II. Authority and Responsibility for HRPP.

A. The VPR of TTUHSC El Paso has been given the authority and responsibility by the President of TTUHSC El Paso to establish, maintain, and oversee the HRPP including the TTUHSC El Paso Institutional Review Boards (IRBs). The VPR serves as the Institutional Official and signatory for HRPP-related matters, in accordance with Federalwide Assurance #00020736. 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

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administrative responsibility for the day-to-day operation of the TTUHSC El Paso HRPP lies with the TTUHSC Office of Research Resources Office the IRBs.

B. TTUHSC El Paso has established IRBs to review research involving human subjects. Chairpersons and members of each TTUHSC El Paso IRB will be appointed by the VPR and will serve at the discretion of the VPR. TTUHSC El Paso has established multiple IRBs to manage the workload, and they report to the VPR through the ORR.

C. Research that has been reviewed and approved by a TTUHSC El Paso IRB may be subject to further review, and other review bodies or officials have the right to disapprove the implementation of a research proposal that has been approved by the IRB. However, no one at TTUHSC El Paso 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.

III. Authority and Responsibility of the IRBs.

A. The TTUHSC El Paso IRBs have the authority to approve, require modifications to secure approval, and disapprove all human research activities conducted under the auspices of TTUHSC El Paso. The IRBs also have the authority to suspend or terminate IRB approval of research not being conducted in accordance with IRB 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 TTUHSC El Paso Human Research Protection Program Manual, found here provides details of procedures for carrying out these functions.

B. TTUHSC El Paso IRB members, IRB administrative staff, the ORR Director, and the VPR shall be responsible for ensuring that all TTUHSC El Paso 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. As outlined in the current HRPP Manual, each TTUHSC El Paso 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.

IV. Other.

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