



### Financial Conflict of Interest and the Promotion of Objectivity in Sponsored Activities

Responsible Official: Vice Provost for Research and Sponsored Programs

Responsible Office: Office of Research and Sponsored Programs Administration

#### Policy Purpose

This document sets forth ETSU's policy on the disclosure, evaluation and management of financial conflicts of interest with regards to sponsored activities. This policy is required by and complies with federal regulations including the U.S. Department of Health and Human Services (DHHS), *Responsibility of Applicants for Promoting Objectivity in Research* (42 CFR Part 50, Subpart F) and the National Science Foundation (NSF) *Proposal and Award Policies and Procedures Guide, Chapter IX - Grantee Standards, Part A. Conflict of Interest Policies*.

#### Policy Statement

ETSU and its employees are committed to the principle of free, open and objective inquiry in the conduct of its teaching, research and service missions. In the fulfillment of these missions, it is natural that opportunities arise for its employees to develop relationships with external entities and to explore commercial activities. The University encourages such endeavors as they enhance personal competency and benefit the community and ETSU.

These interactions, however, create the potential for financial conflicts of interest where an individual's financial or personal considerations could affect or appear to affect their ETSU institutional activities. The existence of a real or apparent financial conflict does not necessarily mean that the activity at issue must be avoided or discontinued.

It is through disclosure to ETSU of significant financial interests related to an employee's institutional responsibilities that such activities may be reviewed and, if warranted, managed. The identification of these financial interests does not necessarily imply any improper activities or motives on the part of the individual. The disclosure of significant financial interests is mandatory for all investigators involved in activities sponsored by an external Entity.

#### Authority

- DHHS Regulations, "Promoting Objectivity in Research" (42 CFR §50.601, for grants and cooperative agreements), and "Responsible Prospective Contractors" (45 CFR §94, for contracts).
- FDA, "Financial Disclosure by Clinical Investigators" (21 CFR §54).
- NSF, *Proposal & Award Policies & Procedures Guide, Part II.IX. "Grantee Standards"*.
- OMB Uniform Guidance, 2 CFR 200 § 112 and § 318.
- Federal Acquisition Regulations (FAR) *Subpart 3.11 - Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions*.

## Definitions

### Entity

For the purposes of this Policy, an Entity is any external organization, such as a business, company, or consortium, and includes (but is not limited to) any partnership, corporation, limited liability corporation, unincorporated association, or other institution whether for-profit, academic, or professional.

### Family Member

- 1) A spouse or legal domestic partner;
- 2) (a) A dependent child or (b) stepchild or (c) other dependent (as defined by the Internal Revenue Service) for purposes of determining federal income tax liability during the period covered by the disclosure statement); and
- 3) A related or non-related adult who resides in the same household as the covered individual and with whom the covered individual is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments.

**Financial Conflict of Interest (FCOI)** - FCOI exists when ETSU, through its designated official(s), reasonably determines that an employee's significant financial interest is related to a Sponsored Activity (see definition below) and could directly and significantly affect the design, conduct or reporting of the activity.

**Institutional Responsibilities** - An employee's professional responsibilities on behalf of ETSU, which may include, for example, activities such as research, research consultation, public service, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

**Investigator** - Any individual, including the Project Director/Principal Investigator and any Key Personnel, regardless of title or position, who is responsible for the design, conduct or reporting of a Sponsored Activity, or proposed for such a role, which may include, for example, collaborators or consultants.

**Key Personnel** - Project Director or Principal Investigator (see definition below) and any other Investigator who contributes to the (scientific) development or execution of a Sponsored Activity in a substantive, measurable way, whether or not they request salary or compensation.

**Project Director/Principal Investigator (PD/PI)** - The individual (normally a faculty member) who has primary responsibility for the scientific and technical conduct, reporting, fiscal and programmatic administration of a Sponsored Activity.

