

# **TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO**

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

### **POLICIES AND PROCEDURES MANUAL**



**Version 1.1**

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# CHAPTER 1 ORGANIZATION OF THE TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO CONFLICT OF INTEREST IN RESEARCH COMMITTEE

## 1.1 Introduction and Organizational Summary

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.

This TTUHSC El Paso COIRC Policies and Procedures Manual (PPM) provides the TTUHSC El Paso research community with an overview of the federal regulations and institutional policies that govern financial and nepotistic conflicts of interest in research. The COIRC will serve as the review committee for all relevant research disclosures.

The COIRC PPM will be revised and updated as new guidelines, clarifications and/or other information becomes available. The COIRC, in conjunction with the TTUHSC El Paso research committees, will work with investigators and lab personnel to assist them in meeting both federal and institutional policies and procedures relating to conflicts of interest in research.

The COIRC PPM is based on the following regulations, guidelines and TTUHSC El Paso policies:

- Code of Federal Regulations (42 CFR 50 Subpart F): Promoting Objectivity in Research
- TTUHSC El Paso Operating Policy 73.09: Financial Conflicts of Interest in Research  
<https://elpaso.ttuhsoc.edu/opp/documents/73/op7309.pdf>
- TTUHSC El Paso Operating Policy 73.18: Research Nepotism  
[PLACEHOLDER LINK]
- TTUHSC El Paso COIRC Bylaws  
<https://elpaso.ttuhsoc.edu/research/committees/coirc/bylaws.aspx>
- Guidance from the Office of Human Research Protections (OHRP) to Institutional Review Boards (IRBs)
- Public Health Service (PHS)

## 1.2 Scope of Work

All TTUHSC El Paso investigators and research personnel including, but not limited to, faculty, staff, students and volunteers are included within the scope of these *Policies and Procedures*, as are collaborators and visitors from other organizations actively participating in research on

campus. The COIRC is in place to protect the objectivity of the design, conduct and reporting of research conducted by 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.

Oversight includes:

- Processes to identify and manage any financial conflict(s) of interest (FCOI) and conflicts of interest related to nepotism;
- Manage and report any significant conflicts of interest;
- Provide training and ensure compliance;
- Publicly disclose FCOI related to PHS-funded research.

### 1.3 Components of the COIRC

In order to function effectively, the TTUHSC El Paso COIRC requires commitments and assistance from many areas within the institution. The major components of the TTUHSC El Paso COIRC include:

- **The Institutional Official.** The Vice President for Research (VPR) serves as the Institutional Official with overall responsibility for the TTUHSC El Paso COIRC. Specific duties and responsibilities of the VPR with regard to the COIRC can be found under Institutional Authority. The VPR may appoint a designee to fulfill the duties and responsibilities.
- **Conflict of Interest in Research Committee (COIRC).** The TTUHSC El Paso COIRC has been established by the VPR to review disclosures of significant interests to determine the presence of a COI, 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 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.
- **Office of Research (OR).** The Institutional Official recognizes the OR as the institutional point of contact. OR staff members exercise operational responsibility on a day-to-day basis for the COIRC. This includes COIRC administration, compliance, educational, and quality improvement components of the TTUHSC El Paso COIRC.
- **Research Committees.** The Institutional Review Boards (IRBs), Institutional Biosafety Committee (IBC) and Institutional Animal Care and Use Committee (IACUC) of TTUHSC El Paso collectively review pertinent research projects conducted on this campus. These committees have the authority to approve, require modifications to secure approval, or disapprove all such research and may also suspend or terminate their approval of that research. Cooperation and collaboration with these committees is essential to the COIRC in forming its assessments and enforcing its decisions.
- **Sponsored Programs (SP).** The TTUHSC El Paso SP division of the Office of Research handles grant and clinical trial contract administration. Personnel in

this office review sponsored contracts and funding agreements for compliance with Federal and State regulations as well as with TTUHSC El Paso and COIRC policies and procedures.

- **General Counsel.** The TTU System Office of General Counsel is available to provide advice upon request of the VPR, COIRC, or other individuals involved with the COIRC. The Office of General Counsel may provide legal guidance and interpretation of TTUHSC El Paso policies, and of State and Federal laws and regulations as they relate to financial conflicts of interest.
- **Investigators and Research staff.** Investigators and research staff have a responsibility to fulfill COIRC requirements described throughout this Manual and to comply with all determinations of the COIRC and the VPR.
- **Deans/Department Chairs.** These individuals are responsible for “setting the tone” for responsible conduct and oversight of research in their department or school, for providing opportunities for education regarding ethical actions and compliance, for fostering support for COIRC oversight, and for providing adequate resources to conduct this research at TTUHSC El Paso.
- **All TTUHSC El Paso faculty, staff, students, and volunteers.** Everyone associated with TUHSC El Paso should have a general awareness regarding financial and nepotistic conflicts of interest in research and should consult the COIRC when faced with uncertainty about whether an activity may constitute a breach of policy. Individuals should report allegations of possible research misconduct as outlined in [TTUHSC El Paso OP 73.14, Research Compliance](#) and [TTUHSC El Paso OP 73.07, Honesty in Research and Allegations of Scientific Misconduct](#).

### 1.3.1 Communication between Components

TTUHSC El Paso uses several mechanisms to communicate information relevant to the COIRC. Issues specifically pertinent to conflicts of interest in research are communicated to investigators and staff via institutional electronic mail and the IRIS Announcement feature on an as-needed basis.

