

**Sam Houston State University
Academic Policy Statement 950809**

Financial Conflict of Interest in Research
Pertaining to Sponsored Projects

1. GENERAL

1.01 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 and (c) subcontracts issued by Sam Houston State University as sponsored projects regardless of the source of funds.

1.02 Sam Houston State University (SHSU) recognizes its responsibilities to encourage interaction between its Principle Investigators (PIs) and public and/or private sectors as an important component of its research endeavors. SHSU is committed to conducting research in a manner consistent with the highest standards of integrity and ethics. SHSU adopts this regulation to promote objectivity in research, ensuring that research activities conducted by each Investigator are free from bias resulting from FCOIs.

2. REASON FOR REGULATION

2.01 This regulation implements federal law and regulations adopted by the Public Health Service (PHS) of the U.S. Department of Health and Human Services to address when a Significant Financial Interest (SFI) reasonably appears 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 for SHSU to identify, manage, and report financial conflicts of interest in research. The purpose of this policy is to protect the credibility and integrity of the University and its Investigators, as well as other entities (i.e., other universities or public agencies, etc.), 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 SHSU is responsible for identifying, managing, reducing, or eliminating conflicts of interest that may develop because of financial or other personal interests of an Investigator. Therefore, the University requires Investigators to disclose financial interests related to their responsibilities to SHSU.

2. APPLICABILITY

2.01 Except as otherwise provided by federal law, this policy applies broadly to all Research Activities regardless of the funding source, as well as to Research Activities that do not have external funding.

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. CONFLICT OF INTEREST OFFICIAL

3.01 SHSU's President shall appoint a Conflict of Interest Official (COI Official) who will be responsible for oversight and compliance with this policy. The COI Official shall perform the duties as assigned by this policy and any other duties as assigned by the President.

4. DISCLOSURE OF SIGNIFICANT FINANCIAL INTERESTS

4.01 As per regulatory requirement (§42 CFR 50.603 and 42 CFR 50.604(e)(1)-(3)), SHSU shall require that each Investigator participating in any grant-funded research must disclose to the University's CIO Official the Investigator's SFI (and those of the Investigator's spouse and dependent children):

- (a) Within 30 days of discovering or acquiring a new SFI
- (b) As part of the routing process, prior to the submission of any grant proposal
- (c) Annually during the period of the award, not later than August 31st

4.02 Each Investigator, as defined below, must submit or update a Financial Disclosure Statement as required in Section 4.3 of this regulation that:

- (a) Identifies all Research or Research Activities in which the Investigator is engaged at the time the Financial Disclosure Statement is submitted; and
- (b) Discloses the following information for each SFI held by the Investigator or a Covered Family Member that is reasonably related to the Investigator's Institutional Responsibilities:
 - (1) The total amount of salary or other payments received (from the SFI source) in the preceding 12 months, in rounded, 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 rounded, whole dollar amounts by reference 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 rounded, whole dollar amounts as related to the SFI source;
 - (4) The source of the SFI, 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 member, at its discretion, may require an

Investigator to disclose additional information in order to determine whether the travel at issue constitutes an FCOI

4.03 Investigators shall also submit or update a separate Financial Disclosure Statement for each Covered Family Member within the time periods specified in Section 4.2.

4.04 Investigators shall use the Financial Disclosure Statement form provided in Appendix B to this regulation.

4.05 An Investigator or Covered Family Member shall provide any additional documentation related to the SFIs disclosed on a Financial Disclosure Statement upon request of a member's COI Official.

5. REVIEW OF FINANCIAL DISCLOSURE STATEMENTS

5.01 SHSU's COI Official shall review the Financial Disclosure Statement submitted by each Investigator and determine:

(a) Whether an SFI is related to research in which an Investigator is participating; and

(b) Whether an FCOI exists.

5.02 A COI 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 COI Official reasonably determines that an SFI held by an Investigator or a Covered Family Member could directly and significantly affect the design, conduct or reporting of the Investigator's research.

