

<p>Name of Policy: Financial conflict of interest policy for sponsored programs.</p> <p>Policy Number: 3364- 70-01</p> <p>Approving Officer: President</p> <p>Responsible Agent: Vice President for Research</p> <p>Scope: All University of Toledo Campuses</p>	 <p>Most recent revision date: September 14, 2012</p> <p>Original effective date: March 25, 2008</p>
<p><input type="checkbox"/> New policy proposal</p> <p><input type="checkbox"/> Major revision of existing policy</p>	<p><input checked="" type="checkbox"/> Minor/technical revision of existing policy</p> <p><input type="checkbox"/> Reaffirmation of existing policy</p>

(A) Policy statement

Activities supported by grants, contracts (including clinical trial agreements), cooperative agreements, (herein referred to Sponsored Programs funding) from public and private entities provide valuable sources of funds to support the academic mission of The University of Toledo (“University”). The university actively encourages interaction with both the public and private sectors as an important component of its research, education, and public service activities. The federal government requires that entities receiving federal funding maintain a written policy on financial conflict of interest which is consistent with 42 C.F.R. 50 entitled “Promoting Objectivity in Research.” Furthermore, the State of Ohio also has several statutes concerning conflict of interest, including sections 102.03 and 2921.42 to 2921.43 of the Ohio Revised Code. Investigators involved in such interactions may receive personal financial compensation in accordance with this policy so long as it is consistent with all other applicable institutional policies, and federal and state laws and regulations.

(B) Purpose of policy

Federal financial conflict of interest regulations (FCOI) have specific requirements for FCOI education, disclosure, review, reporting and management. The purpose of this policy is to ensure that the design, conduct and reporting of sponsored research will be free from bias resulting from any Investigator’s Financial Conflict of Interest, and to ensure compliance with applicable federal regulations and policies. Additionally, this policy sets forth the principles for identifying those individuals who should report Significant Financial Interests and situations that pose a potential for financial conflicts of interest.

This policy is applicable to all Investigators involved in Sponsored Programs administered through the University, regardless of the source of funds.

This policy does not specifically address compliance with Ohio Ethics laws or disclosure. University employees and faculty should review University of Toledo Board of Trustees bylaw 3364-1-06 and applicable University policy with respect to application of these laws and rules to

employees of the University. Additional information may be obtained on the Ohio Ethic's Commission website at www.ethics.ohio.gov.

(C) Procedure

Each Investigator responsible for the design, conduct, or reporting of research supported or proposed for support by any sponsor via a grant or Sponsored Program agreement is required to file a financial disclosure. For the purposes of this policy, disclosure is required from:

- (1) all Investigators (including students or other trainees) listed by name on a Sponsored Program proposal, regardless of role;
- (2) any Investigator, regardless of institutional status or affiliation, not named on the proposal but whom the PI knows or suspects will be involved in the design, conduct, or reporting aspects of the sponsored program, including persons who are sub-grantees, contractors, collaborators or consultants; and
- (3) all Investigators, regardless of institutional status or affiliation added to the program team after the proposal is submitted.

The financial conflict of interest disclosure must be submitted:

- (1) no later than the time of application for funded research;
- (2) at least annually, during the period of the award; and
- (3) within thirty (30) days of discovering or acquiring (through purchase, marriage or inheritance) a new significant financial interest.

The financial disclosure must include the Significant Financial Interests of the Investigator (and those of the Investigator's spouse and dependent children), which reasonably appears to be related to the Investigator's institutional responsibilities.

A Significant Financial Interest exists with regard to:

- (1) a publicly traded entity if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds \$5000. Remuneration includes salary and any payment for services (e.g. consulting fees, honoraria, paid authorship, travel reimbursement). Equity interest includes any stock, stock option or other ownership interest based on public prices or other fair market value.
- (2) a non-publicly traded entity, if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated exceeds \$5000, or the Investigator (or the Investigator's spouse or dependent children) holds ANY equity interest (e.g. stock, stock option or other ownership interest).
- (3) intellectual property rights (e.g. patents, copyrights), royalties from such rights and agreements to share in royalties related to such rights.

Significant financial interest does NOT include the following types of financial interests:

- (1) Salary, royalties or other remuneration paid by the Institution to the Investigator,

- (2) Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency or by an institution of higher education
- (3) Income from service on advisory committees or review panels for a federal, state or local government agency or an institution of higher education
- (4) Income from mutual funds or retirement accounts as long as the investor does not directly control the investment decisions made by these investment vehicles

This financial disclosure must be either in writing on a University disclosure form or electronically, as determined by the then-current process established by the institution. The disclosure must be personally completed by the Investigator. If in writing, the disclosure form must be personally signed by the Investigator. Stamped or "per" signatures are not acceptable on the disclosure form.

(D) Roles and Responsibilities

The Principal Investigator (PI) for each Sponsored Program is responsible for assuring that all Investigators working on his/her project complete the required financial disclosure form. The PI is also responsible for identifying all Investigators, not named on the proposal, paid or unpaid, who will be involved in the design, conduct, or reporting of the Sponsored Program. Such Investigators should be named on the PI's financial disclosure.

Every investigator responsible for the design, conduct or reporting of research that is connected to a Public Health Service sponsored proposal must complete Financial Conflict of Interest training. These investigators are required to complete training regarding financial conflicts of interest regulations and responsibilities:

- (1) every four years;
- (2) when there is a policy revision that affects the requirements for investigators;
- (3) when the investigator is new to the institution; or
- (4) when an investigator is found to be out of compliance with the policy or the management plan.

