

1. PURPOSE

- 1.01 This policy outlines the procedures and responsibilities necessary to avoid and/or resolve Conflicts of Interests (COIs) whether Financial Conflicts of Interest (FCOIs) or Conflicts of Commitment (COCs) in research in accordance with federal laws to address significant conflicts when they appear to affect or bias the design, conduct, or reporting of research.
- 1.02 The University is responsible for identifying, managing, and eliminating COIs in research that may develop because of financial interests or time commitments of Investigators (whether Principal Investigators (PIs), CO-Principal Investigators (CO-PIs), or any other individual who participates in the design, conduct, or reporting of sponsored research. Therefore, the University requires Investigators to disclose COIs related to their research activities.

2. APPLICABILITY

- 2.01 This policy applies to all University employees engaged in sponsored research. The University is concerned with two broad types of conflict:

Financial Conflicts of Interest (FCOI), which typically involves potential financial gain or personal benefit to an employee or related individuals or entities; and

Conflicts of Commitment (COC), which typically arise when otherwise acceptable outside activities may compromise the fulfillment of an employee's basic job responsibilities to the University.

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

3. DEFINITIONS

- 3.01 Conflicts of Commitment (COCs) denotes situations in which an Investigator's external relationships or activities have the possibility (either in actuality or in appearance) of interfering or competing with the

University's educational, research, or service missions, or with that individual's ability or willingness to perform the full range of duties and responsibilities associated with his or her position. It includes the performance of duties for an external entity substantially similar to or in competition with any portion of the individual's employment responsibilities as described in the individual's position description, letters of appointment, and workload assignments.

- 3.02 Conflict of Interest (COI) is the conflict between an Investigator's interests and professional judgement. Conflicts of Interests can be FCOI's and/or COC's.
- 3.03 Disclosure of Significant FCOIs and COCs means an Investigator(s) disclosure of significant COIs to the University.
- 3.04 Family refers to an employee's spouse, domestic partner, children, parents, siblings, grandparents, parents-in-law, brothers-in-law, sisters-in-law, or any member of one's household.
- 3.05 Financial Conflict of Interest (FCOI) arise when Investigators are in a position to gain, or appear to gain, financial advantage or personal benefit (broadly construed) arising from their university positions, either through outside professional activities or through research, administrative, or educational actions or decisions at the University or when an Investigator uses university employment to obtain unauthorized privileges, benefits, or things of value for oneself or others.
- 3.06 Conflict of Interest Report is a report of a FCOI or a COC to the University or an awarding component.
- 3.07 Financial interest means anything of monetary value, whether or not the value is readily ascertainable.
- 3.08 Institution means Sam Houston State University unless otherwise indicated.
- 3.09 Institutional responsibilities are the Investigators professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on COIs, which may include activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels.
- 3.10 An investigator is a Principal Investigator (PI), a Co-Principal Investigator (CO-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.

- 3.11 Manage means taking action to address a FCOI or a COC, which can include reducing or eliminating the financial conflict of interest or time commitment to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
- 3.12 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.
- 3.13 Significant financial interest means:
 - a. A financial interest consisting of one or more of the following interests of the Investigator (and/or 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 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.
- 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 agencies, 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.

Investigators must disclose, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration of the trip. 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 COI with the funded research.

- c. Significant financial interest does not include:
- (1) Salary, royalties, or other remuneration paid by the Institution 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 agencies, 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 agencies, 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.
- (6) Regardless of the above minimum requirements, an Investigator in their own best interest may choose to disclose any other financial or related interest that could present an actual or perceived COI.

4. CONFLICT OF INTEREST OFFICIAL

The University President shall appoint a COI Official who will be responsible for oversight and compliance with this policy. The COI is the Chief Research Officer at Sam Houston State University.

5. DISCLOSURE OF SIGNIFICANT FINANCIAL CONFLICTS OF INTERESTS, CONFLICTS OF COMMITMENT, AND OUTSIDE EMPLOYMENT

5.01 University employees are required to disclose actual, apparent or potential FCOIs or COCs in three ways:

- a. Within 30 days, as potential conflicts arise but preferably before participating in the activity;
- b. As part of the proposal process for sponsored research awards. All Investigators (if required by the sponsor) must certify that no conflicts exist in the routing certification process and as required by the sponsor in sponsored research proposals;

- c. As part of the annual Disclosure campaign distributed by The Office of Research and Sponsored Programs (ORSP).
- 5.02 Each Investigator must submit to or update with the ORSP a Conflict of Interest Disclosure Statement using the Outside Interests Disclosure form (OID) as defined below. This Disclosure Statement:
- a. Identifies potentially conflicting research or research activities in which the Investigator is engaged at the time the financial disclosure statement is submitted to the ORSP; and
 - b. Discloses the following information for each significant conflict of 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) 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;
 - (4) A description of research conducted under any external (non-university) awards or subawards that are not managed by SHSU including details pertaining to other affiliations other than SHSU 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 Conflict of Interest Disclosure Statement using the OID for each immediate 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 having an interest in a

company and then purchasing goods or services from that company on behalf of the University.

- b. Individuals may not participate in the hiring process or any employment-related decisions pertaining to their family members. Likewise, they may not be in a position to supervise a family member as an employee of the University or otherwise review or participate in reviewing a family member's work as an employee of the University.
- c. Employees are required to promptly complete a conflict-of-interest disclosure 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.
 - (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 Conflict of Interest Disclosure Statement using the OID (<https://shsu.app.cayuse.com/>).

