EAST TENNESSEE STATE
UNIVERSITY

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

Policy Effective Date: Insert • Policy Revised: Insert
Procedures Effective Date: Insert • Procedures Revised: Insert

Policy Purpose

This policy establishes East Tennessee State University's institutional framework for identifying, disclosing, reviewing, managing, and reporting financial conflicts of interest in Sponsored Activities. The policy is intended to promote objectivity and integrity in the design, conduct, and reporting of Sponsored Activities and to protect the rights, welfare, and safety of human participants and animal subjects.

ETSU administers its Financial Conflict of Interest Program in accordance with applicable law, regulation, award terms, and sponsor requirements. Financial conflict of interest reviews are coordinated, as applicable, with ETSU's Institutional Review Board and Institutional Animal Care and Use Committee.

Applicability

This policy applies to all Investigators who participate or plan to participate in Sponsored Activities and to the ETSU officials, offices, and units responsible for administering those activities. Applicable financial conflict of interest requirements also must be addressed in agreements with Subrecipients, contractors, and collaborators as required by law, regulation, award terms, or sponsor requirements.

Responsible Official, Office, and Interpretation

The Vice Provost for Research is responsible for the review and revision of this policy. For questions about this policy, please contact the Office of Research and Sponsored Programs Administration. The Provost, in consultation with the Office of University Counsel, has final authority to interpret this policy.

Defined Terms

A defined term has a specific meaning within the context of this policy.

Designated Official (DO)

The individual or individuals appointed by the Vice Provost for Research to administer ETSU's Financial Conflict of Interest Program and make the determinations assigned to the Designated Official under this policy.

Entity

An external organization, including a business, company, consortium, partnership, sole proprietorship, corporation, limited liability company, unincorporated association, academic institution, professional organization, government, or other organization.

Family Member

A spouse or legal domestic partner; a dependent child, stepchild, or other dependent as defined by the Internal Revenue Service for the period covered by the disclosure; or a related or non-related adult who resides in the same household as the Investigator and is financially interdependent with the Investigator.

Financial Conflict of Interest (FCOI)

A Significant Financial Interest that ETSU reasonably determines is related to a Sponsored Activity and could directly and significantly affect the design, conduct, or reporting of the Sponsored Activity.

Institutional Responsibilities

An employee's professional responsibilities on behalf of ETSU, including, as applicable, research, research consultation, public service, teaching, professional practice, institutional committee service, and service on review or monitoring panels.

Investigator

Any individual, regardless of title or position, who is responsible for the design, conduct, or reporting of a Sponsored Activity or is proposed for such a role. The term includes the Project Director/Principal Investigator, Senior/Key Personnel, collaborators, consultants, and research staff when they perform those responsibilities whether or not they request salary or compensation.

Project Director/Principal Investigator (PD/PI)

The individual with primary responsibility for the scientific or technical conduct, reporting, and fiscal and programmatic administration of a Sponsored Activity.

Senior/Key Personnel

The Project Director/Principal Investigator and any other individual identified by ETSU as senior/key personnel in an application, progress report, or other report required by regulation, award terms, or sponsor policy.

Significant Financial Interest (SFI)

A financial interest of an Investigator or the Investigator's Family Member that reasonably appears to be related to the Investigator's Institutional Responsibilities and meets a disclosure category or threshold established in the Procedures or required by applicable law, regulation, award terms, or sponsor requirements.

Sponsored Activity

Research, instruction or training, service, or another scholarly project or program that is supported, in whole or in part, by funding or resources external to ETSU's general operating budget and is governed by an agreement with an external Entity setting forth terms and conditions.

Subrecipient

A legal Entity that receives a subaward from a pass-through Entity to carry out a portion of a Sponsored Activity and has responsibility for programmatic decision-making and compliance with applicable award requirements, as distinguished from an Entity providing routine goods or services.

