1. PURPOSE

1.01 This policy establishes the procedures and responsibilities necessary to identify, disclose, manage, and monitor Financial Conflicts of Interest (FCOIs) applicable to all sponsored research activities funded through a grant or cooperative agreement. FCOIs related to federally funded research are addressed in accordance with applicable federal regulations, specifically 42 CFR Part 50 Subpart F. Other types of conflicts, including Conflicts of Commitment (COCs), are governed under separate institutional policies. This policy applies specifically to FCOIs that could directly and significantly affect the design, conduct, or reporting of research.

1.02 Sam Houston State University (hereafter the University) adopts this policy for all Investigators (as defined below) engaged in externally funded research. It establishes processes to identify, disclose, and manage Investigator financial conflicts of interest to protect research integrity, ensure all safety of human and animal subjects, and maintain public trust in externally funded research.

2. APPLICABILITY

2.01 This policy applies to all University employees engaged in sponsored research awarded to or facilitated by the University. This includes all individuals who meet the definition of an Investigator as defined below.

2.02 Except as otherwise provided by law, this Policy applies broadly to all sponsored research activities regardless of the funding source.

2.03 It is the Investigator's responsibility to be aware of other ethical considerations involved in sponsored research (e.g., Academic Policy Statement 221114 Responsible and Ethical Conduct of Research, Academic Policy Statement 920808 Misconduct in Academic Research and Scholarship, etc.).

2.04 This policy and the associated federal regulations do not apply to SBIR or STTR Phase I applications or awards.

3. DEFINITIONS

3.01 Disclosure of financial conflicts of interest means an investigator reporting to the university of any actual, potential, or apparent financial conflicts of interest in accordance with this policy.

3.02 Covered Family Member includes an investigator's spouse, dependent child, stepchild or other dependent, for purposes of determining federal income tax liability during the period covered by the SFI disclosure, and a related or non-related, unmarried adult who resides in the same household as the investigator and with whom the investigator is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments.

3.03 Conflict of Interest Report is a report of a FCOI to the University or an awarding component.

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

3.05 Institution or University means Sam Houston State University unless otherwise indicated.

3.06 Institutional Responsibilities means an Investigator's professional responsibilities performed on behalf of the University, as defined by their appointment, position description, or assigned roles. These responsibilities include, but are not limited to, research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards (IRBs) or Data and Safety Monitoring Boards (DSMBs). To ensure disclosures are not too narrow in scope, Investigators must disclose all Significant Financial Interests related to the full breadth of their Institutional Responsibilities, rather than limiting disclosures solely to activities directly tied to sponsored research responsibilities.

3.07 An Investigator is a Principal Investigator (PI), or any other personnel, regardless of title or position, at the Institution who is responsible for the design, conduct, or reporting of research for a funded project, or one proposed for funding, by commercial sponsors, federal and/or state agencies, or subcontracts by the University. Investigator also refers to an individual who is not at the Institution but who is responsible for the design, conduct, or reporting of sponsored research, such as a collaborator or consultant.

3.08 Manage means taking appropriate actions to address an FCOI, including reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, the integrity of the design, conduct, and reporting of research will be free from bias.

3.09 Research means a systematic investigation, study, or experiment designed to develop or contribute general knowledge. The term encompasses basic and applied research and results in a wide range of professional work products, intellectual property, and product development (i.e., published articles, a book or book chapter, a diagnostic test, a new procedure or unique drug, 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 such as grants, contracts, cooperative agreements, awards, or fellowships.

3.10 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).

3.11 NIH means the biomedical research agency within the Public Health Service (PHS) that funds and conducts research to improve health and advance scientific knowledge.

3.12 Significant Financial Interest (SFI) means:

a. A domestic or foreign (non-United State) financial interest consisting of one or more of the following interests of the Investigator (and/or those of the Investigator's family members) that reasonably appear to be related to the Investigator's Institutional Responsibilities (see definition above) performed on behalf of the University:

(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 the 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 including any stock, stock options, or other ownership interests, 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 options, or other ownership interests).

