UTSouthwestern Medical Center CTSA Program

Texas Health Resources



Texas Health Resources (THR)

Texas Health Resources is a faith-based, nonprofit health system that cares for patients across North Texas.

- THR has more than 23,000 employees of wholly owned/operated facilities and consolidated joint ventures
- 27 hospital locations 19 acute care hospital locations, 5 short stay hospitals, 2 rehabilitation hospitals, 1 transitional care hospital
- More than 80 outpatient facilities, surgery centers, behavioral health facilities, fitness centers and imaging centers
- More than 6,200 physicians with active staff privileges
- Service area is across 16 counties: Collin, Cooke, Dallas, Denton, Ellis, Erath, Grayson, Henderson, Hood, Johnson, Kaufman, Parker, Rockwall, Somervell, Tarrant and Wise.
- Texas Health Research departments Human Research Protection Program Office (HRPPO), Research Administration (RA) and Clinical Research Trials
- All human-subject research conducted by THR employees/THR-credentialled individual or at a THR hospital/clinic or that is accessing THR data **must** be reviewed and approved by the THR HRPPO and THR Research Administration **in addition** to the IRB **prior** to beginning the research project.
 - Human Research Protection Program Office (HRPPO) is responsible for ensuring that all THR engaged human-subject research is conducted ethically and in compliance with federal regulations and THR policies.
 - o Research Administration Office ensures all agreements and payments for procedures are appropriately in place. Ensures appropriate patient billing and research coding are appropriately applied post study initiation. And reviews and sets up non-THR individual's access to THR systems or facilities.
- All studies in which THR is a performance site, must have a THR employee or THR credentialed individual listed on the study.
- The following items are **required** for all studies in which THR is a performance site:
 - Completed Study Questionnaire
 - o Completed and signed Entity Reviewer form.
 - o Both of these forms can be found under "Forms and Templates" at: https://www.texashealth.org/Research/Review-Board-and-Committee
- Other items may be required depending on the study specifics. Such items could include, but not limited to a Data Use Agreement, a THR Coverage Analysis, completion of Contractor Questionnaire and additional items related to being a contractor, Contractual agreement for services, etc.
- After final review and approval, a letter from the THR HRPPO will be sent to the PI and study team noting site approval has been granted.



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Data

- All data that is being used outside of THR by non-THR individuals must at a minimum have a Data Use Agreement (DUA) in place. THR and UTSW have a Master DUA and for each individual study an Exhibit is created under that DUA.
- You may not send any THR data to another institution without prior permission from THR. This includes registries, other University collaboratives and/or other UTSW Affiliates (i.e., Parkland Hospital, Children's Hospital, etc.). THR requires a study specific Data Use Agreement with all other institutions receiving THR data even if that data has been combined with UTSW data.
- As part of the use of THR Data, THR must be noted in all publications stemming from the use of the data.
- THR has a Research Data Analytics team that can assist with research data requests. The THR individual listed on the study will be able to submit these requests or you can reach out to one of the THR Research Administration staff for assistance.

Access

• Requesting access to a THR system (i.e., electronic medical record) or THR hospital/clinic (i.e., to consent a patient, complete a survey, etc.) requires being credentialed by the THR hospital or be set up as a THR research contractor. This would need to be indicated while completing the THR Study Questionnaire and would be facilitated by RA.

Hospital Services

• If the study will involve **Hospital services**, a THR Coverage Analysis will need to be completed. Services will be reviewed as whether considered Standard of Care or not by Research Admin. Research Admin will provide any fiscal responsibilities to you for study related items.



Texas Health Resources Email Contacts



Research Compliance - David Chen, Research Compliance Officer/HRPP Manager DavidChen@texashealth.org



Human Research Protection Program - HRPP@texashealth.org



Research Administration - THREResearchAdministration@texashealth.org



Leadership - Teresa Turbeville, Senior Director of Research <u>TeresaTurbeville@texashealth.org</u>