THE UNIVERSITY OF TENNESSEE CHATTANOOGA

Institutional Review Board

How to Submit a New IRB Protocol Application

This document will walk you through the steps of submitting an IRB protocol application in DASH Research IRB, the new IRB submission system of the University of Tennessee. Please contact the Office of Research Integrity if you have any problems or questions about the process.

Who is submitting this protocol?	
Student	**Faculty / Staff**
You will need a faculty advisor for your project. The faculty advisor must be listed as the Local Principal Investigator within DASH Research IRB and will have to submit the protocol for you.	Follow instructions for Faculty / Staff Submissions

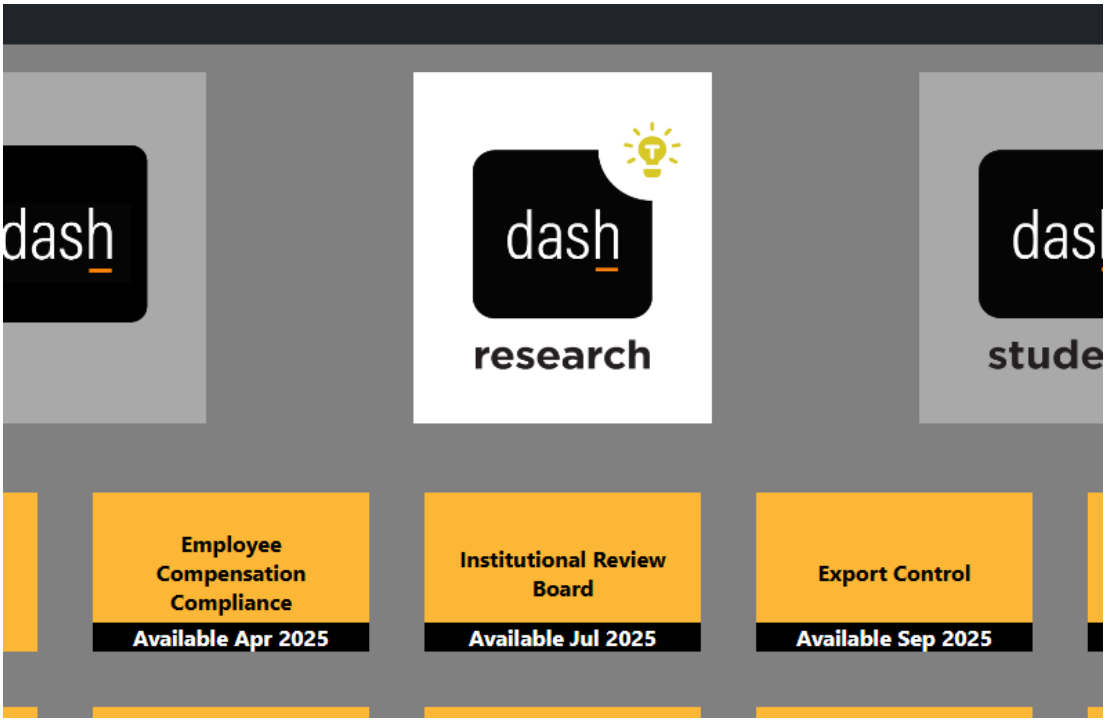
All Investigators – Before starting an online submission
CITI TRAINING: All research team members should take CITI training, or check their training certificate status. https://www.utc.edu/research/research-integrity/institutional-review-board/irb-training. If training isn't complete at the time of the application submission, it will need to be completed before IRB approval.
COMPLETE PROTOCOL DOCUMENT: Determine the level of review (Exempt or Expedited) and complete the Protocol Application Form. Always download a new form from the website before completing and submitting it in case changes are made to the form. https://www.utc.edu/research/research-integrity/institutional-review-board/irb-forms.
INFORMED CONSENT TEMPLATES: When creating your informed consent documents, please refer to and use our consent form templates on our website: https://www.utc.edu/research/research-integrity/institutional-review-board/informed-consent

STUDENT INVESTIGATORS: Students who are not already employees (student workers, GA's, etc.) must be added to the DASH system. Information about this process is still to come.