(3) Intellectual property rights and interests (e.g., patents or copyrights), upon receipt of income related to such rights and interests that, when aggregated, exceeds $5,000 over the preceding 12 months.

It is important to note that disclosure of foreign financial interests differs from disclosure of domestic financial interests. Investigators, including subrecipient Investigators, must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000).

b. Investigators also must disclose annually as part of the annual COI campaign with Office of Research Administration (ORA) and within 30 days of each travel occurrence, 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 located in the United States (US), a US 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 a US institution of higher education. These exclusions apply only to U.S.-based entities. Travel reimbursed or sponsored by any foreign entity, including foreign institutions of higher education or foreign

governments, must be disclosed in all cases.

For reimbursed or sponsored travel related to their institutional responsibilities, Investigators must disclose the occurrence of any such travel when the aggregated value is in excess of $5,000. Disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. The Institution may request additional information, including estimated or itemized monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest.

Exclusions: This disclosure requirement does not apply to travel that is reimbursed or sponsored by the following entities located within the United States:

- A federal, state, or local government agency;
- An institution of higher education;
- An academic teaching hospital;
- A medical center; or
- A research institute that is affiliated with a institution of higher education.

Note: All travel reimbursed or sponsored by any foreign entity, including foreign governments and foreign universities, must be disclosed in all cases.

c. SFI does not include the following types of financial interest. Therefore, investigators do not disclose these:

(1) Salary, royalties, or other remuneration paid by the Institution (e.g., Sam Houston State University) 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 located in the US, a US 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 a US institution of higher education;

(3) Income from service on advisory committees or review panels for a federal, state, or local government agencies located in the US, a US 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 a US Institution of higher education;

(4) Income from investment vehicles such as mutual funds, index funds, or retirement accounts, provided the Investigator does not directly control the investment decisions for those vehicles.

(5) Any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization. Any equity interest in the Institution if the Institution is a commercial or for-profit organization. While federal regulations exempt ownership disclosures if the grant recipient or sub-recipient is a for-profit institution, the University is a non-profit organization. Therefore, this exemption does not apply.

Note: The disclosure exclusions for financial interests associated with a federal, state, or local government agency or Institutions of higher education as defined in 20 U.S.C. 1001(a) is limited to those entities located within the United States. Therefore, when these interests are associated with the governments of another country, which includes local, provincial, or equivalent governments of another country (i.e., not within the United States) or foreign Institutions of higher education, they must be disclosed.

4. CONFLICT OF INTEREST OFFICIAL

The University President shall designate an Institutional Official(s) responsible for the implementation, oversight, and enforcement of this policy. At Sam Houston State University, this role is currently assigned to the Chief Research Officer or designee.

5. DISCLOSURE OF SIGNIFICANT FINANCIAL CONFLICTS OF INTERESTS

5.01 Investigators are required to disclose all SFIs that are related to their Institutional Responsibilities in accordance with this policy. Disclosures must be submitted according to the following schedule:

- Initial Disclosures: At the time of application for externally funded research.
- Annual Disclosures: At least annually as prescribed by the University (on or before August 15) during the award period for each Investigator participating in research under an NIH award.
- New or Discovered SFIs: Within 30 days of acquiring or discovering a new SFI.
- Travel Disclosures: Within 30 days of each reimbursed or sponsored travel occurrence.

The Institution will review all disclosed SFIs to determine whether an FCOI exists and, if so, will take appropriate steps to manage, reduce, or eliminate the conflict in accordance with applicable regulations.

5.02 Each Investigator must submit and update a Significant Financial Interest (SFI) Disclosure Statement to the ORSP, using the Outside Interests Disclosure (OID) form linked below. This SFI Disclosure Statement:

a. Identifies research or research activities in which the Investigator is engaged at the time the SFI disclosure statement is submitted to the ORSP; and

b. Discloses the following information related to any SFI held by the Investigator or immediate family member, including the name of the entity, the nature of the SFI (e.g., equity, honoraria, etc.), and the approximate dollar value (which may be provided in ranges as established by the University):

(1) A description of positions or roles at other foreign or domestic entities (e.g., adjunct, visiting, guest, honoraria, chair, etc.);