6. CERTIFICATION AND REPORTING

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

6.02 SHSU 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

7.01 In cases involving sponsored research, there will be no expenditure of research funds by an Investigator or the University unless the COI 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.

7.02 In cases of unfunded research, the research shall not begin unless the COI 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 a COI Official determines that an FCOI exists, the COI Official shall notify the Investigator 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 A Management Plan must include a description of the following key elements:

- (a) The research affected by the FCOI, including if available the project number;
- (b) The role and principal duties of the Investigator who has the FCOI;
- (c) The conditions or restrictions to be implemented to manage, reduce or eliminate the FCOI;
- (d) A statement explaining how the Management Plan will protect the research from bias resulting from the FCOI;
- (e) How the Management Plan is designed to safeguard objectivity in the research project;
- (f) Confirmation of the Investigator's agreement to abide by the Management Plan;

(g) A statement explaining how the Management Plan will be monitored to ensure compliance and who is responsible for monitoring compliance with the Management Plan; and

(h) Any other information as needed.

8.04 The Management Plan must be signed by the Investigator, the Investigator's supervisor, and approved by the COI Official.

8.05 If an Investigator disagrees with the COI Official's determination that an FCOI exists, the Investigator may appeal the COI Official's determination to the CEO or designee in writing within 10 business days after receiving the COI Official's determination. The decision of the CEO or designee is final.

9. PUBLIC ACCESSIBILITY

9.01 As per regulatory requirement (42 CFR 50.604(a)), Sam Houston State University shall maintain an up-to-date, written, enforced FCOI policy and shall make this policy available via a publicly accessible website.

9.02 For any grant-funded research:

9.02.1 If SHSU's COI Official makes a determination that an FCOI exists that is related to any grant-funded research, the University's COI 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 Investigator in relation to the affected research;

The name of the entity in which the SFI is held;

(d) A description of the SFI that was determined to be an FCOI; and

(e) The approximate dollar value of the SFI. If the dollar value cannot be determined by reference to publicly available prices or another reasonable method, the University's COI 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 SHSU's COI Official shall make this information available in writing to anyone requesting this information within five business days after receipt of a request so long as the following criteria are met:

(a) The SFI was disclosed and is still held by the Investigator;

(b) The University's COI Official has determined that the SFI is related to PHS-funded research; and

(c) The University's COI Official has determined that the SFI is an FCOI.

9.02.3 The information required under this section must remain available to any person requesting this information for three years after the date of the last expenditure on the research project or, if the research activity is unfunded, three years after the date the project terminate.

10. RETROSPECTIVE REVIEW

10.01 Noncompliance, Retrospective Review, and Documentation for PHS-funded Research

10.01.1 In accordance with the regulatory requirement (42 CFR §50.605(a)(3)), if SHSU's COI 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 University's COI Official shall, within 120 days after determining noncompliance:

- (a) Complete a retrospective review of the Investigator'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)).

10.02.2 SHSU's COI 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).

10.02.3 If bias is found, the University's COI Official shall notify the granting agency and submit a mitigation report as required by federal law. If necessary, the COI Official shall update the FCOI Reports described in Section 9.02 of this policy.

11. RESEARCH THROUGH CONTRACTORS OR SUBCONTRACTORS

11.01 If SHSU conducts any grant-funded research through a subcontractor, the University must take reasonable steps to ensure that any subcontractor's Investigator complies with the following:

- (a) Incorporating into a Memorandum of Understanding (MOU) with the subcontractor terms that establish whether SHSU's FCOI policy or that of the subcontractor will apply to the subawardee's Investigators;
- (b) Prior to expenditure of funds and within 60 days of any subsequently identified FCOIs, providing FCOI reports to the Awarding Component regarding all FCOIs of all subcontractors' Investigators consistent with this policy;
- (c) Within 30 days of acquiring a new SFI, requiring each Investigator participating in any grant-funded research to submit an updated disclosure of SFIs.