Policy

1. Institutional Commitment and General Requirements.
   1.1. ETSU is committed to free, open, and objective inquiry in its teaching, research, and service missions. Professional relationships with external Entities and commercial or entrepreneurial activities are encouraged when they advance professional expertise and benefit ETSU and the broader community.
   1.2. A real or apparent financial conflict of interest does not, by itself, establish improper conduct or require that the affected activity be discontinued. ETSU requires timely disclosure and institutional review so that financial interests may be identified and appropriately managed, reduced, or eliminated.

1.3. Investigators and responsible University units must comply with this policy, its Procedures, approved management plans, and applicable law, regulation, award terms, and sponsor requirements.

2. Investigator and Project Director/Principal Investigator Responsibilities.

2.1. Each Investigator must complete required FCOI training, submit complete and accurate SFI disclosures and certifications, provide additional information requested for review or sponsor reporting, update disclosures as required, and comply with any approved management plan.

2.2. Each Investigator must cooperate with institutional reviews, retrospective reviews, mitigation measures, monitoring, and other actions required to administer this policy.

2.3. The PD/PI must identify all Investigators involved in a proposed or ongoing Sponsored Activity and take reasonable steps to ensure that each Investigator completes the training, disclosure, certification, and management requirements applicable to the Sponsored Activity.

3. Institutional Review and FCOI Determinations.

3.1. The Office of Research and Sponsored Programs Administration administers the disclosure and review process. The Designated Official determines whether a disclosed SFI is related to an Investigator's Institutional Responsibilities or a Sponsored Activity and whether the SFI constitutes an FCOI.

3.2. The Designated Official will provide the Investigator written notice of an FCOI determination, any required management measures or corrective actions, and the applicable appeal process.

3.3. When required by applicable law, regulation, award terms, or sponsor requirements, funds may not be expended and the affected activity may not proceed until the review is complete and an appropriate management plan is implemented.

4. Management and Oversight.

4.1. The Designated Official may require a written management plan containing conditions or restrictions reasonably necessary to manage, reduce, or eliminate an FCOI and protect the objectivity and integrity of the Sponsored Activity.

4.2. Management measures must be consistent with applicable law, regulation, award terms, sponsor requirements, and the independent oversight authority of the IRB, IACUC, or another responsible University office or committee.

4.3. The Designated Official or designee will monitor compliance with approved management plans and review active plans periodically in accordance with the Procedures and applicable sponsor requirements.

5. Sponsor Reporting, Noncompliance, and Corrective Action.

5.1. ETSU will report identified FCOIs, management measures, noncompliance, bias, mitigation, and other required information to sponsoring Entities in accordance with applicable requirements.

5.2. When an FCOI is not timely disclosed, reviewed, reported, or managed, or when an Investigator fails to comply with an approved management plan, ETSU will conduct any required retrospective review, implement interim measures, and take appropriate mitigation and reporting actions.

5.3. Failure to comply with this policy, the Procedures, sponsor requirements, or an approved management plan may result in programmatic or administrative corrective action, including retraining, increased oversight, modification of a management plan, restriction of research responsibilities, suspension of proposal submission privileges or access to sponsored funds, removal from a Sponsored Activity, required divestiture or severance of the interest or relationship creating the conflict, and required notification to sponsors, regulators, journals, or other appropriate parties.

5.4. Any employment, faculty, student, or other disciplinary action will be addressed under the otherwise applicable University policy or process. Nothing in this section limits ETSU's ability to impose immediate interim or programmatic measures necessary to protect research integrity, participant safety, animal welfare, University resources, or sponsor compliance.

6. Appeals.

6.1. An Investigator may appeal an FCOI determination, required management plan, or corrective action imposed under this policy.

6.2. Appeals will be reviewed and decided in accordance with the Procedures. The appeal process must provide for review by an official who did not make or substantially participate in the initial decision.

6.3. This appeal right does not replace any separate review or appeal rights available under another University policy or process.

7. Research Involving Human Participants or Vertebrate Animals.

7.1. The Designated Official will coordinate FCOI determinations and management plans with the IRB and IACUC, as applicable. The IRB and IACUC retain their independent authority to impose additional safeguards or restrictions and to determine whether covered research may proceed and under what conditions.

