

Human Research Protection Program

MEMORANDUM

TO WHOM IT MAY CONCERN

DATE: June 8, 2022

FROM: Rhonda Oilepo, MS, CIP, CHRC
Assistant Vice-President of Human Research Administration

RE: Federalwide Assurance

This is to certify that The University of Texas Southwestern Medical Center (UT Southwestern) (IORG0000638) has obtained a Federalwide Assurance (FWA) from the Department of Health and Human Services (DHHS) (FWA00005087). This FWA assures that all UT Southwestern activities related to human subject research, 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. All UT Southwestern IRBs are also in compliance with Title 21 CFR Parts 50 and 56, all other Parts governing the use of investigational devices, drugs, and biologics as well as with good clinical practice (GCP) as adopted by the FDA. The FWA expires on July 21, 2026.

The University of Texas Southwestern Medical Center operates four Institutional Review Boards which are registered with the DHHS Office for Human Research Protections (OHRP) and with the Food and Drug Administration (FDA): IRB00000974, IRB00000975, IRB00000976 and IRB00003142.

This Federal Wide Assurance is applicable to The University of Texas Southwestern Medical Center, inclusive of the Graduate School of Biomedical Sciences, Medical School, School of Allied Health Sciences, UT Southwestern Moncrief Cancer Center, Zale Lipshy University Hospital, and William P. Clements Jr. University Hospital, other centers and organized research units within UT Southwestern Medical Center.

Other institutions covered by the UT Southwestern Medical Center Institutional Review Boards through general IRB Authorization Agreements include the following:

- Parkland Health and Hospital System
- Scottish Rite for Children
- Children's Medical Center
- Texas Health Resources

Any member of the IRB who is the Principal Investigator, Faculty Sponsor, or a Co-Investigator on a protocol is prohibited from serving as a primary or secondary IRB reviewer and must disclose such involvement in projects to be reviewed by the IRB. In addition, the member must physically leave the meeting prior to the committee's review and decision of the research project in which the member is involved.

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. *This prohibition does not apply to federal regulatory oversight agencies (FDA, OHRP, DoD, etc.).*