The Managing Director of the OR serves as a central liaison between the COIRC and other research compliance committees, the VPR, and various other departments as appropriate.

The annual research financial disclosure form serves as the primary tool for assessment of the institutional requirements to be met to ensure appropriate compliance. COIRC members and COIRC administrative staff review the disclosures to verify that these institutional components are adequately met. Examples include training, completion of the required forms by all study personnel, and the creation of approved conflict management plans when necessary. If the COIRC administrative staff determines that any of the institutional requirements necessary to protect participants are lacking, then the disclosing individual will be notified in writing. The disclosing individual will be required to address the issue(s) and to provide additional necessary documents and/or information needed to comply with institutional policies and procedures. As appropriate, the principal investigator (PI) of the study may also be notified and consulted in order to reach a resolution.



## 1.4 About the COIRC

### 1.4.1 Name, Authority, and Formation

The VPR, designated and charged by the TTUHSC El Paso President, has established the COIRC and has the authority to appoint members to the COIRC. The VPR has charged the COIRC with the responsibility and authority to review all research conducted at the University as it may relate to conflicts of interest. The VPR has access to the Internet Medical Research Informational Systems (iRIS) program, which contains all documents, correspondence, and deliberations regarding each disclosure reviewed by the COIRC. This access permits review of all activities of the COIRC as well all documents submitted, however the COIRC functions independently as a research oversight committee. The COIRC shall base its decisions and actions on regulations and applicable guidance documents referenced in this manual.

The Chair or authorized designee of the TTUHSC El Paso COIRC shall have signatory power for review and actions taken by the COIRC. All documents processed by the COIRC, including electronic documents found in iRIS such as Conflict Management Plans, finalized COIRC minutes, acknowledged/approved documents, documents referenced in electronic letters, and official correspondence, have the full approval of the COIRC Chair/designee and have the authority of signed documents. Handwritten signatures by the COIRC Chair/designee are not required under this policy.

### 1.4.2 Responsibilities

General:

- The COIRC shall make recommendations to the VPR and develop proposals for policies regarding conflicts of interest in research.
- The COIRC shall educate the Institutional community and other stakeholders regarding requirements relating to conflicts on interest in research.
- The COIRC shall maintain cooperative relationships with University committees and the persons involved in research.
- The COIRC shall advise the University, associated departments and investigators on regulations and policies regarding conflicts of interest in research.
- The COIRC shall implement appropriate administrative procedures for regulating conflicts of interest in research.
- The COIRC shall ensure that all covered personnel submit an annual research financial disclosure detailing their financial or nepotistic interests and that these are reviewed in a timely manner to eliminate or lessen any existing conflict.

Review:

The convened COIRC shall review and (when necessary) investigate the information in the completed research financial disclosure forms as well as a summary of the proposed research project(s) to determine whether the significant financial interest is related to the



research project. Relatedness involves a decision that the research could be affected by the significant financial interest, nepotistic interest or related entity. A determination that a COI exists will be made when the COIRC reasonably concludes that the significant 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 COI exists, the COIRC may consider the following factors, including, but not limited to:

- The type and nature of the disclosed interest;
- The funding source, if an FCOI;
- Where and by whom the research was designed;
- Who will be collecting/analyzing the data;
- Any indication that the investigator/research personnel has an incentive to improperly favor an outside entity;
- Any indication that the investigator/research personnel has an incentive to improperly favor certain research personnel;
- Any indication that the investigator/research personnel may have their research duties impacted by obligation to other members of the study personnel;
- Whether incentives exist that may lead to bias or may 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 interest and the proposed project.

#### Oversight of Research:

- The COIRC shall ensure that all research conducted at the University is done so without the undue influence of external entities.
- The COIRC may review public databases or external sources to ensure compliance and accuracy of disclosures.
- The COIRC shall make certain that, if applicable, a Conflict Management Plan (CMP) is enacted and enforced to eliminate or reduce an existing conflict of interest.

#### Reporting:

- For PHS-funded grants awarded to TTUHSC El Paso, the TTUHSC El Paso SP (and, by extension, the COIRC) is responsible for providing financial conflict of interest reports to the PHS Awarding Component prior to the expenditure and funds, and within 60 days of any subsequently identified financial conflict of

interest.

- As required by 42 CFR Part 50, information regarding significant financial interests for PHS-funded research for which a CMP has been developed will be made available to requestors within 5 business days after the TTUHSC El Paso OR receives the request.

## 1.5 Confidentiality of Records

The TTUHSC El Paso COIRC is a “medical committee” as defined under Texas Health & Safety Code chapter 161, and/or other applicable state and federal statutes. All documents generated by, submitted to, or for the purposes of fulfilling COIRC committee duties are considered confidential and privileged as “medical committee documents”. Certain COIRC documents are considered privileged and confidential records, not subject to disclosure, except to authorized TTUHSC El Paso representatives and federal regulatory officials.

## 1.6 Relationship to other TTUHSC El Paso Compliance Committees

The TTUHSC El Paso COIRC functions independently of, but in coordination with, other TTUHSC El Paso Research and Safety Compliance Committees, including, but not necessarily limited to the following:

- Institutional Review Boards (IRBs)
- Institutional Biosafety Committee (IBC)
- Institutional Animal Care and Use Committee (IACUC)

Subcommittees of the COIRC may be appointed by the COIRC Chairperson as deemed necessary to perform the work of the Committee. The Chairperson shall be an ex officio member of any such sub-committees.