8. Subrecipients, Contractors, and Collaborators.
   8.1. Agreements with Subrecipients, contractors, and collaborators must identify the applicable FCOI requirements and establish disclosure, certification, review, and reporting obligations sufficient to allow ETSU to meet its responsibilities to the sponsoring Entity.
9. Roles and Responsibilities.
   9.1. **Vice Provost for Research.**
      9.1.1. Provides institutional oversight of the FCOI Program; appoints the Designated Official; ensures the Program complies with applicable requirements; decides appeals and unresolved matters as provided in this policy and the Procedures; and may delegate operational duties while retaining overall responsibility for institutional compliance.
   9.2. **Designated Official.**
      9.2.1. Solicits and evaluates SFI disclosures; makes relatedness and FCOI determinations; develops, approves, implements, and monitors management plans; oversees retrospective reviews, mitigation measures, and programmatic corrective actions; coordinates with responsible University offices and committees; and ensures required documentation and sponsor reporting.
   9.3. **Office of Research and Sponsored Programs Administration.**
      9.3.1. Administers training, disclosure, certification, review, recordkeeping, and reporting processes; assists the Designated Official with management and monitoring; and verifies that applicable FCOI requirements are addressed for Subrecipients, contractors, and collaborators.
   9.4. **Deans, Center or Institute Directors, and Department Heads.**
      9.4.1. Support implementation of this policy within their units and collaborate with the Investigator, PD/PI, and Designated Official in the development, implementation, and oversight of management plans when requested.
   9.5. **Institutional Review Board and Institutional Animal Care and Use Committee.**
      9.5.1. Review relevant FCOI determinations and management plans under their respective authorities and may require additional measures necessary to

protect human participants, animal welfare, and the integrity of the research.

10. Implementing Procedures and Delegated Authority.
    10.1. The Vice Provost for Research may establish and revise procedures, standards, forms, processes, training materials, and sponsor-specific guidance necessary to implement this policy and maintain compliance with applicable law, regulation, award terms, and sponsor requirements.
    10.2. Administrative revisions under this delegation may not materially expand the persons subject to this policy, create corrective or disciplinary authority beyond that established by this policy, eliminate or materially alter the appeal rights established by this policy, or conflict with another University policy.
    10.3. A new or materially revised substantive University policy requirement must proceed through ETSU's established policy development and approval process.

Procedures

1. FCOI Training.
    1.1. Before engaging in a Sponsored Activity, each Investigator must submit proof to ORSPA of successful completion of ETSU's designated FCOI training course.
    1.2. Training is required at least once every four (4) years and immediately when:
        1.2.1. ETSU revises its FCOI requirements in a manner that affects Investigator responsibilities;
        1.2.2. An Investigator is new to ETSU, except that ORSPA may accept prior training that it determines to be equivalent; or
        1.2.3. ETSU determines that an Investigator has not complied with this policy or an approved management plan.
2. Disclosure Timing and Certification.
    2.1. Each Investigator planning to participate in a Sponsored Activity must disclose all domestic and foreign SFIs related to the Investigator's Institutional Responsibilities that are received from or held in an Entity outside ETSU.
    2.2. An Investigator must submit or update an SFI disclosure:
        2.2.1. No later than submission of an application for external project or program support or a request to contract with an external Entity;
        2.2.2. At least annually during the period of the award or agreement; and

2.2.3. Within thirty (30) days after discovering or acquiring a new SFI, including through purchase, marriage, or inheritance.

2.3. When a current and accurate disclosure is already on file within the annual reporting period, the Investigator may certify that the existing disclosure remains current instead of submitting a duplicate disclosure.

2.4. The PD/PI must identify all Investigators involved in the proposed or ongoing Sponsored Activity and ensure that each Investigator has completed the required disclosure or certification.

