

1.17 Policy on Conflict of Interest

1.17.1 Introduction

This document defines East Tennessee State University (ETSU) policy and procedures regarding conflicts of interest in relationship to sponsored programs involving teaching, research, administrative activities and service. This policy applies to all persons employed (either as full-time, part-time, or temporary employees) by ETSU.

It is not the intent of this policy to eliminate all situations of conflict of interest, but rather to enable faculty and staff members to recognize situations that may be subject to question and ensure that such situations are properly reviewed and, if necessary, supervised or monitored. Further, the procedures included in this policy are intended to maintain the professional autonomy of faculty and staff as appropriate to their respective disciplines and professional activities while providing assurance to the University community, the State and Federal governments and most importantly the public, that potential conflicts of interest have been examined and will be conducted in a manner consistent with institutional and public values. Therefore, in accordance with Federal regulations ETSU has a responsibility to manage, reduce, or eliminate any actual or potential conflicts of interest that may be presented by a financial interest of an investigator. Thus, the University requires that investigators disclose any significant financial interest, as defined in section 2B below, that would reasonably appear to be affected by sponsored research.

This policy and the procedures it contains should be viewed as complementing and elaborating Directive No. FP-4, Section XXXIV C of ETSU policy concerning conflict of interest in purchasing and Tennessee Board of Regents (TBR) Policy 1:02:03:10 concerning conflict of interest and TBR Policy 5:01:05:00 concerning outside employment including consulting.

1.17.2 Definitions

1.17.2.1 Conflict of Interest

A potential conflict of interest occurs when there is a convergence between a faculty or staff member's personal financial, relational, or other interests and his/her professional obligations to East Tennessee State University (ETSU) such that an independent observer might reasonably question whether the individual's professional obligations, actions, or decisions related to the University are determined by considerations of personal gain, financial or otherwise.

1.17.2.2 Perceived Conflict of Interest

A perceived conflict of interest means any potential situation where an independent observer might reasonably question whether the Covered Individual has a convergence between personal financial, relational, or other interests that might directly and significantly affect or compromise, or appear to affect or compromise, the design, conduct, reporting or management of research. The effect or compromise contemplated might relate to the collection, analysis, and interpretation of data, the hiring of staff, the procurement of materials, the sharing of results, the choice of

protocol, the involvement or consenting of human participants, and the use of statistical methods.

1.17.2.3 Actual Conflict of Interest

An actual conflict of interest depends on the situation and not on the character or actions of the individual. For purposes of this policy, a conflict of interest exists when the University, through procedures described herein, reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of sponsored projects.

1.17.2.4 Covered Individual

Covered Individual includes any faculty or staff member (whether fully-, partially-, or non-salaried), student worker or graduate assistant, fellow, trainee, administrator or other employee who is involved in research for which ETSU provides facilities, personnel, financial support or is referenced in any way. Covered Individuals for a particular research project who must report potential conflict of financial interest under this policy include the principal investigator/project director, co-principal investigators, and any other person who is responsible for the design, conduct, or reporting of research, educational, or services activities funded, or proposed for funding, by an external sponsor. In this context, the responsibilities for disclosure extend to the Covered Individual's immediate family members.

1.17.2.5 Immediate Family Member

Immediate family member means spouse, dependent children or stepchildren, or relatives related by blood or marriage or other persons living together in the same household.

1.17.2.6 Significant Financial Interest

Significant financial interest means anything of economic or monetary value, with inclusions and exclusions as set forth below. Note that "included" significant financial interests must be disclosed to the University, while "excluded" significant financial interests need not be.

The following inclusions are examples of potential significant conflicts of financial interest that Covered Individuals or Consultants must disclose to the University, prior to initiation of a research project.

1. Inclusions. Significant financial interest includes, but is not limited to, any economic or monetary interest of the types listed in "(a)" through "(e)" below, that is held by a covered individual (or by his/her immediate family member), and that to an independent observer would reasonably appear to affect or be affected by research in which the individual is involved, or that is held by any entity in which a covered individual (or his/her immediate family member) has a financial or fiduciary interest the financial interests of which entity would reasonably appear to an independent observer to affect or be affected by the research (e.g. stock values, etc). (Such an entity may be a financially interested entity):

- a. "Compensation interest," meaning salary, consulting fees, wages, retainers, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts or other emoluments, "in kind" compensation from a financially interested company (or entitlement to the same), or any other thing of economic or monetary value whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the past 12 (twelve) months exceeded \$10,000, or are expected to exceed that amount in the next twelve months;
- b. "Equity interest," meaning i) any equity interest (or entitlement to the same), in a publicly-traded financially interested entity that exceeds \$10,000 in value or represents more than 5% ownership interest in any single entity (see exclusions below), or ii) equity interests, including stock options, warrants, or other convertible securities, of any amount in a non-publicly-traded financially interested entity (or entitlement to the same) whether or not financial value can be determined through reference to public prices;
- c. "Intellectual property interest" meaning i) royalty income or the right to receive future royalties under a patent license or copyright, where the research is directly related to the licensed technology or work; or ii) any other direct or indirect interest in a patent, trademark, copyright, trade secret, know-how or other intellectual property right where the research is directly related to the interest;
- d. "Extraneous research payments," meaning any non-royalty payments or entitlements to payments in connection with the research that are not directly related to the reasonable costs of the research (as specified in the research agreement between the sponsor and the institution), including any bonus or milestone payments to the investigators in excess of reasonable costs incurred, whether such payments are received from a financially interested entity or from the institution;
- e. "Fiduciary relationship," meaning service as an officer, director, or in any other fiduciary role for a financially interested entity, whether or not remuneration is received for such service.