## 1.7 Affiliated Entities

The COIRC reviews all research conducted at TTUHSC El Paso and thus their oversight extends to all research personnel including employees and non-employees, sub-recipients, sub-awardees or collaborators of TTUHSC El Paso involved in research activities unless the home institution of the sub-recipient, sub-awardee, or collaborator has its own written policy on conflict of interest that is in accordance with 42 CFR 50, Subpart F.

## 1.8 Review and Approval of Bylaws

The bylaws shall be reviewed at least annually by the Chairperson of the Committee, the COIRC Lead Analyst, Sr. Director and Managing Director of the Office of Research. Proposed changes to the bylaws will be presented to the full Committee for review and comment. The COIRC Chairperson has authority to provide final approval of the Bylaws.

### 1.8.1 Amendment of Bylaws

The bylaws may be modified or amended as needed at the request of the VPR or designee in

consultation with the COIRC Chairperson.

## **CHAPTER 2 CONFLICT OF INTEREST IN RESEARCH COMMITTEE STRUCTURE AND FUNCTION**

### **2.1 Organization of the COIRC**

There is a single COIRC designated for the TTUHSC El Paso campus.

### **2.2 Membership**

#### **2.2.1 Composition of the COIRC**

The membership shall consist of a minimum of five voting members. The VPR will attempt to include representation from each school (medicine, nursing, dentistry, and graduate school of biomedical sciences) and shall appoint at least one member who is a community representative with no family or financial ties to TTUHSC El Paso. 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.

The Committee shall also host ex-officio members who do not have voting privileges but who shall provide additional guidance and serve as a resource to the committee regarding relevant institutional policies and federal guidelines. Ex-officio members include senior research administrators and compliance personnel from various university bodies.

#### **2.2.2 Member Education**

All COIRC members, voting and non-voting, are required to submit, or have on record, a current *curriculum vitae*, a research financial disclosure form, and must successfully complete the online Conflict of Interest course offered through the University of Miami's Collaborative Institutional Training Initiative (CITI) Program. COIRC members are encouraged to participate in ongoing continuing education. COIRC members also are required to update their research financial disclosure on at least an annual basis or when obtaining a new interest, and are required to renew their training as appropriate. Listed below are the items that are currently REQUIRED to be successfully completed and on file by any new committee member:

- Conflict of Interest Course, the institution-approved basic course for training in financial conflicts of interest administered by CITI.
- Research financial disclosure form.
- Current Curriculum Vitae, updated within two years.

Information provided to new committee members includes:

- Code of Federal Regulations (42 CFR 50 Subpart F): Promoting Objectivity in Research
- TTUHSC El Paso Operating Policy 73.09: Financial Conflicts of Interest in Research

- TTUHSC El Paso Operating Policy 73.18: Research Nepotism
- <https://elpaso.ttuhsu.edu/opp/documents/73/op7309.pdf>
- TTUHSC El Paso COIRC by-laws  
<https://elpaso.ttuhsu.edu/research/committees/coirc/bylaws.aspx>
- COIRC Member Roster;
- TTUHSC El Paso COIRC Policies and Procedures Manual

COIRC members are encouraged to participate in ongoing continuing education on the topics of financial conflicts of interest. Engaging in any of the following is considered evidence of continuing education:

- Attending educational presentations as part of regularly scheduled COIRC meetings, including changes in Federal Regulations, COIRC processes, or forms;
- Reviewing relevant books, periodicals, or handouts furnished to COIRC members;
- Attending TTUHSC El Paso training seminars focusing on relevant topics;
- Attending regional or national seminars or conferences which involve discussion of research ethics.

Required Education: Listed below are the web-based courses that are currently REQUIRED to be successfully completed:

- CITI Conflict of Interest Course – completed at least once every 4 years.
- Research Financial Disclosure – completed on at least an annual basis

### 2.2.3 Appointment

Any interested party may recommend new members, including self-referrals. The VPR or designee shall appoint the members of the Committee for a two-year term and may reappoint them at their discretion. Generally, terms will begin on September 1 of each odd-numbered year. Committee needs will be assessed throughout the year. Each member's annual term shall coincide with the institution's fiscal year. If notice of resignation by the member or non-reappointment by the VPR is not given by August 1 of each year, each member's appointment shall be automatically renewed on a year-to-year basis. Members with more than three (3) unexcused absences per year may be asked to resign from the Committee. At the time of appointment/reappointment the COIRC member will sign an agreement to serve and a confidentiality agreement, and shall disclose any known or potential conflicts of interest.

### 2.2.4 Officers

The officers of the Committee shall be a Chairperson and vice-Chairperson. These officers shall perform the duties prescribed by the bylaws and by the parliamentary authority adopted by the Committee. The VPR shall appoint the Chairperson and vice-Chairperson of the Committee. Unless notice is given to the Officers by the VPR or to the VPR by the Officers, these appointments shall be automatically renewed on a year-to-year basis. In the event of a conflict of

interest between the Chairpersons duties and their own research, the vice-Chairperson shall assume the responsibility of review and decision making. The chairperson and vice-chairperson are considered voting members of the COIRC for purposes of establishing the quorum.

