



Institutional Financial Conflicts of Interests	
Responsible Official: Vice Provost for Research	Responsible Office: Research and Sponsored Programs Administration

### Policy Purpose

This policy defines Financial Conflicts of Interests as it relates to ETSU Sponsored Activities; describes requirements for disclosure of Significant Financial Interests; and sets the process for reviewing and managing conflicts.

### Policy Statement

ETSU must review all potential Financial Conflicts of Interests (“FCI”) when accepting grants or contracts from entities (non-profit and for profit) for research or other activities, including but not limited to Human Subjects Research.

All FCIs must be reviewed whether actual or apparent. ETSU, employees of ETSU, the ETSU Foundation, the ETSU Research Corporation, and Covered Officials must disclose annually all Significant Financial Interests (“SFI”). ETSU must review each SFI to ensure all grants, contracts, and extramurally supported projects (collectively, ‘Sponsored Activities’) received by ETSU are performed with the highest level of integrity. The requirement to disclose SFI, includes, but is not limited to an ETSU employee’s interests in intellectual property from profit and non-profit corporations that may influence the performance of Sponsored Activities.

I. Disclosure of Significant Financial Interests.

A. Disclosure of SFI held by ETSU.

On or before July 1<sup>st</sup>, the individuals listed below shall disclose to the Director of ORSPA the information described hereinbelow.

1. The CEO of the ETSU Foundation shall disclose:

- i. a list of the for profit and non-profit companies that have business relationships with ETSU, the ETSU Foundation, and the ETSU Research Corporation that include, but are not limited to, licensing agreements, patents, invention disclosures, royalty payments; and ETSU, the ETSU Foundation, or the ETSU Research Corporations ownership and/or equity interests and payment distributions. The CEO of the ETSU

Foundation should update this list during the year to reflect the status of relationships as new relationships develop and old relationships conclude; and

- ii. a list of corporate donors that gave Gifts in excess of \$100,000, including an explanation, if known, of how such Gifts are to be used to support Sponsored Activities. The list shall also contain the names of ETSU departments and/or individuals who were recipients of disclosed Gifts.

2. The CEO of the ETSU Research Corporation shall disclose:

- i. a list of the for profit and non-profit companies that have business relationships with ETSU, the ETSU Foundation, and the ETSU Research Corporation that include, but are not limited to, licensing agreements, patents, invention disclosures, royalty payments; and ETSU, the ETSU Foundation, or the ETSU Research Corporations ownership and/or equity interests and payment distributions. The CEO of the ETSU Research Corporation should update this list during the year to reflect the status of relationships as new relationships develop and old relationships conclude; and
- ii. a list of corporate donors that gave Gifts in excess of \$100,000, including an explanation, if known, of how such Gifts are to be used to support Sponsored Activities. The list shall also contain the names of ETSU departments and/or individuals who were recipients of disclosed Gifts.

3. Covered Officials shall disclose Significant Interests held by the individual, and the individuals' Family Members with 30 days of an event that requires disclosure. Covered Officials shall also submit an annual report of the individual's and Family Member's outside professional activities Annual Report of Outside Professional Activities and Significant Financial Interests for the previous calendar year.

## II. Review of Significant Financial Interests.

The Director of ORSPA shall have the primary responsibility for reviewing all disclosed SFI to determine if the interest triggers a potential FCI. The Director of ORSPA will refer any disclosures for which a potential SFI exists to the Vice Provost for Research (VPR) for review.

For Sponsored Activities involving Human Subjects Research, the VPR will evaluate potential SFI and develop a conflict management plan, if necessary, and will submit it to the Institutional Review Board for approval. For Sponsored Activities where a SFI is actual or apparent, the activities will be conducted only when the FCI can be managed in a manner that reduces the potential for undue influence. The VPR shall have the responsibility for reviewing Sponsored Activities involving Human Subjects Research to determine if an Institutional Conflict of Interest exists.

The Director of ORSPA will notify the VPR and the submitting unit of a CFI as part of its regular procedures for the review and approval of such applications.

In the case of a conflict involving the VPR, the Director of ORSPA will notify the Senior Vice President for Academic Affairs. The Senior Vice President for Academic Affairs will develop a management plan, if possible, for managing or reducing a FCI related to the VPR.

### III. Management Plans for FCI.

A management plan for a disclosed FCI related to a Sponsored Activity may include:

- a. Disclosure of the FCI in research in relevant publications, presentations, informed consent forms, and press releases, as appropriate;
- b. Disclosure of the FCI to study personnel, students, trainees, and professional colleagues;
- c. Recusal of the conflicted Covered Official from decision-making regarding applicable grants, contracts, procurements, or other activities affecting or involving research;
- d. Reduction in the magnitude of the financial interest held by the Covered Official and/or ETSU Foundation or ETSU Research Corporation (generally to below the \$100,000 thresholds outlined above);
- e. An agreement between the ETSU employee or ETSU and the entity sponsoring the research to end the fiduciary relationship with the entity prior to the research commencing and not to hold such an interest for a period of two or more years following completion of any related research conducted at or under the auspices of the institution; or
- f. Internal or external oversight by an individual or committee with no FCI related to the project, which may include referring Human Subjects Research review to an external review board or data safety and monitoring board.