The following are financial interests specifically excluded from the need for disclosure.

- 1. Exclusions. Significant financial interest excludes, and therefore is not meant to refer to, the following types or categories of economic or monetary interest:
 - a. "Mutual fund interests," meaning interests of any amount in publicly traded, diversified mutual funds;
 - b. "*De minimis* equity interests," meaning stock or stock options in a publicly traded company that, when aggregated for the covered individual (and/or

his or her immediate family members) meets both the following tests: it does not exceed \$10,000 in value (as measured in reference to public prices or other reasonable measure of fair market value) and does not represent more than a 5% ownership interest in any single entity;

- c. "Outside payments," meaning salary, royalties, and other payments from entities other than the University, or via the University to the individual, that when aggregated for the covered individual (and/or his or her immediate family members), over the next 12 months, are not expected to exceed \$10,000;
- d. "Regular research payments," meaning payments to the University, or via the University to the individual, that are directly related to reasonable costs incurred in the conduct of research as specified in the research agreement between the sponsor and the University;
- e. "University compensation," meaning salary, royalties, and other remuneration for services from the University;
- f. "Public or non-profit income," meaning income for service on advisory committees or review panels for public or non-profit entities, or from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.

1.17.3 Guidelines

1.17.3.1 Each Investigator is required to disclose the following Significant Financial Interests:

- a. Any Significant Financial Interest of the Investigator that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor; or
- b. Any Significant Financial Interest of the Investigator in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by an external sponsor.

Regardless of the above minimum requirements, a Covered Individual, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

1.17.3.2 The ETSU Internal Routing Sheet for Grants and Contracts, under the section Specific Approvals/Requirements, contains a line to indicate whether or not a conflict of interest might arise if the project is funded. Each Covered Individual associated with the proposal must determine whether or not such a conflict could exist. If there is potential for a Significant Financial Interest requiring disclosure each Covered Individual with such a potential conflict shall complete a Significant Financial Interests Disclosure Form and attach all

required supporting documentation. The completed Disclosure Form must be submitted with the proposal and ETSU Internal Routing Sheet to the Office of Research and Sponsored Programs Administration. Supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest should be submitted in a sealed envelope marked confidential and accompany the Disclosure Form and Routing Sheet.

1.17.3.4 As required by Federal regulation, all Significant Financial Interests must be disclosed prior to the time a proposal is submitted. All financial disclosures must be updated by Investigators during the period of the award as new reportable Significant Financial Interests are obtained.

1.17.3.5 The Vice Provost for Research and Sponsored Programs shall conduct an initial review of all financial disclosures. If the initial determination is made that there may be a potential for conflict of interest covered by this policy, than the disclosure information submitted by the Investigator will be referred to the University standing committee on Academic Freedom and Faculty Ethics (AFFE) and will be reviewed by a subcommittee of the AFFE specifically designated by the chair of the AFFE for the purpose of reviewing potential conflicts of interest.

The subcommittee shall be composed of at least 4 faculty members and the Vice Provost for Research shall be an *ex officio* member of this subcommittee. The University Assistant to the President for Legal Affairs may be consulted if the subcommittee believes that this is necessary. A conflict of interest will exist when the AFFE subcommittee reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the proposed sponsored project. The subcommittee shall then determine what conditions or restrictions, if any, should be imposed by the University to manage actual or potential conflicts of interest arising from disclosed Significant Financial Interests.

1.17.3.6 If conflict of interest is determined to exist, the Covered Individual, in cooperation with the academic unit or College, shall develop and present the AFFE subcommittee a Conflict of Interest Resolution Plan that details proposed steps that will be taken to manage, reduce, or eliminate any actual or potential conflict of interest presented by a Significant Financial Interest. At a minimum the Resolution Plan shall include such procedures as:

1. Public disclosure of significant financial interests. In the case of research involving human subjects disclosure alone cannot be used to manage a conflict of interest that might affect participants rights and welfare;
2. Review of research protocol by independent reviewers; and
3. Monitoring of research by independent reviewers.

The AFFE subcommittee shall review the Resolution Plan and, if it deems necessary, add conditions or restrictions, including the following:

1. Ensure that the Conflict Resolution plan includes procedures that ensure that the rights and welfare of human research subjects are not affected by the conflict.
2. Modification of the research plan;
3. Disqualification of the Covered Individual from participation in all or a portion of the research funded;
4. Divestiture of significant financial interests;
5. More frequent continuing review;
6. Severance of relationships that create actual or potential conflicts of interest; or
7. Discontinuance of the research.

