TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER EL PASO

Operating Policy and Procedure

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

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

BACKGROUND:

TTUHSCEP fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of TTUHSCEP. In the review and conduct of research involving human subjects, TTUHSCEP actions will be guided by the principles set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report). TTUHSCEP actions will also conform to all applicable federal, state, and local laws and regulations.

In order to fulfill this mission, TTUHSCEP has established a Human Research Protection Program (HRPP). The mission of the HRPP is to:

- Safeguard and promote the welfare of human research subjects (participants) by ensuring that their rights, safety and well-being are protected;
- Provide timely and high quality review of research involving human subjects.
- Facilitate excellence in research with human subjects.

REVIEW: This HSCEP OP will be reviewed each odd-numbered year (ONY) by the Director of the Office of Research Resources (ORR) or designee and the Vice President for Research (VPR) or designee by June 15.

POLICY/PROCEDURE:

1. **Compliance with Federal Code.**

TTUHSCEP holds a Federal wide Assurance (FWA) with the Department of Health and Human Services' Office of Human Research Protection (DHHS OHRP) (FWA # 00006767). The FWA is the Institution's assurance of compliance that all research involving human subjects will be conducted in accordance with the ethical principles of the Belmont Report and DHHS regulations at 45 CFR 46. TTUHSCEP limits this assurance to federally funded research; however, the regulations under 45 CFR 46, including all of Subparts B, C, and D, provide the practical basis for the review and approval of all research involving human subjects at TTUHSCEP regardless of funding. Further, human research involving investigational drugs, devices, or biologics is conducted in accordance with the Food and Drug Administration regulations found in 21 CFR 50 and 21 CFR 56. International, multi-site clinical trials, in which TTUHSCEP takes part, are to be conducted in accordance with ICH-GCP and in accordance with ethical principles that have their origin in the Declaration of Helsinki.

2. **Authority and Responsibility for HRPP.**

a. The VPR has been given the authority and responsibility by the President of TTUHSCEP to establish, maintain, and oversee the HRPP including the TTUHSCEP Institutional Review Boards (IRBs). The VPR serves as the Institutional Official and signatory for HRPP-related matters, in accordance with Federal wide Assurance #00006767.

Responsibilities of the VPR are delineated in Chapter 1 of the TTUHSC Human Research Protection Program Manual, found here. In performing these duties, the VPR has the authority to delegate activities as necessary to fulfill the duties. The primary administrative responsibility for the day-to-day operation of the TTUHSCEP HRPP lies with the TTUHSC Research Resources Office and the IRBs.

b. Establishment of Institutional Review Board. TTUHSCEP has established IRBs to review research involving human subjects. Chairpersons and members of each TTUHSCEP IRB will be appointed by the VPR and will serve at the discretion of the VPR. TTUHSCEP has established multiple IRBs to manage the workload. However, all TTUHSCEP IRBs will be established by and will report to the VPR through the ORR.

c. Limitation on Authority: TTUHSCEP may review and research projects and has the right to disapprove the implementation of a research proposal that has been approved by the IRB. However, no one at TTUHSCEP or the Texas Tech University System may approve the implementation of any research proposal, nor may it override the decision of the IRB concerning a research proposal that has been disapproved by the IRB.

3. **Authority and Responsibility of the IRBs.**

a. Authorities of IRBs. The TTUHSC EP IRBs have the authority to approve, require modifications to secure approval, and disapprove all human research activities conducted under the auspices of TTUHSCEP. The IRBs also have the authority to suspend or terminate IRB approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. The IRBs have the authority to observe, or have a third party observe, the consent process and conduct of the research. The IRBs have the authority to inspect research facilities, to obtain records and other relevant information relating to the use of human subjects in research, and to take such actions that are in their judgment necessary to ensure compliance with the federal guidelines and regulations, other applicable federal and state laws, and the policies and procedures to be established hereunder. The current TTUHSCEP Human Research Protection Program Manual, found here provides details of procedures for carrying out these functions.

b. Responsibilities of the IRBs. TTUHSCEP IRB members, IRB administrative staff, the ORR, Director, and the VPR shall be responsible for ensuring that all TTUHSCEP personnel, students and affiliated entities comply with applicable federal regulations and institutional policies regarding the conduct of research with human subjects.

c. No research involving human subjects may commence until all required institutional approvals (including IRB approval) are obtained. This prohibition includes data collection for research involving human subjects which meets the criteria for exemption from formal IRB review.

d. Reporting. As outlined in the current HRPP Manual, each TTUHSCEP IRB shall be responsible for reporting to the ORR Director and to the VPR any unanticipated problems involving risks to subjects or serious and continuing noncompliance with IRB requirements and any decision to suspend or terminate approval of research involving human subjects. The VPR, in consultation with the ORR Director, will be responsible for ensuring that required reporting of such events is made to appropriate entities such as OHRP, FDA or NIH.

4. **Other.**

The VPR will respond to initiatives from the President of TTUHSCEP concerning goals of this HSCEP OP.