

**SYRACUSE UNIVERSITY  
HUMAN RESEARCH PROTECTION PROGRAM  
STANDARD OPERATING PROCEDURES**

<b>TITLE: INSTITUTIONAL CONFLICT OF INTEREST</b>		<b>DOCUMENT NUMBER: 032</b>	
<b>REVISION NUMBER</b>	<b>REVISION DATE(SUPERSEDES PRIOR VERSION)</b>	<b>EFFECTIVE DATE</b>	<b>PAGE NUMBER</b>
00		FEBRUARY 1, 2011	1 OF 5

**Title: INSITUTIONAL CONFLICT OF INTEREST**

**1.0 Purpose:**

The purpose of this Standard Operating Procedure (SOP) is to provide a process by which Syracuse University can ensure that the decision-making processes for its financial and research activities related to human subjects research are separate; and that they are independently managed and monitored. This policy establishes the principles and procedures that enable the University to identify and avoid institutional conflicts of interest of a financial nature that present a significant risk to the perceived or actual objectivity of such human subjects research.

In developing this policy and accompanying procedure, the Office of the Vice President for Research has taken into account the issues identified and discussed in "Task Force on Research Accountability-Report on Individual and Institutional Financial Conflict of Interest," published in 2001 by the Association of American Universities (AAU) and available at: [www.aau.edu/research/COI.01.pdf](http://www.aau.edu/research/COI.01.pdf).

**2.0 Policy:**

It is the policy of Syracuse University to ensure that its human-subjects research is conducted with integrity and free from any actual or apparent institutional conflict of interest. Institutional Conflict of Interest can occur whenever the external financial interests or business relationships of the University or of one of its officials are such that their actions could affect, or could reasonably appear to affect, the conduct, review or oversight of the University's human subject research. The potential for institutional conflict of interest that could compromise the integrity of the University's research mission generally arises in one of the three situations described below:

**2.1.** When the University, as an institution, has taken an equity interest in a business enterprise in which University employees conduct, or propose to conduct, research that could affect the value of the equity interest in that enterprise; or when the University holds a patent, license, or right to licensing income on a process, technique, or production that it licenses to external companies, which in turn use University employees to conduct research on that process, technique or product; or

**2.2.** When University officers (i.e. Chancellor, Vice Chancellor, Comptroller, Vice President for Research, or Executive Vice President and Chief Financial Officer) with the authority to act on behalf of the University and to make decisions that have institution-wide implications, or whose decisions could reasonably be seen as affecting the conduct, review, or oversight of human subjects research, holds a significant financial interest in, consults for, serves on the board of, or is otherwise expected to act for the benefit of an entity (any entity recognized by law through which business for profit is conducted, including a sole proprietorship, partnership, firm, corporation, holding company, joint stock company receivership or trust) that has a financial interest in University-sponsored human subjects research.

**2.2.1.** Significant financial interest in a business entity means:

**2.2.1.1.** Salary or other payment for services (e.g. consulting fees) that exceeds or over the next twelve months is reasonably expected to exceed \$10,000;

**2.2.1.2.** Equity interests (e.g. stocks, stock options or other ownership interests) that meet the following tests:

**2.2.1.2.1.** Exceeds \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value (e.g. most recent sales price recognized by the company), or

**2.2.1.2.2.** Constitutes more than a 5% ownership interest in any single entity.

- 2.2.1.3. Intellectual property rights (e.g. patents, copyrights and licensing income from such rights).
- 2.2.1.4. Services as an officer, director, or in any other executive position in an outside business, whether or not remuneration is received for such service.
- 2.3. University receipt of substantial or reoccurring gifts, equipment donations or promises thereof (direct or implied) that are not a part of a disclosed sponsorship or sponsored program from commercial sponsors of human subjects research if there is an actual or implied quid pro quo owed to the donor that relates to, or could give the appearance of relating to, the research.

This policy is distinct from *Syracuse University's Policy on Conflict of Interest for Research Investigators* which provides for the management of conflicts of interest that are personal to individual investigators.

### **3.0 References and Reference Documents:**

*Association of American Universities:* [www.aau.edu/research/COI.01.pdf](http://www.aau.edu/research/COI.01.pdf)

*Syracuse University's Policy on Conflict of Interest for Research Investigators*

[http://supolicies.syr.edu/fac\\_teach/conflict\\_int\\_pi.htm](http://supolicies.syr.edu/fac_teach/conflict_int_pi.htm)

### **4.0 Procedure:**

#### **4.1. Identification of Conflicts.**

- 4.1.1. **Disclosure of University Financial or Business Relationships.** The Director of Technology Transfer and Industrial Development (TT&ID), or designee, shall provide the Office of the Vice President for Research with semi-annual reports, in January and July, that disclose the entities in which the University holds equity positions or from which it has the right to receive licensing income.
- 4.1.2. **Disclosure of Officials Financial or Business Relationships.** University officials and senior administrators shall disclose as a part of their "Financial Disclosure and Conflict of Interest Statements" filed annually with Audit and Management Advisory Services (AMAS) information concerning any significant financial interest in, or position held with a business entity. AMAS shall provide the VPR or his or her delegate, copies of the disclosure statements each October.
- 4.1.3. **University Receipt of Substantial or Reoccurring Gifts or Equipment Donations.** On an annual basis, after the annual Office of Research Integrity and Protections report is complete, ORIP will provide the Office of Advancement and External Affairs a list of departments with active human research protections protocols. In return, the Office of Advancement and External Affairs shall provide a report to the VPR of major donors who donate \$50,000 or more in gifts or equipment donations to those departments with active human research protocols.