Login to DASH via the homepage

https://dash.tennessee.edu/home

Navigate to DASH Research, then to the Institutional Review Board tile.



All Investigators – Filling out the Smart Form

Create a new study

CREATE NEW STUDY: From the Dashboard: Click "Create," Select IRB, then "Create new study"; OR from the IRB tab, click "Create New Study." This process will open the smart form for submitting your application. *You must complete and save the "Basic Study Information" page before a new study will be created in the system. NOTE: all questions with a red asterisk are required for every study.

TITLE OF STUDY: Enter the full title of the study, making sure the title is the same as on any funding documents, if applicable.

SHORT TITLE: This can be the same as the full title (above) or shorter; it will be the title that identifies the study in DASH Research IRB for your reference. Keep it shorter than 50 characters.	
BRIEF DESCRIPTON: Include a few sentences describing your research questions and methods. You will include full details in your attached protocol document.	
WHAT KIND OF STUDY IS THIS? Select "Single-site study" for this question.	
IRB RELIANCE AGREEMENT (Q 5): For most UTC studies, Question 5 will be answered "No." If you are collaborating on a research project overseen by another Institution / IRB, select "Yes."	
LOCAL PRINCIPAL INVESTIGATOR (Student-led project): If a student is completing the smart form, they will need to indicate their faculty advisor as the Local Principal Investigator. Change the name here by clicking the box with 3 dots and selecting your faculty advisor's name on the following page. The person completing the Smart Form will be listed as the primary contact and will receive all notifications from DASH Research IRB, along with the PI.	**LOCAL PRINCIPAL INVESTIGATOR** (Faculty- or staff-led project): If you are the lead investigator, make sure your name is populated already for Q6. If you are completing the smart form for another faculty or staff lead investigator, you will need to change the name to their name by clicking the box with 3 dots and selecting the name of the lead investigator.
WHICH IRB SHOULD OVERSEE THE STUDY? Select "UTC IRB" for Q7.	
ATTACH THE PROTOCOL: Find the Protocol document from the UTC IRB website and download and complete it if you haven't already. Click the "+Add" button to upload the completed protocol. **Only attach the protocol at this step**. You will attach other documents (consent forms, survey documents, etc.) in a later step. ("Name" and "Version number" fields aren't required.)	
CONTINUE: When you click the "Continue" button, your study is assigned a study number, in the format "STUDY0000123" and you will be able to continue adding information pertinent to your study. Your study is saved at this point, and you can come back to it to make changes before it is submitted. It is NOT submitted to the IRB until a later step. Clicking "Exit" will take you out of the smart form and back to the main submission page, without saving information. "Save" will save items on the page.	

Study Funding Sources
IDENTIFY EACH ORGANIZATION SUPPLYING FUNDING FOR THE STUDY: If your project is associated with any grant funding, add your funding source here. Click the Add button to search for funding sources. If you cannot find your funding agency on the list, contact the IRB office for next steps. Otherwise, if your project does not have funding, simply click "Continue." You can add external or internal funding here. For Internal UTC funding, select the department the funding is coming from.

Local Study Team Members	
PI'S COLLEGE/DEPARTMENT: Double check that the listed college and department match the Lead Investigator's college and department.	
IDENTIFY STUDY PERSONNEL (Student-led project): If you are a student completing the smart form and have indicated your faculty advisor's name as the PI, **you will need to add yourself to the study team**. Here is also where you add other students and/or faculty involved in the research study. The principal investigator listed on the first page of the smart form will automatically be included on the study team.	**IDENTIFY STUDY PERSONNEL** (Faculty- or staff-led project): Add any UTC students or other faculty or staff involved in the project. The principal investigator listed on the first page of the smart form will automatically be included on the study team. If you are not the Principal Investigator but are a member of the study team, add yourself on this page.
NOTE: Local study team members can view and edit the submission while it is in the pre-submission state once they are added to the submission. However, **only the PI can submit the study application**.	
EXTERNAL TEAM MEMBER INFORMATION: To add an external team member (someone not affiliated with UTC), click the "Add" button and then in the "Title" field, enter the person's name. You will then need to upload a document for that person, such as a CV or a description of their role in the research. Add their CITI training certificate on this page, as well.	
CONTINUE to move to the next page.	