### V. Appeals.

If an individual or entity with a FCI would like to file an appeal related to a determination of FCI or any management plan related to Sponsored Activities, the appeal is filed pursuant to the process outlined in the Financial Conflict of Interest and the Promotion of Objectivity in the Sponsored Programs Policy.

If an individual or entity with a FCI would like to file an appeal related to a determination of FCI or any management plan related to Human Subjects Research, the appeal is filed pursuant to the process outlined in IRB Policy 12.

If the ETSU President has a FCI conflict of interest and chooses to appeal a decision related to an FCI determination or any imposed management plan, the ETSU President's appeal is filed with the Board of Trustees for review and decision pursuant to their policies and procedures, as well as any applicable ETSU policies. The Board of Trustees decision is final.

#### **Authority:**

Federal Acquisition Regulations (FAR 48 CFR 9.5 Organizational and Consultant Conflicts of Interest) and Defense Federal Acquisition Regulations; Association for the Accreditation of Human Research Protections Program (AAHRPP) Element 1.6.A; and Veteran's Administration: VVHA Standards of Ethical Conduct for Employees of the Executive Branch; TN FOCUS Act.

Previous Policy: (FP-30: Institutional Conflict of Interest)

#### **Defined Terms**

***A defined term has a specific meaning to this policy.***

Covered Official	Any individual with the authority to control or exert pressure over the performance or outcomes of a Sponsored Activity. This includes, but is not limited to the ETSU President, Senior Vice President for Academic Affairs, Vice President Office of Student Life and Enrollment, Vice Provost for Research and Sponsored Programs, Vice President for Clinical Affairs, Chief Financial Officer, Vice President for Advancement, Chief Operating Officer, Chief Executive Officer ETSU Foundation, Chief Executive Officer, and ETSU Research Corporation.
Family Member	Includes: (1) a spouse; 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	Occurs when the ETSU Foundation, the ETSU Research Corporation, or an Covered Official has or forms a relationship with for profit and non-profit entities; receive major gifts from sponsors; hold equity interests in a business entity in which ETSU employees propose to conduct research that may affect the value of the equity interest (including Human Subjects Research); or when the ETSU Foundation or the ETSU Research Corporation hold a patent or license.
Gifts	Gifts (including gifts in kind) to the University exceeding \$100,000 in total value (over a five-year period) from a sponsor of ETSU Sponsored Activities or a company that owns or controls products being studied or tested, or a philanthropic unit or an individual affiliated with these companies.
Human Subjects Research	This term is used as defined by the Department of Health and Human Services (HHS) and the Office for Human Research Protections (OHRP) in applicable federal laws and regulations as amended from time to time (including, without limitation, 45 CFR Part 46 and 21 CFR Part 56), regardless of the source of research funding or whether the research is otherwise subject to federal regulation.
Significant Financial Interests	ETSU, the ETSU Research Corporation, or the ETSU Foundation are determined to have a Significant Financial Interest if it has ownership, control, rights to, or received any of the following: (1) Royalties or other payments from licenses or other technology transfer agreements related to University intellectual property rights, when such payments are in excess of \$100,000 and received within the past 12 months from a for-profit or non-profit company proposing to support a sponsored project/activity that falls within the scope of this policy; (2) Gifts/gifts-in-kind and donations in excess of \$100,000 received within the past twelve months from a for-profit or non-profit company proposing to support a sponsored project/activity that

falls within the scope of this policy; or (3) through technology licensing activities or investments related to such activities, has obtained an equity or ownership interest (other than a mutual fund) in a publicly traded company worth more than \$100,000 as determined by reference to publicly listed prices, received within the past 12 months from a for-profit company supporting or proposing to support a sponsored project/activity that falls within the scope of this policy; or (4) any equity interest or an entitlement to equity of any value, including options or warrants, in a non-publicly traded company whose value cannot be determined by reference to publicly listed prices (i.e., equity interest in a start-up company) and which is supporting or proposing to support a sponsored project/activity that falls within the scope of this policy.

A covered Official has a Significant Financial Interest if it has ownership, control, rights to, or received any of the following: (1) Royalties from licenses or other technology transfer agreements related to University intellectual property rights, when such payments are in excess of \$5,000 and received within the past 12 months from a for-profit company supporting or proposing to support a sponsored project/activity that falls within the scope of this policy; (2) Payments—e.g., salary, consulting fees, honoraria, or gifts—in excess of \$5,000 and received within the past twelve months from a for-profit or non-profit company proposing to support a sponsored project/activity that falls within the scope of this policy; (3) Any equity or other ownership interest in a non-publicly traded company proposing to support a sponsored project/activity that falls within the scope of this policy; or (4) A position giving rise to a fiduciary duty in a for-profit or non-profit company proposing to support a sponsored project/activity that falls within the scope of this policy.

**Sponsored Activity**

Those activities which are supported, in whole or in part, by funding external to the general operating budget of ETSU, the ETSU Foundation or the ETSU Research Corporation. 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.

**Policy History**

Effective Date:

Revision Date:

**Procedure**

## Procedure

Effective Date:

Revision Date:

Financial Conflict of Interest and the Promotion of Objectivity in Sponsored Programs Policy; IRB Policy 12;

### Related Form(s)

HR Policy on Conflicts of Interest

### Scope and Applicability

Primary:

Secondary: