

East Tennessee State University

Policy Title: Financial Conflict of Interest and the Promotion of Objectivity in Sponsored Programs

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Responsible Official: Vice Provost for Research and Sponsored Programs

Responsible Office: The Office of Research and Sponsored Programs

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 may 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. A financial conflict of interest depends on the situation, and not on the character or actions of the individual.

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. It is the expectation that all employees involved in extramurally sponsored activities adhere to this policy and voluntarily disclose significant financial interests. The disclosure of significant financial interests is mandatory for all investigators involved in sponsored research.

Purpose

This document sets forth ETSU's policy on the disclosure, management, and resolution of financial conflicts of interest with regards to sponsored projects/programs. This policy is required by and is intended to establish compliance with the U.S. Department of Health and Human Services (DHHS) regulations (42 CFR Part 50, Subpart F) *Responsibility of Applicants for Promoting Objectivity in Research* and the financial conflict of interest policy of the National Science Foundation (NSF).

Definitions

Family Member

- (1) a spouse;
- (2) a dependent child or stepchild or other dependent, for purposes of determining federal income tax liability during the period covered by the disclosure statement; and
- (3) a related or non-related, unmarried 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 project and could directly and significantly affect the design, conduct or reporting of the project.

Institutional responsibilities

Defined as an employee's professional responsibilities on behalf of ETSU, 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

	Data and Safety Monitoring Boards.
Investigator	The project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of sponsored research , or proposed for such funding, which may include, for example, collaborators or consultants.
Key Personnel	The project director/principal investigator (PD/PI) and other individuals who contribute to the (scientific) development or execution of a project in a substantive, measurable way, whether or not they request salaries 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 project/program.
Research	A systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (<i>e.g.</i> , a published article, book or book chapter) and product development (<i>e.g.</i> , a diagnostic test or drug).
Significant Financial Interests (SFI)	<p>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 reasonably appears to be related to the Investigator's institutional responsibilities:</p> <ul style="list-style-type: none"> • With regard to any publicly traded entity, a <i>significant financial interest</i> 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 <i>significant financial interest</i> 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 spouse or dependent children) holds any equity interest (<i>e.g.</i>, stock, stock option, or other ownership interest); or • Intellectual property rights and interests (<i>e.g.</i>, patents, copyrights), upon receipt of income in excess of \$5,000 related to such rights and interests.
Sponsored Project/Program	Those activities which are 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 agreements.
Procedures	
Disclosure	Key personnel on all sponsored program proposals must assess their significant financial interests and disclose any interests that may represent a potential financial conflict of interest to the Office of Research and Sponsored Programs. Only personnel who meet the definition of "Investigator" on proposals for sponsored research funding are required to submit a Significant Financial Interest Disclosure Form prior to the submission of the proposal, regardless of the nature of their significant financial interests.

	<p>When Principal Investigators submit proposals for sponsored research funding to the Office of Research and Sponsored Programs Administration (ORSPA), they must identify all Investigators on their project and ensure that required financial disclosures to ETSU from all listed persons have been submitted according to deadlines.</p> <p>Investigators involved in sponsored research are required to disclose their significant financial interests (and those of the Investigator’s spouse and dependent children) that reasonably appear to be related to the Investigator’s institutional responsibilities:</p> <ul style="list-style-type: none"> • no later than at the time of application for extramurally funded research; • within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new Significant Financial Interest; and • at least annually, in accordance with the specific time period prescribed by ETSU, during the period of award. <p>All Investigators are required to complete an SFI Disclosure Form for each sponsored research proposal and submit it to ORSPA no later than the time of application. If a significant financial interest is indicated on the SFI Disclosure Form, an SFI Disclosure Attachment must also be completed and submitted. ORSPA will coordinate notifications of this requirement.</p>
<p>Contents of Disclosure: Significant Financial Interests/Sponsored Travel</p>	<p>The following interests are considered to be significant financial interests and, subject to the exclusions provided below, an Investigator’s SFI disclosure must include the following information in regard to the Investigator and family members, <i>but only in regard to interests that reasonably appear to be related to the individual’s institutional responsibilities</i>:</p> <p>(1) 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:</p> <ul style="list-style-type: none"> • as to payments received: <ul style="list-style-type: none"> ○ salary; and ○ any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and ○ 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; <p>(2) Payments received from a non-publicly traded entity or equity interest in a non-publicly traded entity:</p> <ul style="list-style-type: none"> • the total amount and source of payments received in the preceding twelve months from an entity that is not publicly traded that, when aggregated, exceed \$5,000, including (i) salary; and (ii) any payment for services other than salary, such as consulting fees, honoraria, or

