Getting started in Research

The Texas Health Resources' entity that oversees all research at THR, by THR employees and/or involving THR patients or their data is **Texas Health Research & Education Institute.** These handouts are to assist you in navigating the research processes. If you need assistance, please reach out to our team via HRPP@texashealth.org or THREResearchAdministration@texashealth.org

As background, Research is defined as the systematic investigation into and study of materials and sources to establish facts and reach new conclusions. 45 CFR Part 46 of the Federal Regulations defines a human subject as: a living individual about whom an investigator conducting research:

i. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
ii. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

The first step is to determine if your project is Human Subject research based on the federal regulations and therefore requires IRB oversight or if it may be submitted for Exempt determination as this will determine your path/steps to approval (See "**THR NHSR Guidance"** sheet for assistance in making this determination).

Exempt studies (non-Human Subject research) must complete the UTSW REDCap Non-Regulated Survey Non-Human Research Application
*Note - Case reports additionally do require this submission AND patient consent (specific consent for case reports included)

No UTSW username is required to be able to submit Exempt studies. You will need complete a THR entity approval form via https://redcap.link/EntityReviewerForm

If you are unsure if your project may qualify as exempt, please review the THR NHSR (Not Human Subjects Research Determination) Guidance sheet.

Studies requiring Institutional Review Board (IRB) approval
THR utilizes University of Texas Southwestern Medical Center's (UTSW) IRB as our local IRB of record. Other IRBs may additionally be used however regulations require the THR Human Research Protection Program (HRPP) have a formal agreement with every IRB that serves as an IRB for THR studies. THR has an existing agreement to use the UTSW IRB of which no fee is applied to THR unfunded studies.

If you are partnering with someone from a non-THR institution and they note the study already has IRB approval, for you/THR to participate in the study the study will still need to be reviewed by the THR

HRPP office AND have an agreement put in place with that IRB. The THR HRPP office will take care of this as part of their review process. To submit for THR HRPP review, you must initiate the submission in the UTSW IRB system Ethos. You will choose outside IRB to allow it to flow solely to THR HRPP and not the UTSW IRB.

Scientific Review

Texas Health Resources requires every study to undergo a scientific review. This is to ensure that the scientific question being asked is relevant and that the design of the study is appropriate to answer the question. The primary focus of the scientific review is on the scientific merit, feasibility and utilization of resources. Studies that do not undergo an external scientific review (i.e. federal funded studies, corporate sponsored studies, etc.) will be reviewed by the THR Scientific Review committee.

Research study training requirements

You will be required to complete Human Research Protection training via CITI Program. This may be completed as early as you desire. The certificate is good for 3 years. After 3 years, you only need to complete the refresher courses.

To complete your training, please open https://support.citiprogram.org/s/article/updated-guide-to-getting-started and follow the steps to creating your account. Your THR email should be used for your training account. Your affiliation will be **University of Texas Southwestern Medical Center**. The training requirements are:

- HSP (Human Subject Protection)
- HIPAA (Health insurance Portability and Accountability Act in Research)
- GCP (Good Clinical Practices—**Please note this module is only required if the study involves a sponsored Clinical Trial**. This will not apply to Investigator Initiated research)

Access

All THR studies utilize the University of Texas Southwestern (UTSW) electronic systems that are not determined Exempt. Even those **NOT** using the UTSW IRB. As such, you will need to have a UTSW profile.

- To establish a UTSW profile, please complete and have all your study team members complete the "eResearch Access Request" and return the completed form to ResearchAccessRequests@TexasHealth.org. Please allow 2 weeks for the setup of your profile.

Protocol and Informed Consent

A Protocol template has been included to utilize and assist you with writing your protocol. Additionally, if the study requires an Informed Consent, an Informed Consent template has also been included.

*You can also find the forms here https://www.utsouthwestern.edu/research/hrpp/forms/#protocol

Once you have your protocol, your UTSW Username and password, and completed your CITI training you are ready to begin your IRB application submission. (If you need assistance with your submission or navigating the eIRB system, please reach out to our Regulatory Specialist, Mark Butler at MarkButler@texashealth.org or other THRE research team member.)

To submit the study application see "How to Submit a New Protocol Using the Ethos System" handout

After initiating your study in the Ethos system, the following items need to be completed:

- **Entity Reviewer form** https://redcap.link/EntityReviewerForm
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- **Study Questionnaire** https://redcap.link/InitialStudyQuestionnaire will need to be completed
- Each individual that is a part of the study will need to complete a **Conflict of Interest form** https://redcap.link/9zloaelt

If you have any questions, feel free to reach out to any of the research team:

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