**Researcher Conflicts of Interest in UPPS No. 02.02.07**

**Research and Sponsored Program Issue No. 5**

**Activities Effective Date: 04/01/2022**

 **Next Review Date: 10/01/2025 (E3Y)**

**Sr. Reviewer: Assistant Vice President for Research**

**POLICY STATEMENT**

*Texas State University is committed to maintaining integrity of research conducted at or under the auspices of Texas State.*

**01. BACKGROUND INFORMATION**

01.01 To maintain a research environment that promotes the highest standards of integrity and ethics, Texas State University has established this policy to promote objectivity in research and to ensure that all research and sponsored program activity conducted by university researchers is free from bias resulting from conflicts of interest (COI).

01.02 The university is an institution of public trust, and researchers must respect that status and conduct their affairs in ways that will not compromise the integrity of the university or that trust.

01.03 The university recognizes its responsibilities to promote the public good by fostering the transfer of knowledge and encouraging research collaborations between its employees and the public and private sectors. It is often appropriate to reward faculty for participation in these activities through consulting fees, royalty sharing from the commercialization of their work, or other non-financial rewards or benefits. COI, financial or otherwise, are common and often unavoidable in this modern research environment.

01.04 This policy implements federal law and regulations adopted by the Public Health Service of the U.S. Department of Health ([42 C.F.R Part 50, Subpart F](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=8b75aacec77f0f4026c3c9a60325cf01&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#42:1.0.1.4.23.6)) and Human Services ([45 C.F.R. Part, 94, Subpart A](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45)) and the National Science Foundation ([NSF Award and Administration Guide 08-1 January 2008 Chapter V: Grantee Standards](http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510)) to address significant financial interests (SFI) which, because they reasonably appear to affect or bias the design, conduct or reporting of research, are considered financial conflicts of interest (FCOI).

01.05 This policy and resulting administrative procedures are additionally bound to compliance with the [Texas Education Code 51.912](http://www.statutes.legis.state.tx.us/Docs/ED/htm/ED.51.htm#51.912), [The Texas State University System (TSUS) Rules and Regulations, Chapter III sections 12(16)-12(18)](http://gato-docs.its.txstate.edu/tsus/general-counsel/2012-Rules---Regs-with-Feb---May-Revisions-FINAL/TSUS%20Rules%20and%20Regulations.pdf),Texas State’s [UPPS No. 04.04.06](http://policies.txstate.edu/university-policies/04-04-06.html), Outside Employment and Activities, [UPPS No. 01.04.02](http://policies.txstate.edu/university-policies/01-04-02.html), Ethics Policy, [UPPS No. 04.04.07](http://www.txstate.edu/effective/upps/upps-04-04-07.html), Nepotism and Related Employment, and [UPPS No. 02.02.08, Conflicts of Commitment in Research and Sponsored Program Activities.](http://policies.txstate.edu/university-policies/02-02-08.html)

**02. SCOPE**

02.01 Except as otherwise provided by federal law, this policy adopts standards for the disclosure of SFI and the management and reporting of FCOI beyond those required by federal law. Regardless of the funding source, the university requires investigators engaging in research and sponsored program activity to disclose SFI related to their institutional responsibilities.

02.02 With respect to certain specific procedures for the management and reporting of FCOI, this policy distinguishes between Public Health Service-funded research and other research and sponsored program activity.

02.03 This policy does not apply directly to conflicts of commitment situations involving researcher participation in activities external to, and in addition to, their commitment to Texas State. [UPPS No. 02.02.08](http://policies.txstate.edu/university-policies/02-02-08.html), Conflicts of Commitment in Research and Sponsored Program Activities, addresses these situations.

02.04 This policy does not apply to Phase I Small Business Innovation Research/Small Business Technology Transfer proposal applications and awards, but it does apply to Phase II Small Business Innovation Research/Small Business Technology Transfer applications and awards.

**03. DEFINITIONS**

03.01 Vice President for Research – individual ultimately responsible for the oversight of funded and unfunded research and sponsored programs at Texas State. The vice president for Research makes the final decision on resolution, mitigation, or management of all FCOI.

03.02 Conflict of Interest (COI) – occurs when an individual’s private interests compete with their professional obligations to the university to a degree that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial, or otherwise.

