

## Human Research Protection Program Division of Research

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## Texas A&M University Institutional Review Board Compliance Statement

Texas A&M University Institutional Review Boards (TAMU IRBs) are duly constituted, have written procedures for initial and continuing review of all human subjects research; prepare written minutes of convened meetings, and retain records pertaining to the review and approval process; all in compliance with the requirements of the Food and Drug Administration (FDA) regulations 21 CFR Parts 50 and 56, Department of Health and Human Services (DHHS) regulations 45 CFR 46, and International Conference on Harmonization (ICH) E6, Good Clinical Practice (GCP), as applicable. TAMU IRBs also review in compliance with other applicable federal and state laws and regulations governing IRBs and human subjects research.

Texas A&M University holds a current Federalwide Assurance (FWA) with the DHHS Office of Human Research Protections (OHRP), FWA00000092, with an expiration of January 04, 2028.

As per the regulations, each of TAMU's IRBs are registered with OHRP under IRB Organization# IORG0000238 with an expiration date of November 15, 2026. The IRB registration numbers are listed below:

IRB00000397 Texas A&M University - College Station IRB #1

IRB00010159 Texas A&M University - School of Dentistry IRB #2

In lieu of IRB membership lists, the following information pertaining to IRB membership is provided:

The above IRBs meet the IRB membership requirements as outlined in 45 CFR 46.107 and 21 CFR 56.107, both consist of more than 5 members and membership includes scientists and non-scientists, as well as non-affiliated members. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB (§46.107(d) and §56.107(d)). The IRBs are composed of individuals, both female and male, with varying expertise and perspectives.

TAMU has been fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2015.

Sincerely,

Aliese Seawright, MS, CIP

Aliese Seawight

Director, Human Research Protection Program

Texas A&M University