5.05 An Investigator or immediate family member shall provide any additional documentation related to the significant financial interests disclosed on a Conflict of Interest Disclosure Statement upon request of the COI Official.

5.06 An Investigators outside employment can create a COI and may, in some instances, violate laws regarding dual state employment. Therefore, full-time employees should review the SHSU Academic Policy Statement 860811 (Outside Employment for Faculty) and the HR-01 Conflicts of Interest Policy. All university employees must receive prior written approval via the Outside Employment Form executed by the employee's supervisory authorities through the Division Vice President before engaging in outside employment.

6. REVIEW OF FINANCIAL DISCLOSURE STATEMENTS

- 6.01 The COI 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 COI Official may deem appropriate.
- 6.02 An 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 reasonably determines that a significant financial interest held by an Investigator or an immediate family member could directly and significantly affect the design, conduct, or reporting of the Investigator's research.
- 6.04 A COC exists when the COI Official reasonably determines that one's commitment of time and effort are inconsistent with one's commitment to the Institution and its interests.
- 6.05 Appeal. Any Investigator may appeal the decision of the COI in writing to the Provost and Senior Vice President for Academic Affairs (Provost) regarding management of a FCOI or COC. A 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. The Committee's summary of findings and specific recommendations as to modifications of the management plan to eliminate, reduce, or more effectively manage the FCOI or COC will be submitted back to the Provost for review.

7. CERTIFICATION AND REPORTING

- 7.01 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.
- 7.02 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 a COI related to any grant-funded research.

8. 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 COI Official has determined that no COI exists or that any identified COI is manageable under the terms of a management plan that has been adopted and implemented.

9. MANAGEMENT OF FINANCIAL CONFLICTS OF INTEREST AND CONFLICTS OF COMMITMENT

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

9.02 Examples of conditions or restrictions that might be imposed to manage, reduce, or eliminate an Investigator's conflict might include:

- a. Public disclosure of the conflict;
- b. For research projects involving human subjects, disclosure of the conflict 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 conflict;
- d. Requiring a change in personnel and/or responsibilities for all or a portion of the research activities;
- e. Disqualification of personnel from participation in that portion of the research activities that would be affected by the conflict;
- f. Severance of relationships that create the conflict.

9.03 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) for potential COIs.

9.04 The management plan must be signed by the Investigator, the Investigators supervisor, and approved by the COI Official.

9.05 If an Investigator disagrees with the COI Official's determination that an FCOI or COC exists, they may appeal the COI Official's determination in writing to the Provost within ten (10) business days after receiving the COI Official's

determination.

10. PUBLIC ACCESSIBILITY

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

10.02 For any grant-funded research:

a. If the COI Official decides that a COI exists that is related to grant-funded research, the COI Official will make the following key information available to the public:

- (1) The name of the Investigator;
- (2) The title and role of the Investigator in relation to the affected research;
- (3) The name of the entity in which the significant financial interest is held;
- (4) A description of the significant financial interest that was determined to be a COI; and
- (5) 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 methods, the 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).

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 Investigator;
- (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 COI.
- 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.

11. RETROSPECTIVE REVIEW

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

- a. In accordance with the regulatory requirement (42 CFR §50.605(a)(3)), if the COI Official discovers a COI 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 COI Official shall, within 120 days after determining noncompliance:
 - (1) Complete a retrospective review of the Investigators 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
 - (2) 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)).
- 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 COI;

- (5) Entity with which the Investigator has a COI;
 - (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 notify the granting agency and submit a mitigation report as required by federal law. If necessary, the COI Official shall update the COI information.

12. RESEARCH THROUGH CONTRACTORS OR SUBCONTRACTORS

- 12.01 If university sponsored, federally funded research is conducted through a subcontractor, the University must take reasonable steps to ensure that subcontractor's 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 COI policy or that of the subcontractor, apply to the subawardees' Investigators;
 - b. Providing COI reports to the awarding component by subcontractors' Investigators, as defined in this policy, prior to expenditure of funds and within 60 days of any subsequently identified COI;
 - c. Submitting an updated disclosure of significant financial interests within 30 days of acquiring a new significant financial interest by each Investigator participating in grant-funded research.
- 12.02 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 COI 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 COI. COI Disclosure Statement 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. An Investigator, who is faculty, must send a COI Disclosure Statement which has been signed by the department chair and academic dean to the COI Official. Similarly for staff members, the form should be signed by an immediate supervisor.
 - f. Investigators must update their COI Disclosure Statement during the period of an award, as the status of these disclosures change, and report new external affiliations that may constitute additional COI.
- 12.03 In reviewing the disclosure forms relating to research through contractors and subcontractors, the COI 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 COI 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 COI 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.

12.04 If a faculty/staff member is dissatisfied with the COI Official's determination, then the faculty/staff member may appeal this decision.

12.05 The Office of Research Administration (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 COI Official, Council of Academic Deans (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 five (5) 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.

12.06 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.

- 12.07 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 COI 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 COI disclosure as well as certifications that projects comply with company policies.

13. TRAINING, EDUCATION, AND CERTIFICATION

- 13.01 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)).
- 13.02 Each Investigator must certify that they have read this policy and is aware that federal regulations may apply to their sponsored research project. Each Investigator must also certify that they are aware of the various responsibilities regarding disclosure of significant FCOIs and COCs.
- 13.03 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.
- 13.04 The ORSP shall document an Investigators compliance with applicable training requirements. The ORSP shall maintain all documentation related to an Investigator's compliance with this training requirement.
- 13.05 The ORSP shall require all Investigators to comply with the above training requirements if it is determined that COI 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.

