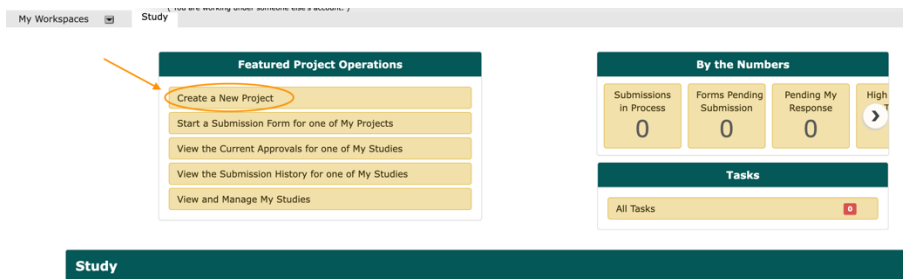


Submitting a New Application to the UTHSC IRB

1. Log into [iMedRIS](https://imedris.uthsc.edu) at <https://imedris.uthsc.edu> with your UT Net ID and password via DUO
 - a. If you need assistance with your UT Net ID and/or password, contact the HELP desk at 901.448.2222 or visit the HELP desk website at <https://uthsc.edu/password/>
 - b. If this is the first time you have logged into iMedRIS and you need your iMedRIS account set up, please contact Anna-Marie Smith at asmith509@uthsc.edu or contact the IRB office at 901.448.4824.
 - c. Non-UTHSC affiliated researchers who do not have a UT Net ID, will need to be sponsored into the UT system. Please contact Anna-Marie Smith at asmith509@uthsc.edu for assistance.
 - d. Prior to accessing iMedRIS, you will need to install the “Duo Mobile App” <https://www.uthsc.edu/its/cybersecurity/duo/>. The University requires this two-factor authentication to protect against cyber-attacks.
2. On your home screen, under “Featured Projects” click “Create a New Project”



3. On the next screen, select the 1st option, “*UTHSC IRB Memphis Form 1: Study/Project Application*” and click the gray button “Start selected Application”

Please select a New Project Application from the list below:

| Form Name | Form Description |
|--|---|
| <input type="radio"/> UTHSC IRB Memphis Form 1: Study/Project Application | UTHSC, LeBonheur Children's Hospital, Methodist Healthcare – Memphis Hospitals, or Regional One Health - Health Science Center Institutional Review Board (IRB) |
| <input type="radio"/> UTHSC Secondary OID Review | Office Use Only - UTHSC Secondary OID Review |
| <input type="radio"/> External Outside Disclosure Form | Health Science Center - eOID (external Outside Interest Disclosure) form should be completed annually. |
| <input type="radio"/> UTHSC IACUC PI SOP Request Form | UTHSC IACUC PI Request for Standard Operating Procedure Approval. |
| <input type="radio"/> UTHSC IBC PROTOCOL APPLICATION | Health Science Center - Memphis Institutional Biosafety Committee (IBC) |
| <input type="radio"/> UTHSC IACUC Protocol | Health Science Center (Memphis) Institutional Animal Care and Use Committee (IACUC) |
| <input type="radio"/> UTHSC Radiation Safety | UTHSC (Memphis) Application for the Use of Radioactive Materials |
| <input type="radio"/> UTHSC RCOI | DO NOT USE THIS FORM (AUTOMATED PROCESS) |
| <input type="radio"/> UT Knox Area IACUC - Satellite Facility | UTK, UTIA, CVM, and GSM IACUC Application for Establishment of a Animal Satellite Housing Facility |
| <input type="radio"/> UT GSM/UTMC Knoxville: IRB Study Application | Submission form for human research conducted at UT Medical Center Knoxville or UT Graduate School of Medicine |
| <input type="radio"/> UTK Knoxville Main Campus IRB Application | Knoxville Institutional Review Board (IRB) |
| <input type="radio"/> UTK - Institutional Biosafety Committee Registration | Knoxville Institutional Biosafety Committee (IBC) |
| <input type="radio"/> UT Knox Area IACUC - Animal Use Protocol | UTK, UTIA, CVM, and GSM Institutional Animal Care and Use Committee (IACUC) |

