an ICOI management plan.
- 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

- Annually, and within 30 days of discovering or acquiring a new SFI, submit a Disclosure Statement that includes information pertaining to their SFIs.
- 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 and approve ICOI management plans that ensure the protection of 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.

Office of Science, Technology Transfer and Economic Outreach

- Semi-annually report invention disclosures, licensing arrangements, and patents to the COI Officer.

University at Buffalo Foundation

- Semi-annually report all substantial gifts received by the University to the COI Officer.

PROCEDURE

Submission of Disclosure by Covered Individuals

Anually, and within 30 days of discovering or acquiring a new SFI, covered individuals must submit a Disclosure Statement that includes information pertaining to their and their immediate family members’ SFIs.

Submission of Disclosure by the University

Using the semi-annual reports submitted by STOR and UBF, the COI Officer will develop a list of UB’s business and financial interests and provide it to the IRB.

Review and Evaluation

The IRB will review all protocols to determine if the project’s sponsor is included on the UB business and financial interests list. If the sponsor is found on the list, the IRB will forward the protocol to the COI Officer to determine if an ICOI exists.

- The COI Officer will review the following to determine if an actual or potential ICOI exists:
  - disclosure statements submitted by covered individuals
  - protocols submitted by the IRB.

- When an actual or potential ICOI exists, UB will only participate in a human subjects research project when the IRB and COI Committee determine that:
  - circumstances exist to justify UB’s participation in the project while still maintaining the protection of human subjects, and
  - an ICOI management plan can be adopted that maintains research integrity and serves the best interests of subjects enrolled in the research.

- The COI Officer and the COI Committee will draft an ICOI management plan. ICOI management plans may include but are not limited to the following:
  - disclose the ICOI to research subjects in the consent form
o disclose the ICOI to any journals or other publications for which the results of the research will be submitted
o monitor research by independent reviewers
o divestiture of the SFI
o severance of relationships that create actual or potential conflicts
o prohibit the conduct of the research.

- the PI must agree to the ICOI management plan as well as any covered individuals with an SFI related to the protocol
- the COI Officer will provide to the IRB documentation of the ICOI review and draft ICOI management plan
- the IRB determines if the ICOI management plan maintains the protection of human subjects and research integrity, and has final authority to approve the plan and research protocol.

The review, evaluation, and approval of the ICOI management plan must be completed prior to the commencement of the project (including enrollment of research subjects).

Annual Report
The COI Officer will annually report all ICOIs to the Vice President for Research and Economic Development.

Contact Information

Conflict of Interest Officer  Phone: (716) 645-0316
516 Capen Hall  Fax: (716) 645-6792
North Campus  Website: www.research.buffalo.edu
Amherst, NY 14260  E-mail: COIOfficer@buffalo.edu

Related Information

University Documents:
Investigator Conflict of Interest -
http://policy.business.buffalo.edu/Policy%20Library/Investigator%20Conflict%20of%20Interest%20Policy.pdf
UB Patent and Invention Policy -
http://www.research.buffalo.edu/ovpr/policies/patents.cfm
Health Sciences Institutional Review Board -
http://www.research.buffalo.edu/rsp/irb/hsirb/default.cfm
Human Research Protection Program Policies and Procedures Manual -
http://www.research.buffalo.edu/forms/hs/ubsop.pdf

Other Documents:
Department of Health & Human Services Regulations -
http://www.hhs.gov/ohrp/humansubjects/index.html

Presidential Approval

Signed by President Satish K. Tripathi  3/25/13
Satish K. Tripathi, President  Date