**Research** - A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug).

**Significant Financial Interests (SFI)** - A financial interest consisting of one or more of the following interests of the Investigator (and / or those of the Investigator's Family Member) that reasonably appears to be related to the Investigator's institutional responsibilities:

- with regard to any 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 and the

value of any equity interest in the Entity as of the date of disclosure, when aggregated, exceeds \$5,000;

- with regard to 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 \$5,000, or when the Investigator (or the Investigator's Family Member) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income in excess of \$5,000 related to such rights and interests.

**Sponsored Activity** - any activity, including research, instruction or training, service or other scholarly project or program, that:

- Is supported, in whole or in part -
  - by funding external to the general operating budget of the institution. Such funding is restrictive in nature in that the activities to be carried out are specified by the external agency through the mechanisms of grants, contracts, and/or other agreements; or
  - with resources external to the institution including but not limited to materials, equipment, space, honorific title or board membership; and
- Involves a *quid pro quo* relationship (i.e., the exchange of anything of value), with an external Entity to an extent that an agreement spelling out terms and conditions is required.

**Subrecipient** - for the purposes of this Policy, a subrecipient is a legal Entity that receives a subcontract from a pass-through Entity to carry out a portion of a Sponsored Activity. A subrecipient has responsibility for programmatic decision making; has its performance measured in relation to whether objectives of a programmatic scope of work were met; and is responsible for adherence to applicable Sponsored Activity requirements specified in the sponsored award, as opposed to providing routine goods or services for the benefit of the pass-through Entity.

## Policy History

Effective Date: 8/1/12

Revision Date: 7/19/13, 3/9/15, 2/9/18, 9/7/18, 6/14/21

## Procedure(s)

### I. Disclosure

All Investigators are required to disclose their significant financial interests (SFI) and those of their Family Members that reasonably appear to be related to the Investigator's institutional responsibilities. An SFI disclosure (SFID) must be made:

- A. At the time of submission of an application for external project/program support or request to contract with an external Entity, unless an up-to-date (within the annual reporting window and updated for any changes) SFID is already on file, in which case, a certification to this effect is required prior to submission of an application for external project/program support or request to contract with an external Entity;
- B. No less than annually during the period of award/agreement;
- C. Within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

Project Directors/Principal Investigators further are required to identify all Investigators involved in their proposed Sponsored Activities and ensure they have disclosed or certified, as appropriate, as outlined in this section.

## **II. Contents of Disclosure: Significant Financial Interests/Sponsored Travel**

- A. The following interests are considered to be significant financial interests** and the Investigator making the disclosure must include the following information in regard to themselves and Family Member(s) for interests that reasonably appear to be related to the Investigator's institutional responsibilities, subject to the exclusions provided below in Section II.B.:
- i. **Payments received from or equity interest in a publicly traded Entity.** The total amount and source of payments received in the preceding twelve months from a publicly traded Entity and the value of any equity interest held in the Entity on the date of disclosure that, when aggregated, exceed \$5,000, including:
    - a) as to payments received,
      1. salary; and
      2. any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and
    - b) as to equity interests held, any stock, stock options, or other ownership interest or entitlement to such an interest, valued by reference to public prices or other reasonable measures of fair market value.
  - ii. **Payments received from or equity interest in a non-publicly traded Entity.** The total amount and source of payments received in the preceding twelve months from a non-publicly traded Entity and the value of any equity interest held in the Entity on the date of disclosure that, when aggregated, exceed \$5,000, including:
    - a) as to payments received,
      1. salary; and
      2. any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and
    - b) as to equity interests held, any stock, stock options, or other ownership interests or entitlement to such an interest, described in detail as to their nature;
  - iii. **Intellectual property and royalties.**
    - a) a description of intellectual property rights held and any agreements to share in royalties related to those rights; and
    - b) the amount and source of royalty income that the Investigator or Family Member received or had the right to receive in the preceding twelve months.
  - iv. **Travel.** Reimbursed or sponsored travel in the preceding 12 months, including the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration.
  - v. **Incentives.** Money, gifts, or anything of monetary value above and beyond the actual costs of conducting the sponsored activity, including, but not limited to finder's fees, referral fees, or recruitment bonuses for enrolling participants in any Sponsored Activity.

