


Name of Policy: Financial conflict of interest		 Effective date: July 9, 2024 Original effective date: March 25, 2008	
Policy Number: 3364-70-01			
Approving Officer: President			
Responsible Agent: Vice President for Research			
Scope: All University of Toledo campuses			
Keywords:			
	New policy		Minor/technical revision of existing policy
X	Major revision of existing policy		Reaffirmation of existing policy

(A) Policy statement

The United States government requires that entities receiving federal funding maintain a written policy on financial conflict of interest that is consistent with current regulations. The university of Toledo seeks to ensure that the objectivity and integrity of the investigator, the university, and academic research, training, or other activities are not compromised or perceived to be compromised by matters of financial benefit or personal gain.

(B) Purpose of policy

The purpose of this policy is to ensure that the design, conduct, and reporting of sponsored activities are free from bias or potential conflicts of interest resulting from an investigator’s financial interests, and to ensure compliance with applicable federal regulations, sponsor requirements, and university policies. Federal financial conflict of interest (FCOI) regulations have specific requirements for FCOI training, disclosure, review, reporting, and management. These regulations include but are not limited to 2 C.F.R 200 (uniform administrative requirements, cost principles, and audit requirements for federal awards), 42 C.F.R 50 Subpart F (Promoting Objectivity in Research), National Science Foundation “proposal and award policies and procedures guide,” chapter IX, section a: “conflict of interest policies,” and the CHIPS and science act of 2022, subtitle D – research security.

(C) Scope

This policy applies to all university faculty, staff, and students (including post-doctoral fellows and scholars) regardless of title or position, involved in the design, conduct, or reporting of sponsored activities.

The scope of this policy does not include provisions of Ohio ethics law as applied to university of Toledo employees in their roles as public employees (see policy 3364-25-50). University policy 3364-70-05 addresses conflict of interest requirements for study personnel of human subjects research and applies to both funded and unfunded studies. University policy 3364-25-18 addresses potential conflicts of interest and nepotism in hiring and supervision.

(D) Definitions

- (1) Sponsored activity means research, training, service, clinical trial, and instructional activity involving funds, materials, or other compensation from external funding sources and established by grant, contract, cooperative agreement, or other funding mechanism.
- (2) Investigator means the project director, principal investigator, co-principal investigators, and other persons who are responsible for the design, conduct, or reporting of sponsored activities on behalf of the university, or as designated by the federal sponsor. Persons who do not make independent decisions regarding the design, conduct, or reporting of the sponsored activity, and only work on or are engaged in the activity do not generally meet the definition of an investigator.
- (3) Family member means immediate family, including the investigator's spouse or domestic partner, and dependent children or step-children.
- (4) Financial interest means any interest of monetary value that belongs to an investigator or his/her family member.
- (5) Institutional responsibilities means an investigator's professional responsibilities on behalf of the university, which may include but are not limited to: research, research consultation, teaching, professional practice, and service on panels including institutional review boards, or safety monitoring boards.
- (6) External financial interest (EFI) means any foreign or domestic external financial interest of the investigator or family member that reasonably appears to be related to the investigator's institutional responsibilities.
- (7) Public health service (PHS) agencies include agencies such as the national institutes of health (NIH), the food and drug administration (FDA), the centers for disease control (CDC), the substance abuse and mental health services administration (SAMHSA) and other agencies that require adherence to PHS policies and regulations.
- (8) Significant financial interest (SFI) means any EFI of the investigator or family member that meets certain criteria determined by the sponsor, as follows:

- (a) For PHS funded research activities or those where sponsors stipulate adherence to PHS requirements, SFI is defined within 42 C.F.R. 50.603 or subsequent revision.
 - (b) For all other sponsored activities, SFI is defined as in chapter IX – grantee standards of the national science foundation “proposal and award policies and procedures guide,” or as designated by the sponsor.
 - (c) All income or remuneration from foreign colleges, universities, governments, and other entities must be included in EFI disclosures.
- (9) Financial conflict of interest (FCOI) exists when the university determines that a financial or management interest could directly and significantly affect, or be perceived to affect, the design, conduct, or reporting of the sponsored activity.
- (10) Manage means taking action(s) to address an FCOI to ensure that the design, conduct, and reporting of the sponsored activity will be free from bias.
- (11) Institutional official (IO) means the vice president of research or his/her designee, who shall appoint chair(s) and members of the conflict of interest (COI) review committee and report FCOI matters to external agencies as required by federal regulations or the terms of sponsored program agreements.
- (12) Foreign talent recruitment program means any program, position, or activity that includes compensation in the form of cash, in-kind compensation, including research funding, promised future compensation, complimentary foreign travel, and also includes things of non de minimis value such as, honorific titles, career advancement opportunities, or other types of remuneration or consideration directly provided by a foreign country, university or entity at any level (national, provincial, or local) or their designee.
- (E) Disclosure and training
- (1) All investigators must complete an EFI disclosure for themselves and family member(s) according to the following requirements:
 - (a) Before submitting a proposal for a sponsored activity;
 - (b) At least annually during the performance period of a sponsored activity;
 - (c) Within thirty days of discovering or acquiring (i.e. through purchase, marriage, or inheritance) a new external financial interest; and
 - (d) Upon being added as an investigator to a sponsored activity.
 - (2) Investigators are required to disclose their participation in all funds from foreign sources that may be related to foreign talent recruitment programs. Participation in foreign talent programs may be prohibited for investigators engaged in research that is funded by federal sponsors (see section 10631 of the CHIPS and science act of 2022).

