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)
- GCP (Good Clinical Practices) for Researchers—**Please note this module is only required if the study involves a Clinical Trial, is NIH funded, or the sponsor requires it**)

Your CITI account must link to UTSW's ETHOS account. Use the same email that was used for your UT Southwestern account. If you have previously completed the above CITI you may select the refresher courses.

Submitting a New Protocol

All research applications for review must be submitted using the UTSW ETHOS System. 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. These forms require an ETHOS STU number to complete. Please initiate your study in ETHOS prior to completing these.

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

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.

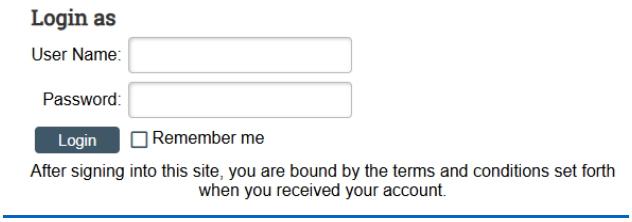
Note: Access to UT Southwestern Medical Center's internal research system (ETHOS) requires an active UT Southwestern Login ID.

If you do not have an active UT Southwestern-issued Login ID, then you will need to obtain one. Complete the User Request form located here https://redcap.link/UTSW_access_request

Accessing UT Southwestern systems

After you have your User Name and password go to: https://ethos.swmed.edu/ETHOS

Enter your UTSW log in credentials on the ETHOS home page and this will take you to the main Dashboard where you can initiate a new study, access existing studies or otherwise make submissions into this system.



If you are inside THR's network this link should work to directly connect you to this system. If you are outside THR's network, you may need to connect to UTSW through their VPN or use one of UTSW's approved methods of connecting to their systems. Please contact UTSW for more information on this.

Should you encounter issues accessing any of the listed UTSW resources, please contact UTSW support by either…

- Entering a support ticket in UTSW ServiceNow –Request that ticket be assigned to Network Services team
- Contacting the UTSW helpdesk via phone at 214-648-7600

Please be sure to let them know you are a THR user.

PLEASE NOTE: You may NOT begin enrolling on a THR campus until you receive THR Performance Site Approval from THR's Human Research Protection Program (HRPP) Office, even once your IRB approval is received.

Initiating and Completing the ETHOS 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 you log into ETHOS you will see "Create New Study" on the left side of your screen. Selecting this will open the loading page to initiate a new study.
3. To get your IRB number answer the questions on the loading page.
   a) Answer 1-7 based on your study. For THR studies the answer to question 8 & 9 is "No".
   b) If this is a reliance study approved by an outside IRB (Advarra, WCG, TCU, or other non UTSW IRB. The answer to #6 will be "YES". If it is being reviewed by UTSW IRB please select "NO".
4. Once you answer question number 9 and hit continue this should generate your IRB number on the next page. This will be STU and an 8 digit number. Please record and use this on all the THR required documents where an IRB or STU number is requested.
5. *If you need to exit ETHOS and return to your study, repeat logging in and once logged in you should see a list of studies assigned to you. Click on the applicable study name to access your study.*
6. *Click the **Edit Study** button and the study smartform will re-open. You may edit any study until the PI submits it for IRB review at which time the SmartForm is locked.*
7. Answer all questions on the SmartForm as they apply to your study. Click the "continue" button on the bottom right of each page to proceed through the smartform. As you answer questions about your study, the form may add or remove pages and or sections as needed based upon your responses. Any item with an * is mandatory.
8. If there are any required forms to be attached to the ETHOS smartform the UTSW templates can be found here https://www.utsouthwestern.edu/research/hrpp/forms
   a) Examples of these could be Form A – Protocol, form E – consent.
   b) *If you have used the old eIRB system before. Form B and C are no longer required and are now part of the smart form. Other forms such as HIPAA waivers or consent waivers are now part of the SmartForm and will no longer be attachments.*
9. Section 3. Add study personnel, once added use the update function to add credentials, roles and responsibilities for each person listed on the study and whom should receive automatic notifications from ETHOS. #2 add whom ever is the primary coordinator for the study, this may be the same as the PI or some other person, but they must be listed in #1 on this page.
10. Section 7 Identification/Recruitment plans. As you add study target populations to the smartform, in the pop up box. If you have recruitment materials approved or to be approved. Select under 1.2 Recruitment process – select B (subjects will self -identify (respond to study advertisements. This will add sections to the form to add recruitment materials to the smartform. Each selection here will require different information to be added or selected depending upon how you are going to recruit or identify potential

subjects for your study.

