



# 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 Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Operating Policy and Procedure (HSCEP OP) is to protect the objectivity of the design, conduct and reporting of research conducted by TTUHSC El Paso researchers and to protect the 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<sup>1</sup> (PHS) as well as guidance from the Office of Human Research Protections to Institutional Review Boards<sup>2</sup> (IRBs) 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 HSCEP OP will be reviewed August 1 of each even-numbered year (ENY) by the chairperson of the TTUHSC El Paso Conflict of Interest in Research Committee (COIRC), the assistant managing director of the Office of Research (OR) or designee, and the senior director of the OR with recommendations for revision submitted to the vice president for research (VPR) or designee.

### **POLICY/PROCEDURE:**

#### **I. 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, both foreign and domestic, 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.

#### **II. Applicability**

- A. TTUHSC El Paso. This policy applies to all TTUHSC El Paso investigators/research personnel and applies to all research, regardless of funding.

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<sup>1</sup> 42 CFR 50 Subpart F—Promoting Objectivity in Research, effective February 28, 2022  
[Financial Conflict of Interest: HHS Guidance \(2004\) | HHS.gov](https://www.hhs.gov/ohrt/guidance/2004/)

- B. Non-TTUHSC El Paso. The policy also applies to sub-recipients, sub-awardees, or collaborators of TTUHSC El Paso involved in research activities.
- C. Not applicable. This policy does not apply to:
- Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) program phase I applications
  - Institutional conflicts of interest or conflicts of commitment

### III. **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(s)/research 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 FCOI.

*Family member:* For the purpose of this policy, family members shall be defined as the disclosing individual's:

- Spouse, step-children, spouse's parents, children's spouses and step-parents (1st degree within the 1st degree of affinity - marriage);
- Spouse's siblings, grandparents, grandchildren, sibling's spouse, step-grandparents and grandchild's spouses (1st degree within the 2nd degree of affinity – marriage);
- Parent, or child (1st degree within the three degrees of consanguinity – blood);
- Siblings, grandparents and grandchildren (2nd degree of consanguinity – blood);
- Great-grandparents, great-grandchildren, uncle, aunt, nephew and niece (3rd degree of consanguinity– blood); and
- Household members.

*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/research personnel. The VPR or designee and the TTUHSC El Paso COIRC, including the chairperson or designee of that committee, are authorized to review disclosures to determine whether a potential FCOI exists.

*Institutional Responsibilities:* A broad term describing all activities that derive from one's training and expertise of investigators/research personnel that relates 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 FCOI and CMPs.

*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.

*Research Personnel:* any personnel participating in research regardless of funding source.

*Significant Financial Interest:* A financial interest of the investigator/research personnel and/or family members that meets one or more of the following definitions:

- A. In a domestic or foreign publicly traded company, an aggregate value of \$5000 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;
- B. In a domestic or foreign non-publicly traded company, an aggregate value of \$5000 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.);
- C. Any amount of equity (e.g., stock, stock options, or other ownership or interest) in a domestic or foreign non-publicly traded company, regardless of whether the immediate value of the equity is known;
- D. Any income received (regardless of amount) related to intellectual property rights and interests (patents, copyrights, etc.);
- E. Any reimbursed or sponsored travel related to one's institutional responsibilities that were 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.<sup>1 2</sup>

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<sup>1</sup> 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 /research 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 FCOI and will not require further review by the COIRC.

<sup>2</sup> Disclosure will include, at a minimum, the purpose, the sponsor, the destination and the duration of each trip

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/research 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/family member making the disclosure 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.

#### IV. **Responsibilities of Investigators/Research Personnel**

- A. TTUHSC El Paso investigators/research personnel shall have the following responsibilities with regard to the disclosure and management of significant financial interests:

Disclosure. All investigators, research personnel, research administrative staff and members of the following TTUHSC El Paso research compliance committees: Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), and COIRC are required to disclose all significant financial interests for themselves and their family members on at least an annual basis, determined by the date of their last disclosure. A grace period of no more than 30 days following expiration is allowable for individuals who do not have an active Conflict Management Plan (CMP). Submission of financial disclosures is completed via the iRIS research administration software.

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

1. *Requirement for Protocol Review:* Investigators/research personnel must submit their initial disclosure forms or annual updates prior to final approval granted by the corresponding research committee.
2. *Changes:* Any changes to significant financial interests for investigators/research personnel or family members must be reported within thirty (30) days of discovering or acquiring a new significant financial interest.

3. *Review of Disclosures*: Completed disclosure statements will be submitted to the OR, 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 the iRIS research administration software database available to the OR and Sponsored Programs (SP) personnel. Grant proposals and iRIS submissions will be checked against these records by the appropriate committee. Any proposals/submissions by persons who have declared a significant financial interest will be referred to the COIRC Chairperson or designee by SP for an initial determination (See Section 5(E), below). Documentation of completed disclosures will be maintained by the OR for a minimum of 3 years.

