MD Anderson Institutional Review Board
Statement of IRB Compliance

This letter is to confirm that the University of Texas MD Anderson Cancer Center's (MD Anderson) Institutional Review Boards have written procedures for initial and continuing review of clinical trials; prepare written minutes of convened meetings; and retain records pertaining to the review and approval process of the clinical trials. These actions are taken in compliance with requirements under FDA regulations 21 CFR Parts 50 and 56, HHS regulations 45 CFR 46, and requirements under the International Conference on Harmonization (ICH) E6 and Good Clinical Practice (GCP) guidelines, as applicable.

The MD Anderson IRBs also review clinical trials in compliance with other applicable federal and state laws and regulations governing IRBs and research with human subjects. Each of the MD Anderson IRBs is registered with the federal Office of Human Research Protections (OHRP) under Federalwide Assurance number FWA00000363 with an expiration date of October 17, 2024.

In addition, the MD Anderson IRBs operate in compliance with the portions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA Privacy Rule) that apply to research, as described in 45 CFR Parts 160 and 164, as appropriate.

In accord with the regulations, each of the five MD Anderson Cancer Center IRBs is registered with OHRP under IRB Organization # IORG0000083 with an expiration date of November 6, 2021. The IRB registration numbers are listed below:

IRB00000121 U of Texas MD Anderson Cancer Center IRB#1-Clinical
IRB00002203 U of Texas MD Anderson Cancer Center IRB#2-Clinical
IRB00003869 U of Texas MD Anderson Cancer Center IRB#3-Executive Session
IRB00005015 U of Texas MD Anderson Cancer Center IRB#4-Psychosocial/Behavioral
IRB00006023 U of Texas MD Anderson Cancer Center IRB#5-Clinical

Wanda A. Quezada, CIP, CCRP
Director, Office of Human Subjects Protection
U.T. MD Anderson Institutional Review Boards