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.

BACKGROUND: TTUHSC 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 TTUHSC. In the review and conduct of research involving human subjects, TTUHSC 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). TTUHSC actions will also conform to all applicable federal, state, and local laws and regulations.

In order to fulfill this mission, TTUHSC 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 HSC OP will be reviewed each odd-numbered year (ONY) by the Assistant Vice President for Research Integrity, with recommendations for revisions forwarded to the Senior Vice President for Reswi wior0RhIOn.5 (r)-3 (e)24.1 (v)-30cn orevfo0 Tw 2..o0 Tw 2..o0.015.6 ( )]T

Texas Tech University Health Sciences Center holds a Federal wide Assurance (FW
Department of Health and Human Services' Office of Human Research Protection (
(FWA # 00006767). The FWA is the Institution's assurance of compliance that all re
involving human subjects will be conducted in accordance with the ethical principles
Belmont Report and DHHS regulations at 45 CFR 46. This Assurance applies to fed
research; however, the regulations under 45 CFR 46, including all Subparts, provide
basis for the review and approval of all research involving human subjects at TTUHS
of funding. Further, human research involving investigational drugs, devices, or biol
conducted in accordance with the Food and Drug Administration regulations found i
and 21 CFR 56. International, multi-site clinical trials in which TTUHSC takes part,
conducted in accordance with ICH-GCP and in accordance with ethical principles th
origin in the Declaration of Helsinki.

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

a. The Senior Vice President for Research and Innovation (SVPRI) has been given the authority and responsibility by the President of TTUHSC to establish, maintain, and oversee the HRPP including the TTUHSC Institutional Review Boards. The SVPRI serves as the Institutional Official and signatory for HRPP-related matters, in accordance with Federalwide Assurance 00006767. Responsibilities of the SVPRI are delineated in Chapter 1 of the TTUHSC Human Research Protection Program Manual, found here. In performing these duties, the SVPRI has the authority to delegate activities as necessary to fulfill the

duties. The primary administrative responsibility for the day-to-day operation of the TTUHSC HRPP lies with the TTUHSC Research Integrity Office and the IRBs.

b. Establishment of Institutional Review Board. TTUHSC has established Institutional Review Boards (IRBs) to review research involving human subjects. Chairpersons and members of each TTUHSC IRB will be appointed by the SVPRI and serve at the discretion of the SVPRI. TTUHSC has established multiple IRBs to manage the multi-campus workload. However, all TTUHSC IRBs will be established by and will report to the SVPRI through the Research Integrity Office (RIO).

c. Limitation on Authority: TTUHSC 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 TTUHSC 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 IRBs have the authority to approve, require modifications to secure approval, and disapprove all human research activities conducted under the auspices of TTUHSC. 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 part observe, the consent process and conduct of the research. The IRBs have 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 their 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. The current TTUHSC Human Research Protection Program Manual, found here provides details of procedures for carrying out these functions.

b. Responsibilities of the IRBs. TTUHSC IRB members, IRB administrative staff, the Research Compliance Officer, the Assistant VP for Research Integrity, and the SVPRI shall be responsible for ensuring that all TTUHSC 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 Human Research Protection Program Manual, each TTUHSC IRB shall be responsible for reporting to the Assistant VP for Research Integrity and to the SVPRI 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 SVPRI, in consultation with the Assistant VP for Research Integrity, 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 Assistant Vice President for Research Integrity will respond to initiatives from the SVPRI concerning the goals of this HSC OP.