Research and Sponsored Programs (RSP) is responsible for:

- (1) collecting all financial disclosure forms;
- (2) reporting Significant Financial Conflict of Interests of University Investigators and subrecipients to the agencies/sponsors of Sponsored Programs;
- (3) establishing the process for such reporting; and
- (4) providing administrative support to the conflict-of-interest review committee(s).

The Vice President for Research will:

- (1) appoint a standing Conflict of Interest committee to review all financial disclosures;

- (2) promptly notify the applicable awarding agency if an Investigator fails to comply with this Policy, a FCOI Management Plan, or if bias is found with the design, conduct or reporting of NIH funded research. A Mitigation Report will be included with the notification.

The Conflict of Interest Committee will, prior to expenditure of Sponsored Programs funding for each study:

- (1) review disclosed SFIs and determine if a Financial Conflict of Interest exists;
- (2) when a FCOI is found, develop and implement a plan to management plan for the FCOI, and
- (3) document reviews consistent with the applicable federal Agency's regulatory requirements.

The Institution will:

- (1) Monitor an Investigator's compliance with the management plan on an ongoing basis until the completion of the project.
- (2) Maintain all FCOI-related records that meet or exceed the regulatory requirements:
 - (a) for at least three (3) years from the date the final expenditures report is submitted to the Agency, and
 - (b) From other dates specified in 45 CFR 74.53(b) and 92.42(b), where applicable
- (3) When establishing sub-recipient agreements, include whether the sub-recipient will follow the FCOI policy of the awardee Institution or the FCOI policy of the sub-recipient
- (4) Ensure a response within 5 days to any written public request of any significant financial conflict of interest disclosed by senior/key personnel that meets the following conditions:
 - (a) The financial interest is disclosed and still held,
 - (b) It is related to the funded research, and
 - (c) It was determined to be a Financial Conflict of Interest
- (5) Establish a process to make available information to the public concerning identified FCOI held by senior/key personnel. In response to a written request, the Institution will disclose, at a minimum:
 - (a) The name of the Investigator,
 - (b) The Investigator's title and role with respect to the research project,
 - (c) The name of the entity in which the Significant Financial Interests is held,
 - (d) The nature of the Significant Financial Interest, and
 - (e) The approximate dollar amount of the interest or a statement that the interest is one whose value cannot be readily determined.

(E) Enforcement

All persons subject to this Policy are expected to comply with it fully and promptly. Whenever an Investigator has violated this Policy, for example, by failure to disclose a Significant Financial Interest, the Vice President for Research or the Conflict of Interest Committee may refer the

matter to the appropriate University official or committee for disciplinary action or other appropriate action.

Violations of this Policy and/or the FCOI federal regulations that constitute falsification in proposing, performing, reporting or reviewing research shall be handled in accordance with the University policy and procedures governing allegations of research misconduct.

(F) Definitions

(1) *Sponsored Program* means research, training, and instructional projects involving funds, materials, or other compensation from outside sources under agreements that contain any of the following: The agreement binds the university to a line of scholarly or scientific inquiry specified to a substantial level of detail; a line-item budget is involved; financial reports are required; the award is subject to external audit; unexpended funds must be returned to the sponsor at the conclusion of the project; or the agreement provides for the disposition of either tangible or intangible properties that may result from the activity. For more information see University Research and Sponsored Programs policy.

(2) *Investigator* includes any individuals, whether salaried or not salaried, whether holding faculty status or not, who, on behalf of the university are responsible for the design, conduct or reporting of the Sponsored Programs; this includes laboratory personnel, students, trainees, volunteers, subcontractors and consultants.

(3) *Family Members* means immediate family, including the Investigator's spouse or domestic partner, and dependent children.

(4) *Financial Interest* means anything of monetary value, whether or not the value is readily ascertainable.

(5) *Institutional Responsibilities* means an Investigator's professional responsibilities on behalf of the institution, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Safety monitoring Boards.

(6) *Manage* means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

(7) *Significant Financial Interest (SFI)* means

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that appears to be related to the Investigator's institutional responsibilities:

(a) With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the

disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5000. Remuneration may include salary and any payment for service (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option or other ownership interest, as determined through reference to public prices or other measures of fair market value.

- (b) With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option or other ownership interest); or
 - (c) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- (2) Any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value is not readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state or local government agency, an Institution of higher education, an academic teaching hospital, a medical center or a research institute that is affiliated with an Institution of higher education.
 - (3) An SFI does not include salary, royalties or other remuneration paid by the Institution to the Investigator, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by government agencies or institutions of higher education; or income from service on advisory committees or review panels for government entities or institutions of higher education

(F) Forms

Financial disclosure form (RSP102) may be found at <http://utoledo.edu/research/RC/COI3/Forms.html>.

(G) Policy implementation

Process and procedures for implementation of this policy in compliance with DHHS and NSF regulations will be the responsibility of Research and Sponsored Programs.

<p>Approved by:</p> <p><u>/s/</u> Lloyd A. Jacobs, M.D. President</p> <p><u>September 24, 2012</u> Date</p> <p><i>Review/Revision Completed by: Vice President for Research FCOI policy review committee</i></p>	<p>Policies Superseded by This Policy:</p> <ul style="list-style-type: none">• <i>Previous 3364-70-01, review date August 24, 2012</i> <p>Initial effective date: March 25, 2008 Review/Revision Date: August 19, 2011; August 24, 2012; September 14, 2012 Next review date: September 14, 2015</p>
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