	<p>paid authorship; and</p> <ul style="list-style-type: none"> • a description of any equity interest held in an entity that is not publicly traded, including any stock, stock options, or other ownership interests or entitlement to such an interest; <p>(3) Intellectual property and royalties:</p> <ul style="list-style-type: none"> • a description of intellectual property rights held and any agreements to share in royalties related to those rights; and • the amount and source of royalty income that the investigator or covered family member received or had the right to receive in the preceding twelve months; <p>(4) Travel:</p> <ul style="list-style-type: none"> • 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. <p>The following interests are <u>not</u> significant financial interests and need not be disclosed on the disclosure statement:</p> <ol style="list-style-type: none"> (1) salary, royalties, or other remuneration paid by the institution to the investigator, if the investigator is currently employed or otherwise appointed by the institution; (2) 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; (3) 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; (4) 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 (5) 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.
Required Submission of Revised Forms	If there is a material change (an acquisition of a significant financial interest) to the information provided on the SFI Disclosure Form and/or SFI Disclosure Attachment, a new form must be submitted to ORSPA within 30 days of that change.
Disclosure Review	ORSPA will provide timely review of completed SFI Disclosure Forms and SFI Disclosure Attachments and will notify individuals upon completion of such review.
Management Plans	Upon reviewing the investigator’s SFI Disclosure Attachment, 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

	<p>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."</p> <p>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.</p>
Dispute Resolution	<p>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). 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.</p>
Investigator Training	<p>All Investigators must complete training prior to engaging in research related to any extramurally funded research grant or contract and at least every four years, and immediately under the designated circumstances:</p> <ul style="list-style-type: none"> • Institutional FCOI policies change in a manner that affects Investigator requirements • An Investigator is new to an Institution • An Institution finds an Investigator noncompliant with ETSU’s FCOI policy or management plan. <p>All Investigators/key personnel, including the PD/PIPD/PI, must submit evidence of completion of training along with their <u>first</u> SFI Disclosure Form.</p>
Public Accessibility	<p>Prior to the expenditure of any funds under a sponsored research project, ETSU shall ensure public accessibility, by providing a written response within five business days of a request (must be in the form of a letter addressed to the VPR), of information concerning any Significant Financial Interest disclosed to the Institution that meets the following three criteria:</p> <ul style="list-style-type: none"> • The Significant Financial Interest was disclosed and is still held by the Investigator for the sponsored research project identified by the Institution in the grant application, progress report, or any other required report submitted to the sponsoring agency; • The Institution determines that the Significant Financial Interest is related to the sponsored research; and • the Significant Financial Interest is a Financial Conflict of Interest
Record Retention	<p>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 termination of the award to which they relate, or the resolution of any government action involving those records, at which time they shall be destroyed.</p>

<p>Subrecipients, Contractors, and Collaborators</p>	<p>These entities, who are working under subagreements from ETSU that are funded by the Public Health Service (PHS), must comply with federal regulations (42 CFR Part 50 Subpart F, grants and 45 CFR Part 94, contracts).</p> <p>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 that its policy complies with federal regulation (42 CFR part 50 Subpart F).</p> <p>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.</p> <p>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.</p>
<p>Roles and Responsibilities</p>	
<p>Vice Provost for Research</p>	<ul style="list-style-type: none"> • Provide guidelines consistent with federal regulations • Review SFI Disclosure and Attachment(s) • Determine if a SFI represents a FCOI • Develop and implement Management Plans
<p>ORSPA</p>	<ul style="list-style-type: none"> • Collects Investigator/key personnel information as listed by PD/PIPD/PI's on the Internal Routing Form; • collects SFI disclosures on all new and renewal grant and contract submissions; • provides training and guidance materials in FCOI regulations, requirements, and obligations; • maintains SFI disclosure records according to ETSU record retention policies and sponsor requirements; • provide FCOI reports to the funding agency; and • subsequent to the initial disclosure, reports to the funding agency within 60 days any newly identified FCOI and how the FCOI has been managed, reduced, or eliminated.
<p>Institutional Review Board (IRB)</p>	<p>The IRB queries all Investigators submitting new, continuing, or modification protocols regarding whether those individuals have completed an SFI Disclosure Form. <i>There is a separate Institutional Review Board FCOI policy and process for "Investigators" engaged in funded (including internal and external sources) or unfunded human subject research.</i></p>
<p>University Committee on Animal Care (UCAC)</p>	<p>UCAC queries all Investigators submitting new, continuing, or modification protocols regarding whether those individuals have completed the SFI Disclosure Form.</p>
<p>Deans, Center/Institute Directors, and Department Heads</p>	<p>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, the</p>

	Principal Investigator, as applicable, in the development, completion, and oversight of management plans within their school, department, center, or institute.		
PD/PI	PD/PI's must identify all Investigators/key personnel responsible for the design, conduct, or reporting of their sponsored program(s) to ORSPA at the time of proposal submission and ensure that each Investigator/key personnel files an SFI Disclosure Form as required. If an Investigator/key personnel's SFI requires a management plan, the PD/PI will collaborate with him or her, the head of the responsible unit (or designee) and the VPR (or designee) to develop the management plan.		
Investigators/key personnel	Investigators/key personnel must submit a SFI Disclosure Form, and if needed, a SFI Disclosure Attachment at the time of an initial submission, annually to coincide with the submission of the progress report, and within 30 days of an acquisition of a significant financial interest. Should a management plan be required, Investigators/key personnel will collaborate with the PD/PI, as applicable, the head of the responsible unit (or designee) and the VPR (or designee) to develop the plan. Investigator responsibilities include adherence to management plans.		
Related Forms			
SFI Disclosure Form			
SFI Disclosure Attachment Form			
Links			
TBR Conflicts of Interest Policy			
DHHS Final Rule			
Revision Dates			
July 19, 2013; March 9, 2015			
Subject Areas			
Academic	Research	Finance	Human Resources
✓	✓	✓	✓