## 2.3 Committee Staff

### 2.3.1 Initial Education

Listed below are the items that are currently REQUIRED to be successfully completed within the first week of employment:

- Conflict of Interest Course, the institution-approved basic course for training in financial conflicts of interest administered by CITI.
- Research Financial Disclosure form.

Additional education is conducted by the supervisor or designee during the first month of employment and continues as needed throughout the employee's tenure, the information presented during the first month includes and is designed to provide education on the following topics:

- TTUHSC El Paso Conflict of Interest in Research Policies and Procedures
- Interaction between the COIRC Office and the Committee;
- Terms and federal regulations;
- Meeting basics (quorum, voting procedures, etc.);

Information provided to new staff members during the first month of employment includes:

- Code of Federal Regulations (42 CFR 50 Subpart F): Promoting Objectivity in Research
- TTUHSC El Paso Operating Policy 73.09: Financial Conflicts of Interest in Research
- TTUHSC El Paso Operating Policy 73.18: Research Nepotism
- TTUHSC El Paso COIRC Bylaws
- COIRC Member Roster;
- TTUHSC El Paso COIRC Policies and Procedures Manual

### 2.3.2 Continuing Education

COIRC staff are encouraged to participate in ongoing continuing education on the topics of financial conflicts of interest. Engaging in any of the following is considered evidence of continuing education:

- Attending educational presentations as part of regularly scheduled COIRC meetings, including changes in Federal Regulations, COIRC processes, or forms;

- Reviewing relevant books, periodicals, or handouts furnished to COIRC members;
- Attending TTUHSC El Paso training seminars focusing on relevant topics;
- Attending regional or national seminars or conferences which involve discussion of research ethics.

Required Education: Listed below are the web-based courses that are currently REQUIRED to be kept current:

- CITI Conflict of Interest Course – completed at least once every 4 years.
- Research Financial Disclosure – completed on at least an annual basis

Evaluation of staff performance is an ongoing activity involving each staff member and their supervisor. Completion of training, educational activities and performance improvement is formally evaluated annually as part of the TTUHSC El Paso performance management program. The formal evaluation process includes a self-evaluation and further evaluation by both the direct supervisor and/or next-level supervisor. Feedback is provided individually by the direct supervisor. Growth plans for the upcoming year will generally be agreed upon by the employee and direct supervisor.

## 2.4 Meetings

Meetings will be held as needed, as determined by the COIRC Chairperson or designee. The agenda, draft minutes from previous meeting, and all appropriate material will be available for review by all voting members. Members should review the materials before each meeting. Staff of the Office of Research will provide administrative support for the COIRC.

### 2.4.1 Attendance

The importance of COIRC member attendance cannot be overstated. Member absences may affect the quorum and therefore the ability to conduct business. Notification of an expected absence is required. Members absent more than 3 times in a fiscal year may be asked to resign from the committee.

### 2.4.2 Quorum

A COIRC meeting shall only be convened when a quorum is present. 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.

### 2.4.3 COIRC Member COI

When a COIRC member has a conflict of interest as defined by Institutional policy relating to a matter before the COIRC, he/she shall make the conflict known and recuse him/herself from the consideration of that matter.

## 2.4.4 Considerations for Review

The COIRC shall consider in its deliberations and base its decisions relating to conflicts of interest in research on the Code of Federal Regulations, TTUHSC El Paso Operating Procedure and other relevant external and internal reference documents.

## 2.4.5 Expedited Subcommittee

An expedited meeting may be called by the Chairperson to review a new research financial disclosure, and approval must be granted prior to the next scheduled COIRC meeting. All members are invited, and a minimum of four members is required to review the research 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.

## 2.4.6 Special Meetings

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.

## 2.4.7 Minutes

Written minutes of each convened meetings will be in sufficient detail to demonstrate the following:

- Attendance at the meetings and presence of a quorum,
- Actions taken by the COIRC regarding each agenda item, 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 will be retained for three years following the meeting.

## 2.5 Investigator/PI Responsibilities

### 2.5.1 Investigator Conflicts of Interest

All TTUHSC El Paso investigators and study personnel are bound to the policies set forth in [TTUHSC El Paso OP 52.06 Standards of Conduct and Ethics](#), [TTUHSC El Paso OP 10.05 Conflicts of Interest and Commitment](#), [TTUHSC El Paso OP 73.09 Financial Conflicts of Interest in Research](#) and TTUHSC El Paso Operating Policy 73.18: Research Nepotism.

Unaffiliated investigators may also be bound to these policies if their own institutions do not



have internal conflict of interest policies. Failure of any PI or associated research personnel to comply with these policies may result in immediate suspension of research privileges and/or additional sanctions as described in section 2.7 of this manual. In accordance with the TTUHSC El Paso Conflict of Interest in Research Policy, all research personnel are required to disclose any financial conflicts of interest as outlined in the policy. These disclosures are to be made at least annually, and are to be updated more frequently as circumstances change.

## 2.5.2 Annual Research Financial Disclosure

All PIs are required to submit an annual research financial disclosure which details all financial interests that they and their family members have experienced in the prior twelve months, as well as any research activity undertaken with personnel who they are related to. The PI is to submit this disclosure outside of the prescribed cycle whenever a significant interest develops, within thirty days of discovering the new interest (e.g. when obtaining a new financial interest; when joining a study wherein a family member is currently listed as personnel; when an external change results in two current research personnel to become family such as in the event of marriage). The PI is to be as truthful and as forthcoming as possible when describing their disclosed interests so that the COIRC can make an accurate assessment. If requested, the PI should be prepared to furnish receipts or records relating to potential conflicts of interest as requested by the COIRC.

