



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 73.09, **Financial Conflicts of Interest in Research**

PURPOSE: The purpose of this HSC OP is to protect the objectivity and integrity of research conducted by Texas Tech University Health Sciences Center (TTUHSC) researchers and to protect TTUHSC researchers from the consequences of financial conflicts of interest. Such conflicts could directly and significantly affect all facets of research, and may arise when interaction with public and private sectors produces financial interests for TTUHSC or its researchers. The contents of this policy comply with requirements established by the Public Health Service¹ as well as guidance from the Office of Human Research Protections to Institutional Review Boards²² and include processes to identify and manage any Financial Conflict(s) of Interest (FCOI); to manage and report any Significant Financial Interests and FCOI; to provide training and compliance; and to publicly disclose FCOI related to PHS-funded research.

REVIEW: This OP will be reviewed by August 1 of each even-numbered year (ENY) by the Chairperson of the TTUHSC Conflict of Interest in Research Committee (COIRC) and the Associate Vice President for Research Integrity, with recommendations for revision forwarded to the Executive Vice President for Research & Innovation (EVPRI).

POLICY/PROCEDURE:

1. Introduction

TTUHSC recognizes its responsibility as a public institution of higher education to promote interaction between its employees and the public and private sectors, and that such interaction is an important component of its research activities. TTUHSC further recognizes that those interactions may give rise to conflicts of interest.

Financial conflicts of interest may arise due to the nature and scope of research activities conducted at TTUHSC. A financial conflict of interest may be actual, potential or perceived, and, if not properly identified and managed, could compromise or appear to compromise the integrity and reputation of the institution and its employees. TTUHSC is aware that conflicts may occur in the normal conduct of activities, and it is essential that any significant conflict of interest be appropriately identified, reported, reviewed, and managed.

This policy applies to financial conflicts of interest in research, and is separate from, but complementary to other TTUHSC and TTU System policies and rules related to conflicts of interest and commitment. These related policies include [HSC OP 10.05, Conflict of Interest and Commitment Policy](#) and portions of [TTU System Regents' Rule, Chapter 3](#)

2. Applicability

- a. TTUHSC. This policy applies to all TTUHSC Senior/Key personnel who are involved in the design, conduct, or reporting of externally funded sponsored projects, including, but not limited to research, instruction and public service grants administered through TTUHSC's Office of Sponsored Programs, as well as personnel involved in non-exempt research that involves human subjects, regardless of the funding source.

¹ 42 CFR 50 Subpart F—Promoting Objectivity in Research, effective August 24, 2012.

² <http://www.hhs.gov/ohrp/policy/fguid.pdf>, dated May 5, 2004.

- b. Non-TTUHSC. The policy also applies to sub-recipients, sub-contractors or collaborators of TTUHSC involved in Public Health Service (PHS) research activities unless the home institution of the sub-recipient, sub-contractor, or collaborator has its own written policy on conflict of interest that is in accordance with 42 CFR 50, Subpart F.
- c. Not applicable. This policy does not apply to non-research Conflicts of Interest or Conflicts of Commitment. Please refer to [HSC OP 10.05 Conflict of Interest and Commitment Policy](#).

3. **Definitions**

Advisory Board: made up of TTUHSC peers in the field who shall review, discuss, and approve an Investigator's CMP. The Investigator and COIRC, or the Chairperson or designee of that committee, shall work together to choose an appropriate board, which must include a minimum of three (3) members who will be signatories to the CMP and annual CMP updates as applicable.

Conflict of Interest in Research Committee (COIRC): a TTUHSC committee established in accordance with Section 5 of this policy.

Disclosure: The requirement for an Investigator and Senior/Key Personnel to notify TTUHSC of all significant financial interests truthfully and in a timely manner. Disclosures are required to be in sufficient detail to permit a determination of the potential for a financial conflict of interest.

Family member: Spouse, unmarried domestic partner, dependent children.

