

## GENERAL

- A. This policy establishes procedures to be followed in resolving actual and potential faculty and/or staff financial conflicts of interest (FCOI) pertaining to sponsored projects. This policy applies to all sponsored projects funded by (a) commercial sponsors, (b) federal and/or state agencies with specific conflict of interest requirements, and (c) subcontracts issued by Sam Houston State University (defined from this point forward as “the University”) as sponsored projects regardless of the source of funds.
- B. The University recognizes its responsibilities to encourage interaction between its Principal Investigators (PIs) and public and/or private sectors as important components of its research endeavors. The University is committed to conducting research in a manner consistent with the highest standards of integrity and ethics. The University adopts this policy to promote objectivity in research, ensuring that research activities conducted by each PI are free from bias resulting from FCOIs.

## REASON FOR POLICY

This policy establishes the procedures and responsibilities to avoid and resolve FCOIs in accordance with federal law and regulations adopted by the Public Health Service (PHS) of the U.S. Department of Health and Human Services to address significant financial interests when they reasonably appear to affect or bias the design, conduct, or reporting of research.

## PROCEDURES AND RESPONSIBILITIES

### 1. PURPOSE AND BACKGROUND

- 1.01 This policy outlines the general procedures required to identify, manage, and report FCOI in research. The purpose of this policy is to protect the credibility and integrity of the University and its PIs, as well as other entities (i.e., other universities or public agencies), so the public trust and confidence in research activities are maintained. For that purpose, this policy adopts standards for the disclosure, management, and reporting of FCOI as required by federal law.
- 1.02 The University is responsible for identifying, managing, reducing, and eliminating financial conflicts of interest that may develop because of

financial interests of its Investigators, that is, the financial interests of the PI and the individuals who participate in the design, conduct, or reporting of sponsored research. Therefore, the University requires PIs to disclose financial interests related to their research activities.

## 2. APPLICABILITY

- 2.01 Except as otherwise provided by law, this policy applies broadly to all sponsored research activities regardless of the funding source.
- 2.02 In addition to the topics addressed in this policy, there may be ethical considerations that are distinct and separate from FCOI questions.

## 3. FINANCIAL CONFLICT OF INTEREST OFFICIAL

The University President shall appoint a Financial Conflict of Interest official (FCOI official), from outside the Office of Research and Sponsored Programs (ORSP) to report to the President, who will be responsible for oversight and compliance with this policy.

## 4. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

- 4.01 As per regulatory requirement (§42 CFR 50.603 and 42 CFR 50.604(e)(1)-(3)), the University shall require that each PI participating in grant-funded research must disclose to the FCOI official the PI's significant financial interest (and those of the PI's spouse and dependent children):
  - a. Within 30 days of discovering or acquiring a new significant financial interest.
  - b. As part of the routing process, prior to the submission of any grant proposal.
  - c. As required by the specific federal agency or funding partner, during the period of the award, not later than August 31<sup>st</sup>.
- 4.02 Each PI must submit to or update with the ORSP a Financial Disclosure Statement as defined below [Note: the form is attached as **Attachment A** to this policy] and as required in section 4.03 of this regulation. This statement:

- a. Identifies any potentially conflicting research or research activities in which the PI is engaged at the time the financial disclosure statement is submitted to the ORSP; and
  - b. Discloses the following information for each significant financial interest held by the Investigator or an immediate family member (spouse, significant other/domestic partner, parents, parents-in-law, siblings, children, or other relatives living at the same address as the faculty/staff member):
    - (1) The total amount of salary or other payments received (from the significant financial interest source) in the preceding 12 months, in whole dollar amounts;
    - (2) A description and the value of any equity interest (e.g., stock, stock options, or other ownership interest or entitlement to such an interest) in whole dollar amounts as compared to public prices or other reasonable measures of fair market value;
    - (3) A description and the value of any intellectual property or royalty interests in whole dollar amounts as related to the significant financial interest source;
    - (4) The source of the significant financial interest, including the source's name and principal address; and
    - (5) For each occurrence of reimbursed or sponsored travel, the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration of the trip. Each sponsor agency, at its discretion, may require a PI to disclose additional information in order to determine whether the travel at issue constitutes an FCOI.
- 4.03 Investigators shall also submit to or update with the ORSP a separate Financial Disclosure Statement for each immediate family member (see examples in section 4.02) within the time periods specified in section 4.02.
- 4.04 Investigators shall use the Financial Disclosure Statement form provided in **Attachment A** to this regulation.

