

3364-70-01 Financial conflicts of interest.**(A) Policy statement**

The United States government requires that entities receiving federal funding maintain a written policy on financial conflicts 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 projects or human subject research is 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 education, 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. 50.603, and National Science Foundation "proposal and award policies and procedures guide," chapter IX, section a: "conflict of interest policies."

(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 projects or human subject research, whether funded or unfunded by an external sponsor.

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 rule 3364-25-50 of the Administrative Code). Rule 3364-25-18 of the Administrative Code addresses potential conflicts of interest and nepotism in hiring and supervision.

(D) Definitions

- (1) Sponsored program means research, training, 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 includes any individual who is responsible for the design, conduct or reporting of the sponsored program on behalf of the university, or human subject research study personnel as defined by rule 3364-70-05, including laboratory personnel, students, trainees, volunteers, subcontractors and consultants.
- (3) Family member means immediate family, including the investigator's spouse or domestic partner, and dependent children or step-children.
- (4) Financial interest is any interest of monetary value that belongs to an investigator or the investigator's 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 rules 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 projects or those where sponsors stipulate adherence to PHS requirements, SFI is defined within 42 C.F.R. 50.603:

(i) For any publicly traded entity, a significant financial interest exists if the equity interest is five per cent or greater or if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds five thousand dollars.

(ii) For any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds five thousand dollars; or

(iii) Intellectual property rights and interests from sources other than the university (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(b) For projects funded by a non-PHS agency (i.e., NSF), SFI is defined as:

(i) Anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options or other ownership interests); and intellectual property rights from sources other than university (e.g., patents, copyrights and royalties from such rights) that exceeds an aggregated value of ten thousand dollars as determined through reference to public prices or other reasonable measures of fair market value, or represents more than a five per cent ownership interest in any single entity.

(ii) Not included in SFI:

(a) Income from seminars, lectures or teaching engagements sponsored by a federal, state or local government agency, an accredited U.S. college or university, a U.S. academic health center, or a U.S. research institution that is affiliated with U.S. college or university.

(b) Service on advisory committees or review panels for a federal, state or local government agency, an accredited U.S. college or university, a U.S. academic health center, or a U.S. research institution that is affiliated with U.S. college or university.

(c) All income or remunerations from foreign colleges, universities, governments and entities must be included in EFI and SFI 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 research.

(10) Manage means taking action(s) to address an FCOI to ensure that the design, conduct, and reporting of the sponsored program or research protocol will be free from bias.

(11) Institutional officer (IO) means the vice president of research or designee, who shall appoint chair(s) and members of the conflict of interest (COI) review committee and report COI matters to external agencies as required by federal regulations or the terms of sponsored program agreements.

(D) 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 any proposal for a sponsored project or any protocol for human subject research (unfunded or funded);

- (b) At least annually, during the period of a sponsored project award or upon protocol renewal;
- (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 funded project or human subject research protocol.

(2) Investigators who have not properly disclosed their EFI or whose disclosures have expired may be prohibited from conducting sponsored program activities or human subject research until a current disclosure has been submitted and reviewed.

(3) Financial conflict of interest training

All investigators participating on any PHS sponsored research must complete 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 any current FCOI management plan.

(E) Determinations

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

- (1) Review new and updated EFIs.

The reviewer(s) may require investigators to provide additional information regarding the nature of the EFI.

- (2) Determine whether an EFI is related to a particular sponsored project or protocol on a case-by-case basis.
- (3) When an FCOI is identified, develop a management plan for implementation to eliminate, mitigate or manage the conflict.
 - (a) For human subject research protocols, the SFIs and FCOIs will be reported to the appropriate institutional review board (IRB). The convened IRB will have full and final authority for implementing the COI committee decisions.
 - (b) Management plans will be provided to the investigator's department chair or unit supervisor, grants accounting, or other individuals or departments as needed to ensure compliance with the management plan through the completion of the project.
- (4) As required by PHS rules, the IO or designee, shall report FCOIs to the sponsor prior to expenditure of federal funding or within sixty days of the university discovering an FCOI after the project has begun.

(F) 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.

(G) Record retention and confidentiality

- (1) EFI 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, agreement or protocol.
- (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.

(H) Noncompliance

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

The university will conduct retrospective reviews for PHS 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.

(I) References

- (1) UT FCOI procedures: local URL TBD
- (2) PHS federal regulations, 42 C.F.R. part 50 subpart F—Promoting Objectivity in Research: <https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:1.0.1.4.23#sp42.1.50.f>
- (3) NSF *Proposal & Award Policies & Procedures Guide*: https://www.nsf.gov/pubs/policydocs/pappg19_1/nsf19_1.pdf

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