03.03 COI Official – the person appointed by the chief research officer who is responsible for implementing this policy and the requirements herein. The COI official is the assistant vice president for Research.

03.04 COI Review Committee – an ad hoc committee that may be assembled at the discretion of the COI official to provide expertise or recommendations regarding FCOI and related mitigation or management plans. Depending on the nature of both the FCOI and the research or sponsored program activity, voting members of the COI Review Committee may consist of faculty and professional academic and administrative staff and community members appointed by the COI official. Nonvoting members may include representatives from the Division of Research (DoR), Institutional Review Board, and The TSUS Office of General Counsel.

03.05 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.

03.06 Disclosure of Significant Financial Interests (SFI) – The investigator is required by this policy to submit an SFI disclosure on their own behalf or on behalf of a covered family member, if applicable, once annually at a minimum. SFI disclosures must be updated if an investigator’s interests change.

03.07 Financial Conflict of Interest (FCOI) – an SFI that could directly and significantly affect the design, conduct, or reporting of research or research activities. Examples of FCOIs include, but are not limited to:

a. situations where the investigator occupies a position in an enterprise seeking to engage in a business relationship with the university;

b. situations in which an investigator, while serving as a consultant to an external organization, has access to a colleague’s unpublished, privileged information, such as proposals or papers that have potential value, and the investigator seeks to provide that information to the external organization;

c. situations where an investigator directs students into a research area or other activity from which the investigator intends to realize personal financial gain. A conflict may arise if students are directed to areas of lesser scientific or scholarly merit to enhance the potential for monetary gain or if the financial potential exists only for the investigator;

d. disclosure or use for personal profit of unpublished information coming from research or other confidential institution sources, or assisting outside organizations by giving them access to such information, except as may be authorized by official institutional policies; or

e. situations in which an investigator can require others to purchase a product in which the investigator has a proprietary interest and from which the investigator will receive income.

03.08 FCOI Report – In the case of an FCOI affecting Public Health Service-funded research, prior to the university’s expenditure of any funds under a Public Health Service-funded research project, the university must provide to the Public Health Service an initial FCOI report regarding any investigator SFI found by the university to be an FCOI in accordance with the Public Health Service regulation. The university must also provide an FCOI report whenever an investigator does not disclose an SFI in a timely manner or whenever the university, for whatever reason, does not review a disclosed SFI and the university then determines that a FCOI exists. The university must also provide an annual FCOI report, due at the same time the university is required to submit the annual progress report, multi-year progress report, or at the time of extension.

03.09 Institutional Responsibilities – include the investigator’s professional responsibilities within the investigator’s field of discipline on behalf of the university, including teaching, research, research consultation, professional practice, committee memberships and service. This term includes consulting and other external employment such as the examples in Sections 04.01 and 04.02 of [UPPS No. 02.02.08](http://policies.txstate.edu/university-policies/02-02-08.html), Conflicts of Commitment in Research and Sponsored Program Activities. However, this term does not include external employment approved under [UPPS No. 04.04.06](https://policies.txstate.edu/university-policies/04-04-06.html), Outside Employment and Activities.

03.10 Investigator – the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research or sponsored program activities. This does not include students unless a student works independently of the principal investigator or senior personnel. Nor does it include adjunct faculty members unless the adjunct faculty member conducts research or sponsored program activities on behalf of the university.

03.11 Management Plan – a plan for addressing or mitigating an FCOI.

1. Managing an FCOI may mean reducing or eliminating the conflict by imposing one or more conditions or restrictions to ensure that the design, conduct, and reporting of research will be free from bias. Examples of conditions or restrictions that might be imposed to manage an investigator’s FCOI include, but are not limited to:

1) public disclosure of financial conflicts of interests (e.g., when presenting or publishing the research; to staff members working on the project; to institution’s Institutional Review Board);

2) for research projects involving human subjects research, disclosure of FCOI to participants;

3) appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;

4) modification of the research plan;

5) change of personnel or personnel responsibilities, or disqualifications of personnel from participation in all or a portion of the research;

6) reduction or elimination of SFI (e.g., sale of an equity interest); or

7) severance of relationships that create financial conflicts.

b. In the case of an FCOI affecting Public Health Service-funded research, neither the federal regulation nor Public Health Service prescribes a specific format for an institution’s management plan, but a description of the management plan is one of the key elements of the FCOI report. Public Health Service regulations require that the FCOI report contain a description of the key elements of the management plan including the following:

1) the 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.