- 4.05 An Investigator or immediate family member (see examples in section 4.02) shall provide any additional documentation related to the significant financial interests disclosed on a Financial Disclosure Statement upon request of a member's FCOI official.

## 5. REVIEW OF FINANCIAL DISCLOSURE STATEMENTS

- 5.01 The FCOI official shall ensure adherence to relevant University policies such as the Faculty Handbook, the Academic Policy Manual, The Texas State University System's Intellectual Property Policy, the Ethics Policy for Regents and Employees of The Texas State University System, Texas Government Code Chapter 572 and other University documents the FCOI official may deem appropriate. The FCOI official shall also review the Financial Disclosure Statement submitted to the ORSP by each Investigator and determine:
- a. Whether a significant financial interest is related to research in which an Investigator is participating; and
  - b. Whether an FCOI exists.
- 5.02 An FCOI official may request additional information about an Investigator's Financial Disclosure Statement to determine if an FCOI exists.
- 5.03 An FCOI exists when the FCOI official reasonably determines that a significant financial interest held by an Investigator or an immediate family member (see examples in section 4.02) could directly and significantly affect the design, conduct, or reporting of the Investigator's research.
- 5.04 Appeals of the decision of the FCOI official will be handled by the Council of Academic Deans (CAD). A request for appeal may be submitted in writing by the PI to the FCOI official within ten (10) class days of receipt of the FCOI decision who will forward all documents pertaining to the conflict in question to the CAD. The CAD will give a judgment on their findings, with a majority vote of the CAD determining the outcome. An additional appeal can be made of the decision of the CAD, should this be deemed necessary by any parties involved. While the Department/College can participate in drafting the Management Plan, it is ultimately the burden on the

PI to appeal any decision of the FCOI official. This final appeal will be decided upon by the University President. The President's decision will be final.

6. CERTIFICATION AND REPORTING

6.01 Federal regulations require the University to include specific certifications and agreements regarding this regulation and FCOI in each application for funding submitted for any grant-funded research.

6.02 The University shall comply with the reporting requirements in 42 CFR §50.602 and 45 CFR §94.5, which require the submission of reports to the appropriate federal funding agency within a certain period of time after the University identifies an FCOI related to any grant-funded research.

7. NO EXPENDITURE OF RESEARCH FUNDS

In cases involving sponsored research, there will be no expenditure of research funds by an Investigator or the University unless the FCOI official has determined that no FCOI exists or that any identified FCOI is manageable under the terms of a management plan that has been adopted and implemented.

8. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

8.01 If an FCOI official determines that an FCOI exists, the FCOI official shall notify the PI in writing and work with the Investigator to develop a management plan specifying the steps to be taken to manage, reduce or eliminate the FCOI.

8.02 Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate an Investigator's FCOI include, but are not limited to:

- a. Public disclosure of the FCOI (e.g., when presenting or publishing the research);
- b. For research projects involving human subjects, disclosure of the FCOI to the participants;

- c. Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of research against bias resulting from the FCOI;
  - d. Modification of the research plan or research activities;
  - e. Requiring a change in personnel and/or responsibilities for all or a portion of the research activities;
  - f. Disqualification of personnel from participation in that portion of the research activities that would be affected by the FCOI;
  - g. Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
  - h. Severance of relationships that create an FCOI.
- 8.03 In the absence of a requirement from specific sponsor agencies, the University will follow National Institutes of Health (NIH) management plan guidance as cited in 42 CFR §50.605(a)(1).
- 8.04 The management plan must be signed by the PI, the PI's supervisor, and approved by the COI official.
- 8.05 If a PI disagrees with the FCOI official's determination that an FCOI exists, the PI may appeal the FCOI official's determination in writing within ten (10) business days after receiving the COI official's determination. Appeals of the decision of the FCOI official are handled as outlined in §5.04 above.