- For the first few questions of the IRB application, you will provide your study/project title, the name of the institutions and/or departments associated with your study/project, the list of key study/project personnel including their contact information and designating their study/project responsibilities, and whether your study/project will require review by an ancillary committee.
- Next, designate whether your study/project has a funding source, including a source that will provide study drug/biologic/device at no cost. Note that industry-sponsored studies will be assessed a review fee. The UTHSC IRB fee schedule is located on the IRB website at <https://uthsc.edu/research/compliance/irb/about/fees.php>
- Next, you will be asked to designate the level of IRB review for your project. If you do not know if your study should receive Exempt/Not Human Subject Research (NHSR), Expedited, or Full Board review, call the IRB office at 901.448.4824 for assistance or refer to the [Levels of IRB Review](https://uthsc.edu/research/compliance/irb/researchers/tools-guides.php) located on the IRB website at <https://uthsc.edu/research/compliance/irb/researchers/tools-guides.php>
- The application will guide you through the required sections depending on the type of research [Exempt/Not Human Subject Research (NHSR), Expedited, or Full Board] you are conducting.
- Be sure to click **Save and Continue to Next Section** to save your responses and move to the next set of questions in the application.
- Required questions of the application will be marked with an *

10. If you forget to respond to a required question, the system will give you a prompt.
11. If you are unsure about a question, please contact the IRB office for assistance.
12. Once you have completed and saved the last page of the electronic application, you will enter the **Routing Form (instructions are in blue font)** and be prompted to upload the appropriate study/project documents, such as:
 - a. Sponsor Protocol
 - b. Grant Application
 - c. Informed Consent(s) – The UTHSC IRB requires consent(s) to follow the templates located on the IRB website at <https://uthsc.edu/research/compliance/irb/researchers/consent-forms.php>
 - d. Investigator’s Brochure
 - e. Drug/Device package inserts
 - f. Manufacturer’s instructions
 - g. Data collection instruments
 - h. Subject eligibility checklist
 - i. Surveys/Questionnaires
 - j. Recruitment materials
13. Once you have completed the application and uploaded a copy of the appropriate study/project documents, route the submission to the
 - a. Principal Investigator (PI),
 - b. Co-/Sub-Investigators,
 - c. Faculty Advisor if PI is a student, resident or fellow,
 - d. Department Chair, and
 - e. Hospital Service Chief (for studies conducted at Regional One Health facilities)

so that they may apply their electronic signatures to the submission. These individuals will receive an email notification letting them know that a submission requires their review and signoff. From their iMedRIS home screen, under **All Tasks**, they should click the paper/pencil icon next to the **Submission Routing Signoff** to view the study application and other study documents. Once they are ready, they can apply their electronic signature by clicking either **Approve** or **Deny**, entering their UT NetID and password, and saving.

For additional assistance, the UTHSC IRB provides a **Routing, Workflow Tracking, and Signoff Guide** at <https://uthsc.edu/research/compliance/irb/researchers/tools-guides.php>

14. The UTHSC IRB will not receive the submission until all of the appropriate individuals have applied their electronic signatures.
15. Depending on where you will conduct your research, separate institutional approval may be required. Institutional contacts for affiliate institutions are located on the IRB website at <https://uthsc.edu/research/compliance/irb/about/affiliates.php>
16. Please note that all key personnel listed on a study/project must:
 - a. Provide a copy of his/her CV/Resume. If the IRB has previously received a copy of a researchers CV/Resume and uploaded it into the system, an additional copy is not required.
 - b. Provide documentation of current Collaborative IRB Training Initiative (CITI) training. The UTHSC IRB will not issue approval for proposed studies, continuations, & revisions unless all key study/project personnel have current CITI training. If you have completed CITI training at another institution you may either affiliate your training certificate via CITI website or provide a copy of your training certificate with your submission to the UTHSC IRB.

If you or some of the key study personnel on your study/project have not completed/renewed CITI training, please have these individuals log into www.citiprogram.org and complete either:

Option 1: Basic Human Subject Protections + Good Clinical Practice (Basic HSP + GCP) combination course (22 modules). For recertification in three years, you will be required to take the entire course again.

OR

Option 2: Human Subjects Training Basic Biomedical (Biomed) course (18 modules) **plus:**

GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) course (14 modules).

For recertification in three years, a shortened refresher course for these is available. Biomedical researchers may want to select this option if involved in a multicenter trial and these courses are required by the sponsor.