03.12 Research Integrity and Compliance (RIC) – Within DoR, RIC is responsible for ensuring compliance with federal regulations, laws, and policies governing the conduct of research. RIC assists the COI official with the implementation of this policy and the requirements herein.

03.13 Pre- and Post-Award Support Services – Within DoR, Pre- and Post- Award Support Services provides investigators assistance with proposal submission, grants accounting, and other aspects of research or sponsored program activity.

03.14 Research or Sponsored Program Activity – any systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research, scholarship (e.g*.*, a published article, book, or book chapter) and product development (e.g*.*, a diagnostic test or drug). The term also includes educational activities funded, or proposed for funding, by the National Science Foundation and other sponsors or funders.

03.15 Senior or Key Personnel – the investigator and any other persons identified as senior or key personnel by the university in a grant application, progress report, or any other report submitted to a sponsor or funder by the university pursuant to the requirements in this policy.

03.16 Significant Financial Interest (SFI)

a. An SFI is a financial interest consisting of one or more of the following interests of the investigator (and those of the investigator’s covered family members) that reasonably appears to be related to the investigator’s institutional responsibilities:

1. With regard to any publicly-traded entity, an SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
2. With regard to any non-publicly-traded entity, an SFIexists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000, or when the investigator (or the investigator’s covered family members) holds any equity interest (e.g., stock, stock option, or other ownership interest);
3. intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests; or
4. travel that is sponsored or reimbursed. Investigators participating in Public Health Service-funded research or submitting a proposal to the Public Health Service must disclose reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education (as defined in [20 U.S.C. 1001(a)](http://www.gpo.gov/fdsys/search/pagedetails.action?packageId=USCODE-2011-title20&granuleId=USCODE-2011-title20-chap28-subchapI-partA-sec1001)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. At a minimum, the investigator shall disclose the purpose of the trip, the identity of the sponsor or organizer, the destination, and the duration. In accordance with this policy, the COI official will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the Public Health Service-funded research.

b. Significant financial interest does not include the following types of financial interests:

1. salary, royalties, or other remuneration paid by the university to the investigator if the investigator is currently employed or otherwise appointed by the university, including intellectual property rights assigned to the university and agreements to share in royalties related to such rights;
2. income from 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;
3. income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government agency, an institution of higher education (as defined in [20 U.S.C. 1001(a)](http://www.gpo.gov/fdsys/search/pagedetails.action?packageId=USCODE-2011-title20&granuleId=USCODE-2011-title20-chap28-subchapI-partA-sec1001)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education;
4. income from service on advisory committees or review panels for a federal, state, or local government agency, an institution of higher education (as defined in [20 U.S.C. 1001(a)](http://www.gpo.gov/fdsys/search/pagedetails.action?packageId=USCODE-2011-title20&granuleId=USCODE-2011-title20-chap28-subchapI-partA-sec1001)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; and
5. travel that is reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education (as defined in [20 U.S.C. 1001(a)](http://www.gpo.gov/fdsys/search/pagedetails.action?packageId=USCODE-2011-title20&granuleId=USCODE-2011-title20-chap28-subchapI-partA-sec1001)), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

**04. PROCEDURES**

04.01 COI Official

a. The COI official shall perform the duties established in this policy relating to the review of SFI disclosures and the management and reporting of FCOI.

04.02 Investigator Compliance – In addition to other responsibilities as specified in this policy and the corresponding procedures, investigators shall be responsible for:

a. reading, understanding and complying with this policy and with the corresponding procedures, as applicable;

b. informing all co-investigators, staff, students, contractors, collaborators, sub-recipients, and other individuals responsible for the design, conduct, or reporting of the investigator’s research of their obligation to comply with this policy;

c. cooperating with the COI official and the DoR to ensure compliance with all requirements set forth in this policy;

d. complying with the terms and conditions of SFI disclosures and management plans as described in this policy and in related procedures;

e. certifying at several stages of the proposal submission process that:

1) they do not have an FCOI or potential FCOI with the funder of the proposed research, and that they have a current SFI disclosure on file; or

2) disclosing any FCOI or potential FCOI with the funder of the proposed research, submitting an updated SFI disclosure and, if applicable, additional information as required by the COI official in order to make a determination regarding FCOI.

