



# TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

## Operating Policy and Procedure

**HSC OP:** 73.06, **Research Involving Human Subjects**

**PURPOSE:** The purpose of this Health Sciences Center Operating Policy and Procedure (HSC OP) is to provide a framework for compliance with state and federal laws with regard to research involving human subjects.

**REVIEW:** This HSC OP will be reviewed 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 June 15.

### **POLICY/PROCEDURE:**

#### **1. Compliance with Federal Code.**

The TTUHSC adopts and continues its policy that all research involving human subjects conducted at TTUHSC or in affiliation with TTUHSC shall be conducted in accordance with federal regulations including but not limited to 45 Code of Federal Regulations (CFR) 46 established by the Department of Health and Human Sciences, and 21 CFR 50 and 21 CFR 56 as established by the Food and Drug Administration.

#### **2. Compliance Policies.**

In furtherance of that policy TTUHSC directs as follows:

- a. The Executive Vice President for Research (EVPR) shall be designated by the President for overall institutional responsibility and signatory for IRB-related matters, in accordance with Federalwide Assurance 00006767.
- b. Establishment of Institutional Review Board. TTUHSC shall establish an Institutional Review Board (IRB) whose members shall be appointed by the EVPR. All members serve at the discretion of the EVPR. Multiple IRB Committees may be established under one Federalwide Assurance to manage the multi-campus workload. However, all IRBs will be appointed by and have reporting responsibilities to the EVPR for a one year appointment, subject to reappointment.
- c. Responsibilities of IRB. The IRB and its staff shall be responsible in conjunction with the EVPR of TTUHSC for monitoring that all TTUHSC personnel, student researchers, and affiliated entities comply with applicable federal regulations and guidelines. The IRB shall review and approve, require modifications of, or disapprove all TTUHSC research involving human subjects in accordance with the administrative policies and procedures to be established hereunder. In addition, the IRB shall monitor and conduct continuing review of research at intervals of at least once per year. It shall continue to be the responsibility of the administrative officers of TTUHSC and each principal investigator to carry out the decisions of the IRB.
- d. Authorities of IRB. The IRB has the authority to inspect research facilities, obtain records and other relevant information relating to the use of human subjects in research, and take such actions that are in its judgment necessary to ensure compliance with the federal guidelines and regulations, other applicable federal and state law, and the policies and procedures to be established hereunder, including action to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

- e. Reporting requirements. The IRB shall report to the EVPR and federal government (OHRP, NIH, FDA) officials:
  - (1) any unanticipated problems involving risks to subjects or serious or continuing noncompliance with IRB requirements; and
  - (2) any suspension or termination of IRB approval of research.
- f. Administrative policies. The IRB, with responsible oversight by the EVPR, shall establish appropriate administrative policies and procedures to implement this policy.
- g. The Associate Vice President for Research (AVPR) will respond to initiatives from the EVPR concerning the goals of this operating procedure.