Getting started in Research

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

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 considered Exempt. This will determine your path/steps to approval.

Exempt studies must complete the Y1 or Y2 form to request an IRB exemption.

- The Y1 form is for use when all data/specimens in the research will be anonymous to investigators and study is **not** FDA regulated.
- The Y2 form is for projects not intended as Research (QI, Program evaluation, case report, etc.). *Note - Case reports do require submission of a Y2 form AND patient consent (specific release/consent for case reports)

If you are unsure if your project may qualify as exempt, exempt projects must be able to answer "No" to all questions listed in Item 6 on page 2 of the Y1 form or in Section 5 on page 2 of the Y2 form. If your study meets the criteria, submit the Y1 or Y2 form (whichever is appropriate for your project), along with the signed Entity Reviewer form (https://redcap.link/EntityReviewerForm) to HRPP@UTSouthwestern.edu and cc MaryHendricks@texashealth.org and DavidChen@texashealth.org
Please allow 2 weeks for review.
If deemed as Exempt, you will receive a letter from the UTSW Human Research Protection Program Office stating that your study does not meet the definition of research under federal regulation 45 CFR 46.102 and therefore does not require IRB approval or oversight. If not deemed as Exempt, you will need to follow the steps to submit your study to the IRB for review.
*If deemed Exempt and you later publish your study data, you will utilize this letter when asked for documentation of IRB approval.

Institutional Review Board (IRB)
THR utilizes University of Texas Southwestern Medical Center's (UTSW) IRB as their local IRB of record. Other IRBs may additionally be used, but regulations require the THR Human Research Protection Program (HRPP) have a formal agreement with every IRB that serves as an IRB for THR 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.

Research study training requirements

1. 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 is recommended to 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)

2. **All** THR studies utilize the University of Texas Southwestern (UTSW) electronic systems. 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
You may use the below link to download a protocol template. Other forms such as Informed Consent are additionally available there.
* 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:
There are 2 parts to the submission process. First part is within **Velos** and then the second part is within **eIRB**

Registering the Study in Velos
Velos is a study management tool and is the first step to submitting your Protocol through the eIRB System. Use this link to Velos https://velos.swmed.edu/
1. From the Velos Login screen, type the following information in the corresponding fields (Username and Password are case sensitive):

Username
Password
Then click **Login**

*Pop-up blockers must be disabled for this application

2. From the Homepage click **Manage Protocols** from the left navigation toolbar. Click **New**.

3. The Velos **required** fields on the Summary page include:
   - Study Entered By
   - Principal Investigator
   - Primary Research Coordinator
   - Long Study Title
   - Objective(s)
   - Org. Affiliated with Study (select Texas Health Resources)
   - Is this a cancer affiliated study
   - Phase
   - Research Funding Type
   - Blinding
   - Sponsor name (if internal select THR)

The following forms are required to be uploaded under the "Documents" tab within Velos for all studies in which THR is engaged.

- Entity Reviewer form https://redcap.link/EntityReviewerForm
  *After submission of the Entity Reviewer form via the link, Research Administration will facilitate the form's required signatures for you and provide you with the executed document for uploading.

4. Enter your **e-Signature** field (default e-Signature is "1234) and click **Submit**

5. Click on the **Local Sample Size** link on the Summary tab and enter the local sample size, if applicable.

6. Click the **More Study Details** link.
   a. If you do not want the study to appear on the UTSW Find a Clinical Trial (FaCT) website, then click the "Remove my study from Find a Clinical Trial" checkbox.
   b. Epic Interface Fields do not apply to THR entities.
   c. Complete any items that apply

7. Enter your **e-Signature ("1234")** and click the **Submit** button

8. Click on the **Site/Team** tab to add study team

9. Click **Add/Edit Study Team Member** link

10. Enter the information in the **First Name** and **Last Name** field and click **Search**.

11. Click the checkbox associated with the user and click in the **Role** filed to select the appropriate role. This does not affect anyone's study roles, this is only used to determine access to the submission a default roll is "other study personnel". (Study rolls and responsibilities are defined in eIRB on UTSW form B.)