B. Training. All investigators/research personnel and members of TTUHSC El Paso research compliance committees (IRB, IBC, IACUC, 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/research personnel. Training will be required more frequently for those who do not comply with this policy or as part of a CMP. 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/research personnel must complete initial training prior to the expenditure of funds. Principal Investigators are responsible for ensuring that current research personnel complete initial training. Failure to complete training may result in restriction of access to grant funds until training has been completed.
2. Investigators/research personnel conducting research with human subjects, animals, or chemical/biohazardous materials, 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 a TTUHSC El Paso research committee.

C. Confidentiality of Intellectual Property. Research personnel at TTUHSC El Paso may not share data or intellectual property with external entities that has been obtained from federally-funded, state-funded, private foundation-funded, or institutionally-funded research performed at TTUHSC EP without prior approval.

## V. **Conflict of Interest in Research Committee**

A. Establishment of Committee. The TTUHSC El Paso COIRC has been established by the VPR to review disclosures of significant financial interests to determine the presence of a FCOI, the nature and magnitude of the conflict, the degree to which the conflict is related to the research, and the extent to which research might be affected by this financial interest. The COIRC is also charged with periodic review of previously approved CMPs. The COIRC will work with investigators/research personnel to develop appropriate CMPs, provide copies of the CMPs to appropriate

review committees and administrators, and will obtain and review annual reports regarding ongoing CMPs.

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 purpose of fulfilling COIRC duties are confidential and privileged as “medical committee documents.”

- B. Membership. The COIRC will consist of at least 5 voting members.
1. Appointment will attempt to include representation by each School (Medicine, Nursing, Dentistry, and Graduate School of Biomedical Sciences) to serve on the COIRC.
  2. The VPR will appoint at least one additional member of the COIRC whom shall be a community representative with no family or financial ties to TTUHSC El Paso.
  3. Non-voting ex-officio members shall include senior research administrators and compliance personnel from various university bodies.
  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 COIRC shall be independent of the direct line of institutional authority for research.
  6. Members will be appointed to a 2-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 2-year term by the VPR. The chairperson may be reappointed for successive terms.
  3. *Administrative support:* The OR assistant managing director will appoint a staff person to provide administrative support to the COIRC.

4. *Quorum*: Quorum for this committee to conduct business is defined as fifty percent of members, plus one. A simple majority of voting members must be present for a quorum. This may include members present via teleconference. A quorum is not present when a sitting member who is present is required to recuse him/herself for any reason. If a quorum is lost at any time during the meeting, no further action shall be taken by the COIRC until a quorum is attained.
5. *Materials*: Prior to each convened meeting of the COIRC, members will be given materials sufficient for conducting the business of the meeting. Materials will be accessible by members via the iRIS research administration software prior to the meeting.
6. *Expedited Meeting*: An expedited meeting may be called by the Chairperson to review a new financial disclosure, if an approval must be granted prior to the next scheduled COIRC meeting. All members are invited, and a minimum of four members are required to review the financial disclosure. Action is approved by majority vote. Business conducted at an expedited meeting is reported to the full committee at the next scheduled meeting.
7. *Special Meeting*: Special meetings may be called by the Chairperson and may also be requested by any member of the Committee. The purpose of the meeting must be stated in the notice. Except in cases of emergency, at least three days' notice shall be given. For purposes of taking action, a quorum of members is required. Standard meeting minutes will be recorded for business conducted at the special meetings.
8. *Minutes*: Written minutes of each convened meeting 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; notation of members who were not present during deliberations and voting due to a conflict of interest; major points of discussion of research related issues and their resolution. Meeting minutes and materials are recorded in the iRIS research administration software and shall be maintained for a minimum of 3 years after the meeting date.

E. Duties of Chairperson.

*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 FCOI" or (ii) "possibly related FCOI." In order to make the initial determination the COIRC Chairperson (or his/her designee) will be provided, at a minimum, with the investigator's/research 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.