(2) A description of access to graduate students, lab space, materials, etc. at a foreign or domestic entity other than SHSU;

(3) A description of paid travel or travel reimbursement from a foreign or domestic source, including the specific details and subject to the exclusions set forth in Section 3.10.b of this policy;

(4) A description of equity interests (e.g., stocks, stock options) in any non-publicly traded entity or in a publicly traded entity when the value exceeds the disclosure threshold;

(5) A description of intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests; and

(6) A description of research conducted under any external (non-university) awards or subawards that are not managed by the University including details pertaining to other affiliations other than the University listed on publications; participation in any foreign talent recruitment programs; collaborations (joint projects, proposal reviews, or other educational activities) with foreign entities, institutes, university labors or private entities; and engagement in evaluating proposals for foreign committees related to research and research policy, or education within the past five (5) years.

5.03 Investigators shall also submit a Financial Conflict of Interest Disclosure Statement using the OID form for each family member.

a. An employee may be considered to have a conflict of interest when he or she or any member of that person's family possesses a significant financial interest in an activity that involves the employee's university responsibilities, such as but not limited to having an interest in a company/individual and then purchasing goods or consultation services from that company on behalf of the University.

b. Individuals may not participate in the hiring, supervision, or evaluation of family members for any role supported by sponsored research funds. This includes decisions such as hiring a relative as a research assistant, consultant, or contractor; setting their pay; or reviewing their work on the project. For example, a Principal Investigator may not hire or supervise a spouse or other relative on their grant. This restriction applies specifically to sponsored research activities and does not extend to general employment relationships within a department or college. Family relationships need to be disclosed, and a management plan put in place.

c. Employees are required to contact ORA and promptly complete an OID form when the employee or a member of the employee's family:

(1) may receive a financial or other material benefit from information confidential to the University;

(2) is involved in a business venture as owner, operator, consultant, or major investor seeks to or is conducting business with the University; or

(3) receives, within a calendar year, a single gift, or multiple gifts with a cumulative value in excess of $100 from a current or prospective vendor or service provider.

5.04. Investigators and co-investigators are required to complete and certify the Financial Conflict of Interest Disclosure Statement using the OID form (https://shsu.app.cayuse.com/)

5.05 ORA manages the FCOI disclosure process. When a potential conflict is identified through a disclosure, ORA forwards the information to the designated COI Official for review. Investigators are required to provide any additional documentation related to their disclosed significant financial interests upon request by the COI Official. If the identified conflict involves a family member of the Investigator, it will be addressed and managed as part of the FCOI management plan.

6. REVIEW OF FINANCIAL DISCLOSURE STATEMENTS

6.01 The COI Official shall ensure adherence to the applicable Texas State University System Rules and Regulations, relevant University policy, including the Faculty Handbook, the Academic Policy Manual, Texas Government Code Chapter 572, and other University documents the COI Official may deem appropriate.

6.02 The COI Official may request additional information about an Investigator's Financial Disclosure Statement or Conflict of Commitment Statement to determine if a conflict exists.

6.03 A FCOI exists when the COI Official determines that a significant financial interest is related to the research (i.e., the SFI could be affected by the research or the SFI is in an entity whose financial interest could be affected by the

research). The Investigator may be involved in this determination. An FCOI exists when the COI Official determines the "related SFI" could directly and significantly* affect the design, conduct, or reporting of the externally funded research. *Significantly means that the financial interest would have a material effect on the research.

7. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST

7.01 If the COI Official determines that a FCOI exists, they shall notify the Investigator in writing and work with them to develop a management plan specifying the steps to be taken to reduce or eliminate the conflict.

7.02 Examples of conditions or restrictions that might be imposed to manage an Investigator's conflict might include:

a. Public disclosure of the FCOI in publications and presentations;

b. Disclosure of the FCOI to research personnel working on the study;

c. Disclosure of the FCOI to appropriate oversight bodies, as applicable (e.g., Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), Data and Safety Monitoring Board (DSMB));

d. For research projects involving human subjects, disclosure of the FCOI directly to the participants;

e. Appointment of an independent evaluator with the authority to suggest or implement measures to protect the design, conduct, and reporting of research against bias resulting from the FCOI;

f. Requiring a change in personnel and/or responsibilities, or reduction if the Investigator's role in all or a portion of the research;

g. Disqualification of personnel from participation in that portion of the research affected by the FCOI; and/or

h. Severance of relationships that create the FCOI.