Financial Conflict of Interest (FCOI): a significant financial interest that could directly and significantly affect or appear to affect the design, conduct, or reporting of a project.

- FCOI in Research: Any financial interest related to the research.

Financial Conflict of Interest Management Plan or Conflict Management Plan (CMP): A detailed description of the actions to be taken to address a manageable FCOI. The TTUHSC COIRC, including the Chairperson or designee of that committee, shall work with the Investigator to select an Advisory Board to draft and execute a CMP that will set forth the steps to reduce, mitigate, or eliminate that Investigator's conflict in order to provide a reasonable expectation that the design, conduct and reporting of research will be free of bias. Each CMP will also require the Investigator's Chair to acknowledge the CMP. In the event an Investigator does not have a Chair, the EVPRI shall acknowledge the CMP.

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

Institutional Official: The EVPRI shall serve as the Institutional Official with authority to require disclosures of significant financial interests from TTUHSC Investigators and Senior/Key Personnel. The EVPRI and the TTUHSC Conflict of Interest in Research Committee (COIRC), including the Chairperson or designee of that committee are authorized to review disclosures to determine whether a potential financial conflict of interest exists.

Institutional Responsibilities: A broad term describing all activities that derive from one's training and expertise and that relate to his or her description of job duties performed for TTUHSC.

Investigator: the project director or principal investigator and any other person who is responsible for the design, conduct or reporting of research or other externally funded activities administered through TTUHSC's Office of Sponsored Programs.

Institutional (or Organizational) Conflict of Interest (ICOI): A situation in which licensing, technology transfer, patents or investments of—or gifts to—TTUHSC or the financial interests of TTUHSC Senior administrators (Deans, Vice Presidents or President) might affect, or reasonably appear to affect institutional processes for the design, conduct, reporting review or oversight of research, including research with human subjects.

Reporting: The requirement for TTUHSC to notify PHS funding agencies and the public of information related to a financial conflict of interest and conflict management plans.

Research: A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health. The term encompasses basic and applied research and product development.

Senior/Key Research Personnel: the principal investigator and any other person designated as senior/key personnel in a grant application or progress report submitted to a funding agency. For research involving human subjects, study coordinators will be considered key research personnel.

Significant Financial Interest:

A financial interest of the Investigator, Senior/Key Personnel and/or Family Members that meets one or more of the following definitions:

- 1) In a publicly traded company, an aggregate value of \$5,000 or more in payment received from the company in the previous 12 months plus the value of any equity interest in the company as of the date of disclosure. Payment includes salary and payment for other services (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) In a non-publicly traded company, an aggregate value of \$5,000 or more in payment received from the company in the 12-month months preceding the disclosure. Payment includes salaries and payment for other services (consulting fees, honoraria, paid authorship, etc.);
- 3) Any amount of equity (e.g., stock, stock options, or other ownership or interest) in a non-publicly traded company, regardless of whether the immediate value of the equity is known;
- 4) Any income received (regardless of amount) related to intellectual property rights and interests (patents, copyrights, etc.) broadly relevant to human health;
- 5) Board or executive relationship, regardless of compensation; or
- 6) Any reimbursed or sponsored travel related to one's Institutional Responsibilities that was paid on one's behalf, even if the exact value of the travel is unknown. Travel reimbursements by a government agency, an institution of higher education, an academic teaching hospital, medical center, or research institute affiliated with an institution of higher education does NOT need to be reported as a significant financial interest.^{3, 4}

The term *significant financial interest* does not include the following types of financial interests:

- (1) salary, royalties, or other remuneration paid by TTUHSC to the Investigator, Senior/Key Personnel or family member(s) if the person making the disclosure is currently employed or otherwise appointed by TTUHSC. This includes intellectual property rights assigned to TTUHSC and agreements to share in royalties related to such rights;
- (2) TTUHSC salary paid by a sponsor;
- (3) income from investment vehicles, such as mutual funds and retirement accounts, as long as the person making the disclosure/family member does not directly control the investment decisions made in these vehicles;

³ One example of travel that must be disclosed is travel to pharmaceutical-sponsored investigator's meetings where the purpose of the meeting is to learn how to conduct a multi-site clinical trial that is expected to be conducted at TTUHSC. Investigators and/or key study personnel are mandated to attend such meetings in order to conduct the clinical trial at TTUHSC. Therefore, travel to these meetings must be disclosed as part of this policy, but will not generally be considered to create a financial conflict of interest and will not require further review by the COIRC.

