



Statement of Compliance

Texas Health Resources (THR) complies with the regulations of the United States Food and Drug Administration (FDA) as described in 21 CFR Parts 50 and 56 and the United States Department of Health and Human Services (DHHS) regulations described in 45 CFR Part 46.

THR complies with Good Clinical Practice (GCP) also referred to as ICH E6 only to the extent those guidelines are compatible with the DHHS and FDA regulations. THR's electronically signed regulatory documents are generated in compliance with 21 CFR Part 11 regulations regarding electronic medical records and electronic signatures.

THR's FWA # is: FWA00013095