7.03 In the absence of a requirement from a specific sponsor agency, the University will follow National Institutes of Health (NIH) guidance for the management of COIs, as outlined in 42 CFR §50.605.

7.04 The management plan must be signed by the Investigator and the Investigator's supervisor and approved by the appointed COI Official.

7.05 Ongoing Monitoring. Whenever the University implements a management plan, the University shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the federally-funded research project. This monitoring may include, but is not limited to, periodic reviews of research data, publications, and financial records to ensure adherence to the conditions and restrictions specified in the management plan.

8. APPEALS

The Investigator who is the subject of a COI determination may appeal the COI Official's decision regarding the management of a FCOI or COC by submitting a written appeal to the Provost and Sr. Vice President for Academic Affairs (hereafter Provost).

An Appeals Committee (Appeals Committee), formed by the Provost, will review the disclosure and management plan and any recommendations of the academic supervisors to manage the FCOI or COC. Upon completion of this review, the Committee will submit to the Provost its summary of findings and any specific recommendations as to modifications of the management plan to eliminate, reduce, or more effectively manage the FCOI or COC.

8.01. Initiating an Appeal

A written notice of appeal must be submitted to the Provost within fifteen (15) business days of the Investigator receiving written notification of the COI Committee's final determination. The written appeal must include a clear statement of each ground for appeal. Grounds for appeal may include, but are not limited to:

- The existence of new, material evidence that was not previously available or considered;
- Any procedural errors that materially affected the outcome; and/or
- A management plan that is disproportionate or not commensurate with the identified conflict.

8.02 Review of Appeal

Upon receipt of the appeal, the Provost will review the stated grounds and supporting documentation. At the Provost's discretion, the Provost may form an *ad hoc* Appeals Committee to conduct a review of a timely and properly submitted appeal. The Appeals Committee shall be composed of no fewer than three (3) individuals with appropriate subject matter expertise and no conflicts of interest or prior involvement in the original determination.

8.03 Appeals Committee Review

The Appeals Committee will evaluate the original disclosure, the COI Committee's management plan, the grounds for appeal, and any newly submitted evidence. The Appeals Committee may interview or obtain written statements from the Investigator and/or other persons with knowledge of relevant facts and request any additional documentation relevant to the evaluation of grounds for appeal. Upon completion of its review, the Appeals Committee will prepare a written summary of findings and recommendations for the Provost, which may include:

- Affirmation of the original management plan;
- Modification of the plan to better address the conflict; or
- Elimination of the plan if it is determined that no conflict exists.

8.04 Final Decision

The Provost will review the recommendations of the Appeals Committee (if convened) and issue a final determination. The Provost may affirm, modify, or overturn the original COI management plan, in whole or in part. The decision of the Provost is final and binding.

8.05 Record keeping and Reporting

The Institution shall maintain records of all Investigator disclosures of financial interests, as well as all reviews of and responses to such disclosures, regardless of whether the disclosure results in a determination of a Financial Conflict of Interest (FCOI). This includes documentation of any actions taken under the Institution's policy and, where applicable, any retrospective reviews conducted. Records shall include, at a minimum: (1) all financial interest disclosures submitted by Investigators; (2) documentation of the Institution's review and determination of whether a Financial Conflict of Interest exists; and (3) records of any management

plans, mitigation measures, or other actions taken in response to identified conflicts. All such records shall be retained for a period of not less than seven (7) years. The retention period shall begin on the date of submission of the final expenditures report for the applicable project or, where applicable, from such other dates as specified in 2 C.F.R. § 200.334 for particular circumstances. Access to these records shall be limited to authorized institutional officials and as required, to representatives of federal agencies or other authorized entities for purposes of audit, review, or oversight, in accordance with applicable laws, regulations, and institutional policies governing confidentiality and record access.

