


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

(A) Policy statement/preamble

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. Individuals 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.

(B) Purpose of policy

It is the purpose of this policy to set forth the principles for identifying those Individuals who should report significant Financial Interests and situations that may pose a potential for conflicts of interest in compliance with applicable federal and state of Ohio laws, regulations, and policies. This policy is applicable to all Sponsored Programs administered through the University, regardless of the source of funds.

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 “Responsibility of Applicants for 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.

(C) Disclosure is required

All Individuals responsible for the design, conduct, or reporting of research or educational activities supported or proposed for support by any sponsor via a grant or Sponsored Program agreement, are required to file a financial disclosure form:

- (a) Annually,
- (b) Whenever a new transaction or activity is proposed that might involve a potential conflict of interest or whenever there is a change in interests that might pose a conflict of interest,
- (c) Whenever there is a change in a previously reported potential conflict of interest.

The following is a list of those who must complete a financial conflict of interest disclosure form:

- (a) All Individuals (including students or other trainees) listed by name on the proposal, regardless of role.
- (b) Any Individual, 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.
- (c) All Individuals, regardless of institutional status or affiliation added to the program team after the proposal is submitted.

It is the policy of The University of Toledo that all “Individuals” described in paragraphs (a), (b) and (c) above are deemed to be “investigators” as defined in 42 C.F.R. 50 “Responsibility of Applicants for Promoting Objectivity in Research.”

Anytime an Individual is or appears to be in a position to influence university business, research or other decisions in a way that could lead to any form of personal gain for the Individual or his/her Family Members, the Individual must obtain approval of the proposed activity before commencing the activity. All financial conflict of interest disclosure forms must be reviewed before the proposed activity may commence.

For the purposes of this policy, disclosure of Financial Interests is required when any of the following situations occur:

- (a) The aggregated annual income received by an Individual and/or Family Member exceeds or is expected to exceed \$10,000,
- (b) When equity or ownership interest is valued at \$10,000 or more,
- (c) When equity or ownership interest is valued at five percent (5%) or more (determined through the use of published prices or other reasonable measures of the fair market value),
- (d) When there is a commitment for future royalties (except commitments made via the university policies on patents and intellectual property)
- (e) When an Individual and/or Family Member holds stock options in a business (regardless of estimated value), or has an option to purchase stock or equity (regardless of estimated value of said option), or owns any amount of a non-publicly traded stock,
- (f) When an Individual and/or Family Member holds an Executive Position in a business,

- (g) When the Individual, and/or Family Member hold an advisory board position for a company from which there is a sponsored program agreement in which they participate.

This disclosure must be made in writing by each Individual. This disclosure document must be completed and signed by that Individual him or herself. Stamped or "per" signatures are not acceptable on this disclosure document.

(D) Roles and Responsibilities

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

Research and Sponsored Programs (RSP) is responsible for collecting all financial disclosure forms and reporting potential financial conflict of interests to the agencies/sponsors of Sponsored Programs. RSP is also responsible for providing administrative support to the conflict-of-interest review committee(s).

(E) 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) Individuals means, university faculty, and others holding regular academic rank in any track. Also included in this category are other 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, and consultants. Individuals, as described in this policy, are "Investigators" as defined in 42 C.F.R. 50.
- (3) Family Members means immediate family, including the Individual's spouse or domestic partner, and dependent children.
- (4) Financial Interest means an interest in a business consisting of : (a) any stock, stock option (see below), or similar ownership interest in such business, but