A significant financial interest for the investigator or their family that requires reporting is defined as:

- 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;
- 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.);
- 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;
- Any income received (regardless of amount) related to intellectual property rights and interests (patents, copyrights, etc.);
- 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.

The following are not regarded as constituting a significant financial interest and as such are not required to be reported:

- 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;
- 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;
- 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
- 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.

A significant interest in regards to nepotism must be reported when individuals within the definition of “family member” as established by HSCEP OP 73.09 plan to collaborate on a research project. These are 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.

### 2.5.3 Conflict Management Plan

If the COIRC determines that a conflict of interest exists or appears to exist following their review, they are empowered to create and enforce a CMP to eliminate or minimize the conflict. The PI is obligated to comply with the measures and provisions agreed upon in the plan. Additional information regarding CMPs can be found in section 2.6.4 of this manual.

### 2.5.4 Preventing a COI

PIs are tasked with actively avoiding the creation of a conflict of interest in research at all times. Prevention is preferable to correction, to those ends the COIRC has assembled a short guide detailing the most common sources of FCOIs and how they may be avoided:

<http://elpaso.ttuhs.edu/research/committees/coirc/COITips.aspx>. Each PI is responsible for compliance with all federal regulations and institutional policies when conducting research at TTUHSC El Paso.

## 2.5.5 Training

All investigators/research personnel and members of TTUHSC El Paso research compliance committees (IRB, IBC, IA CUC, NRCOIC, TTUSORC, 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:

- 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.
- Investigators/research personnel and other study personnel conducting research with human subjects, animals or 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 the TTUHSC El Paso IRB, IBC or IA CUC.

## 2.6 COIRC Actions

### 2.6.1 Research Financial Disclosure Review Requirements

In conducting the review of proposed research, the COIRC must obtain information in sufficient detail to make the determinations required under federal regulations and institutional policies. This review may be conducted administratively for disclosures with no interest to report; disclosures with a reported interest will undergo primary review by the Chairperson/designee who will make the determination to clear the disclosure if no COI exists or refer the matter for consideration by the full committee if a conflict does appear to exist. Review of Financial Disclosures are completed via the iRIS research administration software. The outcome of each review is reflected on the user's iRIS account via corresponding colored flags; the disclosing individual will receive a letter explaining the outcome of their review and any actions, if any, must be taken.

### 2.6.2 Additional Information

The COIRC or designated member may request additional information of a researcher as part of the assessment of a research financial disclosure. The request may refer to clarification of statements made in the disclosure or a request to provide supporting documentation of the claims made therein, these notices are sent electronically via the iRIS system with a response deadline. The COIRC may request that the respondent meet with the committee or a subcommittee in person to discuss the requested material in certain cases.

### 2.6.3 Cleared Review

The COIRC or designee may determine that there is no real or apparent FCOI following review, in which case they may decide to clear the disclosure in one of two manners:

- Cleared with no possibility for COI, this designation is made when the disclosed interest does not pose an immediate COI and cannot reasonably be expected to pose a COI in the future.
- Cleared with the possibility of COI, this designation is made when the disclosed interest does not pose an immediate COI but may feasibly pose a COI in the future. Personnel with this designation will be monitored when joining future studies to ensure that a COI does not arise.

### 2.6.4 CMP Required

Following review, the COIRC may determine that a real or apparent COI exists. For the purposes of safeguarding the University, the PI, and the integrity of the research, these scenarios are functionally identical. The individual with an FCOI will be asked to divest from the competing interest. If the individual is unwilling or unable to divest, the COIRC will work to mitigate the effect of this real or apparent FCOI by creating a CMP as defined by TTUHSC El Paso OP 73.09 which appropriately limits or eliminates the FCOI completely. For COI matters concerning nepotism, disclosing individuals will be required to provide justification for the involvement of related personnel and a CMP to mitigate potential effects of the COI on the research as defined by OP 73.18.

These plans are crafted in collaboration with the VPR, OR, SP, the disclosing individual and the committee that oversees that particular study (IRB, IBC or IACUC as applicable) to ensure the feasibility and applicability of the CMP. Once agreed upon and signed, the disclosing individual is bound to comply by the provisions of the plan. Applicable representatives of the TTUHSC El Paso administration and members of the individual's research team will be apprised of the CMP provisions as deemed appropriate. The COIRC is tasked with enforcement of the CMP to the extent possible. 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 or animals, 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
- Audit of study activity or procedures by TTUHSC El Paso Research Compliance personnel as determined by the corresponding research committee for the

protocol (IRB, IA CUC, IBC).

- Disclosure of personnel relationship to the study sponsor

## 2.6.5 Reports and Follow-Up

Investigators/research personnel who have ongoing CMPs shall provide written reports at intervals indicated by the COIRC regarding action taken under the CMP, or on an annual basis as described by TTUHSC EP OP 73.09. Reports shall be submitted to the COIRC chairperson or designee. 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.

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.

A conflict of interest determination by the COIRC and 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.

