

MEMORANDUM

TO WHOM IT MAY CONCERN

FROM: Kimberly Summers, PharmD, Director of Research Regulatory Programs

RE: Federalwide Assurance

This is to certify that The University of Texas Health Science Center at San Antonio (IORG0000312) has obtained a Federalwide Assurance from the Department of Health and Human Services (DHHS), FWA00005928, in which it assures that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the Belmont Report and will be reviewed and implemented in compliance with DHHS human subjects regulations, 45 CFR 46, Subparts A-D. The University of Texas Health Science Center at San Antonio also complies with FDA human subjects regulations under 21 CFR 50 and 56 and with good clinical practice (GCP) as adopted by the FDA. The University of Texas Health Science Center at San Antonio operates four Institutional Review Boards which are registered with the DHHS Office for Human Research Protections and with the Food and Drug Administration: IRB00000553 , IRB00002691, IRB00002692 and IRB00009608. The IRB registrations expire April 21, 2018.

This Federal Wide Assurance is applicable to THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO, including the Medical School, the Dental School, the School of Nursing, the Graduate School of Biomedical Sciences, the School of Health Professions, and to the UT Medicine (formerly University Physicians' Group). The Cancer Therapy And Research Center And CTRC Research Foundation were formally separate institutions with their own FWA, but they have merged with UTHSCSA and now fall under UTHSCSA's Federal Wide Assurance.

Other institutions covered by the University of Texas Health Science Center at San Antonio Institutional Review Boards through general IRB Authorization Agreements include the following:

SOUTH TEXAS VETERANS HEALTH CARE SYSTEM
UNIVERSITY HEALTH SYSTEM - BEXAR COUNTY, TEXAS
TEXAS BIOMEDICAL RESEARCH INSTITUTE (formerly Southwest Foundation for Biomedical Research)
THE SOUTHWEST RESEARCH INSTITUTE

In addition, IRB Authorization Agreements have been executed establishing provisions for the UTHSCSA IRB to review human research being conducted (1) at THE CHRISTUS SANTA ROSA HEALTH CARE CORPORATION facilities by UTHSCSA faculty and CSRHC Family Practice Residents; and (2) by faculty of THE UNIVERSITY OF TEXAS, AUSTIN, GRADUATE SCHOOL OF PHARMACY, who are located in and are operating out of the University of Texas Health Science Center at San Antonio.

DHHS originally approved this FWA on November 19, 2003. The approval currently expires February 26, 2020.

The Institution's Human Research Protection Program was fully accredited by the Association for the Accreditation of Human Research Protection Programs, Inc., in 2009 and received approval for a five year reaccreditation in 2012.

If you require further clarification, please do not hesitate to write or call.

(It is not our policy to provide the sponsor with a copy of the IRB membership list. If a list was provided previously, it was not with our knowledge or approval.)