⁴ Disclosure will include, at a minimum, the purpose, the sponsor, the destination and the duration of each trip.

- (4) income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an Institution of higher education; or
- (5) income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

4. **Responsibilities of Investigators and Senior/Key Personnel**

TTUHSC Investigators and Senior/Key research personnel shall have the following responsibilities with regard to the disclosure and management of significant financial interests:

- a. Disclosure. All Investigators and Senior/Key research personnel and voting members of TTUHSC research compliance committees (IRB, IACUC, IBC, RDBC, COIRC) are required to disclose all significant financial interests for themselves and their Family Members on at least an annual basis. The disclosure process for researchers has been merged with the process required for all TTUHSC employees as is outlined in HSC OP 10.05, Article IV, and [here](#). Annual disclosure is required for all TTUHSC employees, including Investigators and research personnel who do not have any significant financial interests to disclose.
 - 1) *External funding.* Investigators and Senior/Key personnel seeking external funding for a sponsored project, including, but not limited to, research, instruction or public service grants, must complete their initial financial disclosure forms or annual updates no later than the time of application for funding.
 - 2) *Non-exempt research with human subjects.* Investigators and study coordinators intending to conduct non-exempt research with human subjects must complete their initial disclosure forms or annual updates prior to final IRB approval of the project.
 - 3) *Changes.* Any changes to Significant Financial Interests for Investigators, Senior/Key Personnel or Family Members must be reported within thirty (30) days of discovering or acquiring a new Significant Financial Interest.
 - 4) *Review of Disclosures:* Completed Disclosure statements for those who identify as being involved in the design, conduct and reporting of research will be sent to the TTUHSC Institutional Compliance Office and to the Research Integrity Office (RIO). RIO staff will conduct a preliminary review to verify that the research portion of the form has been properly completed and that a disclosure was necessary. Information regarding significant financial interests and proposed or current research activities will be entered into a financial disclosure database which will be available to RIO and Office of Sponsored Programs (OSP) personnel as well as to Conflict of Interest in Research Committee (COIRC) members. Grant proposals and IRB submissions will be checked against the database. Any proposals/submissions by persons who have declared a Significant Financial Interest will be referred to the COIRC Chairperson or designee for an initial determination (See Section 5.e.1, below). Documentation of completed Disclosures will be maintained in the Research Integrity Office for a minimum of 3 years.
- b. Training. All TTUHSC employees, including those involved in research activities, (Investigators and Senior/Key research personnel and voting members of TTUHSC research compliance committees IRB, IACUC, IBC, RDBC, COIRC) must complete training related to the contents of this policy and federal regulations about objectivity in research at least annually, and more frequently if there are significant changes to this policy or related regulation that affect the responsibilities of Investigators or Senior/Key Personnel. Training may be required more frequently for those who do not comply with this policy or as part of a Conflict Management Plan. Training specifically related to research activities found in 42 CFR 50, Subpart F has been incorporated into TTUHSC's required annual training and disclosure process for all employees. The required training can be accessed through Cayuse (on the COI Disclosure tab) for TTUHSC employees with TTUHSC email address eRaider password.