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 (spouse, parents, parents-in-law, siblings, children, or other relatives living at the same address as the faculty/staff member) meet any of the criteria stated in a-c above.
- e. Each faculty/staff member participating in a sponsored project covered by this policy must disclose whether or not he or she has external affiliations that may constitute a conflict of interest by falling within the criteria stated in paragraphs a-d above. A disclosure must be completed prior to the university's acceptance of the sponsored project or issuance of a purchase order or subcontract for the acquisition

of goods and services. A disclosure form (Attachment B) is to be sent to the Office of Research and Sponsored Programs through the faculty member's department chair and academic dean. For staff members, the form should be sent through the immediate supervisor. Positive disclosures will be reviewed by a Conflict Review Committee consisting of the Associate Vice President for Research and Sponsored Programs, and the General Counsel, The Texas State University System.

f. All financial disclosures must be updated by the investigator(s) during the period of the award as new reportable significant financial interests are obtained.

11.03 In reviewing the positive disclosures, the Conflict Review Committee will consider the following guidelines and will apply them, as appropriate (See Attachment A):

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, and other university documents the Conflict Review Committee 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 Conflict Review Committee 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. Does not accept the sponsored project award.

3. Accepts the sponsored project subject to suitable modifications in either the sponsored project award document or the external organizational affiliation(s) of the faculty/staff member or faculty/staff member's family.

11.04 If the faculty/staff member is dissatisfied with the Conflict Review Committee's conclusion, the faculty/staff member may appeal to the Vice President for Academic Affairs who will consult with the faculty/staff member and Conflict Review Committee as he/she deems necessary and appropriate to the particular circumstance. The decision of the Vice President for Academic Affairs shall be final.

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

11.06 SHSU's Post Award office shall maintain the records pertaining to each disclosure in strict confidence. Access to such records will be limited to the faculty/staff member, the Conflict Review Committee, The Vice President for Academic Affairs and others who have a legal right to review the records.

11.07 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.

11.08 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 the case of such discrepancies, the sponsors' requirements will generally prevail.

11.09 Collaborators/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 (PHS). 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.

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 annually that the Investigator is aware of and has read this regulation, the applicable University rule, and any related procedures. Also, each Investigator is aware of the responsibility regarding disclosure of SFIs and of applicable federal regulations.

12.03 Prior to engaging in research on behalf of the University and at least every four years thereafter if there is continued research activity, each Investigator shall complete training on this policy and other applicable policies, regulations, rules, and laws. Furthermore, each Investigator shall immediately complete training for the following reasons:

- a. If the University revises its FCOI policy that affects requirements of Investigators
- b. An Investigator is new to the University
- c. An Investigator is not in compliance with the policy or management plan

12.04 The University's Office of Research and Sponsored Programs (ORSP) shall document an Investigator'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 University shall require all Investigators to comply with the above training requirements as required by the specific federal agency.

13. DEFINITIONS

13.01 Disclosure of Significant Financial Interests means an Investigator's disclosure of significant financial interests to an Institution.

13.02 Financial Conflict of Interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

13.03 FCOI Report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

13.04 Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

13.05 HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

13.06 Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

13.07 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.

13.08 Investigator means the principal investigator(s), co-investigator(s), and any other personnel, regardless of title or position, at SHSU who is responsible for the design, conduct, or reporting of research or scholarly activities funded or proposed for funding by any or all of the three entities listed above, or proposed for such funding, which may include collaborators or consultants.

13.09 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.

13.10 PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator under this subpart.

13.11 PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

13.12 PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this subpart.

13.13 Public Health Service Act or PHS Act means the statute codified at 42 U.S.C. 201 *et seq.*

13.14 Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this subpart, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant or cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, or research resources award.

13.15 Senior/Key Personnel means the PD/PI and any other person identified as senior/key personnel by the Institution in the grant application, progress report, or any other report submitted to the PHS by the Institution under this subpart.

13.16 Significant Financial Interest (SFI) means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) 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;

(ii) 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

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) 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. The Institution'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 PHS-funded research.

(3) This term Significant Financial Interest *does not* include:

a. 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;

b. 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;

c. 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;

d. financial interests in business enterprises or entities if the value of such interests do 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;

e. 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

f. 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.