Human Research Subject Training

Prior to receiving approval of a study, you must be up to date on your Human Research Subject training. THR requires the use of the CITI program to meet the required training. Login into CITI (via http://www.citiprogram.org/) and click "add Institutional Affiliation" on the home page. Then type/choose "University of Texas Southwestern Medical Center" (UTSW) and check the box to agree to Terms of Service and finish the selection. After affiliating with UTSW, you will then be able to view and take the courses under their Institution by clicking the "View Courses" button next to "University of Texas Southwestern Medical Center" on the home page. Your training is required to be renewed every 3 years.

- HSP for Researchers (Human Subject Protection)
- HIPAA (Health insurance Portability and Accountability Act in Research)
- GCP (Good Clinical Practices) for Researchers—**Please note this module is only required if the study involves a Clinical Trial**)

Your CITI account must link to UTSW's eIRB account. Use the same email that was used for your UT Southwestern account.

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. The following forms are required to be completed for all studies in which THR is engaged.

- THR Study Questionnaire
- Entity Reviewer form
- Conflict of Interest Disclosure (only required for THR employees and affiliated/credentialed physicians)

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.

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 HRPP@texashealth.org

Accessing UT Southwestern systems

*Note your User Name and password are the same for logging into the UT Southwestern main page, Velos and eIRB

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

 (Login facilitated through "Pulse Connect Secure") or you may go to https://www.utsouthwestern.edu 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.

1. 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

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

3. The Velos required fields on the Summary page should include:

   - Study Entered By
   - Principal Investigator
   - Long Study Title

- Objective(s)
- PI's Primary Department (select Texas Health Resources)
- Cancer related study Y/N
- Phase
- Research Funding Type
- Study Type
- Blinding
- Primary Sponsor Name (if the sponsor is not listed they must be added to UTSW vendor list using UTSW's Sponsor request form)

4.
5. 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. Below this section do not complete as they do not apply to THR studies.
6. Enter your **e-Signature** and click the **Submit** button **NOTE:** Do not navigate off this page until this is completed or you will lose your work and a Velos number and submission will not be generated. Save this Velos number once created.
7. Click on the **Site/Team** tab to add study team
8. Click **Add/Edit Study Team Member** link
9. Enter the information in the **First Name** and **Last Name** field and click **Search**.
10. Click the checkbox associated with the user and click in the **Role** filed to select the appropriate role
11. Enter your **e-Signature** and click the **Submit** button
12. In the site/Team tab, click the **Add New Organization** link
13. Select Texas Health Resources from the drop-down list.
14. Click the **Study Status** tab, you will have two steps under this tab. to complete.
    a) Select "add new status" (will show in light blue on right center of screen)
    b) leave the organization as default "UT Southwestern Medical Center and Affiliates", Status type, select from the drop down "IRB", Study status, from the drop down "IRB-Submission initiated".
    c) Your name should default in "documented by" section and select date in the "status valid from" line. This is typically the current date.
    d) Enter your **e-signature** and click **Submit**
    *The **IRB-Submission Initiated** status will send the study to the eIRB system.
    d) then repeat "a" above.
    e) select organization, this time as "Texas Health Resources" from the drop down. Then for status type, select "performance site" from the drop down and Study status is "performance site – Submitted".
    f) repeat "c above then enter your **e-signature** and click **Submit** .
17. Within 5 to 10 minutes of adding IRB submission, you will receive the "**IRB-Draft Study Created**" status indicating the study is now in the eIRB system.

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

Completing the eIRB Application

1. From the 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.
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. Insure all UTSW required forms are attached to the eIRB Smartform. These can be accessed here https://www.utsouthwestern.edu/research/hrpp/forms
    a) the minimum required forms for all submissions is a form B (study personnel) and form c (study population)
7. Click the **Continue** button to proceed to the next section
8. Specific to THR studies:
a) Section 5.1.1.a you must upload your THR entity reviewer form here for each THR entity involved in the research.
        a.
9. Once all section of the SmartForm have been completed, If the study is being sent to local IRB only - notify the PI that the study is ready to be submitted. If the study is going to a Central IRB please follow instructions specific to reliance studies, and do not submit at this time.
    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, Primary Coordinator and Primary Administrative Contact.

9. The PI must submit the study using their log in credentials
    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.
    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. You can also see information on the study status in the history tab under your studies home page.