Initial training is required as follows:

- 1) For federal awards processed through TTUHSC's Office of Sponsored Programs (including, but not limited to, research, instruction, and public service grants), Investigators and Senior/Key Personnel must complete initial training prior to the expenditure of funds. Principal investigators are responsible for ensuring that current Senior/Key Personnel complete initial training. Failure to complete training may result in restriction of access to grant funds until training has been completed.
- 2) Investigators and other study personnel conducting non-exempt research with human subjects, regardless of funding source, are required to complete the required training. New research proposals submitted without up-to-date conflict of interest training for all study personnel may not receive final approval by the TTUHSC IRBs.

5. **Conflict of Interest in Research Committee**

- a. Establishment of Committee: The TTUHSC Conflict of Interest in Research Committee (COIRC) has been established by the EVPRI to review Disclosures of Significant Financial Interests to determine the presence of a Financial Conflict of Interest, the nature and magnitude of the conflict, the degree to which the conflict is related to the research, and the extent to which the interest could be directly and substantially affected by the research. The COIRC is also charged with periodic review of previously approved Conflict Management Plans (CMPs). The COIRC will work with Investigators and Senior/Key Personnel to develop appropriate CMPs, will provide copies of the CMPs to appropriate review committees and administrators, and will obtain and review annual reports regarding ongoing CMPs.
 - 1) The COIRC and any sub-committees established under this policy shall be considered **"medical committees"** as defined under Texas Health and Safety Code 161.031, and/or other applicable state and federal statutes. All documents generated by, submitted to, or for the purposes of fulfilling COIRC Committee duties are confidential and privileged as "medical committee documents."
- b. Membership: The COIRC shall consist of at least seven voting members.
 - 1) The COIRC Chairperson and Vice Chairperson will be elected to a three-year term by a simple majority vote of the full COIRC. Votes may be cast by email. The Chairperson/Vice Chairperson may be re-elected for successive terms.
 - 2) The Dean of each School (Medicine, Nursing, Health Professions, Pharmacy, Graduate School of Biomedical Sciences, and Population and Public Health) shall appoint at least one faculty member from that School to serve on the COIRC.
 - 3) The EVPRI will appoint two additional members of the COIRC. At least one member shall be a community representative with no family or direct financial ties to TTUHSC.
 - 4) Non-voting Ex-officio members shall include: 1) the Associate Vice President for Research integrity, 2) the Associate Vice President, Office of Sponsored Programs, and 3) a representative of the TTU System Office of General Counsel.
 - 5) All COIRC members (including Ex-officio) are required to submit annual disclosures of significant financial interest and complete the institutional training as required elsewhere in this policy.
 - 6) Committee members should be individuals who have sufficient seniority, research expertise, and independence to evaluate competing interests at stake and make credible and effective recommendations. All voting members of the COIRC shall be independent of the direct line of institutional authority for research.
 - 7) Members will be appointed to a 3-year term and may be reappointed.
- c. Members with a Conflict: COIRC members shall not participate in reviews, deliberations or decisions in which the member has an actual or perceived conflict of interest as determined by the COIRC or the member him/herself. Those with a conflict may provide objective information requested by the COIRC.

d. Meetings.

- 1) *Frequency:* Meetings will be held as needed, as determined by the COIRC Chairperson or designee.
- 2) *Administrative support:* The Associate Vice President for Research Integrity will appoint a staff person to provide administrative support to the COIRC.
- 3) *Quorum:* A simple majority of voting members must be present for a quorum. While every effort will be made to reach consensus, decisions will be my majority vote. A quorum may include members present via teleconference.
- 4) *Materials:* Prior to each convened meeting of the COIRC, members will be given materials required for conducting the business of the meeting. Materials may be provided to members via secure email.
- 5) *Minutes:* Written minutes of each convened meetings will be in sufficient detail to document the following: 1) Attendance at meetings and presence of quorum, 2) actions taken by the COIRC, and 3) the vote on these actions including number of members voting for, against, or abstaining. Meeting minutes and materials shall be maintained for a minimum of 3 years after the meeting date.

e. Duties of Chairperson.