3. Disclosure Categories, Thresholds, and Exclusions.

3.1. An Investigator must disclose the following interests of the Investigator and the Investigator's Family Member when the interest reasonably appears related to the Investigator's Institutional Responsibilities:

3.1.1. **Publicly traded Entities.**

3.1.1.1. The value of remuneration received from an Entity during the preceding twelve (12) months and the value of any equity interest in the Entity on the date of disclosure when the aggregated value exceeds $5,000. Remuneration includes salary and payments for services such as consulting fees, honoraria, and paid authorship. Equity includes stock, stock options, and other ownership interests valued by public prices or another reasonable measure of fair market value.

3.1.2. **Non-publicly traded Entities.**

3.1.2.1. Remuneration received from an Entity during the preceding twelve (12) months when the aggregated value exceeds $5,000, and any equity interest in the Entity held by the Investigator or Family Member, regardless of value.

3.1.3. **Intellectual property and royalties.**

3.1.3.1. Intellectual property rights and interests, including patents and copyrights, upon receipt of income related to those rights or interests, including the source and amount of royalty income received or entitled to be received during the preceding twelve (12) months.

3.1.4. **Reimbursed or sponsored travel.**

3.1.4.1. Travel related to the Investigator's Institutional Responsibilities that was reimbursed or paid on the Investigator's behalf during the preceding twelve (12) months. The disclosure must include the purpose of the trip, sponsor or organizer, destination, duration, monetary value if known, and other information requested by the Designated Official.

3.1.4.2. Travel disclosure is not required when the travel is reimbursed or sponsored by a U.S. federal, state, or local government agency; a U.S. institution of higher education; a U.S. academic teaching hospital or medical center; or a research institute affiliated with a U.S. institution of higher education.

3.1.5. **Foreign financial interests.**

3.1.5.1. All financial interests received from or held in a foreign Entity during the preceding twelve (12) months, including income from seminars, lectures, teaching engagements, advisory committee or review panel service, and reimbursed or sponsored travel. Foreign Entities include foreign institutions of higher education and foreign national, regional, provincial, local, or equivalent governmental entities.

3.1.6. **Contingent compensation and incentives.**

3.1.6.1. Any payment, remuneration, equity interest, bonus, commission, finder's fee, referral fee, recruitment bonus, gift, or item of monetary value above the actual cost of conducting the Sponsored Activity when it is dependent on the outcome of the Sponsored Activity or connected to participant enrollment or referral.

3.1.7. **Other interests or relationships.**

3.1.7.1. Any other interest or relationship, including paid or unpaid service on a governing body, that might constitute a conflict or appearance of a conflict in connection with a proposed or ongoing Sponsored Activity.

3.2. The following interests are excluded from SFI disclosure unless a sponsor requires otherwise:

3.2.1. Salary, royalties, or other remuneration paid by ETSU to an Investigator currently employed or appointed by ETSU, including intellectual property assigned to ETSU and agreements to share royalties related to those rights;

3.2.2. An ownership interest in ETSU held by an Investigator if ETSU is a commercial or for-profit organization;

3.2.3. Income from mutual funds, retirement accounts, or similar investment vehicles when the Investigator does not directly control the investment decisions; and

3.2.4. Income from seminars, lectures, teaching engagements, advisory committees, or review panels sponsored by a U.S. federal, state, or local government agency; a U.S. institution of higher education; a U.S. academic teaching hospital or medical center; or a research institute affiliated with a U.S. institution of higher education.

4. Initial Review and Determination.

4.1. ORSPA will review each completed disclosure for administrative completeness and provide the disclosure and any relevant information to the Designated Official.

4.2. The Designated Official will determine whether an SFI is related to a Sponsored Activity and, if so, whether it could directly and significantly affect the design, conduct, or reporting of the Sponsored Activity and therefore constitutes an FCOI.

4.3. Reviews and determinations will be completed within sixty (60) days after receipt of a completed disclosure unless a shorter period is required by the sponsoring Entity.

4.4. The Designated Official will document the determination and provide the Investigator written notice as required by the policy.

