



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 73.08, **Faculty Status Guidelines for Conduct of Clinical Research**

PURPOSE: The purpose of this Health Sciences Center Operating Policy and Procedure (HSC OP) is to outline the responsibilities of TTUHSC faculty and affiliated others in using TTUHSC's research infrastructure to conduct clinical research on grants, contracts and clinical trials.

REVIEW: This HSC OP will be reviewed November 1 of each odd-numbered year (ONY) by the Associate Vice President for Research (AVPR), with recommendations for revisions forwarded to the Executive Vice President for Research (EVPR) by November 15.

POLICY/PROCEDURE:

In accordance with TTUHSC Institutional Review Board (IRB) Policies and Procedures, the following categories of faculty (and affiliated others) in all HSC schools will have specific responsibilities when conducting clinical research that is funded by industry sponsors:

1. Full-time TTUHSC faculty employees (where research is considered as part of the faculty member's job duties):

- Must use the TTUHSC IRB
- Must pay an IRB review fee and a Continuing Review fee upon receipt of invoice, **IF** the study is funded by an industry sponsor
- Must use the TTUHSC Director of Contracting in the Clinical Research Center to process Confidential Disclosure Agreements and Clinical Trials Agreements
- School of Medicine faculty physicians are covered under the TTUHSC Professional Liability Self-Insurance Plan; other HSC schools should check their malpractice policies
- Employees are covered by the Texas Torts Claims Act if actions are in the course and scope of employment and in good faith

State employees are covered by the Texas Tort Claims Act for acting within the course and scope of their job duties, which may for many faculty positions include research. Some School of Medicine faculty are also covered by the TTUHSC SOM Professional Liability Self-Insurance Plan, which would also cover liabilities related to research activities when research is part of the job duties.

2. Part-time (any amount less than 100%) TTUHSC faculty employees (where research may be considered as part of the faculty member's job duties):

- Must use the TTUHSC IRB
- Must pay an IRB review fee and a Continuing Review fee upon receipt of invoice, **IF** the study is funded by an industry sponsor
- Must use the TTUHSC Director of Contracting in the Clinical Research Center to process Confidential Disclosure Agreements and Clinical Trials Agreements
- These School of Medicine Faculty need to check with the Professional Liability Office for malpractice coverage on a case by case basis; other HSC schools should check their malpractice policies
- Employees are covered by the Texas Torts Claims Act if actions are in the course and scope of employment and in good faith

State employees are covered by the Texas Tort Claims Act for acting within the course and scope of their job duties, which may for many faculty positions include research. Some School of Medicine faculty are also covered by the TTUHSC SOM Professional Liability Self-Insurance Plan, which would also cover liabilities related to research activities when research is part of the job duties.

**3. Faculty member with a TTUHSC faculty appointment (usually clinical)
(self-employed or employed by another entity, not a TTUHSC-compensated employee)**

- Must use the TTUHSC IRB if using staff, facilities, or resources of TTUHSC
- Must have an institutional IRB Agreement or Unaffiliated Investigator Agreement in place to use the IRB
- Must pay an IRB review fee and a Continuing Review fee upon receipt of invoice
- Professional Liability coverage by the TTUHSC Self-Insurance Plan is not provided by the TTUHSC Self-Insurance Plan, but the faculty member should check with their own Professional Liability Plan to confirm coverage
- Texas Torts Claims Act does not apply (because not an employee, but may apply if performing services under a contract)

4. Self-employed or employed by another entity without a TTUHSC faculty appointment

- Can use the TTUHSC IRB only if they:
 1. Have a Federal-wide Assurance approved by the Department of Health and Human Services
 2. Have designated a TTUHSC IRB by executing and signing an IRB Agreement with written approval by the Executive Vice President for Research
 3. Have agreed that the TTUHSC Research Compliance Office shall have access upon request to research project records for audit and compliance purposes
- Must pay an IRB review fee and a Continuing Review fee upon receipt of invoice
- Cannot use TTUHSC on the heading of the consent form or suggest that the research is being conducted, approved, or sponsored in any way by TTUHSC. Any consent form must be approved by the IRB.
- Cannot use TTUHSC facilities for conduct of the research
- Malpractice coverage is the responsibility of the PI and/or the employing entity

For clinical trials that are currently operating, the faculty status of the Principal Investigator (PI) will be verified at the time of Continuing Review. For new IRB submissions, faculty status will be verified at time of IRB submission of protocol.

- 5. The Associate Vice President for Research (AVPR) will respond to initiatives from the EVPR concerning the goals of this operating procedure.**