

REVIEW: This OP will be reviewed by August 1 of each even-numbered year (ENY) by the due

- 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 SVPRI shall acknowledge the CMP.

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

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

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

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*

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 SVPRI 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 SVPRI 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 Assistant Vice President for Research integrity, 2) the Director of the 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

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

- 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