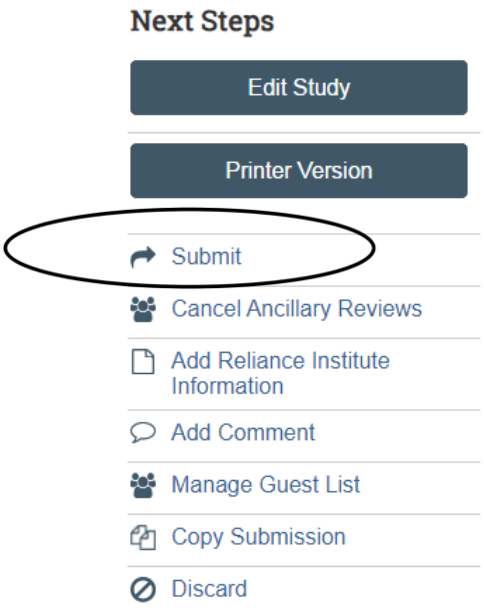
11. Section 9 – **Reliance studies only** – local IRB you will not see this section
    a. #2.1 - THR does not require the study wide approval letter sp you may use a blank document for this field. If you have a study wide approval letter from a study sponsor you may also add it to this study here but it is not required.
    b. #3.0 add the IRB approval for THR's site here. Then complete the rest of the questions on this page.

12. Items specific to THR studies:
    a) Section 4 Funding and other support - #1 Funding Source – Select the last item "External Funding not managed through UTSW SPA" and then how are they Classified, for profit, departmental funding, etc. Then enter item 1.5 your sponsor funding source (examples: "THR department funds", a commercial sponsor name, "THR Foundation grant" or name of other funding for your study.)
    b) Section 4.1 – This should populate based on what you entered on the previous page. Select the items showing and then continue.
    c) Section 6 Study Summery/Consent forms - item #16 Upload Other Documents: You must upload your signed THR entity reviewer form here for each THR entity involved in the research.
    d) Section 9.0 - line 6 # 6.1 HIPAA waivers. As applicable, **this should be issued by the IRB of record.** THR does not issue these. If your study requires a full waiver of HIPAA (e.g. chart reviews) or a partial waiver of HIPAA (for things such as recruitment and pre- screening of potential subjects prior to approaching for consent and HIPAA auth.) **you must insure that the IRB of record issues this and it is listed and described on the IRB approval letter for THR's site.**

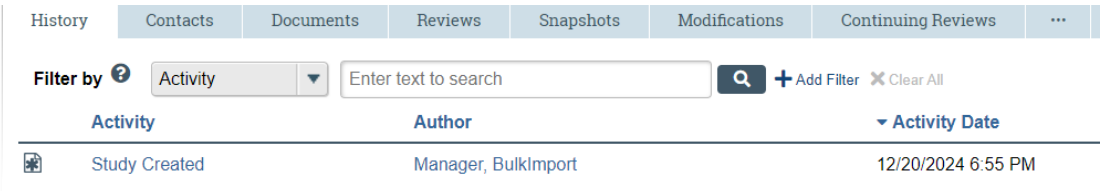
13. Once all sections of the SmartForm have been <u>completed</u>, if the study is being sent to **local IRB only** - notify the PI that the study is ready to be submitted.

    If the study is going to a Central IRB please follow instructions specific to reliance studies. Reliance studies are submitted in ETHOS once central IRB approval has been received and the IRB approved documents are added to the smartform. Please do not submit until all these items have been completed.

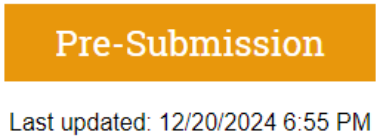
14. The PI must submit the study using their log in credentials.
    a) Log into ETHOS as described above.
    b) A list of the PI's studies should show under the IRB tab. Click on the study name link to access the study.
    c) Select the **Edit Study** button when in the Draft state. To make any needed changes.
    d) Click on the **Exit** link to leave the form and return to the study main page.
    e) Submit the study to the IRB by clicking on the **Submit Study** button and complete the PI Assurance and click OK.



Once submitted make sure it shows up in the History section on the study main page



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. Such as this study is pre-submission status.



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You can also see information on the study status in the history tab under your studies home page.

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