

Financial Conflicts of Interest in Sponsored Activities

Original Implementation: January 30, 1996

Last Revision: July 28, 2015

1. Introduction

The purpose of this policy is to protect the credibility and integrity of Stephen F. Austin State University's (SFA) faculty and staff by ensuring public trust and confidence in the university's research and grants, contracts, and other sponsored agreements (grants) by identifying and then managing, reducing, or eliminating actual or potential conflicts of interest.

A potential conflict of interest occurs when divergence exists between the private interests of individuals and their professional obligations to the university, to the extent that an independent observer might reasonably question whether an individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation and not on the character or actions of the individual. In some cases, it also might be appropriate to voluntarily report apparent nonfinancial conflicts of interest and the steps taken by SFA to mitigate them, such as relationships between grant and university personnel.

The university shall take all necessary steps to assure that any identified actual or potential financial conflicts of interest are managed, reduced, or eliminated prior to the university's expenditure of any funds under an award, and if required by a sponsor, certify to the funding agency that this has been done or report conflicts that cannot be satisfactorily managed, reduced, or eliminated.

As defined in section II, all investigators are required to disclose any significant financial interest that could directly or indirectly affect the design, conduct, and/or reporting of research and/or affect professional judgment in the conduct of grants.

Federal awarding agencies must establish conflict of interest policies for their awards that require the awardee to disclose in writing any potential conflict of interest (2 C.F.R. § 200.112). This policy has been developed to address financial conflicts of interest in grants in general, with specific requirements to address regulations for Public Health Service supported research. Investigators will be required to comply with each individual federal awarding agency's policies. State laws regarding employee conduct may also apply to situations involving potential financial conflicts of interest.

Additional requirements are outlined in section VI that pertain specifically to Public Health Service (PHS) sponsored research grants and to research sponsored by other federal agencies

with similar financial conflict of interest regulations.

2. Definitions

Compliance Coordinator (CC): an individual in the Office of Research and Sponsored Programs (ORSP) designated to coordinate financial conflict of interest requirements for grants at the proposal and award stages.

Disclosure of significant financial interests: an investigator's disclosure of significant financial interests to the university.

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.

Financial conflict of interest (FCOI): a significant financial interest that could directly and significantly affect the design, conduct, or reporting of grant activities.

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

Institutional responsibilities: an investigator's professional responsibilities on behalf of the university, which for faculty includes teaching, research, service and other scholarly and professional activities and for staff includes job-related activities.

Institutional Official (IO): the provost and vice president for academic affairs.

Investigator: a project director (PD) or principal investigator (PI) and any other person, regardless of title or position, who is identified as: (a) senior/key personnel in the grant application, progress report, or any other report submitted to a funding agency; (b) a responsible party on applications for the use of human or animal subjects; and (c) responsible for the design, conduct, or reporting of grant activities.

Manage/Management Plan: taking action to address a FCOI, which can include reducing or eliminating the conflict of interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

Public Health Service (PHS): an entity of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, which includes agencies such as the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Health Resources and Services Administration (HRSA).

Research: 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 and product development..

Responsible Official (RO): the director of the Office of Research and Sponsored Programs.

Significant financial interest: a financial interest that must be disclosed by an investigator that: (a) consists of one or more of the following interests of the investigator, and/or the investigator's spouse and dependent children, or any other financially interdependent individual in the household; (b) which reasonably appears to be related to the investigator's institutional responsibilities; and (c) was received, obtained, or held during the twelve (12) months preceding the disclosure.

Information that must be disclosed by an investigator includes:

1. Payments from or an equity interest in a publicly-traded entity 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 together exceed \$5,000. Remuneration includes any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);
2. Payments from or an equity interest in a non-publicly traded entity if the value of any remuneration received from the entity in the twelve months preceding the disclosure exceeds \$5,000 and any equity interest is held;
3. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; and
4. Travel payments (reimbursements or amounts paid on behalf of the investigator) related to institutional responsibilities (this requirement only applies to investigators with PHS supported research or other Federal sponsors with similar FCOI requirements).

Information that is excluded from disclosure by an investigator includes:

5. Salary, royalties, or other remuneration paid by the university to the investigator if the investigator is currently employed or otherwise appointed by SFA, including intellectual property rights assigned to SFA and agreements to share in royalties related to such rights;
6. Income from certain investment vehicles, such as mutual funds and retirement accounts, as long as the investigator does not directly control the investment decisions made in these vehicles; and
7. Income from seminars, lectures, or teaching engagements, or income from service on

advisory committees or review panels 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.

Regardless of the above minimum requirements, investigators 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.

