TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

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 Chief Compliance Officer (CCO), with recommendations for revisions forwarded to the Senior Vice President for Research and Innovation (SVPRI) by June 30.

POLICY/PROCEDURE:

1. **General Research Oversight**

   a. Senior Vice President for Research and Innovation. The SVPRI is responsible for the oversight of the research compliance program at TTUHSC with specific compliance oversight responsibilities delegated to the Research Integrity Office. The SVPRI is the designated Institutional Official (IO) for TTUHSC's Human Research Protection Program.

   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. In RIO, the Assistant Vice President for Research Integrity is the designated Research Integrity Officer.

   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, IBC Bylaws, and RDBC Procedural Manual
4) Financial Conflicts of Interest in Research: HSC OP 73.09; HSC OP 73.21
5) Export Controls: HSC OP 73.16
6) Human Embryonic Stem Cells: HSC OP 73.19
7) Quality Improvement Review: HSC OP 73.18
8) Allowable Research Grant Expenditures HSC OP 65.04
9) 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 (RCO) / 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. Institutional Biosafety Committee;
iv. Conflict of Interest in Research Committee
v. Embryonic Stem Cell Committee
vi. Quality Improvement Review Board

5) Representative from Office of General Counsel, appointed by the Senior Associate General Counsel (ex-officio, without vote)
6) Chief 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) Serve as liaisons for their School/Department to reinforce and communicate non-confidential information to faculty and staff concerning duties and obligations pertaining to research compliance; and
7) Review reports of assessments, inquiries, and investigations of concerns and/or complaints related to research compliance, provided that such review does not conflict with other TTUHSC policies, bylaws or guidelines.

i. If an official appeal of a research committee's or subcommittee's decision is submitted to the SVPRI and approved by the SVPRI based on the merits of that request on a case by case basis, the RCC has the authority to review the matter and issue a finding to the SVPRI.[1]

d. Meetings. The RCC shall meet at least 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 Assessments, Inquiries, and 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 SVPRI or Office of Research division directors, RCC, and/or the Chief 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. Internal Assessments, Inquires, and Investigations.

1) A TTUHSC research oversight committee (Section 4(b)(4)) may conduct its own assessment, inquiry, or investigation into an allegation of research non-compliance with HSC policies or that committee's bylaws, procedural manual, or approved-protocol.
2) The committee must inform and work with the Research Integrity Officer.
3) The committee shall report its findings to the SVPRI for the SVPRI to acknowledge and/or confirm findings.

c. Access to Records. The Principal Investigator (PI), 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 Chief Compliance Officer, or members of an *ad hoc* compliance audit committee.

d. Reports.

1) Written reports of 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.
2) Mandated reporting to state or federal agencies will be determined by regulations, law, or guidance as appropriate.

6. Research Non-Compliance with the Requirements of the Human Research Protection Program

a. In order to comply with 45 CFR 46.108(a)(4)(i) and 21 CFR 56.108(b)(2), TTUHSC IRB will promptly report to the Office for Human Research Protections (OHRP) and US Food and Drug Administration (FDA) all applicable events adversely affecting the rights, welfare, and/or safety of human research participants. The required reporting events include any Serious and/or Continuing Non-Compliance with federal policy or with determinations made by the IRB.

[1]Subject-matter expertise of the appropriate research oversight committee will not be reviewed by the RCC, the RCC will review whether the findings have merit, are based on the Preponderance of Documentation, and are fair based on the evidence available at that time.

b. Definitions.

1) Allegation of Non-Compliance is an assertion or report of non-compliance.
2) Documentation is any document, tangible item, or testimony offered or obtained during a non-compliance review that tends to prove or disprove the existence of an alleged fact.
3) Human Research Protection Program Manual outlines the controlling policies and procedures of TTUHSC's Human Research Protection Program (HRPP). Please refer to this manual for more detailed guidelines.
4) Non-Compliance is the failure to follow federal, state, or local regulations governing human subject research, institutional policies related to human subject research, an IRB-approved research protocol, or the requirements or determinations of the IRB. This may pertain to the PI, research staff, or any member or component of the HRPP.
    i. Serious Non-Compliance: Means actions or omissions by any members of the HRPP that are known or should be known to create an increase in risk to subjects, adversely affects the rights, welfare and safety of the research subjects, or adversely affects the scientific integrity of the study. Willful violation of policies and/or federal regulations may also constitute serious non-compliance.
    ii. Continuing Non-Compliance: Means a pattern of repeated actions or omissions by any member of the HRPP that are known or should be known to create an increase in risk to subjects, adversely affect the rights, welfare and safety of research subjects, or adversely affect the scientific integrity of the study.
5) Preponderance of Documentation means proof of information that, when compared to the information opposing it, leads to the conclusion that the fact at issue is more probably true than not.

c. Examples. Examples of Non-Compliance include, but are not limited to:

1) Conducting human subject research without first obtaining IRB and institutional approval or an IRB declaration of exemption, including collecting data for human subject research activities without prior IRB approval;
2) Deviating from or violating the provisions of an IRB-approved protocol;
3) Failing to secure IRB approval of a protocol due for periodic continuing review prior to its expiration date;
4) Permitting a protocol's IRB approval to lapse without stopping all research-related activities and submitting a report to the IRB, or in the event of an overriding safety concern or ethical issue such that it would be in the individual subject's best interest to continue study participation, not arranging with the IRB to continue those activities;
5) Deviating from written TTUHSC policies and procedures governing research with human subjects; and
6) Failure of any organization with a defined responsibility for oversight of any part of the HRPP to fulfill its obligations.

d. Allegation of Non-Compliance.