With the exception of research involving human subject in which case the Resolution Plan must be reviewed by the IRB, when the Resolution Plan is approved by the AFFE subcommittee following review and any changes made by the subcommittee are acceptable to the Covered Individual the research may be conducted.

If the Covered Individual contests the conditions and restrictions imposed by the AFFE subcommittee, the Covered Individual may appeal the decision of the AFFE subcommittee to the Vice President to which his or her unit reports. The appeal should include reasons why the conditions or restrictions imposed by the subcommittee would be either ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare. The Vice President may, upon review of the AFFE subcommittee's recommended Resolution Plan and the Covered Individual's appeal, approve that, to the extent permitted by Federal regulations, the research go forward without the conditions and restrictions imposed by the AFFE subcommittee. In cases that do not involve human research subjects the Vice President shall make the final decision regarding resolution of the conflict or potential conflict. If the research involves human subjects the IRB's determination shall be final (refer to IRB Policies 17A and 17B).

1.17.3.7 The approved Resolution Plan shall be incorporated into a Memorandum of Understanding between East Tennessee State University and the Investigator that details the conditions and restrictions imposed upon the Investigator in the conduct of the project or in the relationship with the Business Enterprise or Entity.

The Memorandum of Understanding shall be signed by the Investigator, the Covered Individual's Departmental Chair or Unit Head, and on behalf of the University, by the Vice Provost for Research and Sponsored Programs and if the research involves human subjects by the chair of the IRB.

Actual or potential conflicts of interest will be satisfactorily managed, reduced, or eliminated in accordance with the Resolution Plan and all required reports

regarding conflict of interest submitted to the sponsor prior to expenditure of any funds under an award. For example, the Public Health Service requires the University to report to the PHS Awarding Component the existence of a conflicting interest (but not the nature of the interest or other details) found by the University and assure that the interest has been managed, reduced, or eliminated. NSF only requires the University to report conflicts which cannot be satisfactorily managed, reduced, or eliminated. The Vice Provost for Research shall be responsible for monitoring compliance with the Resolution Plan on behalf of the AFFE and shall report any deviations from the Resolution Plan to the AFFE within 10 working days of discovering the deviation. The AFFE will then determine whether the deviation is sufficient to constitute a violation of the Resolution Plan. If the research involves human subjects the chair of the IRB will be informed of the deviation and will report it to the IRB for review.

1.17.3.8 Records of Covered Individual's financial disclosures and of actions taken to manage actual or potential conflicts of interest, shall be confidentially retained by the Office of Research and Sponsored Programs until 3 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.

1.17.3.9 Whenever a Covered Individual has violated this policy or the terms of the Memorandum of Understanding, the AFFE shall recommend sanctions which may include disciplinary action ranging from a public letter of reprimand to dismissal and termination of employment. **If the violation involves research using human subjects the IRB will make an independent determination and recommendation for sanctions based on protection of human subjects in research.** If the violation results in a collateral proceeding under University policies regarding misconduct in science, then the AFFE shall defer a decision on sanctions until the misconduct in science process is completed. The AFFE's recommendations on sanctions shall be presented to the Investigator's Vice President and to the President of the University who shall make final determination regarding disciplinary action. The President shall enforce the disciplinary action.

In addition, the University shall follow Federal regulations regarding the notification of the sponsoring agency in the event an Investigator has failed to comply with this policy. The Vice Provost for Research, as Institutional Official, is responsible for such notification. The sponsor may take its own action as it deems appropriate, including the suspension of funds for the Investigator until the matter is resolved.

1.17.3.10 Collaborators/subrecipients/subcontractors from other academic or not-for-profit institutions must either comply with this policy or provide a certification from their institutions that they are in compliance with Federal policies regarding investigator significant financial interest disclosure and that their portion of the project is in compliance with their institutional policies. Subcontractors from commercial firms need not make a certification, except when the prime award is from the Public Health Service. The PHS requires a certification from any subcontractor, including commercial firms, stating that it is in compliance with Federal policies regarding investigator significant

financial interest disclosure and that its portion of the project is in compliance with company policies.

- 1.17.3.11** Independent contractors acting as consultants to ETSU for research and sponsored programs activities to which this policy applies must declare any potential conflict of interest in accord with this policy.
- 1.17.3.12** If the conflict of interest is found for a sponsored study involving human research subjects the Office of Human Research Protection shall be informed upon receipt of the conflict of interest disclosure by the Vice Provost for Research and shall receive the Conflict of Interest Resolution Plan for review as part of the review of the research protocol. Institutional Review Board (IRB) Policies 17A and 17B shall be followed in these cases. The research may not begin until the IRB has accepted the Resolution Plan.
- 1.17.3.13** In the event that the Covered Individual must also declare a conflict of interest to the James H. Quillen Veterans Affairs Medical Center the Vice Provost for Research of East Tennessee State University and the Associate Chief of Staff for Research at the Veterans Affairs Medical Center shall work with the respective applicable committees to develop a common Conflict of Resolution Plan.

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