Study Scope
QUESTIONS 1 AND 2: These questions relate to FDA-regulated research. If you would answer either of these questions with "Yes," please contact the IRB office. Your application may need to go through the UTHSC-Memphis IRB as the UTC IRB is not equipped to review FDA-regulated research. We have a reliance agreement with UTHSC-Memphis to review any FDA-regulated research studies we have.
NUMBER OF PARTICIPANTS TO BE ACCRUED LOCALLY: Please provide the **maximum** number of participants you plan to enroll in your study.
CONTINUE to move to the next page.

Local Research Locations
ONLINE ONLY RESEARCH: If the study involves only online surveys/interviews, add a location and write "Online" in the location name. No further information is needed.
ON-CAMPUS RESEARCH: If in-person activities are happening on UTC's campus, select "University of Tennessee - Chattanooga" from the drop-down menu. You can use the search function to find locations. Use % as a wild card ("%Chatt" will find Chattanooga locations)
OFF-CAMPUS LOCATIONS: If in-person activities are happening at a location off campus, then you will add a location. If the location isn't listed, add its name, address, and contact information, if applicable.
MULTIPLE LOCATIONS: It is possible to add multiple locations if research is happening in multiple places.
CONTINUE to move to the next page.

Local Site Documents
CONSENT FORMS: Upload all necessary consent and assent forms. For more information and templates for consent forms, see the UTC IRB website.
RECRUITMENT MATERIALS: Upload all recruitment materials, including flyers and email scripts. Once the study is approved, finalized documents will have IRB approval information on them for distribution.
OTHER ATTACHMENTS: Include survey instruments, interview scripts, and any other relevant documentation such as site approval letters, Memoranda of Understanding (MOUs), or Data Use Agreements (DUAs).
CONTINUE to move to the next page.
Click "Finish" to save your progress and exit the form. This does not submit the form.

IMPORTANT! You must click "Submit" on the study workspace before your protocol application is submitted to the IRB.

Notice your study number and short title appear at the top of the study workspace. Under the study information, you'll see a flow chart that shows you where your application is in the submission process.

SUBMIT STUDY (student-led study): If you are the student who completed the study smart form, notify your faculty advisor that they need to login to DASH Research and submit the study for IRB review. They will do this by clicking the "Submit" link on the left side of the screen, under "Next Steps."	**SUBMIT STUDY** (faculty- or staff-led study): If you are the principal investigator, submit the study by clicking the "Submit" link on the left side of the screen, under "Next Steps." If you are not the PI, notify them that they need to login to DASH Research to complete the submission process.

The Study will move to the Pre-Review stage of the process. Monitor your email for requests for clarification or other updates to your Study protocol application. You should see a graphic illustration of the workflow showing your Study is in the Pre-Review stage, as shown below:

AFTER SUBMISSION

COI DISCLOSURE PROFILE: Everyone who is added to an IRB study will be asked to update their COI disclosure profile. You will receive an email with instructions about how to complete this task.

REQUEST FOR CLARIFICATION: You may receive a request for clarification from the IRB Administrator. You will receive an email notification which will link back to your study workspace. You can make revisions to the study and reply to the request for clarification within the system. See our guidance document for responding to requests for clarification.

APPROVAL: If no modifications are needed or after you've completed the requested modifications, the IRB office will finalize your documents and send you an approval letter. Any finalized documents (such as consent forms and survey questions) cannot be changed without prior approval from the IRB via a modification request.

IMPLEMENTING YOUR STUDY: All approved study documents, including the informed consent forms, surveys, recruitment materials, etc. are finalized and "stamped" with the IRB approval information in the upper right-hand corner. Only those finalized, stamped documents may be used in your study. They can be found under the Documents tab of the workspace for your study.