## 9. PUBLIC ACCESSIBILITY

- 9.01 As per regulatory requirement (42 CFR 50.604(a)), the University shall maintain and timely date the FCOI policy and shall make this policy available via a publicly accessible website.
- 9.02 For any grant-funded research:
- 9.02.1 If the FCOI official makes a determination that an FCOI exists that is related to grant-funded research, the FCOI official will make the

following key information available to the public as specified in 9.02.2:

- a. The name of the Investigator;
- b. The title and role of the PI in relation to the affected research;
- c. The name of the entity in which the significant financial interest is held;
- d. A description of the significant financial interest that was determined to be an FCOI; and
- e. The approximate dollar value of the significant financial interest. If the dollar value cannot be determined by reference to publicly available prices or another reasonable method, the FCOI official shall include a statement to that effect. Dollar values may be provided within ranges (e.g., \$0-\$4,999; \$5,000-\$10,000; \$10,000-\$20,000; \$20,000-\$50,000; \$50,000-\$100,000. Amounts over \$100,000 may be stated in increments of \$50,000).

9.02.2 The FCOI official shall make this information available within five (5) business days after receipt of a request so long as the following criteria are met:

- a. The significant financial interest was disclosed and is still held by the PI;
- b. The FCOI official has determined that the significant financial interest is related to sponsored research; and
- c. The FCOI official has determined that the significant financial interest is an FCOI.

9.02.3 The information required under this section must remain available to persons requesting this information for three years after the date of the last expenditure on the research project, or three years after the date the project terminates, whichever is later.

## 10. RETROSPECTIVE REVIEW

### 10.01 Noncompliance, Retrospective Review, and Documentation for Funded Research.

10.01.1 In accordance with the regulatory requirement (42 CFR §50.605(a)(3)), if the FCOI official discovers an FCOI related to any grant-funded research that was not timely identified or managed, or if an Investigator fails to comply with a management plan, the FCOI official shall, within 120 days after determining noncompliance:

- a. Complete a retrospective review of the PI's research activities and any grant-funded research project to determine if any research, or portion thereof, conducted during the period of noncompliance, was biased in the design, conduct, or reporting of such research; and
- b. Implement any measures necessary, including but not limited to halting the Investigator's participation in any affected research project, to remediate the noncompliance between the date the noncompliance was identified and the date the retrospective review is completed (in accordance with 42 CFR §50.604(j)).

10.01.2 The FCOI official or designee shall document each retrospective review, including but not limited to the following key elements:

- a. Project number;
- b. Project title;
- c. Investigator contact(s);
- d. Name of the Investigator with the FCOI;
- e. Entity with which the Investigator has an FCOI;
- f. Reason(s) for the retrospective review;

- g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- h. Findings of the review; and
- i. Conclusions of the review (i.e., determination, recommended actions, and remedial measures implemented).

10.01.3 If bias is found, the FCOI official shall notify the granting agency and submit a mitigation report as required by federal law. If necessary, the FCOI official shall update the FCOI information as described in section 9.02 of this policy.

## 11. RESEARCH THROUGH CONTRACTORS OR SUBCONTRACTORS

11.01 If University sponsored, federally funded research is conducted through a subcontractor, the University must take reasonable steps to ensure that subcontractor's investigators and collaborators comply with the following:

- a. Incorporating into a written agreement, such as a Memorandum of Understanding (MOU) or contract, terms that establish whether the University FCOI policy or that of the subcontractor, apply to the subawardee's investigators;
- b. Providing FCOI reports to the awarding component regarding FCOIs by subcontractors' PIs, as defined in this policy, prior to expenditure of funds and within 60 days of any subsequently identified FCOIs;
- c. Submitting an updated disclosure of significant financial interests within 30 days of acquiring a new significant financial interest by each PI participating in grant-funded research.

11.02 In those circumstances in which the University is engaged in or intends to engage in a sponsored project with a commercial organization, or has subcontracted or intends to subcontract to an external organization under one of the University's sponsored projects, a conflict of interest may occur when a faculty/staff member's affiliation with the external organization meets any of the following criteria:

