



Institutional Biosafety Committee

How to Respond to a Clarification Request in DASH Research Safety

This document will walk you through the steps of responding to a request for clarification in DASH Research Safety. This pertains to any protocol/modification/continuing review that has been submitted and the IBC requests clarifications and/or revisions to the protocol (Specialist Review, Member Review and/or Committee Review states in the Safety module). Please contact the Office of Research Integrity at ibc@utc.edu if you have any problems or questions about the process.

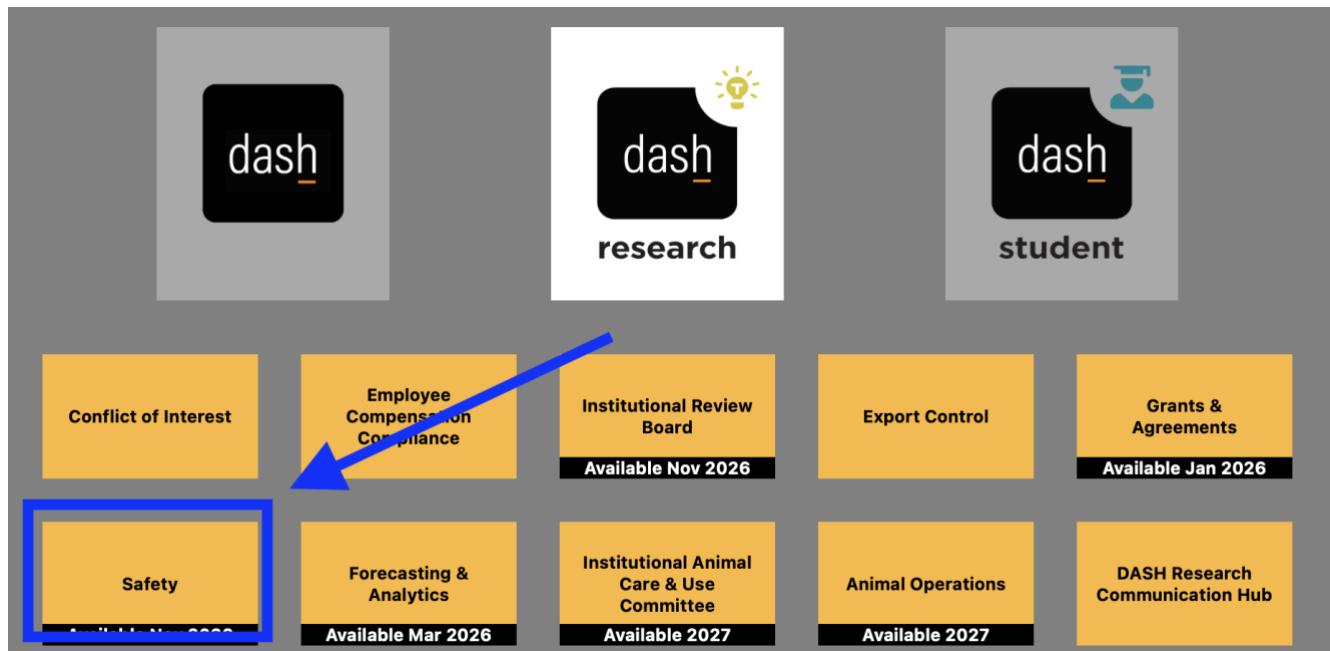
WHEN TO USE THESE STEPS

After submission, you may receive an email from the DASH Research Safety system indicating that a reviewer has questions or requires modifications to the protocol, and therefore, action is needed on your part. You can follow the link from the email or use the steps below to login to DASH Research Safety.

Login to DASH via the homepage

<https://dash.tennessee.edu/home>

Navigate to DASH Research, then to the Safety tile.



NAVIGATE TO THE PROTOCOL

FROM THE SYSTEM-GENERATED EMAIL NOTIFICATION: From the email notification that you received, click on the link to the protocol. This should take you to the protocol workspace within DASH Research Safety.

FROM THE DASHBOARD: Any protocol in which you are listed as the Principal Investigator (PI) or listed as a protocol team member should appear in “My Inbox” if action is required. Look for the relevant study and click the title (in blue text) from the list.

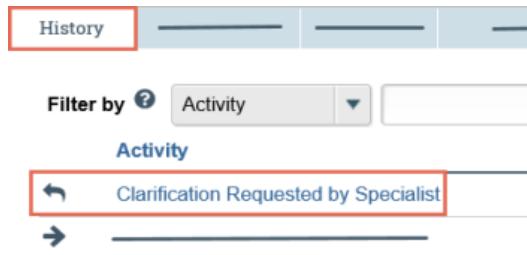
FROM THE SAFETY MODULE: Within the DASH Research Safety module, look for the relevant study within the “In-Review” tab. In both this tab and protocol workspace you will see the status of the protocol. It should be in a “Clarification Requested” or “Modifications Required” status on the flowchart.

VIEWING THE REVIEWER NOTES

Reviewer notes are field/page-level comments that are entered directly onto the SmartForm by the reviewer. Outlined below are the various ways to view reviewer notes within the protocol workspace and within the protocol itself.