## 2.7 Compliance Oversight

### 2.7.1 Non-Compliance

A situation, event or process in research activities that is inconsistent with Federal and/or local regulations applying to conflicts of interest in research. Non-compliance, or breach, of this policy by the investigator/research personnel may include, but is not limited to:

- Significant interest(s) not disclosed in a timely manner;
- Financial disclosure form not submitted in a timely manner as scheduled, a grace period of 30 days following expiration is allowed for individuals who do not have 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

### 2.7.2 Action upon Breach

If an alleged or actual policy breach occurs, the chair of the COIRC may elect to enact an immediate temporary suspension of the individual's research privileges. If the individual is the Principal Investigator 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. The administrative staff for all TTUHSC El Paso research committees verify study personnel's FCOI status at regular review intervals and studies are ineligible to receive initial or continuing approval if listed personnel present an expired or unresolved status. 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 COI 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 COI 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, examples of such sanctions are indicated in section 2.7.3 of this manual.

### **2.7.2.1 Retrospective Review**

Within 120 days of being made aware of a policy breach related to an FCOI, 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, 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).

### **2.7.2.2 Additional Training**

Any policy breach by an investigator or by research personnel will result in additional training regarding institutional policies and the federal regulations for the investigator/research personnel.

### **2.7.3 Intentional Non-Compliance**

Non-compliance that the COIRC has determined was part of an intentional plan to deceive the COIRC or TTUHSC El Paso regarding one's financial or nepotistic interests. The COIRC may recommend additional sanctions to the VPR in such cases. 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.

## 2.8 Institutional Reporting Requirements

### 2.8.1 Financial Conflict of Interest Reporting Requirements for PHS-funded Research

Before the expenditure of any funds under a PHS-funded research project, 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.

### 2.8.2 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; e) How the management plan will be monitored to ensure compliance; and f) Other information as needed.

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.



### **2.8.3 Reporting New Information.**

New FCOIs 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.

### **2.8.4 Reporting Breaches**

Policy breaches, as defined in Section 2.7.1 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.

### **2.8.5 Sub-recipient Monitoring for PHS-funded Research**

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 SP 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.

### **2.8.6 Following TTUHSC El Paso Policies.**

If 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 expenditure of funds.

### **2.8.7 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.

### **2.8.8 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.

### **2.8.9 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 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).

## **CHAPTER 3 RESEARCHER AND RESEARCH STAFF INFORMATION**

The purpose of this chapter is to provide guidance to research investigators and personnel on ethical conduct of research in accordance with applicable laws, regulations and TTUHSC El Paso policies and procedures. In addition to the information found in this Manual, investigators and research staff or those who wish to learn more about the TTUHSC El Paso COIRC can find more information at the TTUHSC El Paso COIRC website. Contact information for COIRC administrative staff as well as links to other helpful information can be found there.

### **3.1 Prerequisites for all research personnel**

#### **3.1.1 Educational Requirements**

All PIs and research personnel are required to receive training on financial conflict of interests prior to beginning any research-related activities. This training will be verified prior to iRIS access being granted. Initial approval of IRB, IBC and IA CUC submissions will be withheld until all research personnel have been verified as having completed/updated their training and research financial disclosure forms.

#### **3.1.2 Annual Research Financial Disclosure**

All research staff must have a current Annual Research Financial Disclosure statement on file with the OR in accordance with TTUHSC El Paso OP 73.09 Financial Conflicts of Interest in Research. The Research Financial Disclosure form is submitted from within the iRIS research administration software.

#### **3.1.3 Conflict of Interest Training**

All PIs and research personnel involved in research activities must complete conflict of interest training every 4 years. The training is available through the University of Miami at [www.citiprogram.org](http://www.citiprogram.org).

### 3.1.3.1 CITI Instructions

**Registration:** To begin the on-line course, go to the CITI website and select "Register". Next, enter "Texas Tech University Health Sciences Center-El Paso" as your organization affiliation. Continue through the multiple step process to establish your User name and Password. On the CITI registration page you will need to select the **Conflict of Interest Course**. You will then have access to the required modules. TTUHSC El Paso personnel must use their TTUHSC El Paso email address for registration. More information on CITI Training can be found at the CITI Program Support Center.

**Course Completion:** Upon successful completion of the course, you will be able to download a course transcript. TTUHSC El Paso is also notified of your successful completion of the course. You will be required to achieve an overall score of at least 80% to successfully complete the courses.

## 3.2 Avoiding Financial Conflicts of Interest in Research

A financial conflict of interest arises when an individual's conduct or professional relationship with entities outside of the university begin to create a divide between the responsibilities they owe to the institution and those related to the external interests. With respect to research, a potential conflict of interest may introduce implicit or explicit bias into the design, conduct or interpretation of research findings or raise questions about possible bias. Such conflicts undermine the public trust in the objectivity of academic research, and **Conflicts of Interest in Research** risk placing both the institution and the investigator in the spotlight of public scrutiny. As stated in TTUHSC El Paso OP 73.09, any individual performing research activities at TTUHSC El Paso is charged with the duty to avoid or minimize the opportunity for such conflicts, to disclose any conflicts as they develop, and to comply faithfully with the university in divesting from those conflicts or managing them as deemed appropriate.

The following guidelines provide useful information regarding how to avoid conflicts of interest in research. For questions on topics or situations not described below, please contact COIRC Lead Analyst Josh Cardoza at 915-215-5220 or [Josue.Cardoza@ttuhsc.edu](mailto:Josue.Cardoza@ttuhsc.edu).