- a. The faculty/staff member is an officer, director, partner, trustee, employee, advisory board member, or agent of an external organization either funding a sponsored project or providing goods and services under a sponsored project on which the faculty/staff member is participating in any capacity.
- b. The faculty/staff member is the actual or beneficial owner of more than five percent (5%) of the voting stock or controlling interest of such organization or corporation.
- c. The faculty/staff member has dealings with such an organization or corporation from which he or she derives income and/or goods/services of more than \$5,000 per year, exclusive of dividends and interest.
- d. The faculty/staff member's immediate family meet any of the criteria stated in a-c above.
- e. Each faculty/staff member participating in a sponsored project must disclose external affiliations that may constitute a FCOI as defined by the criteria in the preceding paragraphs. Disclosure forms must be completed prior to the University's acceptance of a sponsored project or issuance of purchase orders or initiation of subcontracts for the acquisition of goods and services. A PI who is faculty must send a Financial Disclosure Statement (**Attachment A**) which has been signed by the department chair and academic dean to ORSP. Similarly for staff members, the form should be signed by an immediate supervisor. These forms will be reviewed by the FCOI official.
- f. The PI must update the FCOI disclosure form(s) during the period of an award as the status of these disclosures change and report new external affiliations that may constitute additional FCOI.

11.03 In reviewing the disclosure forms relating to research through contractors and subcontractors, the FCOI official will:

- a. Ensure adherence to relevant University policies such as the Faculty Handbook, the Academic Policy Manual, The Texas State University System's Intellectual Property Policy, the Ethics Policy for Regents and

Employees of The Texas State University System, Texas Government Code Chapter 572 and other University documents the FCOI official may deem appropriate.

- b. Consider the nature and extent of the financial interest in the relationship of the faculty/staff member and external organization.
- c. Give special consideration to the terms and conditions of sponsored project agreements that may mitigate or complicate the given situation.
- d. Consult with and obtain additional information from the faculty/staff member as either the FCOI official or the faculty/staff member feel may be helpful in resolving actual or potential conflicts.
- e. Act in a timely manner so as not to delay unduly the conduct of the sponsored project.
- f. Recommend that the University may take one of the following actions:
  - (1) Accepts the sponsored project award.
  - (2) Not accept the sponsored project award.
  - (3) Accepts the sponsored project subject to suitable modifications in the sponsored project award document, or
  - 4) Accepts the sponsored project subject to suitable modifications in the external organizational affiliation(s) of the faculty/staff member or the external organizational affiliation(s) of the faculty/staff member's family.

11.04 If a faculty/staff member is dissatisfied with the FCOI official's determination, then the faculty/staff member may appeal this decision. Such appeals are addressed by section 5.04 of this policy.

11.05 Violations of this policy, such as willful concealment of financial interests, may result in sanctions being imposed upon the violating individual. Sanctions may include disciplinary action ranging from a public letter of reprimand to dismissal and termination of employment. The FCOI official

will review allegations of violations and will make recommendations regarding the imposition of sanctions to the Provost and Vice President for Academic Affairs. The decision of the Provost and Vice President for Academic Affairs with regard to the imposition of sanctions shall be final.

- 11.06 The Post Award office (the Office of Research Administration or ORA) will maintain records pertaining to research through contractors and subcontractors and all submitted disclosure forms in strict confidence. Access to such records will be limited to the faculty/staff member, the FCOI official, CAD, the Provost and Vice President for Academic Affairs, and others who have a legal right to review the records.

Records will be retained for three years after the latter of:

- a. The termination or the completion of the award to which they relate, or
- b. The resolution of any government action involving those records.

- 11.07 Certain sponsors, particularly federal agencies, may have requirements that differ from this policy with regard to the timing and frequency of faculty/staff disclosures and other provisions as well. In cases of such discrepancies, sponsor requirements will generally supersede university requirements.

- 11.08 Investigators and subcontractors from other academic or not-for-profit institutions must either comply with this policy or provide a certification from their institutions that their portion of the project is in compliance with their institutional policies and their institutional policies are in compliance with federal regulations regarding FCOI disclosure. Subcontractors from commercial firms need not make such certifications, except as required by external funding agencies. Some external funding agencies require certifications from subcontractors, including commercial firms, establishing compliance with federal policies regarding FCOI disclosure as well as certifications that projects are in compliance with company policies.

## 12. TRAINING, EDUCATION, AND CERTIFICATION

- 12.01 The University is responsible for complying with the training requirements under federal law (e.g., 42 CFR §50.604(b); 45 CFR §94.4(b)).