9. CERTIFICATION AND REPORTING

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

9.02 The University shall comply with the reporting requirements in 42 CFR §50.605(b) and 45 CFR §94.5, which require the submission of FCOI reports to the appropriate federal funding agency (such as the NIH) prior to the expenditure of funds and within required timeframes whenever an FCOI is identified.

In lieu of an external summary document, the content, submission timing, and mandatory reporting triggers for all required FCOI reports are specified in the table below:

Report Type	**Content Required**	**Submission Timing / Triggers**
Initial FCOI Report	Grant/Contract number, PI/Project Director, entity name with FCOI, nature of FCOI, value of financial interest (or statement that it cannot be readily determined), basis for agreement that interest conflicts with research, and key elements of the management plan.	Prior to expenditure of funds, or within 60 days of identifying a new FCOI during an ongoing project (or within 60 days of a new Investigator joining).

Report Type	**Content Required**	**Submission Timing / Triggers**
Annual FCOI Report	Status of the FCOI (whether it is still being managed or no longer exists) and any updates/changes to the management plan.	Annually at the same time as the annual progress report (RPPR) submission or upon grant extension.
Revised FCOI Report	Updates describing actions taken to manage the FCOI and mitigate any newly identified risks following a retrospective review.	Promptly following completion of a retrospective review where noncompliance or a previously unmanaged FCOI is identified.
Mitigation Report	Project details, key personnel involved, methodology of review, findings, and conclusions regarding whether bias was found in the design, conduct, or reporting of the research.	Promptly following a retrospective review if bias is determined to have affected the design, conduct, or reporting of NIH-funded research.

10. NO EXPENDITURE OF RESEARCH FUNDS

In cases involving externally funded 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 can be managed under an adopted and implemented management plan.

11. PUBLIC ACCESSIBILITY

11.01 As per regulatory requirement (42 CFR 50.604(a)), the University shall maintain and timely date this FCOI Policy and shall make this Policy available via a publicly accessible website.

11.02 For any grant-funded research:

a. If the COI Official determines that a FCOI exists and the FCOI is held by an individual identified as Senior/Key Personnel on a PHS-funded research project, the Institution will make the following information available to the public in accordance with applicable federal requirements:

(1) The name of the Senior/Key Personnel;

(2) The title and role of the individual with respect to the research project;

(3) The name of the entity in which the significant financial interest is held;

(4) The nature of the Significant Financial Interest; and

(5) The approximate dollar value of the significant financial interest or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures. 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).

b. The COI Official shall make this information available within five (5) business days after receipt of a request so long as the following criteria are met:

(1) The significant financial interest was disclosed and is still held by the Senior/Key Personnel;

(2) The COI Official has determined that the significant financial interest is related to sponsored research; and

(3) The COI Official has determined that the significant financial

interest is a FCOI.

c. The information required under this section must remain available to persons requesting this information for three (3) years after the date of the last expenditure on the research project, or three (3) years after the date the project terminates, whichever is later.

12. RETROSPECTIVE REVIEW

12.01 Noncompliance, Retrospective Review, and Documentation for Funded Research.

Whenever, in the course of an ongoing federally-sponsored research project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI to the University, the designated official(s) shall, within sixty (60) days: review the disclosure of the SFI; determine whether it is related to the sponsored research; determine whether a FCOI exists; and if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, or will be, taken to manage such FCOI.

Whenever the University identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the University during an ongoing-sponsored project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the SFI; determine whether it is related to the sponsored research; determine whether a FCOI exists; and if so: implement, on at least an interim basis a management plan that shall specify the actions that have been, or will be, taken to manage such FCOI going forward. Depending on the circumstances, the University may implement additional interim measures regarding the Investigator's participation in the research project until the retrospective review is complete.

a. In addition, whenever an FCOI is not identified or managed in a timely manner, including,

(1) Failure by the Investigator to disclose a Significant Financial Interest (SFI) that is determined by the Institution to constitute an FCOI; or

(2) Failure by the Institution to review or manage such an FCOI; or

(3) Failure by the Investigator to comply with an FCOI management plan,

the University will, within 120 days of the University's determination of noncompliance, complete a retrospective review.