Grants: all externally funded activities, including but not limited to research, public service, instruction, and/or training activities funded by grants, contracts, cooperative agreements, or other sponsored agreements.

3. Responsibilities Regarding FCOI

1. **Investigator** – It is the responsibility of the investigator to:
 1. file and update a PI/PD Conflict of Interest (FCOI) Disclosure and Certification for Sponsored Projects form with each grant application and a Disclosure of Substantial Interest form as needed. ;
 2. file and update a Disclosure of Substantial Interest form in other instances as outlined in this policy;
 3. acknowledge in the disclosure form their understanding of this policy and applicable federal regulations;
 4. provide additional information and documentation required to meet the terms of this policy when requested by university officials; and
 5. complete FCOI training as required by this policy.
2. **Institutional Official (IO)** – It is the responsibility of the IO to:
 1. review Conflict of Interest (FCOI) Disclosure and Certification for Sponsored Projects and Disclosure of Substantial Interest forms related to grants;
 2. determine if a FCOI exists with regard to grant funding, appoint a committee as required to assist in the decision, and make recommendations regarding management of any such conflict of interest;
 3. if indicated, develop a plan for management of the conflict in consultation with the investigator and in conjunction with the appointed committee, the university's general counsel and other university officials, as appropriate; and
 4. determine the appropriate individual to monitor implementation of the plan, as needed.
3. **Compliance Coordinator (CC)** – It is the responsibility of the CC to:
 1. verify that Conflict of Interest (FCOI) Disclosure and Certification for Sponsored Projects and as needed, Disclosure of Substantial Interest forms are

- on file for investigators prior to submitting applications to any entity;
 - 2. verify that Conflict of Interest (FCOI) Disclosure and Certification for Sponsored Projects and as needed, Disclosure of Substantial Interest forms are on file for investigators after an award is made and prior to the expenditure of funds;
 - 3. provide disclosure and reporting requirements to any subrecipients related to an award from a Federal sponsor; and
 - 4. communicate with the investigator regarding the status of the project with regard to compliance with this policy, including applicable training requirements.
4. **Responsible Official (RO)** – It is the responsibility of the RO to:
- 1. provide general oversight to the FCOI reporting and management process as it relates to research and other sponsored activities;
 - 2. participate in the review of Conflict of Interest (FCOI) Disclosure and Certification for Sponsored Projects and Disclosure of Substantial Interest forms and in the development of management plans, as requested by the IO; and
 - 3. submit conflict of interest reports to the sponsoring agency as required by the PHS or any other Federal agency.
4. **FCOI Reporting and Review Procedures**
- 1. **Timeline for Disclosures**
 - 1. all investigators are required to disclose significant financial interests on the Conflict of Interest (FCOI) Disclosure and Certification for Sponsored Projects form and as needed, a Disclosure of Substantial Interests form prior to the submission of every grant application;
 - 2. during the year as needed and no later than thirty (30) calendar days after a new, reportable significant financial interests is obtained such as an increase in value that meets the reporting threshold, as well as the acquisition of new interests that are reportable (for example, through purchase, marriage, or inheritance); and
 - 3. for new investigators, within thirty (30) calendar days of joining an active grant.
 - 2. **Disclosure Period** - Each individual completing the Disclosure of Substantial Interest form must list any financial interests for the preceding twelve (12) months that appear to be related to the investigator’s institutional responsibilities and that might reasonably appear to affect the grant activities funded, or proposed for funding.
 - 3. **Disclosure Review Process** - The IO shall conduct an initial review of all financial disclosures related grants in consultation with the RO or other official designee of the university, as appropriate. If an initial determination is made that there may be a potential for conflict of interest covered by this policy, additional information will be

requested from the investigator.

A potential FCOI also may be referred to an investigating committee for review. If it is determined by the IO that a committee should be formed, members will be appointed by the IO after consultation with the RO, who serves as chair. If it is determined that a conflict of interest exists, the IO and/or the investigating committee shall determine what conditions or restrictions, if any, should be imposed by the university to manage actual or potential conflicts of interest arising from such disclosures.

4. **Records Retention** - Records of investigator financial disclosures, the university's review and response to disclosures, and of actions taken to manage actual or potential conflicts of interest, as applicable to grants shall be retained by ORSP according to each sponsor's retention requirements, or the resolution of any government action involving those records, or where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 for PHS supported research or other agency regulations.
5. **Enforcement** - The IO shall be responsible for determining and implementing sanctions on investigators who have violated this policy in terms of a conflict of interest resolution. The investigator shall be notified in writing of the recommended sanctions within twenty-one (21) calendar days of the discovery of the violation. If the sanctions involve a recommendation for termination of employment, the university's termination procedures shall be invoked. The university must take action as warranted by the seriousness of the violation including, but not limited to, one or more of the following:
 - removal from the activity;
 - special monitoring of future work;
 - letter of reprimand;
 - probation with conditions specified; and/or
 - termination.