## 3.3 Consulting Work

### 3.3.1 General Consulting Work; Speaking Engagements; Speaker's Bureau:

- Keep up-to-date records of any remuneration that you receive for these activities for accurate and complete reporting in annual university disclosures.
- Ensure that your consulting or speaking activities do not violate university or federal regulations.
- **Do not perform these activities for any company with which you are currently involved in research. This is a conflict of interest.**
- Your relationship/agreement with a company does not grant them any claim or intellectual property rights to discoveries made during your activities as an employee of the university, including those made while using university resources or facilities.
- Relationships with external entities must be disclosed accurately and completely in relevant publications or presentations.

### 3.3.2 Service on Medical Advisory Boards:

- Keep up-to-date records of any remuneration, stock, or other equity that you receive for these activities for accurate and complete reporting in annual university disclosures.
- Ensure that your consulting or speaking activities do not violate university or federal regulations.
- **Do not perform these activities for any company with which you are currently involved in research. This is a conflict of interest.**
- Your relationship/agreement with a company does not grant them any claim or intellectual property rights to discoveries made during your activities as an employee of the university, including those made while using university resources or facilities.
- Relationships with external entities must be disclosed accurately and completely in relevant publications or presentations.

### 3.3.3 Service on Boards of Directors:

- Be as thorough as possible when disclosing your position to the university as certain roles are disallowed depending on the degree of implied fiduciary and/or managerial duty.
- Keep up-to-date records of any remuneration, stock, or other equity that you receive for these activities for accurate and complete reporting in annual university disclosures.
- Ensure that your consulting or speaking activities do not violate university or federal regulations.
- **Do not perform these activities for any company with which you are currently involved in research. This is a conflict of interest.**
- Your relationship/agreement with a company does not grant them any claim or intellectual property rights to discoveries made during your activities as an employee of the university, including those made while using university resources or facilities.
- Relationships with external entities must be disclosed accurately and completely in relevant publications or presentations.

## 3.4 Investment, Entrepreneurship, Ownership

### 3.4.1 Stock or Equity Holding

- Keep up-to-date records of the valuation of your holdings for accurate and complete reporting in annual university disclosures.
- Divest from companies that sponsor or are otherwise involved in an area in which you conduct or plan to conduct research.
- Relationships with external entities must be disclosed accurately and completely in relevant publications or presentations.

### 3.4.2 Small Business Innovation Research/ Small Business Technology Transfer (SBIR / STTR)

- Notify the COIRC as soon as possible once the decision has been made to seek this avenue of funding, preferably prior to the registration of a company or submission of funding application for guidance Phase I SBIR and STTR applications are not covered under 42 CFR 50 however Phase II and beyond are covered.
- A specialized CMP will be created to manage your interest in the newly formed company if necessary.
- A Notice of Intent (NOI) will need to be filed with SP and is subject to their rules and regulations.

### 3.4.3 Licensing TTUHSC El Paso Intellectual Property

- The rights to all intellectual property (including all forms of patented and unpatented inventions, tangible research property, copyrightable works, copyrights, trademarks, and trade secrets) created as part of your university responsibilities or developed using university resources belong to the Texas Tech University System per Regents' Rules 10.03.1. The only exceptions are specific items that are exempted by contract or research agreement.
- The sole decision-making authority in regards to the patenting and licensing of TTU intellectual properties rests with the Office of Research Commercialization (ORC).
- The ORC will prevent the creation of a conflict of interest by avoiding the licensure of TTU System intellectual properties to companies in which the inventor has a significant investment or financial interest.
- Relationships with external entities must be disclosed accurately and completely in relevant publications or presentations.

For further guidance on intellectual property, patents, and licensing, please visit the [Office of Research Commercialization](#).

### 3.4.4 Company Founder

- Keep up-to-date records of the valuation of your financial holdings in the company; be fully accurate regarding your position and duties when reporting in annual university disclosures.
- Be aware that your involvement in research as certain roles will be disallowed due to your implied fiduciary and/or managerial duty.
- Ensure that your consulting activities do not violate university or federal regulations.
- Distance your activities as an agent of the company to the fullest extent possible from your duties and role as an employee of the university.
- Your position in the university cannot grant your company undue advantage (e.g., access to study results, unless they are the sponsors of that study), nor does it grant the company any claim or intellectual property rights to discoveries made during your activities as an employee of the university, including those made while using university resources or facilities.
- Relationships with external entities must be disclosed accurately and completely in relevant publications or presentations.

## 3.5 Sponsored or Reimbursed Travel

### 3.5.1 Externally Funded Travel

- If the travel and associated costs are being reimbursed to you, maintain records of the amount for accurate and complete annual disclosure to the university.
- If the travel and associated costs are being paid directly by a sponsor, maintain a log of length of stay, transportation arrangements, per-diem etc., in order to provide an accurate description and estimation of the trips cost in annual disclosures.
- Do not accept protracted or luxurious trips, as they are subject to conflict of interest rules and regulations.

## 3.6 Financial Conflicts of Interest and Foreign Components

### 3.6.1 Reporting Foreign Interests

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.

