

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

TITLE: INDIVIDUAL FINANCIAL CONFLICT OF INTEREST			DOCUMENT NUMBER: 038
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Title: INDIVIDUAL FINANCIAL CONFLICT OF INTEREST

1.0 Purpose:

This procedure outlines the process for reporting and disclosing any conflicts of interest in human subjects research.

2.0 Policy:

It is the policy of the Syracuse University (SU) Institutional Review Board (IRB) that all Investigators shall disclose in writing to the IRB all conflicts of interest for themselves and their spouses, domestic partner and dependent children. For purposes of this policy, a conflict of interest is a financial interest that could affect or appear to affect the design, conduct, or reporting of the research. Financial interests that require disclosure are defined in the *Syracuse University's Policy on Conflict of Interest for Research Investigators* (http://supolicies.syr.edu/fac_teach/conflict_int_pi.htm)

An Investigator with a conflict of interest in a research project involving human participants may not conduct that research unless the conflict of interest is eliminated or managed. The IRB will not approve a research protocol where a conflict of interest is neither eliminated nor managed. The IRB has the final authority to determine whether a conflict of interest has been eliminated or managed appropriately.

IRB approval of a means to manage a conflict of interest is not final University approval for the research to be conducted. The Vice President for Research has final authority to allow or disallow research. However, no research involving human participants may be conducted by SU Investigators if the IRB has not approved it.

Investigators shall cooperate fully with the IRB and any other individuals or groups involved in the review of the pertinent facts and circumstances regarding any conflict of interest disclosed.

This policy is not intended to prohibit Investigators' relationships with companies that have no influence on the design, conduct, or publication of a study and that occur prior to the initiation of a sponsored study or after publication of its results. However, compensation in the form of an economic interest which may be affected by the outcome of the study shall be avoided. (Examples of conflicts of interest due to compensation which require disclosure pursuant to this Policy include, but are not limited to, consulting agreements, speaking or other fees, honoraria, gifts, licensing revenues, equity interests, loans or notes, including stock options, regardless of value, expectations of receiving equity interests, and/or other fees or compensation received from sponsors.)

3.0 References and Reference Documents:

Syracuse University's Policy on Conflict of Interest for Research Investigators
(http://supolicies.syr.edu/fac_teach/conflict_int_pi.htm)

4.0 Procedure:

4.1 Investigator Responsibilities.

- 4.1.1** Investigators must disclose to the IRB all significant financial interest in association with the human subjects research project under review.
- 4.1.2** Disclosures must be performed:
 - 4.1.2.1** With the initial IRB application using the application form; and
 - 4.1.2.2** Within 10 days of becoming aware of any previously undisclosed significant financial interest using the "Request for Amendment".
- 4.1.3** The Investigator must comply with all recommendations of the SU Conflict of Interest

Committee (COIC) to minimize the conflict.

4.2 IRB Committee Responsibilities.

- 4.2.1 The IRB may approve the research pending review and approval of the COIC. Following the final determination of the COIC, the IRB receives the protocol for final review and approval. If the COIC determines that a significant financial interest was not present, the research may be approved by an expedited procedure. Otherwise the research and the recommendations of the COIC are reviewed by the convened IRB.
- 4.2.2 The IRB may choose to accept or not accept the recommendations of the COIC. If the IRB does not accept the recommendations of the COIC it will include in its decision the reasons for non-acceptance in a letter to the COIC and the Investigator.

4.3 ORIP Responsibilities.

- 4.3.1 The ORIP Director forwards disclosures of significant financial interest involving human subjects research to the Vice President for Research.
- 4.3.2 The ORIP Administrator makes appropriate database (*Infoed*) entries assuring documentation of the conflict of interest and the nature of the conflict in the notes section of *Infoed*.
- 4.3.3 The ORIP Administrator will assure that determination letters for all studies that involve a conflict of interest include a statement that the research may not commence until a final determination has been rendered by the COIC.
- 4.3.4 When ORIP receives notice of acceptance or non-acceptance of the COIC's decision from the IRB, the ORIP administrator will send the appropriate determination letter (approved or disapproved) to the Investigator.

4.4 Institutional Responsibilities.

- 4.4.1 If there is a conflict of interest, the conflict is reviewed by the COIC and will not be eligible for approval until the Vice President for Research certifies that the financial conflict has been reviewed and is being managed at the appropriate level of oversight.
- 4.4.2 The IRB, Investigator and ORIP will be informed in writing of the outcome.
- 4.4.3 If the Vice President for Research becomes aware of a previously undisclosed individual financial conflict of interest involving human subjects research, through his leadership of the COIC or otherwise, he/she will notify the Chair of the IRB within ten business days.

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Approved by: BR Ware 7-20-08
Ben Ware, Ph.D. Date
Institutional Official
Vice President for Research and Dean of the Graduate School
Syracuse University

Diane A Young 7-20-08
Diane Young, Ph.D. Date
Chair of the Institutional Review Board
Syracuse University

Tracy Crump 7-15-08
Tracy Crump, M.S.W. Date
Director of Office of Research and Integrity Protections
Syracuse University