Submitting a New Protocol

All research applications for review must be submitted using the UTSW Velos and eIRB Systems. This includes studies that will be reviewed by an outside IRB.

Per THR policy, for THR to be engaged in a study and listed as a site, the principal investigator, co-investigator or study staff must be an employee, medical staff member or otherwise be affiliated with a THR Entity and have expertise and/or a "scope of practice" that is consistent with the needs of the study. THR may not be listed as a site for a study without an appropriate THR individual listed.

Note: Access to UT Southwestern Medical Center's internal research systems (eIRB; Velos) requires an active UT Southwestern Login ID. You additionally will need to complete your Human Subject Protection Training modules within CITI (Collaborative Institutional Training Initiative at <u>https://about.citiproqram.org/en/homepage/</u>). If you have already completed your training, you must ensure that you have affiliated yourself with UT Southwestern Medical Center

If you do not have an active UT Southwestern-issued Login ID, then you will need to obtain one. Complete the User Request form and submit it via email to <u>HRPP@texashealth.org</u>

Accessing UT Southwestern systems

*Note your User Name and password are the same for logging into the UT Southwestern main page, Velos and eIRB. The user name in Velos is case sensitive.

After you have you User Name and password go to: <u>https://myutsouthwestern.swmed.edu</u>

(Login facilitated through "Pulse Connect Secure") or you may go to <u>https://www.utsouthwestern.edu</u> and then click on "MyUTSW"

Type the following information in the corresponding fields: User Name Password Then click **Login**

From the initial page after logging in, click on MyUTSouthwestern

Click on **Tools** on the right of the top bar

You will now see links to both Velos and 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.

 From the 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

- From the Homepage click Manage Protocols from the left navigation toolbar. Click New
- 3. The Velos required fields on the Summary page should 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.

- THR Study Coverage Analysis
- Entity Reviewer form
- If the study is a Phase 1 or Phase 2 study or involves genetic testing that is not part of the normal/standard of care disease screening process a IO IRB Reviewer Form is required
- If the study is a commercially sponsored study a word version of the Clinical Trial Agreement and budget must be submitted to **Research Administration**
- Conflict of interest forms completed in RedCap should be completed (only for THR employees or affiliated/credentialed physicians) prior to submission to the Human Research Protection Program Office (HRPPO) for review of this study.

- 4. Enter your e-Signature in the e-Signature field (default 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 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 rolls, 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 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 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 mandetory fields.

19. Enter your e-signature and click Submit

You may NOT begin enrolling on a THR campus until you receive THR Performance Site Approval.

Completing the eIRB Application

 From the Login screen, type the following information in the corresponding fields (Username and Password are case sensitive): Username

Password

Then click Login

 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. 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
- 8. 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.
- 9. 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.
- 10. Once all section of the SmartForm have been completed, notify the PI that the study is ready to be submitted.
 - a. Click the Send Email to Study Team button from the Study Work space
 - b. Type your message in the text box
 - c. Click **OK** to send message
 - d. The message will be sent to the Principal Investigator and Primary Coordinator and Administrative Contact.
- 11. The PI must submit the study.
 - a. Log into elRB
 - 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.