Additionally, the university shall follow PHS and other applicable Federal regulations regarding the notification of a sponsoring agency in the event an investigator has failed to comply with this policy.

Individuals may appeal the judgment and/or the sanction. A written statement of the grounds for the appeal must be submitted to the president of the university within thirty (30) working days of written notification of the sanctions. Grounds for appeal include, but are not limited to, previously unconsidered material evidence, sanctions not commensurate with the finding, and failure to follow the prescribed process. Upon receipt of a written appeal, the president shall evaluate the evidence and make a determination. The president shall open an investigation if circumstances so dictate.

The president's decision shall be conveyed to all parties within thirty (30) working days.

5. **FCOI Information Dissemination and Training**

1. **Information Dissemination** - The Office of Research and Sponsored Programs will inform each investigator applying for grants of the university's policy on financial conflicts of interest, the investigator's responsibilities regarding disclosure of significant financial interests, and any applicable Federal regulations regarding FCOI. Such information will also be posted on the ORSP website.
2. **Mandatory Training** - Each investigator who is awarded a PHS research award or an award from a Federal agency with similar FCOI training requirements shall complete a training session on FCOI prior to engaging in the grant activity and subsequently every four (4) years. In addition, training is required for these individuals immediately when: (1) the university revises its financial conflict of interest policies or procedures in any manner that affects the requirements of investigators; (2) an investigator on a PHS supported award is new to the university; or (3) if the university finds that an investigator is not in compliance with this policy or a prescribed FCOI management plan.
3. **Subrecipients** - If the university carries out research through a subrecipient (e.g., subcontractors or consortium members) that is supported by the PHS or by a Federal agency with similar FCOI reporting and/or training requirements, the university (awardee institution) will take reasonable steps to ensure that any subrecipient investigator complies with the training requirement described in B. above by incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the university or that of the subrecipient will apply to the subrecipient's investigators. The agreement referenced shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the university. Such time period(s) shall be sufficient to enable the university to provide timely FCOI reports, as necessary, to the PHS or other Federal agencies as required by the agency.

6. **Special Provisions for Managing and Reporting Financial Conflicts of Interest for Public Health Service (PHS) Supported Research**

1. **Management Plan**

For PHS supported research, resolution of any potential or actual conflicts of interest shall not be required until after funding has been approved and prior to any expenditure of funds under the PHS supported award. Prior to the expenditure of any funds under a PHS-funded research project, the IO shall develop and implement a management plan that shall specify the actions that have been and shall be taken to manage such financial

conflict of interest.

The IO, along with any investigating committee, the investigator, the RO, and other university officials as required, shall proceed to resolve any actual or potential problems revealed by the initial review of financial disclosures. In order for the conflict to be managed, reduced, or eliminated, the IO may recommend:

1. public disclosure of significant financial or related interests(e.g., during presentations or in publications);
2. for research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants prior to participation;
3. monitoring of sponsored activities by independent reviewers;
4. modification of the research or other sponsored activity plan;
5. Change in personnel and/or disqualification from participation in all or a portion of the activity funded that would be affected by the significant financial interests;
6. divestiture of significant financial interests; and/or
7. severance of relationships that create actual or potential conflicts of interest.

If the IO, along with any investigating committee determines that imposing conditions or restrictions would either be ineffective or inequitable, and that the potential negative impacts that may arise from a significant financial interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, the IO and committee may recommend that, to the extent permitted by federal regulations, the sponsored activity go forward without imposing such conditions or restrictions. In these cases, the IO in consultation with the RO shall make the final decision regarding resolution.

The approved written resolution plan shall detail the conditions or restrictions imposed upon the investigator in the conduct of the sponsored activity or in the relationship with the enterprise or entity.

Actual or potential conflicts of interest shall be satisfactorily managed, reduced, or eliminated in accordance with these guidelines and all required reports regarding conflicts of interest submitted to the sponsor prior to the expenditure of any funds under an award.

2. Retrospective Review

For PHS supported research, whenever a significant financial interest is discovered that was not disclosed in a timely manner by an investigator, or for whatever reason, was not previously reviewed by the university during an ongoing PHS supported research

project (including subrecipients), the IO shall within sixty (60) calendar days:

1. review the significant financial interest;
2. determine whether it is related to PHS-funded research;
3. determine whether a financial conflict of interest exists; and, if so implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward.