- 1) *Initial Determination of Relatedness:* The EVPRI, as Institutional Official, delegates the authority to the Chairperson of the COIRC to review Disclosures of Significant Financial Interest and to make an initial determination of its relatedness to the proposed project. The Chairperson (or designee) may make an initial determination of: (i) "no related financial conflict of interest" or (ii) "related financial conflict of interest that has been sufficiently managed." In order to make the initial determination, the COIRC Chairperson (or his/her designee) will be provided, at a minimum, with the Investigator's or Senior/Key Personnel's most recent Disclosure of Significant Financial Interest and a brief description of the proposed project(s). The initial review and determination shall be made in writing and reported to the COIRC at its next convened meeting. At any point in the initial review, the COIRC Chairperson may elect to refer the matter to the COIRC for input prior to making a determination. Any determination by the Chairperson of possible relatedness, or the appearance of relatedness that has not been sufficiently managed will be referred to the full COIRC for further review.
- 2) The Chairperson or designee will be responsible for leading the convened meetings of the COIRC, encouraging full discussion of each agenda item, notifying the Institutional Official and Investigators of actions taken by the COIRC, consulting with Investigators regarding preparation of management plans, and other duties as assigned by the EVPRI.

f. Duties of Committee Members.

- 1) *General:* The COIRC is responsible for making a final determination that Significant Financial Interests of Investigators or Senior/Key Personnel create a Financial Conflict of Interest or the appearance of a conflict of interest with proposed research activities. The Committee will determine the need for a CMP to manage, reduce or eliminate the FCOI prior to expenditure of funds and/or enrollment of human subjects in the conflicted project. The Committee will review proposed Conflict Management Plans, and may request changes, or give final approval of proposed Management Plans. The Committee will also review ongoing CMPs to determine whether they remain adequate to manage the FCOI.
- 2) *Potential FCOI:* If a real or potential FCOI is identified that had not been previously managed, the COIRC Chairperson or designee will call a meeting (meetings via email, audio- or videoconference are acceptable) of the COIRC to determine the need to manage, reduce or eliminate the conflict before the expenditure of any funds or the enrollment of any research participants.

- 3) *Potential ICOI: If a real or potential ICOI is identified*, the COIRC may be called upon to assist with the development of a conflict management plan when investments of, or gifts to the institution affect or appear to affect institutional processes for the design, conduct, reporting, review, or oversight of research. These situations will be referred to the COIRC for review by the TTUHSC Conflict of Interest and Commitment Committee (COICC), by the TTUS Office of General Counsel and/or the TTUS Institutional Conflict of Interest Committee, by the Associate Vice President for Research Integrity, or by the EVPRI. If the ICOI involves reputational risk to TTUHSC or potential risk to human research subjects, a plan to manage, reduce, or eliminate the conflict will be developed by the COIRC (with input from the Institutional Review Board if requested). Possible management strategies include, but are not limited to eliminating the financial interest, recusing a conflicted institutional official from decision-making regarding research activity related to the conflict, requiring oversight of decision-making from an independent third party, or obtaining outside IRB review. If the ICOI involves research with human subjects, any draft management plan will be shared with and approved by the relevant TTUHSC IRB prior to implementation.
- 4) *COIRC Review*: The convened COIRC shall review and (where necessary) investigate the information in the completed financial disclosure form as well as a summary of the proposed project(s) to make a determination as to whether any significant financial interest is related to any ongoing project. Relatedness involves a determination that the significant financial interest could be affected by the research or is in an entity whose financial interest could be affected by the research. A determination that a financial conflict of interest exists will be made when the COIRC reasonably determines that the significant financial interest is both related and could directly and significantly affect the design, conduct or reporting of the proposed research. (42 CFR 50.604[f]).

