



# TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

## Operating Policy and Procedure

**HSCEP OP:** 73.14, **Research Compliance**

**PURPOSE:** This Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) Operating Policy and Procedure (HSCEP OP) establishes the objectives and operation of compliance oversight of research activities conducted by or through TTUHSC El Paso.

**REVIEW:** This HSCEP OP will be reviewed by October 1 of every odd-numbered year by the assistant managing director and senior director of the Office of Research and the institutional compliance officer (ICO) or his/her designee, with recommendations for revisions submitted to the vice president for research (VPR) or his/her designee by October 31.

### **POLICY/PROCEDURE:**

#### **I. General Research Oversight**

- A. The VPR or his/her designee is responsible for the oversight of the research compliance program at TTUHSC El Paso, with specific compliance oversight responsibilities delegated to the Office of Research.
- B. The Office of Research is authorized to monitor compliance with applicable laws, regulations, Regents' Rules, and TTUHSC El Paso policies related to the appropriate conduct of research activities and the funding of research activities at or through TTUHSC El Paso. The Office of Research works with appointed research committees, other divisions within the Office of Research, the TTUHSC El Paso Office of Institutional Compliance, Texas Tech University System (TTU System) offices, affiliates such as University Medical Center, El Paso Children's Hospital, and The Hospitals of Providence, and TTUHSC El Paso schools and departments on matters pertaining to research compliance.
- C. Nothing in this policy shall supersede or replace TTUHSC El Paso policies addressing a specific research area.

#### **II. Obligations of TTUHSC El Paso Members**

TTUHSC El Paso faculty, staff, students, volunteers, and vendors are expected to follow federal and state laws and TTUHSC El Paso policies regarding research activity conducted on behalf of TTUHSC El Paso and/or using TTUHSC El Paso facilities. See [HSCEP OP 52.16 - Vendor Interactions](#) for more information regarding TTUHSC El Paso policy on Vendor Interactions.

- A. Disclosure of Research Funding (Texas H.B. 1295: Texas Education Code, Section 51.954-955).
  1. All state employees must conspicuously disclose the research source(s) within any public communication or venue, including the following examples:
    - Oral presentations and reports (stated on slide)
    - Posters (included in text)
    - Publications (in acknowledgements or in other appropriate sections) News articles, newsletters, press releases, public reports (within article)

- Website pages (included in text)
  - Tech Talk (within text or video)
2. The research source refers to the name of the funder (for federal grants and contracts, the number must also be included).
  3. The principal investigator in collaboration with sponsored programs is responsible for reviewing agency award documents to ensure appropriate disclosure requirements are met.

### III. Areas of Research Compliance Oversight

- A. The Office of Research provides compliance oversight for the research activities listed below, which are conducted by TTUHSC El Paso faculty, staff, and students using TTUHSC El Paso facilities.
- B. The Office of Research may also provide compliance oversight for activities taking place outside of TTUHSC El Paso facilities when required by regulation, or when such oversight is agreed to in writing by TTUHSC El Paso.
- C. Compliance-specific activities related to each type of research may be found in HSCEP OPs, administrative manuals, or bylaws for the following research activities:
  1. Animals: [HSCEP OP 73.03](#) and [IACUC](#) policies
  2. Human Subjects: [HSCEP OP 73.06](#) and [HRPP Administrative Manual](#)
  3. Hazardous Chemicals and Biological Materials: [HSCEP OP 73.05](#), [HSCEP OP 73.12](#), and [IBC Bylaws](#)
  4. Recombinant/Synthetic DNA: [HSCEP OP 73.05](#) and [IBC Bylaws](#)
  5. Financial Conflicts of Interest in Research: [HSCEP OP 73.09](#)
  6. Research Nepotism: [HSCEP OP 73.18](#)
  7. Research Export Controls: [HSCEP OP 73.16](#)
  8. Allowable Research Grant Expenditures: [HSCEP OP 65.04](#)
  9. Scientific Misconduct: [HSCEP OP 73.07](#)
- D. Federal Procurement Requirements, 2 CFR 200.318, General Procurement Standards and 2 CFR 200.319, Competition

### IV. Research Compliance Committee

- A. A Research Compliance Committee (RCC) has been established to advise on issues and concerns related to funded grants and/or research activities conducted at or through TTUHSC El Paso. The RCC, and any subcommittees established under this policy, shall each be considered a “medical committee,” as defined under Texas Health and Safety Code § 161.031(a), and/or other applicable state and federal statutes. All documents generated by the RCC, submitted to the RCC, or created for the purposes of fulfilling the RCC’s duties are confidential and privileged and shall be identified as “confidential/medical committee document.”
- B. The RCC shall consist of the following members, who shall have voting privileges, unless otherwise noted:

