



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

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

PURPOSE: The purpose of this HSCEP OP is to protect the objectivity of the design, conduct and reporting of research conducted by Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) researchers and to protect TTUHSC El Paso researchers from the consequences of a conflict of interest. These conflicts of interest could directly and significantly affect research and may arise through an interaction with public and private sectors. The contents of this policy comply with requirements established by the Public Health Service,¹ as well as guidance from the Office of Human Research Protections to Institutional Review Boards² 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 El Paso Conflict of Interest in Research Committee (COIRC) and the Director of the Office of Research Resources (ORR) or designee, with recommendations for revision submitted to the Vice President for Research (VPR) or designee.

POLICY/PROCEDURE:

1. Introduction

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

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

2. Applicability

- a. TTUHSC El Paso: This policy applies to all TTUHSC El Paso Senior/Key personnel who are involved in the design, conduct, or reporting of externally funded research as well as personnel involved in non-exempt research that involves human subjects, regardless of the funding source.
- b. Non-TTUHSC El Paso: The policy also applies to sub-recipients, sub-contractors or collaborators of TTUHSC El Paso 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:

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

- Small Business Innovation Research (SBIR) Program Phase I applications
- Institutional Conflicts of Interest or Conflicts of Commitment

3. Definitions

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

Disclosure: The requirement for an Investigator and Senior/Key Personnel to notify TTUHSC El Paso 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 and dependent child.

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

Financial Conflict of Interest Management Plan or Conflict Management Plan (CMP): A detailed description of the actions taken to address an FCOI. The plan will set forth the steps to reduce, mitigate, or eliminate the conflict in order to provide a reasonable expectation that the design, conduct and reporting of research will be free of bias.

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

Institutional Official: The VPR or designee shall serve as the Institutional Official with authority to require disclosures of significant financial interests from TTUHSC El Paso Investigators and Senior/Key Personnel. The VPR or designee and the TTUHSC El Paso 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 El Paso.

Investigator: the project director or principal investigator and any other person who is responsible for the design, conduct or reporting of research.

Reporting: The requirement for TTUHSC El Paso 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 and 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 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.);
- 5) 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 El Paso to the Investigator, Senior/Key Personnel or family member(s) if the person making the disclosure is currently employed or otherwise appointed by TTUHSC El Paso. This includes intellectual property rights assigned to TTUHSC El Paso 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 person making the disclosure/family member 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, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education; or
- (4) 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 El Paso 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 all voting members of TTUHSC El Paso research compliance committees (IRB, IACUC, IBC, COIRC) are required to disclose all significant financial interests for themselves and their Family Members on at least an annual basis. A link to TTUHSC El Paso Financial Disclosure form can be found here: https://elpasottuhsc.co1.qualtrics.com/jfe6/form/SV_6PhkholTTBWMUR

Annual reports are required from these investigators and research personnel even if they do not have any significant financial interests to disclose.

- 1) *External funding*. Investigators and Senior/Key personnel seeking external funding for

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 El Paso. Investigators and/or key study personnel are mandated to attend such meetings in order to conduct the clinical trial at TTUHSC El Paso. 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.

a research project must submit 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 submit 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 will be submitted to the ORR, who will conduct a preliminary review to verify that the form has been properly completed and signed. Improperly completed forms will be returned to the respondent for correction. Once properly completed, information from the form will be housed in a financial disclosure database available to ORR and Office of Sponsored Programs (OSP) personnel and will be manually entered in the iRIS research administration software. Grant proposals and IRB submissions will be checked against the software. 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 4.e.1, below). Documentation of completed Disclosures will be maintained in the ORR for a minimum of 3 years.
- b. Training: All Investigators and Senior/Key research personnel and voting members of TTUHSC El Paso research compliance committees (IRB, IACUC, IBC, COIRC) must complete training related to the contents of this policy and federal regulations about objectivity in research at least once **every four years**, 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 will be required more frequently for those who do not comply with this policy or as part of a Conflict Management Plan. TTUHSC El Paso uses an online training program provided by the Collaborative Institutional Training Initiative (CITI). The training program can be found at <https://www.citiprogram.org/Default.asp>.

Initial training is required as follows:

- 1) For federal awards, 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 will not receive final approval by the TTUHSC El Paso IRBs.

5. Conflict of Interest in Research Committee

- a. Establishment of Committee: The TTUHSC El Paso Conflict of Interest in Research Committee (COIRC) has been established by the VPR 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 COIR Committee duties are confidential and privileged as “medical committee documents.”

b. Membership: The COIRC will consist of at least 5 voting members.