1) Reporting. Investigators, research staff and any other member of the HRPP are required to report any potential, observed, suspected, or apparent Non-Compliance to the IRB, the Research Integrity Officer, the RCO, SVPRI, or EthicsPoint. This refers to all Non-Compliance, whether or not it may be Serious and/or Continuing Non-Compliance. An allegation may be referred to other institutional offices for evaluation and management as appropriate.
2) Handling of Allegation. Any allegation of Non-Compliance will be referred to the Research Integrity Officer and RCO. In most instances, the Research Integrity Officer, RCO, or designee will submit a written inquiry to the related PI for the research study in question. However, in cases where the identity of the complainant must be protected or is otherwise warranted, the RCO may conduct a directed audit in response to the allegation. Once either the response from the PI or the audit report has been received, the Research Integrity Officer, in conjunction with the IRB Chair, may conclude that the allegations have a basis in fact (an initial assessment). In such cases, the Research Integrity Officer and the IRB Chair will initiate and complete an inquiry into the matter. Otherwise, no further action is taken under this policy and the PI is informed that the IRB

considers the issue to be resolved. Note: the allegation may be referred to other institutional entities for evaluation and management as appropriate.

3) Inquiry. The Research Integrity Officer, RCO, and IRB Chair or designee may use any of the following mechanisms to investigate the allegation(s) or Non-Compliance event: (1) communicate directly with the PI and/or relevant study team, (2) communicate with the complainant(s), (3) contact any other relevant internal departments at TTUHSC, and/or (4) form a sub-committee of subject matter experts from the IRB.
4) Actions of convened IRB. The convened IRB will confirm by vote whether there is a recommendation of Serious and/or Continuing Non-Compliance for the IO's final determination. If the convened IRB finds that the Non-Compliance is serious and/or continuing, it may immediately suspend the research if it finds that doing so is necessary to eliminate apparent immediate hazards to the research subject. The IRB will specify any required corrective and preventative actions.
5) Authority. The IO has the authority to confirm the IRB's recommendation of Serious and/or Continuing Non-Compliance. The IO may refer the matter to the RCC under section 4(c)(7) above to further consider the Non-Compliance. For this limited purpose, the IO may (i) appoint additional voting members (up to 3) to the RCC drawn from appropriate divisions across TTUHSC and/or (ii) remove regular members if there could be a perceived conflict. This group will report its findings to the IO in a timeframe prescribed by the IO.
6) Reporting. The PI of the affected research study will be apprised of the convened IRB's findings and/or recommendations in an issued inquiry report reviewed and approved by the IO. This report will also contain any corrective actions required by the IRB, IO, TTUHSC, or other relevant regulatory agencies.
7) Corrective and Preventative Actions. Depending on the circumstances, the IRB or IO may require any of the following corrective actions, or any other additional actions appropriate for the local context:
    - Warning letter: Issue a letter of warning to the investigator;
    - Publications and presentations: (i) Recommendation to contact journal as appropriate and/or (ii) data cannot be described as being a part of a TTUHSC IRB-approved study;
    - Recollection of data: Data are collected again, but with IRB approval;
    - Notification to participants: In some instances, the IRB may require the investigators to notify all participants of the investigator's failure to obtain IRB approval, when such information might relate to participants' willingness to continue to take part in the research, or to provide additional information to past participants;
    - Re-consent: The participants are provided the opportunity to consent to the use of their data for research purposes, using IRB approved documents;
    - Modification: of the continuing review schedule, of the research protocol, of the information disclosed during the consent process;
    - Training: Require additional training or retraining of the investigator and researchers conducting the project;
    - Funding agency notification: (i) If the study is federally funded, then the IRB staff must notify Sponsored Projects to report that the research was conducted without prior IRB approval to determine applicable reporting requirements; (ii) industry or private sponsor will depend on individual agreement terms;
    - Monitoring: of the research or the consent;
    - Suspension and/or termination of applicable study, including authority to suspend additional studies under the PI until corrective action plan is completed;
    - Referral: to other organizational entities such as legal counsel, risk management, human resources, faculty affairs, Institutional Compliance, the Office of Sponsored Programs, or other appropriate School or Department;
    - Notification to outside collaborating institutions or organizations; and
    - Report: to OHRP and other federal or state agencies. If there was any risk of harm to the participants, the IRB will report the incident to OHRP and appropriate officials as required by the Federal Wide Assurance.

If a corrective action plan is submitted with a finding of Serious and/or Continuing Non-Compliance, the completion of that corrective action plan will require the signature of the PI, Chair, Dean, and IO.

7. 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.