04.03 Disclosure of SFI – Each investigator must disclose their SFI (and those of the investigator’s covered family members) that reasonably appear to be related to the investigator’s institutional responsibilities.

a. Investigators must disclose SFI via a Disclosure of Significant Financial Interests form, available on the [DoR website](http://www.txstate.edu/research/orc/researcher-conflict-of-interest.html).

b. Investigators shall submit or update a Disclosure of Significant Financial Interests form:

1) at least annually. Investigators are encouraged to submit their SFI disclosure at the beginning of the fall semester. If investigators submitting a proposal do not have a current annual SFI disclosure on file, they will be required to do so before proposal submission;

2) for those investigators participating in Public Health Service-funded research, not later than the application date for Public Health Service-funded research;

3) investigators who will be joining an ongoing Public Health Service-funded research project must submit a SFI disclosure prior to being added to the Public Health Service-funded grant account;

4) investigators must submit a modified SFI disclosure within 30 days of acquiring a new SFI; and

1. investigators or covered family members shall provide any additional documentation related to the SFIs disclosed on an SFI disclosure form upon request of the COI official.

04.04 Receipt, Processing, and Recording of SFI Disclosures – Receipt, processing, and recording of SFI disclosures is the responsibility of the director of RIC who provides the COI official with a report of SFI disclosures received.

04.05 Review of SFI Disclosures – An FCOI exists when the COI official reasonably determines that an SFI held by an investigator or a covered family member could directly and significantly affect the design, conduct, or reporting of the investigator’s research.

1. SFI Affecting Public Health Service Funding – The COI official shall review the Disclosure of Significant Financial Interest form submitted by each investigator and determine whether any SFI is related to Public Health Service-funded research and if a FCOI exists by making a reasonable determination that the SFI:
2. could be affected by the Public Health Service-funded research; or

2) is in an entity whose financial interest could be affected by the Public Health Service-funded research.

1. SFI Affecting Non-Public Health Service-Funded Projects – If the SFI is not related to Public Health Service-funded research, the COI official shall determine whether it could directly and significantly affect the design, conduct, or reporting of the investigator’s research or sponsored program activities.
2. The COI official may confer with the directors of Research Integrity and Compliance, Pre- and Post-Award Support Services, and Technology Transfer and Contracts regarding the SFI and the determination of whether it could directly and significantly affect the design, conduct, or reporting of the investigator’s research or sponsored program activities.
3. The COI official may request additional details about information on any investigator’s Disclosure of Significant Financial Interest form.

04.06 Appointment of COI Review Committee – The COI official may, at their discretion, appoint a COI Review Committee. The COI Review Committee will:

a. review the SFI and may require the investigator to provide additional information regarding the SFI; and

b. provide recommendations to the COI official regarding elimination or mitigation of the FCOI, identifying mechanisms to effectively manage the FCOI and safeguard objectivity of the research or sponsored program activity.

04.07 Account Set-Up and Expenditures – The director of Post-Award Support Services will ensure there will be no expenditure of sponsored research funds by an investigator or the university unless the COI official has determined that no FCOI exists or that any identified FCOI is manageable under the terms of a management plan that has been adopted and implemented.

04.08 Certification and Reporting – The university shall comply with the reporting requirements in [42 C.F.R Part 50, Subpart F](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=8b75aacec77f0f4026c3c9a60325cf01&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#42:1.0.1.4.23.6), [45 C.F.R. Part, 94, Subpart A](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45), and the [National Science Foundation Award and Administration Guide 08-1 January 2008 Chapter V: Grantee Standards](http://www.nsf.gov/pubs/manuals/gpm05_131/gpm5.jsp#510).

1. The university will submit specific certifications and agreements regarding this policy and FCOI in each application for funding submitted for Public Health Service-funded research.
2. The university will submit reports to the appropriate federal funding

agency within a certain period of time after the university identifies an FCOI related to Public Health Service-funded research.

1. If the university finds that it is unable to satisfactorily manage an FCOI

related to a National Science Foundation-funded research, the COI official will notify the National Science Foundation’s Office of the General Counsel.

04.09 Investigator Notification – If the COI official determines that an FCOI exists, the COI official shall notify the investigator in writing.