#### **4.2. Review of Disclosure Information.**

- 4.2.1. The Office of Research Integrity and Protections (ORIP) assists, supports and reviews all proposed human subjects research. The VPR shall provide the director of ORIP with copies of the "Financial Disclosure and Conflict of Interest Statements" received annually from AMAS, the semi-annual reports received from the Office of Technology Transfer and Industrial Development, and the annual report of major donors from the Executive Vice President for Advancement and External Affairs. The director of ORIP will compile the information to use as a reference when reviewing research protocols and will keep the information confidential.
- 4.2.2. The director of ORIP shall review all proposed human-subject research proposals it receives with the disclosure information provided by the VPR to identify any actual or potential institutional conflict of interest present in the protocols. The ORIP director shall review Section 2-Funding Information and Section 10- Financial Conflict of Interest of the human research protocol and refer any human subject research protocol for which an actual or potential institutional conflict of interest has been indentified to the VPR in accordance with Section 4.3. below. Once the institutional conflict of interest is resolved, the affected protocol shall be returned to ORIP for review by the University's Institutional Review Board (full board protocols) or IRB Chair (expedited and exempt protocols).

#### **4.3. Responding to Information Reflecting Potential Institutional Conflict of Interest.**

- 4.3.1. Actual or apparent Conflict of Interest of the Chancellor, Vice Chancellor, or Vice President for Research, he or she shall either:
- 4.3.1.1. Totally divert him or herself of the financial interest; and/or
  - 4.3.1.2. Resign from the board or other position with the external entity that has a financial interest in University sponsored human subjects research. Proposed research cannot be approved or continued until such action is taken by the affected official.
- 4.3.2. In all other Institutional Conflicts of Interest cases the University's Conflict of Interest Committee, in consultation with the VPR shall determine whether to:
- 4.3.2.1. Require TT & ID to divest the University's current equity holdings or right to licensing income; and its right to acquire equity holdings in the future;
  - 4.3.2.2. Propose modifications to the proposed human subjects research that would remove the possibility that the University, or any of its units or officials, would benefit financially from the results of the proposed research;
  - 4.3.2.3. Prohibit the proposed human subject research when in the best interests of the public or the University, upon recommendation from the Director of the Office of Research Integrity and Protections (i.e. During the pending time for review by COI management and/or creation of a management plan the research will be stopped if it is to the best interest of the public or the University).
  - 4.3.2.4. Direct that the University official who holds a significant financial interest divest him or herself of that interest, or remove him or herself from the decision process involving such research; OR
  - 4.3.2.5. If feasible, develop an Institutional Conflict of Interest Management plan.
- 4.3.3. In the event the University's financial interest is in the form of licensing income receivable as a result of a license agreement, the VPR in consultation with University Counsel, will determine on a case-by-case basis the significance and management, if appropriate, of the potential institutional conflict of interest.

#### **4.4. Monitoring Compliance.**

- 4.4.1. The Conflict of Interest Committee is responsible for:
- 4.4.1.1. Review of disclosures that present or appear to present an institutional conflict of interest per 4.3.2;
  - 4.4.1.2. Development of conflict resolution plans;
  - 4.4.1.3. Documenting the Committee's findings and the bases for the approval of conflict resolution plans, including steps to be taken to manage the conflict or minimize the potential for conflict of interest by reducing or eliminating the interest;
  - 4.4.1.4. Oversight of projects that are being managed with respect to conflicts of interest; and
  - 4.4.1.5. Communication to the IRB, and to responsible institutional officials, of summary information about the nature and amount of the institutional financial interest in human subject research, along with the committee's findings.
- 4.4.2. Any member of the Conflict of Interest Committee who has a financial interest in or serves as a paid consultant for an entity that is involved in a research proposal shall not participate in the review under this policy.
- 4.4.3. The University's Audit and Management Advisory Services will annually review cases involving an institutional conflict of interest to ensure that all situations in which a potential exists for institutional conflict of interest have been properly identified and managed to minimize the risks to human subjects have been properly mitigated.
- 4.4.4. On an annual basis (target date of November), subsequent to all reports being submitted to the ORIP director, University officers will meet with the ORIP director to discuss the Institutional Conflict of Interest policy, its effectiveness, conflict management, and possible improvements to the policy.

#### **4.5. Responsibilities of the Vice President for Research.**


- 4.5.1. The Vice President for Research (VPR) has the responsibility for overseeing the process for reviewing, resolving and monitoring institutional conflict of interest that may arise from the

business relationships of either the University or its officials with outside entities. Disclosures that may identify actual or potential institutional conflict of interest shall be handled as described in Section 4.3.

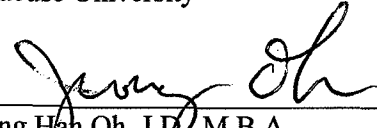
**4.5.2** The Vice President for Research is the University officer responsible for interpreting and overseeing implementation of and compliance with this policy.

SOP 032: Institutional Conflict of Interest

Approved by:

  
Gina Lee-Glauser, Ph.D.  
Institutional Official  
Vice President for Research  
Syracuse University


1/28/11  
Date

  
Jeong Han Oh, J.D., M.B.A.  
Director  
Office of Technology Transfer and Industrial Development  
Syracuse University

1/28/11  
Date

  
Kathleen King, Ph.D.  
Chair of the Institutional Review Board  
Syracuse University

28/January 11  
Date

  
Tracy Crompton, M.S.W.  
Director of Office of Research and Integrity Protections  
Syracuse University

1-27-11  
Date