In addition, if it is determined that the university failed to review or manage such a financial conflict of interest, or the investigator failed to comply with a financial conflict of interest management plan, the IO shall, within 120 calendar days of the university's determination of noncompliance, lead a retrospective review of the investigator's activities and the PHS supported research project to determine whether any PHS supported research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

The retrospective review shall be documented, and shall include at a minimum the following key elements:

4. project number;
5. project title;
6. PD/PI or contact PD/PI if a multiple PD/PI model is used;
7. name of the investigator with the FCOI;
8. name of the entity with which the investigator has a financial conflict of interest;
9. reason(s) for the retrospective review;
10. detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
11. findings of the review; and
12. conclusions of the review.

Based on the results of the retrospective review, if appropriate, the university shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the university shall notify the PHS awarding agency promptly and submit a mitigation report the agency. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the university's plan of action or actions taken to eliminate or mitigate the effect of the bias. Depending on the nature of the financial conflict of interest, the university may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS supported research project between the date that the financial conflict of interest or the investigator's

noncompliance is determined and the completion of the university's retrospective review.

3. Public Disclosure

Prior to the expenditure of any funds under a PHS supported research project, the university shall ensure public accessibility via written response to any requestor within five (5) working days of a request for information concerning any significant financial interest disclosed to the university that meets the following three criteria:

1. the significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;
2. the university determines that the significant financial interest is related to the PHS supported research; and
3. the university determines that the financial interest is a significant financial conflict of interest.

The information provided by written response to any requestor shall include at a minimum the following information:

4. the investigator's name;
5. the investigator's title and role with respect to the research project;
6. the name of the entity in which the significant financial interest is held;
7. the nature of the significant financial interest;
8. the approximate dollar value of the significant financial interest specified in ranges (e.g., \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value; and
9. will note that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 calendar days of the identification by the university of a new financial conflict of interest, which should be requested subsequently.

Information concerning the significant financial interests of an individual subject to this section shall remain available for at least three (3) years from the date that the information was most recently updated.

4. Reporting to PHS Agencies

Prior to the university's expenditure of any funds under a PHS supported research project, the university shall provide to the PHS agency an FCOI report regarding any investigator's significant financial interest found by the university to be conflicting and ensure that the university has implemented a management plan in accordance with PHS regulations. In cases in which the university identifies and eliminates a FCOI prior to the expenditure of PHS-awarded funds, an FCOI report is not required.

For any significant financial interest that the university identifies as conflicting subsequent to the initial FCOI report and during an ongoing PHS supported research project, the university shall provide within sixty (60) calendar days, a FCOI report to the PHS agency and ensure that a management plan has been implemented in accordance with PHS regulations. This includes results of a retrospective review, and in situations in which bias is determined, the university shall promptly notify and submit a mitigation report to the PHS agency.

Any FCOI report shall include sufficient information to enable the PHS agency to understand the nature and extent of the financial conflict, and to assess the appropriateness of the university's management plan. Elements of the FCOI report shall include, but are not necessarily limited to, the following:

1. project number;
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
3. name of the investigator with the significant financial conflict of interest;
4. name of the entity with which the investigator has a financial conflict of interest;
5. nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. value of the financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
7. a description of how the financial interest relates to the PHS supported research and the basis for the university's determination that the financial interest conflicts with such research; and
8. a description of the key elements of the university's management plan, including:
 1. role and principal duties of the conflicted investigator in the research project;
 2. conditions of the management plan;
 3. how the management plan is designed to safeguard objectivity in the research project;
 4. confirmation of the investigator's agreement to the management plan;

5. how the management plan will be monitored to ensure investigator compliance; and
6. other information as needed.

For any financial conflict of interest previously reported by the university with regard to an ongoing PHS-funded research project, the university shall provide to the PHS agency an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists.

5. Remedies

If an investigator fails to comply with this policy, or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of PHS-funded research, the university shall promptly notify the PHS agency of the corrective action taken or to be taken.

Cross Reference: 2 C.F.R. § 200.112; 42 C.F.R. Part 50, Subpart F; 45 C.F.R. Part 94, Faculty Handbook;; Ethics (2.6); Misconduct in Scholarly or Creative Activities (7.19); and Purchasing Ethics and Confidentiality (17.22).

Responsible for Implementation: Provost and Vice President for Academic Affairs

Contact for Revision: Director of Research and Sponsored Programs

Forms: Disclosure of Substantial Interest form; PI/PD Conflict of Interest (FCOI) Disclosure and Certification for Sponsored Projects form

Board Committee Assignment: Academic and Student Affairs