5. Sponsor Reporting.

5.1. The Designated Official will ensure that identified FCOIs are reported and managed at the following times, as applicable:

5.1.1. At proposal submission, including a Just-in-Time submission when required;

5.1.2. Before expenditure of funds under a new award;

5.1.3. At least annually for the duration of the Sponsored Activity for any ongoing FCOI;

5.1.4. Within sixty (60) days after identification of a new FCOI or a revised determination regarding a previously disclosed SFI;

5.1.5. Within sixty (60) days after addition of a new Investigator to an ongoing Sponsored Activity when the Investigator's SFI is determined to constitute an FCOI;

5.1.6. Upon elimination, resolution, or discontinuance of a previously reported FCOI when sponsor notification is required; and

5.1.7. At any other time required by law, regulation, award terms, or sponsor policy, applying the more stringent requirement when requirements differ.

5.2. Each report will include the information required by the sponsoring Entity and a description of the measures implemented to manage, reduce, or eliminate the conflict.

6. <u>Interim Management, Retrospective Review, and Mitigation.</u>

6.1. When an FCOI is identified after expenditure of funds has begun, or when a final management plan cannot be completed before a sponsor reporting deadline, the Designated Official will implement interim management measures sufficient to protect the objectivity of the Sponsored Activity and will submit any required interim report.

6.2. A retrospective review is required when an FCOI was not timely identified, reviewed, reported, or managed including when an Investigator fails to disclose an SFI later determined to constitute an FCOI or fails to comply with an approved management plan; or another circumstance requires review under applicable sponsor requirements.

6.3. The Designated Official will ensure that the retrospective review is completed within one hundred twenty (120) days after the determination of noncompliance, unless a different period is required, to determine whether any portion of the Sponsored Activity conducted during the period of noncompliance was biased in its design, conduct, or reporting as a result of the FCOI.

6.4. The retrospective review documentation will include, at a minimum:

6.4.1. The project number and title;

6.4.2. The name of the PD/PI or contact PD/PI if a multiple-PI/PD model is used;

6.4.3. The names of the Investigator with the FCOI and the Entity involved;

6.4.4. The reasons for the review;

6.4.5. The methodology, review process, reviewers, and documents considered;

6.4.6. The findings; and

6.4.7. The conclusions.

6.5. If the review determines that bias occurred, ETSU will promptly notify the sponsoring Entity and submit a mitigation report describing the impact of the bias, actual or potential harm, supporting information supporting the assessment of harm, and the actions taken or planned to eliminate, reduce, or mitigate the effects of the bias, including an assessment of whether the

Sponsored Activity remains scientifically valid and salvageable. If no bias is found, ETSU will retain the review documentation and submit no mitigation report unless the sponsor requires one.

7. Management Plans and Monitoring.
   - 7.1. When management is required, the Designated Official will consult with the Investigator, the PD/PI when applicable, and the head of the responsible unit or designee to develop a written management plan.
   - 7.2. A management plan may include one or more of the following measures:
     - 7.2.1. Public disclosure of the FCOI, including disclosure to project personnel, the IRB, the IACUC, participants, journals, or audiences receiving presentations of the work;
     - 7.2.2. Appointment of an independent monitor;
     - 7.2.3. Modification of the Sponsored Activity plan;
     - 7.2.4. Change of personnel or responsibilities, or disqualification from part or all of the activity;
     - 7.2.5. Reduction or elimination of the financial interest; or
     - 7.2.6. Severance of the relationship creating the conflict.
   - 7.3. The Designated Official approves the final management plan and is responsible, directly or through a designee, for monitoring and documenting compliance.
   - 7.4. Active management plans will be reviewed no less frequently than annually and whenever relevant financial interests, project activities, or sponsor requirements change.
8. Public Accessibility.
   - 8.1. Before expenditure of funds under a Sponsored Activity, ETSU will make information concerning an identified FCOI publicly accessible as required by applicable law or sponsor requirements.
   - 8.2. For a request subject to the Public Health Service requirements reflected in this procedure, ETSU will provide a written response within five (5) business days after receiving a signed written request addressed to the Vice Provost for Research concerning an SFI that:
     - 8.2.1. Was disclosed and remains held by the Investigator or Family Member;
     - 8.2.2. Was determined to be related to the Sponsored Activity; and
     - 8.2.3. Was determined to constitute an FCOI.