12. Enter your **e-Signature ("1234")** and click the **Submit** button

13. In the site/Team tab, click the **Add New Organization** link

14. Select **Texas Health Resources** from the drop-down list.

15. Click the **Study Status** tab, select add new status, The organization is UTSW, verify and update required fields and submit to eIRB
*The **IRB-Submission Initiated** status will send the study to the eIRB system.

16. Enter your **e-signature ("1234")** and click **Submit**

17. Within 5 to 10 minutes of adding this status, you will receive the "**IRB-Draft Study Created**" status indicating the study is now in the eIRB system.

18. Also under the Study Status tab, select add new status, the organization is THR, and status type is "performance Site", study status "performance site – submitted" complete the mandatory fields.

19. Enter your **e-signature ("1234")** and click **Submit**

Completing the eIRB Application
Use this link to the eIRB Application https://eresearch.swmed.edu/eIRB

1. From the eIRB Login screen, type the following information in the corresponding fields

(Username and Password are case sensitive):
Username
Password
Then click **Login**

2. Once the study has been registered in Velos and study status of "IRB – Submission Initiated" has been added in Velos, the study will appear in the Tasks tab in eIRB as a draft.

3. Click on the hyperlinked study name to access the study.

4. Click the **Edit Study** button.

5. Answer all questions on the SmartForm as they apply to your study.

6. Click the **Continue** button to proceed to the next section

7. Any Co-Investigators must complete the "Indicate Study Participation" activity to agree or decline to participate in a study before the PI will be able to submit the study for review.

To notify the Co-Investigator(s)

a. Click on Notify Co-I Regarding Participation activity.
b. Click OK to send the notification
c. A notification will be sent to ALL Co-Investigators listed on the study *Sub-Investigators or Co-Investigators may also be listed the same as Other Study Personnel in eIRB. They do not need to be listed as Co-Investigators on this smart form. This application does not define study responsibilities. Those are defined to the IRB on UTSW Form B.

8. At a minimum you will have to complete UTSW Form B and C for all studies. Other forms may be required depending on the study. The smart form has directions within it to provide guidance on which forms are required.

*There is an abbreviated pathway within the Smartform if you are using an external IRB. This will send your form solely to the THR HRPP office for review. A letter of approval is required from THR HRPP office prior to moving forward with the external IRB submission.

9. Once all sections of the SmartForm have been completed, the study is ready to be submitted by the PI.

10. For the PI to submit the study.

a. Log into eIRB
b. The study should appear in the Tasks tab. Click on the study name link to access the study.
c. Select the Edit Study button when in the Draft state to view the submission.
d. Click on the Exit link to leave the form and return to the study workspace
e. Submit the study to the IRB by clicking on the Submit Study button and complete the PI Assurance and click OK.

You can check the status of a study by clicking the study name link to access the study. Within the study workspace screen the **Current Status will appear on the left

In addition to submitting the application a **Study Questionnaire** https://redcap.link/InitialStudyQuestionnaire will need to be completed and 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:

Teresa Turbeville, Senior Director of Research teresaturbeville@texashealth.org
Carrie Cantrell, Director of Research Administration carriecantrell@texashealth.org
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Jennifer Johnson, Research Support Specialist jenniferjohnson5@texashealth.org
Mark Butler, Regulatory Specialist MarkButler@texashealth.org

Data

If you need assistance in obtaining large amounts and/or deidentified patient data, **THR's Research Data Analytics** can assist you.

Go to the Service Desk portal → Submit an IT Request → You can use the search word "Research" and select "Reporting Services" → click the checkbox for "Research Reporting Services" → select "Next" → Select the "Options" → Then you should see all of the questions for the ticket.
Or, here is a direct link:
https://thritsprod.service-now.com/sp?id=sc_cat_item_guide&sys_id=ea3606ff1b4e5c503d940f22dd4bcbb9&table=sc_cat_item

Statistician

Please contact our team if you need statistical assistance with your project.