HSC OP: 73.14, Research Compliance

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

REVIEW: This HSC OP will be reviewed on June 1 of every odd-numbered year (ONY) by the Assistant Vice President for Research Integrity and the Institutional Compliance Officer (ICO), with recommendations for revisions forwarded to the Senior Vice President for Research (SVPR) by June 30.

POLICY/PROCEDURE:

1. General Research Oversight
   a. Senior Vice President for Research. The SVPR is responsible for the oversight of the research compliance program at TTUHSC with specific compliance oversight responsibilities delegated to the Research Integrity Office.
   b. Research Integrity Office. The Research Integrity Office (RIO) is delegated the authority to monitor compliance with applicable laws, regulations, Regents Rules and TTUHSC policies related to the appropriate conduct of research activities at or through TTUHSC. The Research Integrity Office works with appointed research committees, other divisions within the Office of Research, the TTUHSC Office of Institutional Compliance, Texas Tech University System offices, and TTUHSC Schools and Departments on matters pertaining to research compliance.
   c. Other Research Related Policies. Nothing in this policy shall supersede or replace TTUHSC policies addressing a specific research area.

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

3. Areas of Research Compliance Oversight
   a. Research at TTUHSC facilities. TTUHSC RIO provides compliance oversight for the research activities listed below which are conducted by TTUHSC faculty, staff and students at TTUHSC facilities.
   b. Research outside of TTUHSC facilities. TTUHSC RIO may also provide compliance oversight for activities taking place outside of TTUHSC facilities when required by regulation, or when such oversight is agreed in writing by TTUHSC.
   c. Types of Research. Compliance-specific activities related to each type of research may be found in HSC Operating Policies, administrative manuals, or bylaws for the following research activities, included but not limited to:
      1) Animals: HSC OP 73.03, and IACUC policies
      2) Human subjects: HSC OP 73.06 and HRPP manual
3) Hazardous Chemicals and Biological Materials and Recombinant/Synthetic DNA: HSC OP 73.04, HSC OP 73.05, HSC OP 73.12, and IBC Bylaws
4) Recombinant/Synthetic DNA: HSC OP 73.05 and RDBC Procedural Manual
5) Financial Conflicts of Interest in Research: HSC OP 73.09
6) Export Controls: HSC OP 73.16
7) Human Embryonic Stem Cells: HSC OP 73.19
8) Quality Improvement Review: HSC OP 73.18
9) Allowable Research Grant Expenditures HSC OP 65.04
10) Research Misconduct: HSC 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 research activity conducted at or through TTUHSC. 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:

1) Assistant Vice President - Research Integrity – Committee Chairperson
2) Research Compliance Officer / Export Controls Officer
3) Director of Safety Services
4) Chairperson of each TTUHSC research oversight committee:
   i. Institutional Review Board (one member may represent both TTUHSC IRBs);
   ii. Animal Care and Use Committee;
   iii. Recombinant DNA Biosafety Committee;
   iv. Institutional Biosafety Committee;
   v. Conflict of Interest in Research Committee
   vi. Embryonic Stem Cell Committee
   vii. Quality Improvement Review Board

5) Representative from Office of General Counsel, appointed by the Senior Associate General Counsel (ex-officio, without vote)
6) 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 TTUHSC research oversight committees listed above, the authority of the research oversight committee(s) shall control.

1) Review and provide input on research related policies and procedures;
2) Review laws, regulations, statutes and guidelines related to research compliance;
3) Recommend the creation of new, and revisions to current, research documentation policies and procedures;
4) Provide input regarding general research compliance activities not under the authority of other research oversight committees;
5) Provide guidance, including identification of possible research risk areas,
6) Review reports of investigations of concerns and/or complaints related to research compliance, provided that such review does not conflict with other TTUHSC policies, bylaws or guidelines.
7) 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 bi-annually or more often as necessary to address research compliance matters not otherwise the responsibility of other TTUHSC research oversight committees.

5. **Audits and Internal Investigations--General**

a. **Research Compliance Audits.**

1) As set forth in separate HSC Operating Policies, RIO staff may conduct routine research compliance audits as part of the monitoring process.

2) Special audits may be conducted by RIO staff or by *ad hoc* committees as set forth in specific TTUHSC Operating Policies, guidelines, or bylaws or at the request of the SVPR or Office of Research division directors, RCC, and/or the Institutional Compliance Officer or other TTUHSC or TTUS administrators.

3) The TTU System Office of Audit Services may also conduct audits related to research activities at TTUHSC. 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 TTUHSC.

b. **Access to Records.** The Principal Investigator, Office of Sponsored Programs and any other research oversight committee designated under any Health Sciences Center Operating Policy shall make available all records for review or audit upon the request of RIO compliance personnel, the Institutional Compliance Officer, 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.**

TTUHSC 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.