9. <u>Record Retention.</u>
   9.1. The Designated Official will retain disclosures, reviews, determinations, management plans, monitoring records, retrospective reviews, mitigation and corrective actions, sponsor reports, and other required documentation.
   9.2. Records will be retained for at least three (3) years after completion of the Sponsored Activity or for the longer period required by University policy, sponsor requirements, applicable law, or resolution of a government action involving the records.
   9.3. The retention period begins on the latest of:
      9.3.1. The date the disclosure is submitted;
      9.3.2. The date the final expenditure report is submitted, including any competitive segment; or
      9.3.3. The date of final resolution of a government action involving the records.
10. <u>Subrecipients, Contractors, and Collaborators.</u>
   10.1. A written agreement with a Subrecipient must require the Subrecipient either to comply with ETSU's FCOI policy or to maintain and apply an FCOI policy that satisfies applicable sponsor requirements.
   10.2. A Subrecipient relying on its own policy must certify compliance in the written agreement and report identified FCOIs to ETSU within a period sufficient for ETSU to satisfy its review and reporting obligations.
   10.3. If the Subrecipient cannot provide the required certification, the agreement must require the Subrecipient and its Investigators to comply with ETSU's policy and procedures and submit required disclosures and reports through the process designated by ORSPA.
11. <u>Research Involving Human Participants or Vertebrate Animals.</u>
   11.1. When a Sponsored Activity involving human participants or vertebrate animals is determined to have an FCOI, the Designated Official will provide written notice of the FCOI and associated management plan to the IRB or IACUC, as applicable, before initial approval, continuing review, or review of a relevant amendment, or as soon as practicable after identification of a new FCOI.
   11.2. The IRB and IACUC will review the information under their respective policies and procedures and may impose additional requirements or restrictions necessary to protect participants, animal welfare, and research integrity.

12. Appeal Procedures.
    12.1. An Investigator must submit a written appeal within thirty (30) calendar days after receiving written notice of the decision.
    12.2. The appeal must identify the decision being appealed, the basis for the appeal, the requested relief, and any supporting documentation.
    12.3. The Vice Provost for Research will decide the appeal unless the Vice Provost made or substantially participated in the initial decision, in which case the Provost or designee will decide the appeal.
    12.4. The reviewing official may request additional information or consultation and may affirm, modify, rescind, or remand the decision. The final institutional decision under the FCOI process will be communicated in writing.
    12.5. Filing an appeal does not automatically stay an FCOI determination, management measure, interim restriction, sponsor report, or corrective action. The reviewing official may grant a stay when consistent with applicable requirements and the protection of research integrity, participants, animals, University resources, and sponsor interests.
    12.6. Employment, faculty, student, research misconduct, IRB, and IACUC matters remain subject to the appeal or review rights provided by their applicable University policies and procedures.

Applicable Forms and Websites

Significant Financial Interest Disclosure Form (web form in ETSURGe); Office of Research and Sponsored Programs Administration Financial Conflict of Interest webpage

Authority and Revisions

Authority: T.C.A. § 49-8-203, et. seq; 2 C.F.R. §§ 200.112 and 200.318; Federal Acquisition Regulation Subpart 3.11; 42 C.F.R. Part 50, Subpart F; 45 C.F.R. Part 94; 21 C.F.R. Part 54; and National Science Foundation Proposal & Award Policies & Procedures Guide, Chapter IX, Part A.

Previous Policy: Same title.

Under T.C.A. § 49-8-203, et seq., the ETSU Board of Trustees delegated authority to ETSU's President on March 24, 2017, to establish policies and procedures for University operations, including this policy. The applicable revision process is set forth in the Policy Development and Rule Making Policy.

Substantive revisions to the Policy section require responsible-office approval, Office of University Counsel review for legal sufficiency, public comment, Academic Council or University Council approval, and approval by ETSU's President.