MEMORANDUM

TO WHOM IT MAY CONCERN

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

RE: Federalwide Assurance

This is to certify that The University of Texas Health Science Center at San Antonio (UT Health San Antonio) (IORG0000312) has obtained a Federalwide Assurance (FWA) 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 September 5, 2021.

This Federal Wide Assurance is applicable to The University of Texas Health Science Center at San Antonio (UT Health San Antonio), including the Medical School, the Dental School, the School of Nursing, the Graduate School of Biomedical Sciences, the School of Health Professions, Mays Cancer Center, and to UT Medicine (formerly University Physicians’ Group).

DHHS originally approved this FWA on November 19, 2003. The approval currently expires February 28, 2025.

The Institution’s Human Research Protection Program was fully accredited by the Association for the Accreditation of Human Research Protection Programs, Inc., in 2009. The Institution received approval for reaccreditations in 2012 and 2017.

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.)