The purpose of this review is to determine whether any research, or portion thereof, conducted during the period of noncompliance was biased in the design, conduct, or reporting of such research.

b. The COI Official shall document each retrospective review, including but not limited to the following key elements:

(1) Project number;

(2) Project title;

(3) Investigator contact(s);

(4) Name of the Investigator with the FCOI;

(5) Entity with which the Investigator has a FCOI;

(6) Reason(s) for the retrospective review;

(7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

(8) Findings of the review; and

(9) Conclusions of the review (i.e., determination, recommended actions, and remedial measures implemented).

c. If bias is found, the COI Official shall promptly notify the granting agency and submit a mitigation report as required by federal law. If new information is discovered during the retrospective review that was not reported to the granting agency, the COI Official shall update the FCOI report information to provide the information as described in this policy.

12.02 Clinical Research Requirements

In addition to the actions described above, the following requirements apply to PHS-funded clinical research involving drugs, devices, or treatments.

a. If the U.S. Department of Health and Human Services (HHS) determines that a PHS–funded clinical research project conducted under the auspices of SHSU, and evaluating the safety or effectiveness of a drug, medical device, or treatment, was designed, conducted, or reported by an Investigator with an unmanaged or unreported FCOI, SHSU will require corrective actions consistent with federal regulations and institutional policy.

b. At a minimum, the Investigator will be required to disclose the identified FCOI in all future public presentations or disclosures of the research results and to request appropriate corrections, errata, or addenda to any previously published or presented research findings, as applicable. Sam Houston State University may impose additional management measures or sanctions as necessary to protect the integrity of the research and to ensure compliance with applicable federal and institutional requirements.

13. RESEARCH THROUGH CONTRACTORS OR SUBCONTRACTORS

13.01 If University-sponsored research is conducted through a subrecipient (e.g., subcontractors or consortium members), the University shall take reasonable steps to ensure that subrecipient Investigators comply with federal FCOI regulations by:

a. Incorporating into a written agreement, such as a Memorandum of Understanding (MOU) or contract, with the subrecipient terms that establish whether the FCOI policy of the University or that of the subcontractor will apply to the subrecipients' Investigators;

(1) If the subrecipient's policy applies, the subrecipient shall certify that its policy complies with federal regulations. The agreement shall specify that the subrecipient must report all identified FCOIs to the University within 50 to 55 days of identification. This ensures the University has sufficient time to review and submit the mandatory FCOI report to the awarding component within the required 60-day window.

(2) If the University's policy applies, the agreement shall specify

the time periods (e.g., 30 days) for the subrecipient to submit all Investigator SFI disclosures to the University for review, management, and reporting.

b. The University shall provide FCOI reports to the awarding component regarding all identified financial conflicts of interest of subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI

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13.02 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 FCOI may occur when an Investigator's Significant Financial Interest (SFI) related to their Institutional Responsibilities is associated with the external organization is associated with the external organization involved in the research.

a. The Investigator receives remuneration from, or holds an equity interest in, an external organization either funding a sponsored project or providing goods or services under a sponsored project on which the Investigator is participating in any capacity.

b. The Investigator holds an equity interest in a non-publicly traded entity involved in the research or receives remuneration from a publicly traded entity involved in the research that exceeds $5,000, when aggregated for the Investigator and the Investigator's spouse and dependent children over the twelve months preceding the disclosure.

c. The Investigator's spouse or dependent children meet any of the criteria stated above.

d. Each Investigator participating in externally funded research must disclose all Significant Financial Interests (SFIs) related to their Institutional Responsibilities in accordance with this policy. SFI disclosures must be completed prior to the expenditure of funds and updated at least annually.

e. Investigators must also update their disclosures within thirty (30) days of acquiring or discovering a new Significant Financial Interest during the period of the award. All disclosed SFIs will be reviewed by the designated Institutional Official to determine whether a Financial Conflict of Interest (FCOI) exists.