VIEWING THE REVIEWER NOTES

1. HISTORY TAB: Below the flowchart, there are several tabs showing information about your protocol. Any activities that have occurred are listed in the “History” tab. Within this tab, click on the most recent “Clarification Requested by....” activity and read the comments.



This area also indicates if there are reviewer notes that need to be addressed and on which page of the protocol they can be found.

2. REVIEWER NOTES TAB: If there are reviewer notes within the protocol SmartForms, click the “Reviewer Notes” tab. For each reviewer note, the associated question and reviewer comments will be shown. If reviewer notes have been resolved, this will also be indicated.

Clicking on the associated “Question:” for each reviewer note will take you directly to the question in the protocol for you to make any needed revisions.



NOTE: “Response Required” means the protocol cannot move forward in the workflow until you respond to the Reviewer Note.

VIEWING THE REVIEWER NOTES

3. WITHIN THE PROTOCOL SMARTFORMS: Reviewer notes can also be found within the protocol itself. Click “Edit Protocol” on the lefthand side of the protocol workspace.

Once the protocol is open, on the lefthand side where the different SmartForm pages are listed, reviewer notes will be indicated by a ‘comment bubble’ (Note icon). This will show the number of reviewer notes on that page. A red ‘dot’ above the icon indicates that a “Response Required” action is necessary.

Within the page, a Note icon will be at the end of the question. It will show the number of reviewer notes for that question and if a response is required (red dot above icon).

Click the Note icon to view the reviewer note.

Basic Information & Funding

Basic Information 2

Protocol Team Members

Funding Sources

Biosafety Summary

Biosafety Summary

Agents, Toxins, & Microorganisms

Bacteria, Yeasts, Fungi, or Parasites

Viruses or Prions

Biohazards

Risk Management

Risk Group and Containment Practices 1

1. * Select admin office:
UTC - Biosafety
2. * Title of protocol: 1
3. * Short title: 1
4. * Provide a succinct description of the proposed experiments that could be used. This description must answer all of the following questions:
 1. What are the goals of the research?
 2. Why are these goals important?
 3. What are the proposed experiments?
 4. How will the proposed experiments help achieve these goals? 1

Description Here

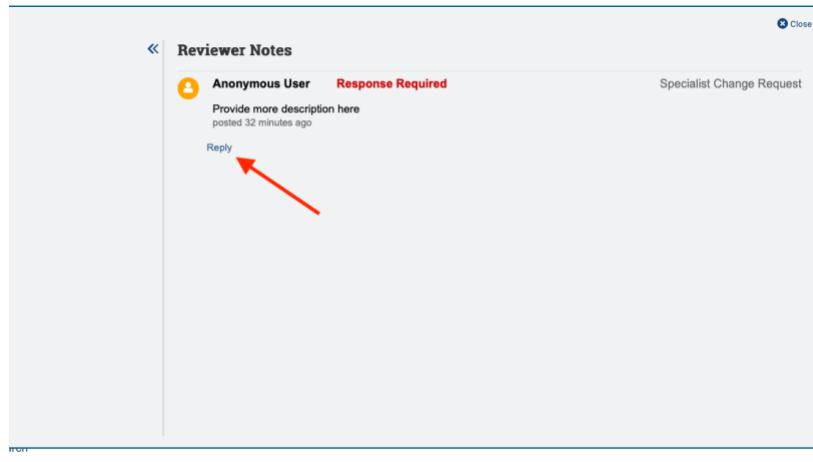
PROTOCOL REVISIONS, RESPOND TO REVIEWER NOTES & CLARIFICATION REQUEST

STEP 1: Edit Protocol: If revisions need to be made within the protocol, navigate to the question with the reviewer notes (via Reviewer Notes tab or within the protocol). Make the required edits to that question.

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”.

STEP 2: Respond to Reviewer Note:

- a) Click the Note icon to view the Reviewer Note.
- b) Click “Reply” and then type your response.
- c) Attach files if needed and click “OK”.
- d) Close the reviewer note.



- e) Respond to all other reviewer notes as needed.

PROTOCOL REVISIONS, RESPOND TO REVIEWER NOTES & CLARIFICATION REQUEST

STEP 3: Submit Response: When you are done updating the protocol and responding to reviewer notes, click “**Finish**” or return to the protocol workspace. Click “**Submit Response**” on the lefthand side of the screen to submit the changes for IBC review. **DON'T FORGET THIS STEP.**

Next Steps



A dialogue box will appear asking you to add notes and attach any relevant documents. Type a response to the reviewer here. Click “**OK**”.

STEP 4: Flowchart status: Notice that the status of the protocol changes in the flowchart. It goes back to the IBC office for the next step of the review.

IMPORTANT! You must click “Submit Response” on the protocol workspace before your revisions are submitted to the IBC.

VIEW THE CHANGE LOG

If changes are made within the protocol submission, you can view the changes within the **“Change Log”** tab. The Change Log shows changes only after the submission has entered the Safety Specialist state. For approved protocols, the Change Log shows only the changes made on the initial submission. Changes from amendments are logged in the Change Log for the amendment.