- vi. **Other.** Any other interests or relationships (including participation on any governing bodies such as a Board of Directors, whether paid or unpaid), that might constitute a conflict of interest or an appearance of a conflict of interest in connection with a proposed or awarded sponsored activity.

**B. The following interests are not significant financial interests** and need not be disclosed on the disclosure statement:

- i. salary, royalties, or other remuneration paid by the institution to the investigator, if the Investigator is currently employed or otherwise appointed by the institution;
- ii. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government, an institution of higher education as defined by [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;
- iii. income from service on an advisory committee or review panel for a federal, state, or local government, an institution of higher education as defined by [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;
- iv. income from investment vehicles, such as mutual funds or retirement accounts, as long as the Investigator does not directly control the investment decisions made in those vehicles; or
- v. travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education as defined by [20 U.S.C. 1001\(a\)](#), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

### **III. SFI Disclosure Review**

The Office of Research and Sponsored Programs Administration (ORSPA) will provide timely review of completed SFI Disclosures and will notify individuals of the outcome upon completion of such review.

### **IV. Management Plans**

Upon reviewing the Investigator's SFI Disclosure, the Vice Provost for Research (VPR) (or designee), after discussion with the Investigator, will decide whether a management plan is needed. Should management of a potential or actual financial conflict of interest be required, the Investigator, the Principal Investigator, as applicable, the head of the responsible unit (or designee), and the VPR (or designee) will work together to draft a "Management Plan."

These written plans will manage, reduce, or eliminate the Significant Financial Interest(s). Such plans will be designed to meet applicable federal regulations, facilitate the local resolution or management of any conflict, minimize administrative burden, and protect the confidentiality of disclosed information. Final management plans are reviewed and approved by the VPR.

### **V. Dispute Resolution**

If the Investigator, the head of the responsible unit (or designee), and the VPR (or designee) cannot agree on a management plan, the matter will be referred to the ETSU Academic Freedom and Faculty Ethics (AFFE) Standing Committee. If the Investigator does not agree with the recommendation of the AFFE, he or she may appeal directly to the VPR. The VPR may ask the AFFE

to provide additional work on the draft management plan. The VPR, after consideration of the AFFE recommendation, shall make the final determination on the management plan.

#### **VI. Financial Conflicts of Interest Training**

Prior to engaging in Sponsored Activities, all Investigators must submit proof to ORSPA of their successful completion of ETSU's designated FCOI training course, which course is required at least every four years and immediately under the designated circumstances:

- A. ETSU's FCOI policies change in a manner that affects Investigator requirements;
- B. an Investigator is new to ETSU, in which case ORSPA, at its sole discretion, may choose to accept certification of prior FCOI training deemed equivalent to its own;
- C. ETSU finds that an Investigator is noncompliant with ETSU'S FCOI policy or a management plan.

#### **VII. Public Accessibility**

Prior to the expenditure of any funds under a Sponsored Activity, ETSU shall ensure public accessibility by providing a written response within five business days of a request (if such request is in the form of a signed letter addressed to the VPR), of information concerning any Significant Financial Interest disclosed to the Institution that meets all of the following three criteria:

- A. the Significant Financial Interest was disclosed and is still held by the Investigator identified by the Institution in the grant application, progress report, or any other required report submitted to the sponsoring agency;
- B. the Institution determines that the Significant Financial Interest is related to the Sponsored Activity; and
- C. the Significant Financial Interest is an actual Financial Conflict of Interest.

#### **VIII. Record Retention**

Records of the Investigator's financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by ORSPA until three years after the date of filing, or the related award has ended, or a resolution is reached for any government action involving those records, after which time they shall be destroyed.

#### **IX. Subrecipients, Contractors, and Collaborators**

Entities working under subagreements issued by ETSU must comply with ETSU's FCOI policy unless the Subrecipient has its own policy that meets, at minimum, the requirements of Public Health Service regulations [42 CFR §50.601](#) (grants and cooperative agreements), or [45 CFR §94](#) (contracts).

If the Subrecipient's Investigators are to comply with the Subrecipient's Financial Conflict of Interest policy, the Subrecipient shall certify as part of the written agreement.

