THE UNIVERSITY OF TENNESSEE CHATTANOOGA

Institutional Review Board

How to Respond to a Request for Clarification

This document will walk you through the steps of responding to a request for clarification in DASH Research IRB. This is for any study that has already been submitted and the IRB office has reviewed it and requested revisions before committee review or approval. Please contact the Office of Research Integrity if you have any problems or questions about the process.

When to use these steps
After submission, you may receive an email from the DASH Research IRB system instructing you that action is needed on your part. You can follow the link from the email or use the steps below to login to DASH Research IRB.

Login to DASH via the homepage

https://dash.tennessee.edu/home

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

Navigate to the Study
From the Dashboard: Any Studies that you are the Lead Investigator on or listed as a study team member should appear in "My Inbox" if they need action from you. Look for the relevant study and click the title (in blue text) from the list.
Study Workspace: Once the study is opened, in the study workspace you can see the status of the study. It should be in a "Clarification Requested" or "Modifications Required" status on the flowchart below the Study basic information.
History Tab: Below the flowchart, there are several tabs you can review about your study. Any action items and steps in the review process are listed in the History tab. Look for the most recent activity or the activity that says, "Clarification Requested." There should be short directions and a PDF Action Form attached. Review the attached action form for the requested clarifications / revisions.
Edit Study: Some requested clarifications may affect the study smart form in DASH Research IRB. Click "Edit Study" on the lefthand side of the screen to make the modifications. Other modifications will need to be made to the study protocol or other study documents. You can download the latest version of your study documents directly from the study smart form or locate them on your computer to make the requested changes. NOTE: If at any time you wish to exit editing the smart form, clicking the "exit" button will not automatically save changes, but a dialogue box will appear asking whether you wish to save changes first, then exit. If you want to save the changes you've made and continue editing the form later, click "save" then "exit."
Updates to study documents: Upload the most recent study documents by clicking the "Update" button next to the previous version of the document. For instance, if you need to upload a new version of the protocol, under Q8 on the main study page where it says, "Attach the protocol," instead of clicking the "+Add" button, you will click the "Update" button. On the local Site Documents page, the process is the same. **Any new documents you add can be added with the "+Add" button, but any changes to previously uploaded documents will be made with the "Update" button.**
Submit Response: When you are done updating the study, click "finish" or to return to the Study workspace, then click "Submit Response" on the lefthand side of the screen to submit the changes for IRB review. If you are not the Lead Investigator, you will have to ask them to submit the response. **DON'T FORGET THIS STEP.** A dialogue box will appear asking you to add notes and attach any relevant documents. If you wish to send any information to the IRB coordinator or upload a document that explains your responses to the reviewers' action form, you can do that here. This is not the place to upload revised protocol and study documents (consent forms, surveys, etc.). If you revised any protocol documents, upload them in the appropriate place(s) in the Smart Form.

Flowchart status: Notice that the status of the study changes in the flowchart. It goes back to the IRB office for the next step of the review. If the clarification was requested during the pre-review stage, it will go back to the pre-review stage to be completed by the IRB Coordinator. If the clarification was requested during the IRB Review stage, it will go back to the IRB for further review.

IMPORTANT! You must click "Submit Response" on the study workspace before your revisions are submitted to the IRB.