- 1) Each School (Medicine, Nursing, and Graduate School of Biomedical Sciences) shall appoint at least one faculty member from that School to serve on the COIRC.
- 2) The VPR will appoint at least 2 additional members of the COIRC, one of whom shall be a community representative with no family or financial ties to TTUHSC El Paso.
- 3) Non-voting Ex-officio members shall include the Director of the ORR, the Director of OSP, and a representative of the TTU System Office of General Counsel.
- 4) 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.
- 5) 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 COIC shall be independent of the direct line of institutional authority for research.
- 6) 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) *Chairperson:* The COIRC Chairperson will be appointed to a 3-year term by the VPR. Chairperson may be reappointed for successive terms.
- 3) *Administrative support:* The ORR Director will appoint a staff person to provide administrative support to the COIRC.
- 4) *Quorum:* A simple majority of voting members must be present for a quorum. This may include members present via teleconference.
- 5) *Materials:* Prior to each convened meeting of the COIRC, members will be given materials sufficient for conducting the business of the meeting. Materials may be provided to members via secure email prior to the meeting.
- 6) *Minutes:* Written minutes of each convened meetings will be in sufficient detail to demonstrate the following: Attendance at meetings and presence of quorum, actions taken by the COIRC, 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 VPR delegates 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 research 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 research 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 will be responsible for leading the convened meetings of the COIRC, encouraging full discussion of each agenda item, for 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 VPR.

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 research 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 will call a meeting 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) *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 research project(s) to make a determination as to whether the significant financial interest is related to the research 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;
 - Any other matter pertaining to the disclosed financial interest and the proposed project.
- 4) *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.
- 5) *Determination of Conflict:* If the COIRC makes a determination that 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 which leads to the conflict, a written Conflict of Interest Management Plan (CMP) must be developed. The CMP must include both a description of the **compelling circumstances** that justify participation of the conflicted investigator(s) in the research project, as well as appropriate actions that will be taken to manage, reduce or eliminate the conflict. The CMP must be reviewed and approved by the COIRC (secure email review and vote is permitted) prior to the expenditure of any funds. If the proposed research involves human subjects, the TTUHSC El Paso IRB must also approve the 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. Review of Updated Disclosures: For Investigators or Senior/Key Personnel who are added to an ongoing research project and/or investigators who disclose a new Significant Financial Interest after a research project has begun, the COIRC will review the Disclosure within 60 days 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.
- h. 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 written 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 research project for which the conflict was identified.

- 2) *Audits:* The VPR or COIRC may also request interim compliance audits of the monitoring plans be conducted by the ORR 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 VPR 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 research 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 VPR if the review is required due to a lapse by the COIRC) shall complete a retrospective review of the Investigator's activities and the research 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 deceive the COIRC or TTUHSC El Paso regarding one's financial interests, the COIRC may recommend additional sanctions to the VPR. 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, 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;
- Non-renewal of appointment or dismissal in accordance with HSC OP 60.01.

The VPR 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 research project, the OSP 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 CMP. 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 is 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 research project
 - b) Conditions of the management plan
 - c) How the management plan is designed to safeguard objectivity in the research 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 research 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 El Paso 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.

8. Sub-recipient Monitoring for PHS-funded Research

- a) General: In cases where TTUHSC El Paso carries out PHS-funded research through a sub-recipient, TTUHSC El Paso will take reasonable steps to ensure that any sub-recipient investigator is adhering to the regulations concerning conflicts of interest in research found in 42 CFR 50. As part of the agreement with the sub-awardee institution, the TTUHSC El Paso OSP will obtain a certification from the sub-awardee institution indicating whether the policies of TTUHSC El Paso or the sub-awardee institution will apply to the sub-recipient investigators.
- b) Following TTUHSC El Paso's policies : If TTUHSC El Paso's policy applies, the agreement must specify a deadline for the sub-recipient to submit disclosures of their researchers' significant financial interests to TTUHSC El Paso. 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) Sub-awardee Institutional policies : If the sub-awardee 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 sub-recipient researchers' FCOI will be reported to TTUHSC El Paso. If such a certification cannot be provided, then TTUHSC El Paso's policies will apply to all sub-awardee investigators for disclosing significant financial interests that are directly related to the sub-recipient's work for TTUHSC El Paso.
- d) TTUHSC El Paso Reporting Responsibility: For PHS-funded grants awarded to TTUHSC El Paso, the TTUHSC El Paso OSP 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.

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 El Paso Office of Research Resources receives the request. In order for TTUHSC El Paso to disclose the information, the following criteria must be met: The Significant Financial Interest must have been disclosed to TTUHSC El Paso 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 Personnel;
- Title and role with respect the research project;
- Name of entity in which the significant financial interest is held;
- The nature of the interest;
- 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 El Paso Office of Research Resources
5001 El Paso Drive
El Paso, TX 79905
Phone: 915-215-4155

10. Amendments or Termination of this Policy

TTUHSC El Paso 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 El Paso and its employees or agents.