To make the determination that an actual, potential, or perceived financial conflict of interest exists, the COIRC may consider the following factors, including, but not limited to:

- The type and nature of the financial interest;
 - The funding source;
 - Where and by whom the research was designed;
 - Who will be collecting/analyzing the data;
 - Indication that the Senior/Key Personnel has an incentive to improperly favor an outside entity;
 - Whether incentives exist that may lead to inappropriate bias or otherwise affect the research results;
 - Impact of the financial interest on the integrity of the research data, including the impact the study outcome may have on the payment of any compensation for the research;
 - Risk to the rights and safety of human subjects, where applicable;
 - Risks to the rights and obligations of students and trainees participating in the project;
 - Impact on the availability of research results to the scientific community for use in the public interest; and
 - Any other matter pertaining to the disclosed financial interest and the proposed project.
- 5) *Determination of No Conflict*: If the COIRC determines that no conflict of interest exists, that determination will be recorded in the COIRC meeting minutes, and no further action will be taken on the matter.
- 6) *Determination of Conflict*: If the COIRC makes a determination that an FCOI does exist, the COIRC shall work with the Investigator or Senior/Key Personnel to determine a method for managing the conflict. If the Investigator or Senior/Key Personnel is unwilling or unable to divest of the significant financial interest creating the conflict, a written Conflict of Interest Management Plan (CMP) must be developed. The plan will include a description of the **compelling circumstances** that justify the participation of the conflicted Investigator(s) in the project, as well as appropriate restriction(s) that will be taken to mitigate potential effects of the conflict on the research.

The CMP must be reviewed and approved by the COIRC (secure email review and vote is permitted) prior to the expenditure of any funds for sponsored projects. If the proposed research involves human subjects, the TTUHSC IRB reviewing the project must also approve the Conflict Management Plan prior to enrollment of any human subjects in the research.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of an FCOI (e.g., when presenting or publishing the research);
- For research projects involving human subjects, disclosure of an FCOI directly to participants;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

g. Duties of Committee Administrative Support

- 1) *General:* If the FCOI involves research with human subjects, any associated CMP and/or COIRC evaluation shall be shared with the appropriate IRB.
- 2) *CMP Management:* Administrative support shall maintain and manage all CMPs, including documentation with a current list of all investigators and research staff who have active CMPs, including amendments, annual CMP reports, and termination (e.g., whether the FCOI has been resolved or removed).

h. Review of Updated Disclosures. For Investigators or Senior/Key Personnel who are added to an ongoing project and/or Investigators who disclose a new Significant Financial Interest after a project has begun, the COIRC will review the Disclosure and make a determination of whether an FCOI exists. If the committee determines that an FCOI exists, the COIRC will determine what, if any, immediate actions must be taken to protect the objectivity and integrity of the research while a final management plan is being developed.

i. Monitoring Conflict Management Plans:

- 1) *Reports:* Investigators or Senior/Key Personnel who have ongoing CMPs shall provide annual—or at any time upon request from the COIRC--written reports regarding action taken under the CMP. Reports shall be submitted to the COIRC Chairperson or designee. Annual reports shall be submitted on or before the anniversary date that the CMP was approved by the COIRC. The Chairperson will review the reports and provide a summary to the COIRC at the next convened meeting. The COIRC may choose to review the report in its entirety. These written reports will be required until the completion of the project for which the conflict was identified.
- 2) *Audits:* The EVPRI or COIRC may also request interim compliance audits of the monitoring plans be conducted by the Research Integrity Office or the TTU System Office of Audit Services. These audits may be requested either for cause or on a routine basis.

6. Noncompliance

- a) Breach. A breach of this policy by an Investigator or Senior/Key Personnel may include, but is not limited to:
- Significant Financial Interest(s) not disclosed in a timely manner;
 - Disclosing inaccurate erroneous or misleading information;
 - Failure to provide additional information to the COIRC or EVPRI regarding a disclosure; or
 - Violation of the terms of an approved conflict of interest management plan.

A breach of the policy by the COIRC might include the failure of the COIRC to provide a timely review of a properly disclosed significant financial interest.