13.03 In reviewing the required disclosures relating to research through contractors and subcontractors, the COI Official will:

a. Ensure adherence to the applicable federal regulations, including 42 CFR Part 50 Subpart F, as well as Texas State University System Rules and Regulations and relevant University policies; Consider the nature and extent of the significant financial interest and its relationship to the Investigator's Institutional Responsibilities and the external organization.

b. Give appropriate consideration to the terms and conditions of sponsored project agreements that may mitigate or complicate the identified FCOIs.

c. Consult with and obtain additional information from the investigator, as deemed necessary by the COI Official, to support the review and determination of any SFI and potential FCOI.

d. Act in a timely manner so as not to delay unduly the conduct of the externally funded project.

e. Recommend that the University may take one of the following actions:

(1) Accept the externally funded project award;

(2) Not accept the externally funded project award;

(3) Accept the externally funded project subject to suitable modifications in the project award document; or

(4) Accept the project subject to suitable modifications in the external organizational affiliation(s) of the investigator or the external organizational affiliation(s) of the investigator's family.

13.04 If an individual is dissatisfied with the COI Official's determination, then they may appeal this decision. Any appeals are governed by the processes outlined in section 8 (Appeals).

13.05 The 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 Senior/Key Personnel, the COI Official, the Provost, and others who have a legal right to review the records.

13.06 Records will be retained for seven (7) 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.

13.07 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.

13.08 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 complies with their institutional policies, and their institutional policies comply 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 comply with company policies.

14. TRAINING, EDUCATION, AND CERTIFICATION

14.01 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)).

14.02 Each Investigator must certify that they have read this policy and are aware that federal regulations may apply to their externally funded research project. Each Investigator must also certify that they are aware of the various responsibilities regarding disclosure of significant FCOIs.

14.03 Prior to engaging in research on behalf of the University and at least every four years during periods of continued research activity, each Investigator 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.

14.04 The 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.

14.05 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.

14.06 Additional training may be required promptly following a determination of noncompliance with this Policy or an approved FCOI management plan, as directed by the ORSP when any of the following circumstances apply:

a. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

b. An Investigator is new to an Institution; or

c. An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

14.07 To supplement the training requirements, Investigators may utilize NIH's training programs, including:

- The NIH Training module: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training.

- The NIH Virtual Seminar (https://www.youtube.com/watch?v=D292YZ6BX24) presentation on FCOI compliance available via the NIH YouTube channel.

15. ENFORCEMENT ACTIONS FOR INVESTIGATOR NONCOMPLIANCE

In the event an Investigator fails to comply with this Policy, the COI Official may recommend suspension of all relevant activities of the Investigator and recommend disciplinary or other administrative action pursuant to this policy to the Provost. Disciplinary actions may include, but are not limited to, a reprimand, oral or written, private or public; a period of suspension with or without pay; a reduction in salary; removal of privileges; or dismissal in accordance with all applicable Texas State University System Rules and Regulations and University policy.

16. USEFUL FCOI AND NIH RESOURCES

- NIH e-mail for FCOI-related inquiries: fcoicompliance@mail.nih.gov
- NIH FCOI Policy Home Page: https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi
- Full Text of 42 CFR Part 50 Subpart F: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F

17. POINT OF CONTACT

For questions related to this policy or to disclose a financial interest, please contact:
Office of Research Administration (ORA)
1 Financial Plaza, Suite 330, Huntsville, TX 77340
936-294-3860; ora@shsu.edu

APPROVED: <signed>
Alisa White, Ph.D., President

DATE: 10/28/2026

CERTIFICATION STATEMENT

This academic policy statement (APS) has been approved by the reviewer 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:	Five years*
Reviewer:	Academic Affairs Council	Review Date:	Fall 2031

Approved: <signed> Date: 10/22/2026

Sumanth Yenduri, Ph.D.,
Provost and Sr. Vice President
for Academic Affairs

*Effective January 2018, Academic Policy Statements will be reviewed on a rotating 5-year schedule. To transition to a distributed review load, some policies may be reviewed prior to the 5-year timeframe, with subsequent reviews transitioning to the 5-year schedule.