### 3.6.2 Foreign Interests and Research Export Controls

Collaboration and/or financial interests held with foreign entities may additionally present a risk to federal law regarding export controls and compliance. Research data and associated activities may involve information and/or technology that is restricted for proprietary reasons or specific governmental access and special dissemination controls may be in place in the interest of national security, economic, or foreign policy concerns when conducting research that is not considered fundamental research or public domain. The primary point of contact for these matters is the TTUHSC El Paso Research Compliance Office. Research personnel who anticipate participation in activities regulated by the Export Administration Regulations (EAR), International Trafficking in Arms Regulations (ITAR) or other federally controlled materials/entities are encouraged to contact the Research Compliance Officer (RCO) for guidance and assistance in obtaining an export license.

Examples of activities requiring Export Control oversight may include, but are not limited to, the following:

- Exports: Transfer by any means of technology, information (written, visual or oral), equipment, software or code, or services to anyone, including a U.S citizen, outside of the United States.
- Deemed Exports: Disclosure of controlled technology or information (written, visual or oral) to a foreign person within the United States.
  - A. Tour of laboratories for foreign visitors
  - B. Laboratories in which foreign nationals (i.e. students or visiting scientists) are working
- Travel: When traveling to foreign countries with technology or information (e.g. traveling with a laptop containing research data, regardless if the computer is personal or university-issued).

For further guidance on Export Controls, please contact the [TTUHSC El Paso Research Compliance Office](#).



## CHAPTER 4 GLOSSARY

**ANNUAL RESEARCH FINANCIAL DISCLOSURE** Annual submission of a research financial disclosure form detailing any significant financial interest within the past 12 months as required by TTUHSC El Paso OP 73.09.

**AUDIT** A systematic and independent examination of research related activities, procedures and documents to determine whether the evaluated research related activities, procedures, and documents were conducted, and the data were recorded, analyzed, and accurately reported in compliance with any prescribed CMP and applicable regulatory requirement(s).

**CLINICAL TRIAL** A research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials are used to determine whether new drugs or devices are safe and/or effective.

**CO-INVESTIGATOR** An individual involved with the PI in the scientific development or execution of a protocol. A coinvestigator typically devotes a specified percentage of time to the protocol and is considered research personnel. A coinvestigator may also be designated as responsible when the principal investigator is unavailable or absent, if he/she has the adequate training and certification to serve in this capacity, and is named on the study application

**COMPLIANCE** Adherence to all the research related requirements and the applicable regulatory and institutional requirements.

**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.

**CONFLICT OF INTEREST IN RESEARCH COMMITTEE** See [TTUHSC El Paso OP 73.09 Financial Conflicts of Interest in Research](#). The Conflict of Interest Committee is appointed by the VPR to review and oversee the management of financial conflicts of interest in research.

**RESEARCH EXPORT CONTROLS** Laws, policies and regulations that control the export of tangible and intangible items, materials, information and/or services. Relating to research, it concerns the restriction or special dissemination controls that may be imposed on the transference of technology and/or information.

**FINANCIAL CONFLICT OF INTEREST (FCOI)** A financial conflict of interest refers to a situation in which an individual's financial considerations may directly or indirectly affect, or have the appearance of affecting, the individual's judgment in exercising any duty or responsibility, including the conduct or reporting of research, owed to the Institution.

**FOREIGN INTEREST** A significant financial interest, as defined in section 2.5.2, held with any foreign entity. All such interests are reportable in accordance with the thresholds set for



their respective category; regulatory exclusions for reporting, such as for income received from institutions of higher education, is applicable only for domestic entities and does not apply to interest held with foreign institutions of higher education or foreign governments.

**INSTITUTIONAL REVIEW BOARD (IRB)** A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. At TTUHSC El Paso, the IRB is deemed to be a medical committee.

**INTENTIONAL NON-COMPLIANCE** Non-compliance that the COIRC has determined 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.

**Ne potistic Conflict of Interest** A nepotistic conflict of interest refers to a situation in which an individual's relationship to a family member participating on the same study may indirectly affect, or have the appearance of affecting, either individual's judgment in exercising any duty or responsibility, including the conduct or reporting of research, owed to the Institution.

**NON-COMPLIANCE** A situation, event or process in research activities that is inconsistent with Federal and/or local regulations applying to conflicts of interest in research. Non-compliance by the investigator/research 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 CMP

**OFFICE OF RESEARCH (OR)** Office responsible for the oversight and direction of the research committees at TTUHSC El Paso, which include the IRB, IBC, COIRC, the TTUHSC El Paso Research Compliance Program, and TTUHSC El Paso educational requirements for all research related activities.

**PRINCIPAL INVESTIGATOR (PI)** A TTUHSC El Paso faculty member who is full-time,

compensated, and with an appointment indicated under HSCEP OP 73.08. The PI has ultimate responsibility for the design and conduct of a research protocol, including supervision of the research personnel, and under whose immediate direction the laboratory research procedures are being carried out.

**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.

**REQUEST FOR ADDITIONAL INFORMATION** A request made by the COIRC for additional information regarding the details of a research financial disclosure or related protocols under review.

**RESEARCH** A systematic or clinical investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge.

**RESEARCH PERSONNEL** Any person, including, but not limited to faculty, staff, students or volunteers performing research for TTUHSC El Paso or using its resources or facilities to carry out research.

**REVIEW (OF DISCLOSURES)** The oversight of researcher's financial disclosures on a periodic basis by the COIRC.

**SPONSOR** A person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation, i.e., the test article is administered or dispensed to, or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., a corporation or agency) that uses one or more of its own employees to conduct an investigation that it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.