THE UNIVERSITY OF TENNESSEE CHATTANOOGA

Institutional Review Board

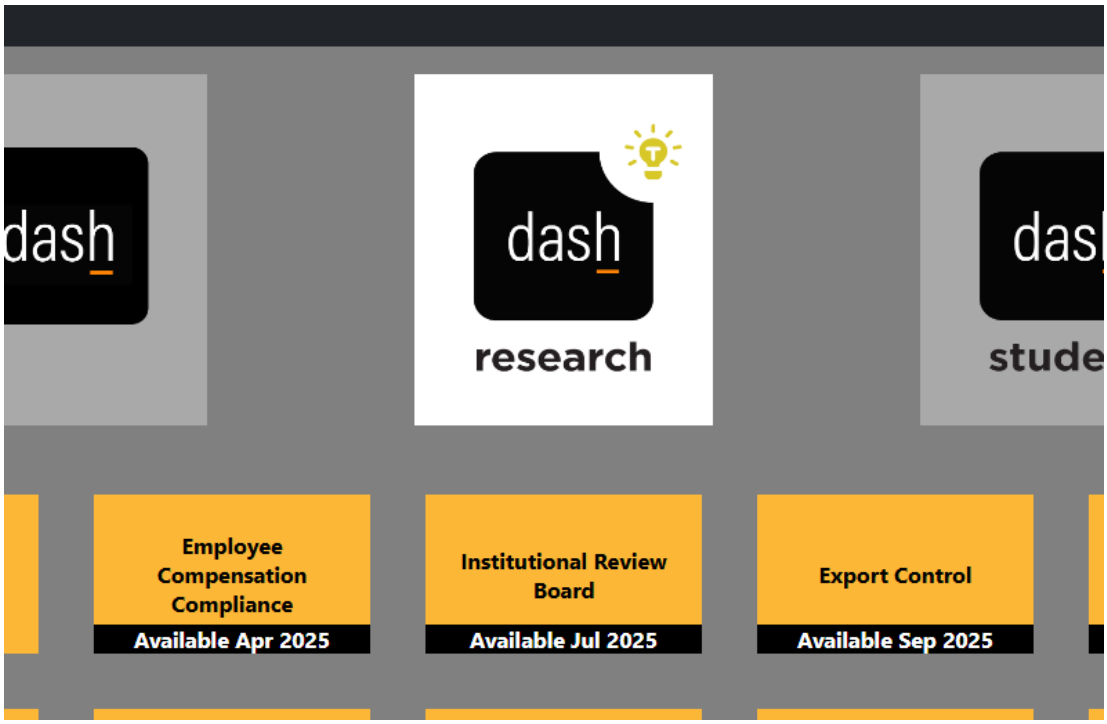
How to Submit a Continuing Review or Modification Request

This document will walk you through the steps of submitting a Continuing Review or Modification request 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.

Login to DASH via the homepage

https://dash.tennessee.edu/home

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



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Filling out the Smart Form	
OPEN EXISTING STUDY: From the IRB inbox > Submissions tab, locate the relevant study and click on it to open the study workspace.	
CREATE MODIFICATION/CR: Click the button on the left that says "Create Modification/CR"	
Choose the purpose of the submission	
CONTINUING REVIEW: If your project is coming up to the end date and a CR is required to continue your project, OR if your project has ended and you want to close it out, choose the CR option if you do not need to make any modifications / changes.	
MODIFICATION / UPDATE: If you need to request a modification to your study and your end date is not changing, select this option.	
MODIFICATION AND CONTINUING REVIEW: If you need to make changes to the study AND modify the end date, select this option.	
MODIFICATION SCOPE: If you are requesting a modification, you will need to select either a change to the study team members and / or to other parts of the study. If you only select one option, you will only be able to change contents in that area. *You can only have one modification request of each type active at a time.	
CONTINUE to begin the mod/CR request.	
CONTINUING REVIEW / STUDY CLOSURE INFORMATION: Complete the form indicating the stage of research your study is in. Enrollment totals should indicate the number of participants enrolled to date. The answers to Q's 1 – 3 may all match. Q4 indicates the number of participants you indicated as the target number in the initial study. Answer Q's 5 & 6. If the first 4 milestones in Q5 are complete, the study will be closed, and no further action is needed. Supporting documents should be attached if any boxes under Q6 are left unchecked.	**MODIFICATION INFORMATION:** Complete the form indicating the study enrollment status and other questions. If you are making substantial changes to the study that impact current subjects, you will need to notify them of this change. In some instances you may need to notify former subjects (Q4). Answer Q5 indicating what changes you are requesting. *It is important to list any changes you are requesting in Q5 so the reviewer knows what areas have been changed that need to be reviewed.
If you are only doing a CR: CONTINUE AND SUBMIT: When you have completed the smart form, click the "continue" button. On the Study Workspace, click "Submit" to submit the CR to the IRB.	**MODIFY STUDY DETAILS:** Modify the study smart form as needed, similarly to how you completed the original study. If you made changes to the methodology or other information found in the protocol, upload the revised protocol on the Study

	Information page (Click “update” next to the original protocol document to replace it).
	UPLOAD ANY REVISED DOCUMENTS: On the Local Site Documents page, upload any revised documents (consent forms or surveys, for instance).
	CONTINUE AND SUBMIT: When you have completed the smart form, click the “continue” button. On the Study Workspace, click “Submit” to submit the Modification request to the IRB.

IMPORTANT! You must click “Submit” on the study workspace before your MOD/CR is submitted to the IRB.

Notice your modification and/or continuing review has its own ID. It will begin with either “MOD,” “CR,” or “MODCR” followed by a series of numbers.

The MOD/CR 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

LOCATING YOUR MOD/CR: After the completion of your MOD/CR, you can see in the breadcrumb trail at the top of the study workspace that it is “housed” under the parent study. You can click on the title of the parent study to navigate back to that study, or go to your IRB inbox. You can navigate to your “Active” protocols, open the parent study, then click on the “Follow-on Submissions” tab to see your MOD/CR.

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 revise the study and reply to the request for clarification within the system. See our guidance document "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 CHANGES: 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.