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INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS

STATEMENT OF COMPLIANCE

The Texas Tech University Health Sciences Center at El Paso Institutional Review Boards (TTUHSC El Paso IRBs) are duly constituted (fulfilling FDA requirements for diversity), allowing only those IRB members who are independent of the investigator and sponsor of the study to vote/provide opinion on the study, have written procedures for initial and continuing review, prepare written minutes of convened meetings, and retain records pertaining to the review and approval process; all in compliance with requirements defined in 21 CFR (Code of Federal Regulations) Parts 50 and 56, and ICH (International Conference on Harmonization) guidance relating to GCP's (Good Clinical Practice). The TTUHSC El Paso IRBs are registered with OHRP/FDA. The Federalwide Assurance Number is FWA00020736. The parent organization number is IORG0008299. The IRB committee registration numbers are 00009945 and 00009946.

The TTUHSC EI Paso IRBs are guided by ethical principles applicable to all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (known as the Belmont Report). The IRB's primary responsibility is to protect the privacy, safety and welfare of the human subject participating in research.

The TTUHSC El Paso IRB Policies and Procedures are available for reference on the TTUHSC El Paso Human Research Protection Program Website: <u>Human Research Protection Program Manual</u>

The Institutional Official is Deborah J. Clegg, Ph.D., Vice-President for Research.

Myrna Arvizo, BMS, CIP, CHRC

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