1. Research Compliance Officer or his/her designee – committee chairperson
  2. Office of Research Assistant Managing Director or his/her designee
  3. Sponsored Programs (SP) Director or his/her designee
  4. Office of Research Senior Director of research committees
  5. Senior Director of Safety Services or his/her designee
  6. Chairperson of each TTUHSC El Paso research oversight committee:
    - a) Institutional Review Board (one member may represent both TTUHSC El Paso IRBs)
    - b) Institutional Animal Care and Use Committee
    - c) Institutional Biosafety Committee
    - d) Conflict of Interest in Research Committee
  7. Representative from General Counsel, appointed by the associate general counsel (ex officio, without vote)
  8. Institutional Compliance Officer (ex officio, without vote)
- C. The RCC shall have the following responsibilities:
1. Review and provide input on research-related policies and procedures.
  2. Provide input regarding general research compliance activities not under the authority of other research oversight committees.
  3. Provide guidance, including identification of possible research risk areas.
  4. Review reports of investigations of concerns and/or complaints related to research compliance, provided that such review does not conflict with other TTUHSC El Paso policies, bylaws, or guidelines.
  5. Serve as liaisons for their schools/departments to communicate non-confidential information to faculty and staff concerning research compliance duties and responsibilities.
  6. Review and provide input on trainings and training requirements for faculty and staff.
  7. Provide input on criteria for and frequency of audits.
  8. Request audits for case-specific investigators, grants, and protocols.

In the event of a conflict with the responsibilities of TTUHSC El Paso research oversight committees listed in IV.B.6 above, the authority of the research oversight committee(s) shall supersede that of the RCC.

- D. The RCC shall meet as needed to address research compliance matters not otherwise the responsibility of other TTUHSC El Paso research oversight committees.

## **V. Compliance Audits and Internal Investigations - General**

### **A. Compliance Audits**

1. As set forth in separate HSCEP OPs, Office of Research staff may conduct routine research compliance audits as part of the monitoring process.
  2. Special audits may be conducted by Office of Research staff or by ad hoc committees as set forth in specific HSCEP OPs, guidelines, or bylaws, or at the request of the VPR or Office of Research directors, the RCC, the institutional compliance officer, or other TTUHSC El Paso or TTU System administrators. A special audit is a tightly-defined audit that focuses on a specific area of concern regarding a research study and its activities. This type of audit may be initiated if areas of concern have been brought to the attention of the Office of Research without the submission of any formal allegations.
  3. The TTU System Office of Audit Services may also conduct audits related to research activities at TTUHSC El Paso. Research compliance audits may be conducted “for cause” based on a specific allegation of research misconduct, or may be requested as a method of collecting objective data to monitor the quality or efficiency of the research processes at TTUHSC El Paso.
- B. The principal investigator, Sponsored Programs, and any other research oversight committee designated under any HSCEP OP shall make available all records for review or audit upon the request of Office of Research compliance personnel or their designee, the institutional compliance officer or his/her designee, or members of an ad hoc compliance audit committee.
  - C. Written reports of audit findings and recommendations shall be distributed as indicated in research-specific HSCEP OPs, bylaws, and procedural manuals. If permitted by those specific policies, bylaws, or manuals, copies of these reports may be made available to the RCC for discussion.

## **VI. Escalations for Non-Compliance**

- A. The Research Compliance Unit and other research administrators from the Office of Research may attempt to communicate with a principal investigator and/or their research personnel for various reasons. Due to the many aspects of research, inquiries may be time-sensitive and contingent on a response from research personnel. In the event that administrators in the Office of Research attempt to contact a principal investigator and/or their research personnel, three attempts to communicate will be made by email and/or phone. If all attempts at communication are unsuccessful, then the Assistant Managing Director of the Office of Research will be made aware and the situation will be escalated to the principal investigator’s department chair. If communication is still unsuccessful, then the situation will be escalated to the Vice President for Research. The VPR will then implement follow-up corrective action.

## **VII. Right to Change Policy**

TTUHSC El Paso reserves the right to interpret, change, modify, amend, or rescind any policy in whole or in part at any time without the consent of its workforce.