- b) Action Upon Breach. If an alleged or actual policy breach occurs, the convened COIRC shall, within 60 days, review the significant financial interest; determine whether it is related to the project; determine whether a financial conflict of interest exists; and, if so, shall 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.
- c) Retrospective Review: Within 120 days of being made aware of a policy breach, the COIRC (or an *ad hoc* committee appointed by the EVPRI if the review is required due to a lapse by the COIRC) shall complete a retrospective review of the Investigator's activities and the project to determine whether any of the research conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of the research.

This retrospective review must be documented and contain, at a minimum, the following elements:

- Project number (for PHS-funded research) and Project Title;
- Principal investigator(s);
- Name of Investigator with the Financial Conflict of Interest;
- Name of entity with which the Investigator has a financial conflict of interest, and description of the nature of the conflict of interest;
- Reason(s) for the retrospective review;
- Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- Findings of the review; and
- Conclusions of the review.

The results of the retrospective review shall be reported to the sponsor or funding agency as required by 42 CFR 50.605. (a)(3)(iii).

- d) Additional Training: Any policy breach by an investigator or research personnel will result in additional training regarding this policy and the federal regulations for the Investigator or Senior/Key Personnel.
- e) Intentional Breach: If the COIRC determines that the breach was part of an intentional plan to circumvent or violate TTUHSC policy, including the policy established under this OP, the COIRC or TTUHSC regarding one's financial interests, the COIRC may recommend additional sanctions to the EVPRI. These sanctions may include, but are not limited to:
- A letter of reprimand to the Investigator with a copy to the Investigator's Chairperson, Dean, EVPRI, Advisory Board (if a CMP was executed), and personnel file;
 - Temporary or permanent suspension of the individual to submit new applications for external funding and/or research involving human subjects;
 - Temporary or permanent suspension of research privileges; or
 - Non-renewal of appointment or dismissal in accordance with HSC OP 60.01.

The EVPRI shall make the final determination regarding which sanctions, if any, shall be imposed on the Investigator or research personnel.

7. **Financial Conflict of Interest Reporting Requirements for PHS-funded research**

- a) Initial Report: Before the expenditure of any funds under a PHS-funded project, the Office of Sponsored Programs will provide to the PHS Awarding Component a Financial Conflict of Interest Report regarding any Investigator or Senior/Key Personnel with a Significant Financial Interest which has been determined by the COIRC to constitute an FCOI and which requires the creation of a CMP. If the management of the FCOI involves elimination of the conflict, no such report is required.
- 1) Report Contents. FCOI reports to the PHS Awarding Component will include sufficient information to enable PHS to understand the nature and extent of the financial conflict, and to assess the appropriateness of the conflict-of-interest management plan. Elements of the report shall include, at a minimum, the following:
- Project Number;
 - Principal investigator;
 - Name and title of the person(s) with the financial conflict of interest;
 - Name of the entity with which the financial conflict of interest exists;
 - Nature of the financial interest;
 - Value of the financial interest, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
 - A description of how the financial interest related to the PHS-funded research and the basis for the determination that the financial interest conflicts with such research; and
 - A description of the management plan itself, to include:
 - a) Role and principal duties of the conflicted Investigator or Senior/Key Personnel on the project;
 - b) Conditions of the management plan;
 - c) How the management plan is designed to safeguard objectivity in the project;
 - d) Confirmation of the agreement of the individual with the conflict to the terms of the management plan;
 - e) How the management plan will be monitored to ensure compliance; and
 - f) Other information as needed.
- b) Frequency of Reports: FCOI reports will be updated on at least an annual basis for the duration of the PHS-funded project (including extensions with or without funds). The annual report will specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists.
- c) Reporting new information: New financial conflicts of interest that are identified after the initial expenditure of funds shall be reported to the PHS Awarding Component within 60 days of the identification of the conflict. The FCOI report shall provide information and an assurance that TTUHSC has implemented an appropriate management plan for the newly identified conflict.
- d) Reporting Breaches: Policy breaches, as defined in Section 6 above, which result in a retrospective review determination that any portion of the research was biased in the design, conduct, or reporting will also require prompt reporting to the PHS Awarding Component. A mitigation report is also required in this case.
- e) Financial Conflicts of Interests and Foreign Components NIH Notice Number NOT-OD-19-114 reminds the extramural community about the need to report foreign activities through documentation of other support, foreign components, and financial conflict of interest to prevent scientific, budgetary, or commitment overlap. This notice also reminds the extramural community of the requirements in 42 CFR Part 50, Subpart F, Objectivity of Research.