(3) Investigators who have not properly disclosed their EFI and funds from foreign financial interests or whose disclosures have expired may be prohibited from engaging in sponsored activities until a current disclosure has been submitted and reviewed.

(4) Financial conflict of interest training

Investigators participating on any PHS sponsored research must complete FCOI training:

- (a) At least every four years;
- (b) When the university substantially revises the FCOI policy in a manner that affects the requirements for investigators;
- (c) When the investigator is new to the university; or
- (d) When an investigator is found to be out of compliance with this FCOI policy or a current FCOI management plan.

(F) Determinations

(1) The COI committee, or administrative staff on behalf of the committee, will:

- (a) Review new and updated EFIs and other disclosures.
 - (i) The reviewer(s) may require investigators to provide additional information regarding the nature of the disclosures.
- (b) Determine whether an SFI is related to a particular sponsored activity on a case-by-case basis.
- (c) Determine if participation in a talent program is prohibited by federal regulations or sponsor policies.

If a prohibited participation in a talent program by an investigator on a sponsored research award is determined, the investigator must either terminate participation in the talent program or be removed from the award.

- (d) When an FCOI is identified, develop a management plan for implementation to eliminate, mitigate, or manage the conflict.

Management plans will be provided to each investigator with an FCOI, the sponsored activity principal investigator, the investigator's department chair or unit supervisor, and other individuals or departments, such as grants accounting, as needed to ensure compliance with the management plan through the completion of the sponsored activity.

- (e) As required by PHS rules, the IO or his/her designee, shall report FCOIs to the federal sponsor prior to expenditure of federal funding or within sixty days of the university discovering an FCOI after the research project has begun.

(G) Appeal

An individual may appeal a COI committee decision in writing to the IO within thirty days of the date of the committee's notification of that decision. The IO will respond within fourteen days of receipt of a written appeal, either affirming or reversing the decision and notify the relevant committee and investigator of his/her decision.

(H) Record retention and confidentiality

- (1) EFI disclosures and all actions taken by the university with respect to these interests will be maintained for at least three years from the termination of the grant, contract, or agreement.
- (2) The information received to comply with this policy shall be handled confidentially, to the extent possible, unless public disclosure is part of the management plan or such disclosure is required by university, federal, or state regulations or sponsoring agencies.

(I) Noncompliance

The COI committee will work cooperatively with investigators to avoid or resolve issues of noncompliance.

The university will conduct retrospective reviews for PHS research projects within one hundred twenty days of a determination that SFIs have not been properly disclosed or when an FCOI is not identified or managed in a timely manner.

Flagrant or repeated noncompliance with policies, procedures, or management requirements will be handled through university disciplinary procedures.

(J) References

- (1) PHS federal regulations, 42 C.F.R. part 50 subpart f - promoting objectivity in research:
<https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50>
- (2) NSF “proposal and award policies and procedures guide” (January 2023):
https://www.nsf.gov/pubs/2022-10/nsf23_1.pdf
- (3) CHIPS and science act of 2022, public law 117-167, subtitle d – research security:
<https://www.congress.gov/117/plaws/publ167/PLAW-117publ167.pdf>

<p>Approved by:</p> <p><i>/s/</i></p> <hr/> <p>Matthew J. Schroeder Interim President</p> <p>Date: July 9, 2024</p> <p>Review/revision completed by:</p> <ul style="list-style-type: none"> • <i>Vice President for Research</i> • <i>FCOI Committee</i> 	<p>Policies superseded by this policy:</p> <ul style="list-style-type: none"> • <i>None</i> <p>Original effective date: <i>March 25, 2008</i></p> <p>Review/revision date: <i>August 19, 2011</i> <i>August 24, 2012</i> <i>September 14, 2012</i> <i>July 22, 2020</i> <i>July 9, 2024</i></p> <p>Next review date: <i>July 9, 2027</i></p>
---	---