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/research personnel of actions taken by the COIRC, consulting with investigators/research personnel 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/research personnel create a FCOI 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 or animals in the conflicted research project. The committee will review proposed CMPs, 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 prior to the initial or continued expenditure of funds or enrollment of research participants.
3. *COIRC Review:* The convened COIRC shall review and (where necessary) investigate the information on 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 FCOI 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 FCOI 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 investigator/research personnel have 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 that 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 a FCOI exists or appears to exist, the COIRC shall work with the investigator/research personnel to develop a written CMP in order to determine the best method for managing the conflict. If the investigator/research personnel is unwilling or unable to divest of the significant financial interest, which leads to the conflict, a written 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 or animals, the TTUHSC El Paso IRB or IACUC must also approve the CMP prior to enrollment of any human subjects or animals in the research. The IRB and IACUC may suggest revisions of the CMP to the COIRC in order to secure their approval. Examples of conditions or restrictions that might be imposed to manage a FCOI 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 the 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 FCOI;
  - Modification of the research protocol/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/research personnel who are added to an ongoing research project and/or investigators/research personnel who disclose a new significant financial interest after a research project has begun, the COIRC will review the disclosure as soon as possible and within 10 business days to make an initial determination of whether a FCOI exists. If the committee determines that a 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. The final plan should be reviewed and voted upon within 60 days.

H. Monitoring Conflict Management Plans.

1. *Reports:* Investigators/research personnel who have ongoing CMPs shall provide annual, written reports (or at any time upon request from the COIRC) 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.
2. *Audits:* The VPR or COIRC may also request interim compliance audits of the monitoring plans be conducted by the OR or the TTU System Office of Audit Services. These audits may be requested either for cause or on a routine basis.
3. A conflict of interest determination made by the COIRC and/or CMP may be appealed to the VPR within thirty (30) days of the date the COIRC notifies the faculty, staff, or student of the COIRC's decision. The decision of the VPR shall be final.

VI. **Noncompliance**

- A. Breach. A breach of this policy by an investigator/research personnel may include, but is not limited to:

- Significant financial interest(s) not disclosed in a timely manner;
- Financial disclosure forms not submitted in a timely manner as scheduled, a grace period of 30 days following expiration is allowed for individuals without an active CMP
- 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 CMP.

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 chair of the COIRC can recommend to the VPR an immediate temporary suspension of the individual's research privileges. In turn, the VPR will consult with the faculty member's Department Chair to determine if a suspension of the individual's research privileges is warranted. If suspension is warranted and the individual is the Principal Investigator (PI) of the study, then all activity on that protocol must be halted as no research activity may take place without PI involvement and oversight per institutional policy. If the individual occupies a role other than PI, then the individual and the PI of their study will receive a notification that the individual is to immediately discontinue all research activity; the PI and other research members may continue their work unless the magnitude of the breach necessitates full suspension of study activities. A breach that results in the discovery of a new or previously undisclosed conflict requires that the COIRC shall, within 30 days, convene to review the significant financial interest to determine whether it is related to the research project;

to determine whether a FCOI exists; and, if so, shall implement, on at least an interim basis, a management plan that shall specify the actions that have been taken and will be taken to manage such FCOI going forward. A breach that is determined to constitute intentional non-compliance by an individual will be referred for possible additional sanctions by the VPR.

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 FCOI;
- Name of entity with which the investigator has a FCOI, 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/research 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 or animals;
- 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.

## VII. **Financial Conflicts of Interest 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<sup>3</sup>. 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.

## VIII. **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 SP will provide to the PHS awarding component a FCOI report regarding any investigator/research personnel with a significant financial interest which has been determined by the COIRC to constitute a 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.
- B. 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 FCOI;
  - Name of the entity with which the FCOI 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/research 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;

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<sup>3</sup> For example, a collaborator outside of the U.S. who performs experiments in support of a PI's NIH-funded project would constitute a foreign component, regardless of whether the foreign collaborator receives funding from that PI's NIH grant. Additional funding from a foreign source for the NIH-supported research of a PI at a U.S. institution would not constitute a foreign component but would necessitate reporting as other support.

- e) How the management plan will be monitored to ensure compliance; and
  - f) Other information as needed.
- C. 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 FCOI no longer exists.
- D. Reporting New Information. New FCOI 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.
- E. 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.

#### IX. **Sub-recipient Monitoring for PHS-funded Research**

- A. General. In cases where TTUHSC El Paso carries out PHS-funded research through a subrecipient, 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 CF 50. As part of the agreement with the sub-awardee institution, the TTUHSC El Paso SP will obtain a certification from the sub-awardee institution indicating whether the policies of the TTUHSC El Paso or the sub-awardee institution will apply to the sub-recipient investigators.
- B. Following TTUHSC El Paso's Policies. If the TTUHSC El Paso's policy applies, then 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 expenditures 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 subawardee 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 SP 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.

## X. 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 OR 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/research 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/research personnel;
- Title and role with respect to 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 130  
Rick Francis St MSC 31001  
El Paso, TX 79905  
Phone: 915-215-4155

## XI. 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.

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Conflicts of interest related to nepotism in research are governed by HSCEP OP [73.18](#) and are not covered under this policy.

Conflicts of interest or concerns related to Export Controls are governed by [HSCEP OP 73.16](#) and are not covered under this policy.