04.10 Investigator Appeal – If an investigator disagrees with the determination that an FCOI exists, the investigator may appeal the COI official’s determination to the chief research officer, or designee, in writing within 10 business days after receiving the COI official’s determination. The decision of the chief research officer, or designee, is final.

04.11 Management of FCOI – If an investigator agrees with the determination that an FCOI exists, the COI official shall work with the investigator to develop a management plan that contains the elements described in Section 03., and complies with the recommended mitigation plan.

1. The management plan must be signed by the investigator, the investigator’s supervisor, and approved by the COI official.
2. In addition to any other monitoring provisions, the investigator, the investigator’s supervisor, and the COI official will actively participate in ongoing monitoring of the management plan.
3. Changes to the management plan must be approved by the COI official.
4. In the case of Public Health Service-funded research, changes to the management plan must be reported per the requirements in [42 C.F.R Part 50, Subpart F](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=8b75aacec77f0f4026c3c9a60325cf01&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#42:1.0.1.4.23.6), and [45 C.F.R. Part, 94, Subpart A](http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45).
5. In the case of National Science Foundation-funded research, if the COI official determines that imposing conditions or restrictions would be either ineffective or inequitable, and potential negative impacts arising from the FCOI are outweighed by the interests of scientific progress, technology transfer or the public health and welfare, the COI official may allow the research to proceed without imposing such conditions or restrictions.

04.12 Public Accessibility

a. If the COI official determines that an FCOI exists that is related to Public Health Service-funded research, the university will make the following 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 SFI is held;
4. a description of the SFI that was determined to be an FCOI; and
5. the approximate dollar value of the SFI. If the dollar value cannot be determined by reference to publicly available prices or another reasonable method, the university 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 university shall make this information available in writing to any requestor within five business days after receipt of a request so long as the following criteria are met:

1. the SFI was disclosed and is still held by the investigator; and
2. the COI official has determined that the SFI is related to Public Health Service-funded research and is an FCOI.

The information required under this section must remain available to any requestor for three years after the date of the last expenditure on the research project.

For each FCOI identified by the COI official that is not related to Public Health Service-funded research, the COI official shall retain all information related to the FCOI in a central location and shall make this information available to the public upon request and as authorized by the [Texas Public Information Act, Texas Government Code, Chapter 552](https://statutes.capitol.texas.gov/SOTWDocs/GV/htm/GV.552.htm).

The COI official is responsible for coordinating with TSUS Office of General Counsel to ensure that all responses to public information requests are made in compliance with federal and state law.

04.13 Noncompliance, Retrospective Review, and Documentation

1. If FCOI related to Public Health Service-funded research is not identified or managed in a timely manner, or if an investigator fails to comply with a management plan, the COI official, or designee, shall, within 120 days after determining noncompliance:
2. complete a retrospective review of the investigator’s research activities and any Public Health Service-funded research project to determine if any Public Health Service-funded 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 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.

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

1. project number;
2. project title;
3. investigator contacts;
4. name of the investigator with the FCOI;
5. entity with which the investigator has an FCOI;
6. reasons 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).

If bias is found, the COI official shall notify the Public Health Service and submit a mitigation report as required by federal law. If necessary, the COI official shall update the FCOI reports described in Section 04.08.

If the COI official discovers an FCOI related to non-Public Health Service-funded research that was not timely identified or managed, the COI official, or designee, shall conduct and document a retrospective review as described above. If bias is found, the COI official shall notify the chief research officer and, if required by law, the COI official shall also notify the funding agency.

* 1. Research Through Sub-Recipients
1. In the case of Public Health Service-funded research, the COI official is responsible for:
2. ensuring any sub-recipient’s compliance with the federal regulation; and

2) reporting identified FCOI for sub-recipient investigators to the Public Health Service.

1. The university will incorporate, as part of a written agreement with a sub-recipient, terms that establish:
2. whether this FCOI policy or that of the sub-recipient will apply to sub-recipient investigators; and
3. include time periods to meet disclosure and FCOI reporting requirements.

Sub-recipient institutions who rely on their FCOI policy must report identified FCOI to the university with sufficient time to allow the university to meet Public Health Service reporting obligations.

Sub-recipient institutions that must comply with this FCOI policy must submit all investigator SFI disclosures to the university with sufficient time to allow the university to review, manage and report identified FCOIs to the Public Health Service.