If the Subrecipient cannot provide such certification, the agreement shall state that Subrecipient Investigators are subject to ETSU's Financial Conflict of Interest policy for disclosing Significant Financial Interests that are directly related to the Subrecipient's work for ETSU. The written agreement shall specify time period(s) for the Subrecipient to report all identified Financial Conflicts of Interest to ETSU. Such time period(s) shall be sufficient to enable ETSU to provide timely FCOI reports to the funding agency.

These individuals must report identified financial conflicts of interest to the Vice Provost for Research and Sponsored Programs, East Tennessee State University, P.O. Box 70565, Johnson City, TN 37614 or in a manner otherwise indicated in the subagreement.

## Roles and Responsibilities

### **X. Project Director/Principal Investigator (PD/PI)**

At time of proposal development and before submission, PD/Pis must notify ORSPA of all Investigators who plan to devote time and effort to the project and ensure that each Investigator files an SFI Disclosure or certification, as appropriate. If an Investigator's SFI requires a management plan, the PD/PI will collaborate with him/her/them, the head of the responsible unit (or designee) and the VPR (or designee) to develop that plan.

### **XI. Investigators**

Investigators must submit a SFI Disclosure:

- at time of submission of an application for external project/program support or request to contract with an external Entity, unless an up-to-date (within the annual reporting window and updated for any changes) SFID is already on file, in which case, a certification to this effect is required prior to submission of an application for external project/program support or request to contract with an external Entity;
- no less than annually during the period of award/agreement; and
- within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

### **XII. Office of Research and Sponsored Programs Administration**

- ensures Investigators submit required SFI disclosures and certifications as outlined in this policy;
- ensures Investigators complete FCOI training as required by this policy;
- verifies subrecipients, contractors and collaborators are bound and are compliant with requirements outlined in this policy for FCOI training and SFI disclosure;
- develops guidelines and provides training and guidance materials in FCOI regulations, requirements and obligations;
- maintains SFI disclosure records according to ETSU record retention policies and sponsor requirements;
- reviews SFI disclosures for potential conflicts of interest;
- recommends to the VPR on the need for, and drafts and monitors FCOI management plans;
- provides FCOI reports to the sponsoring agency when requested;
- reports to the sponsoring agency within 60 days of receiving notice of any newly identified (i.e., subsequent to the initial disclosure) FCOI, including how the FCOI has been managed, reduced or eliminated.

### **XIII. Institutional Review Board (IRB)**

The IRB queries all Investigators submitting new, continuing, or modification protocols regarding whether those individuals have completed an SFI Disclosure.

Note: There is a separate Institutional Review Board FCOI policy and process for "Investigators" engaged in human subject research whether or not funded and regardless of internal or external funding source.

**XIV. University Committee on Animal Care (UCAC)**

UCAC queries all Investigators submitting new, continued or modified protocols regarding whether those individuals have completed ORSPA's SFI Disclosure.

**XV. Deans, Center/Institute Directors, and Department Heads**

These individuals are responsible for compliance with and implementation of this policy within their schools or departments. The head of the responsible unit (or designee) is responsible for collaborating with the Investigator, and/or the Principal Investigator, and the VPR, as applicable, in the development, completion, and oversight of management plans within their school, department, center, or institute.

**XVI. Vice Provost for Research**

- provides guidelines consistent with federal regulations;
- reviews SFI disclosures and makes final determination on whether a SFI represents a Financial Conflict of Interest requiring management;
- reviews, develops, implements, and is the final authority on FCOI Management Plans.

**Related Form(s)**

SFI Disclosure Form

**Scope and Applicability**

Check those that apply to this policy and identify proposed sub-category.

	Governance	
✓	Academic	VP Research, Division of Laboratory Animal Resources
✓	Students	Graduate School, Student Services
✓	Employment	Human Resources
	Information Technology	
	Environmental Health and Safety	
✓	Business and Finance	Grant Accounting
	Facilities and Operations	
	Communications & Marketing	
	Advancement	