- 12.02 Each Investigator must certify that the PI has read this policy and is aware that federal regulations may apply to their sponsored research project. Each Investigator must also certify that the PI is aware of the various responsibilities regarding disclosure of significant financial interests.
- 12.03 Prior to engaging in research on behalf of the University and at least every four years during periods of continued research activity, each PI shall complete training on this policy and other applicable policies, regulations, rules, and laws. Furthermore, upon being notified by ORSP, each Investigator shall arrange with ORSP to complete training. Training may be required for the following reasons:
- a. The University revises this FCOI policy (APS 950809) in ways affecting requirements of Investigators,
  - b. A PI is new to the University,
  - c. A PI is not in compliance with the policy or management plan.
- 12.04 The ORSP shall document a PI's compliance with applicable training requirements. The ORSP shall maintain all documentation related to an Investigator's compliance with this training requirement.
- 12.05 The ORSP shall require all Investigators to comply with the above training requirements if it is determined that FCOI training is mandated by the specific federal agencies associated with their sponsored research projects. Affected Investigator(s) will be notified by ORSP if training is required.

### 13. DEFINITIONS

- 13.01 Disclosure of Significant Financial Interests means a PI's disclosure of significant financial interests to the University.
- 13.02 Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of funded research.
- 13.03 FCOI Report means an Institution's report of a financial conflict of interest to an awarding component.

- 13.04 Financial interest means anything of monetary value, whether or not the value is readily ascertainable.
- 13.05 Institution means Sam Houston State University unless otherwise indicated within.
- 13.06 Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, 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.
- 13.07 Investigator means the PI or a co-investigator, or any other personnel, regardless of title or position, at SHSU who is responsible for the design, conduct, or reporting of research in a funded project, or one proposed for funding, by commercial sponsors, or federal and/or state agencies or through subcontracts by the University. Investigator also refers to an individual who is not at SHSU but who is responsible for the design, conduct, or reporting of sponsored research and may include, for example, a collaborator or consultant.
- 13.08 Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- 13.09 PI means a project director or principal investigator of a funded research project.
- 13.10 Research means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research and results in a wide range of professional work products, intellectual property, and product development (examples may be: a published article, a book or book chapter, a diagnostic test, a new procedure or unique drug, a newly created material or combination of materials). As used in this policy, the term includes any such activity for which research funding is available from a sponsoring agency through a variety of

arrangements (examples are: a grant, a contract, a cooperative agreement, an award, or a fellowship.)

13.11 Significant financial interest means:

- a. A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's immediate family members):
  - (1) 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. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
  - (2) 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 spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
  - (3) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.
- b. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, State, or local government agency, an Institution of higher education as defined at 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.

SHSU's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the funded research.

- c. Significant financial interest does not include:
- (1) Salary, royalties, or other remuneration paid by SHSU to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual rights assigned to the University and agreements to share in royalties related to such rights;
  - (2) Income from seminars, lectures, or teaching engagements sponsored by a Federal, State, or local government agency, an Institution of higher education as defined at 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;
  - (3) Income from service on advisory committees or review panels for a Federal, State, or local government agency, an Institution of higher education as defined at 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;
  - (4) Financial interests in business enterprises or entities if the value of such interests does not exceed \$5,000 or represent more than five percent (5%) ownership interest for any one enterprise or entity when aggregated for the investigator and the investigator's spouse and dependent children.
  - (5) Salary, royalties, or other payments from sponsored projects that, when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$5,000, or

- (6) Regardless of the above minimum requirements, a faculty or staff member in their 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.

Attachment A: [Financial Disclosure Statement](#) Attachment B: [Appendix](#)

APPROVED:                     < signed >                      
Dana G. Hoyt, President

DATE:                     6/17/15                    

**CERTIFICATION STATEMENT**

This academic policy statement (APS) has been approved by the reviewer(s) listed below and represents SHSU's Division of Academic Affairs' policy from the date of this document until superseded.

|              |                           |               |                |
|--------------|---------------------------|---------------|----------------|
| Original:    | August 9, 1995            | Review Cycle: | August 1, ONY* |
| Reviewer(s): | Council of Academic Deans | Review Date:  | August 1, 2017 |
|              | Faculty Senate            |               |                |
|              | Academic Policy Council   |               |                |

Approved:                     < signed >                     Date:                     6/18/15                      
Jaimie L. Hebert  
Provost and Vice President  
for Academic Affairs

**\*ONY = Odd Numbered Year**