



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

HSCEP OP: 73.14, **Research Compliance**

PURPOSE: The purpose of this Texas Tech Health Sciences Center El Paso (TTUHSCEP) Operating Policy and Procedure (HSCEP OP) is to set forth the objectives and operation of compliance oversight of research activities conducted by or through TTUHSCEP.

REVIEW: This HSCEP OP will be reviewed on June 1 of every odd-numbered year (ONY) by the Director of Office of Research Resources (ORR) and the Institutional Compliance Officer (ICO) or designee, with recommendations for revisions submitted to the Vice President for Research (VPR) or designee by June 30.

POLICY/PROCEDURE:

1. General Research Oversight

- a. VPR. The VPR or designee is responsible for the oversight of the research compliance program at TTUHSCEP with specific compliance oversight responsibilities delegated to the ORR.
- b. ORR. The ORR is delegated the authority to monitor compliance with applicable laws, regulations, Regents rules, and TTUHSCEP policies related to the appropriate conduct of research activities at or through TTUHSCEP. The ORR works with appointed research committees, other divisions within the Office of the VPR, the TTUHSCEP Office of Institutional Compliance, Texas Tech University System offices, and TTUHSCEP Schools and Departments on matters pertaining to research compliance.
- c. Other Research Related Policies. Nothing in this policy shall supersede or replace TTUHSCEP policies addressing a specific research area.

2. Obligations of TTUHSCEP Members

TTUHSCEP faculty, staff, students, volunteers and vendors are expected to follow federal and state laws, as well as TTUHSCEP policies regarding research activity conducted on behalf of TTUHSCEP and/or at TTUHSCEP facilities.

- a. Disclosure of Research Funding (Texas H.B. 1295: Texas Education Code, Section 51.954-955).
 - i. All state employees must conspicuously disclose the **research source(s)** within any public communication or venue including, but not limited to, the following examples:
 - Oral presentations and reports (stated on slide)
 - Posters (included in text)
 - Publications (in acknowledgements section)
 - News articles, newsletters, press releases, public reports (within article)
 - Website pages (included in text)
 - Tech View (within article) and Tech Talk (within video)
 - ii. Research source means the name of the funder (for federal grants and contracts,

- the number must also be included).
- iii. The Office of Sponsored Programs will provide written notification regarding this requirement to the principal investigator and all appropriate staff and departments during all new award setup processes.

3. Areas of Research Compliance Oversight

- a. Research at TTUHSCEP facilities. The ORR provides compliance oversight for the research activities listed below which are conducted by TTUHSCEP faculty, staff and students at TTUHSC facilities.
- b. Research outside of TTUHSCEP facilities. The ORR may also provide compliance oversight for activities taking place outside of TTUHSCEP facilities when required by regulation, or when such oversight is agreed in writing by TTUHSCEP.
- c. Types of Research. Compliance-specific activities related to each type of research may be found in HSCEP Operating Policies, administrative manuals, or bylaws for the following research activities, included but not limited to:
 - i. Animals: [HSCEP OP 73.03](#), and IACUC policies
 - ii. Human subjects: [HSCEP OP 73.06](#) and HRPP Administrative manual
 - iii. Hazardous Chemicals and Biological Materials: [HSCEP OP 73.05](#), [HSCEP OP 73.12](#), and IBC Bylaws
 - iv. Recombinant/Synthetic DNA: [HSCEP OP 73.05](#) and RDBC Bylaws
 - v. Financial Conflicts of Interest in Research: [HSCEP OP 73.09](#)
 - vi. Export Controls: [HSCEP OP 73.16](#)
 - vii. Allowable Research Grant Expenditures: [HSCEP OP 65.04](#)
 - viii. Scientific Misconduct: [HSCEP OP 73.07](#)

4. Research Compliance Committee

- a. Establishment of Research Compliance Committee. A Research Compliance Committee (RCC) has been established to advise on issues and concerns related to funded grants and/or research activity conducted at or through TTUHSCEP. The RCC, and any subcommittees established under this Policy, shall each be considered a “medical committee” as defined under Texas Health & 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 a “Confidential – Medical Committee Document”.
- b. Membership. The RCC Committee shall consist of the following members who shall have voting privileges unless otherwise noted:
 - i. ORR Director or designee – Committee Chairperson
 - ii. RCO/Export Controls Officer or designee
 - iii. Director of Safety Services or designee

- iv. Chairperson of each TTUHSCEP research oversight committee:
 - 1. Institutional Review Board (one member may represent both TTUHSC EP IRBs);
 - 2. Institutional Animal Care and Use Committee;
 - 3. Institutional Biosafety Committee;
 - 4. Conflict of Interest in Research Committee.
- v. Representative from of General Counsel, appointed by the Associate General Counsel (ex-officio, without vote)
- vi. Institutional Compliance Officer (ex-officio, without vote)
- c. Responsibilities. The RCC shall have the following responsibilities. In the event there is a conflict with the responsibilities of TTUHSCEP research oversight committees listed in 4b above, the authority of the research oversight committee(s) shall supersede that of the RCC.
 - i. Review and provide input on research related policies and procedures;
 - ii. Provide input regarding general research compliance activities not under the authority of other research oversight committees;
 - iii. Provide guidance, including identification of possible research risk areas,
 - iv. Review reports of investigations of concerns and/or complaints related to research compliance, provided that such review does not conflict with other TTUHSCEP policies, bylaws or guidelines.
 - v. Serve as liaisons for their School/Department to communicate non-confidential information to faculty and staff concerning duties and obligations pertaining to research compliance;
- d. Meetings. The RCC shall meet at least quarterly or more often as necessary to address research compliance matters not otherwise the responsibility of other TTUHSCEP research oversight committees.

5. Compliance Audits and Internal Investigations--General

- a. Compliance Audits.
 - i. As set forth in separate HSCEP Operating Policies, ORR staff may conduct routine research compliance audits as part of the monitoring process.
 - ii. Special audits may be conducted by RO staff or by *ad hoc* committees as set forth in specific TTUHSCEP Operating Policies, guidelines, or bylaws or at the request of the VPR or Office of Research division directors, RCC, and/or the Institutional Compliance Officer or other TTUHSCEP or TTUS administrators.
 - iii. The TTU System Office of Audit Services may also conduct audits related to research activities at TTUHSCEP. Special 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, efficiency of the

research processes at TTUHSCEP.

- b. Access to Records. The Principal Investigator, Office of Sponsored Programs and any other research oversight committee designated under any TTUHSCEP Operating Policy shall make available all records for review or audit upon the request of ORR compliance personnel or designees, the Institutional Compliance Officer or designee, or members of an *ad hoc* compliance audit committee.
- c. Reports. Written reports of audit findings and recommendations shall be distributed as indicated in research-specific HSC policies, 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.

6. Right to Change Policy.

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