The COI official is responsible for ensuring that the university will monitor sub-recipient’s compliance with the Public Health Service FCOI regulations, management plans, and for reporting all identified FCOI to the Public Health Service.

* 1. Training, Education, and Certification

Each investigator engaged in Public Health Service-funded research, including sub-recipient investigators, must complete FCOI training:

prior to engaging in Public Health Service-funded research;

at least every four years; and

3) immediately under the designated circumstances:

* + - 1. the university’s FCOI policy changes in a manner that affects Public Health Service-funded investigator requirements;
			2. a Public Health Service-funded investigator is new to the university; or
			3. the university finds that an investigator is not in compliance with the university’s FCOI policy or an agreed-upon management plan.

b. To satisfy basic FCOI training requirements for investigators engaged in Public Health Service-funded research, the university will require investigators to use training resources available on the [CITI Program](https://www.citiprogram.org/?pageID=668) or [National Institute of Health’s Office of Extramural Research FCOI website](https://grants.nih.gov/aboutoer/intro2oer.htm).

Via resources provided by RIC, the university will also provide additional training specifically regarding:

1. investigator’s responsibilities for SFI disclosures; and

1. the university’s FCOI policy.

04.16 Enforcement

* 1. The COI official will bring any violations of this policy or applicable procedures to the attention of the investigator, who will be given an opportunity to comply.
	2. The investigator shall present a proposal for compliance to the COI official for review and action within 10 business days of the notification of noncompliance. Failure to comply will constitute an intentional violation as discussed in the following section.
	3. The COI official will report repeated or intentional violations of this policy to the funding agency and the chief research officer.
	4. Sanctions may be imposed by the chief research officer, or designee, and may range from a letter of reprimand up to and including termination.

04.17 Recordkeeping – RIC shall maintain all records related to investigators’ SFI disclosures and any FCOI determinations or management plans in a central location. These records shall be kept for the longer of three years from the date of the last expenditure submitted in the case of sponsored research or as required by applicable federal law, see 45 C.F.R. §§[74.53(b)](https://www.gpo.gov/fdsys/pkg/CFR-2010-title45-vol1/pdf/CFR-2010-title45-vol1-sec74-53.pdf), [92.42(b)](http://www.gpo.gov/fdsys/pkg/CFR-2010-title45-vol1/pdf/CFR-2010-title45-vol1-sec92-42.pdf).

04.18 Audit – The university shall provide for regular audits of SFI disclosures, management plans, and related documents and reports to determine individual and institutional compliance with this policy.

04.19 Graduate Students and Postdoctoral Scholars – Graduate students and postdoctoral scholars may not be involved with companies in which their advisor or faculty mentor has an SFI. This means they may not work for the company, undertake training in the company, or do their dissertation research in the company.

a. Graduate students and postdoctoral scholars may undertake educationally-related research activities at companies as long as:

1. their faculty advisor does not have a SFI in the company;
2. the company places no confidentiality or non-disclosure restrictions on the student and permits the student to freely discuss and publish the results of work without delays; and
3. any company patent agreement the student is required to sign is reviewed and approved by the COI official.

b. Graduate student participation in on-campus industry-sponsored research is encouraged as long as:

1. the participation furthers the student’s educational program; and
2. the student’s faculty advisor and the researcher directing the project do not have an SFI in the company sponsoring the campus research project.

c. Postdoctoral scholars may participate in on-campus industry-sponsored research provided that:

1. the participation furthers their professional and academic program; and
2. if the faculty member or researcher directing the project has an SFI in the company, there is a monitoring plan in place that has been approved by the COI official and chief research officer.

Researchers must not allow outside activities or interests to prevent them from meeting their responsibilities to students as teachers, mentors, or supervisors of research.

**05. REVIEWERS OF THIS UPPS**

05.01 Reviewers of this UPPS include the following:

Position Date

Assistant Vice President for Oct 1 E3Y

Research

Director, Research Integrity Oct 1 E3Y

and Compliance

Director, Technology Transfer Oct 1 E3Y

and Contracts

**06. CERTIFICATION STATEMENT**

This UPPS has been approved by the following individuals in their official capacities and represents Texas State policy and procedure from the date of this document until superseded.

Assistant Vice President for Research; senior reviewer of this UPPS

Vice President for Research

President