This regulation, also known as the FCOI regulation, specifies the minimum requirements for Investigators to disclose to their institution their significant financial interests. As outlined previously in [NOT-OD-18-160](#), the requirement to disclose includes financial interests received from a foreign entity. This requirement is distinct and in addition to the reporting of other support and foreign components to the NIH.

8. **Subrecipient Monitoring for PHS-funded Research**

- a) General: In cases where TTUHSC carries out PHS-funded research through a subrecipient, TTUHSC will take reasonable steps to ensure that any subrecipient Investigator is adhering to the regulations concerning conflicts of interest in research found in 42 CFR 50.

As part of the agreement with the subawardee institution, the TTUHSC Office of Sponsored Programs will obtain a certification from the subawardee institution indicating whether the policies of TTUHSC or the subawardee institution will apply to the subrecipient Investigators.

- b) Following TTUHSC's policies: If TTUHSC's policy applies, the agreement must specify a deadline for the sub-recipient to submit disclosures of their researchers' significant financial interests to TTUHSC. The disclosures must be provided in a timely manner in order to allow review and any actions required by the COIRC prior to the expenditure of funds.
- c) Subawardee Institution's policies: If the subawardee institution's policies are followed, the certification must include a statement that the institution's conflict of interest in research policies comply with 42 CFR 50. The certification must also indicate a time frame by which any subrecipient researchers' FCOI will be reported to TTUHSC. If such a certification cannot be provided, then TTUHSC's policies will apply to all subawardee Investigators for disclosing significant financial interests that are directly related to the subrecipient's work for TTUHSC.
- d) TTUHSC Reporting Responsibility: For PHS-funded grants awarded to TTUHSC, the TTUHSC Office of Sponsored Programs is responsible for providing FCOI reports to the PHS Awarding Component prior to the expenditure and funds, and within 60 days of any subsequently identified FCOI.
- e) Additional Requirements for SBIR/STTR subawards (including Phase I and Phase II Awards): Please see TTUHSC OP 73.21. TTUHSC may decline to accept the subaward, or may require modifications to the subaward in order to comply with TTUHSC OP 73.21 and applicable law, regulations, or guidance.

9. **Public Disclosure**

As required by 42 CFR Part 50, information regarding Significant Financial Interests for PHS- funded research for which CMPs have been developed will be made available to requestors within 5 business days after the TTUHSC Office of Research receives the request. In order for TTUHSC to disclose the information, the following criteria must be met: The Significant Financial Interest must have been disclosed to TTUHSC and is still held by the Investigator or Senior/Key Personnel; the Significant Financial Interest must be related to PHS-funded research; and the Significant Financial Interest has been determined to be a conflict of interest.

The information to be shared with requestors will include the following:

- Name of Investigator or Senior/Key study personnel;
- Title and role with respect the project;
- Name of entity in which the significant financial interest is held;
- The nature of the interest; and
- The approximate dollar range of the significant interest (or a statement that the value cannot be readily determined).

Written requests for information can be sent to:

TTUHSC Office of Research
3601 4th Street STOP 6252
Lubbock, TX 79430
Or by phone: 806-743-3600

10. **Amendments or Termination of this Policy**

TTUHSC reserves the right to modify, amend, or terminate this policy at any time. Nothing in this policy should be construed as a contract between TTUHSC and its employees or agents.