THE UNIVERSITY OF TENNESSEE
CHATTANOOGA

dash
research

Institutional Biosafety Committee

How to Submit an Amendment, Continuing Review or De Novo Protocol

This document will walk you through the steps to make changes to an approved protocol (i.e. Amendment), submit a Continuing Review or submit a De Novo protocol on DASH Research Safety. Please contact the Office of Research Integrity at ibc@utc.edu if you have any problems or questions about the process.

<table>
<tr><th colspan="1">WHEN TO USE THESE STEPS</th></tr>
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AMENDMENT: To make any changes to an approved protocol, you need to submit an Amendment. You can submit multiple amendments for review at any given time, including protocol team member changes, providing there is no existing open amendment of the same type.

CONTINUING REVIEW (CR): Principal Investigators are required to complete an annual CR (formerly called 'annual update') within DASH Research Safety. The deadline to submit a CR to the IBC is the anniversary of the protocol approval date. A CR is created to request an extension of the approval period for your protocol.

AMENDMENT/CR: If, at the time of submitting a CR, you need to make changes to your approved protocol, submit an 'Amendment/CR' submission.

DE NOVO SUBMISSION: Your approved protocol is nearing the end of its three-year approval period, and you want to continue the activities. A de novo submission creates a copy of the parent protocol and results in a NEW three-year approval period after IBC approval. Once the de novo submission is approved, the parent protocol is closed, and the de novo submission becomes an active protocol.

NOTE: Failure to submit a CR or a De Novo submission by the deadline specified in the protocol workspace will result in the protocol lapsing or completed, respectively. No activities may take place under a lapsed or completed IBC protocol.
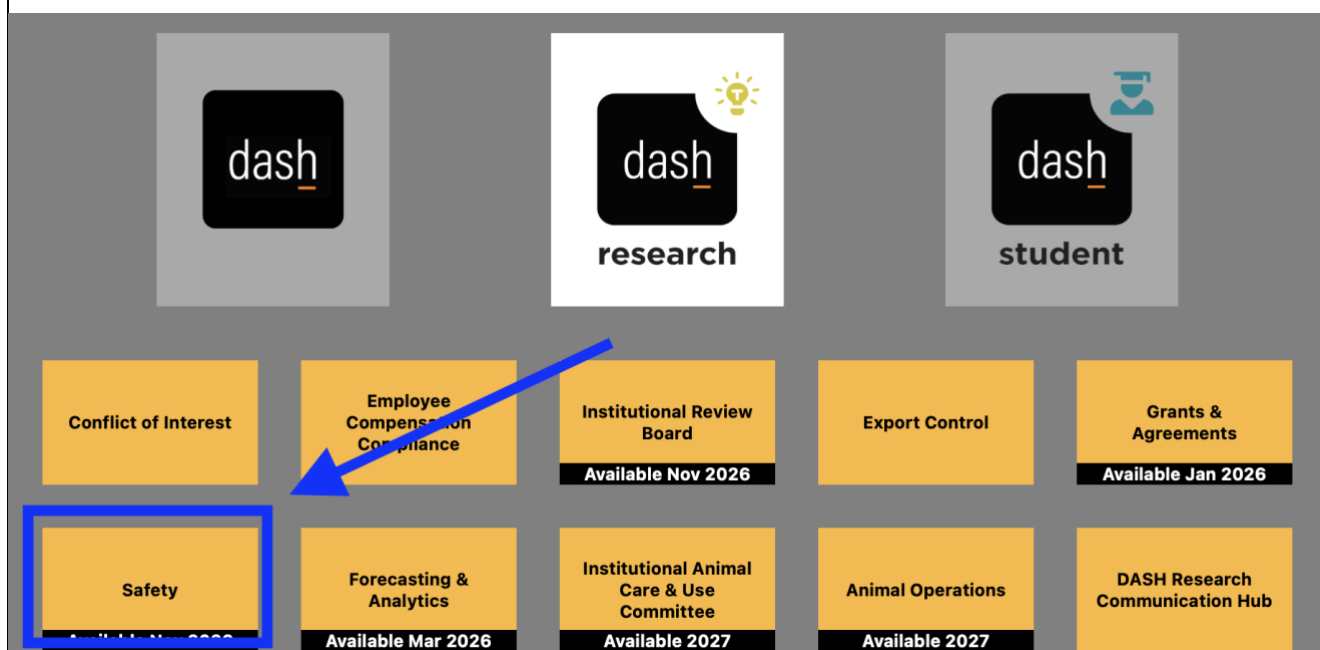
NOTE: If you want to close your protocol, navigate to the protocol workspace. Click on the "**Request Closure**" activity on the left-hand side of the workspace.

NAVIGATE TO THE PROTOCOL

1. Login to DASH via the homepage

https://dash.tennessee.edu/home

Navigate to DASH Research, then to the Safety tile.

2. FROM THE DASHBOARD: Click the '**Safety**' tab along the top of the page.

3. OPEN EXISTING PROTOCOL: From the Safety Submission area, click the '**Active**' tab. Locate the relevant protocol and click on it to open the protocol workspace.

CREATE AMENDMENT, CR or AMENDMENT/CR SUBMISSION (FOLLOW-ON SUBMISSIONS)

CREATE AMENDMENT/CR: On the left-hand side of the workspace, click the "**Create Amendment/CR**" button.

Q1: TYPE OF SUBMISSION: **Choose the purpose of the Submission**. Select whether the submission is an Amendment, CR or a combination of both.

NOTE: If you select "Continuing Review" and realize you need to make changes to the protocol, you will need to convert the submission type to "Amendment/CR". See below for instructions on how to convert the submission type.

Q2. AMENDMENT TYPE: **If your submission is an Amendment or Amendment/CR, select the appropriate amendment type.**

Protocol Team Member Information: Select this amendment type to add or remove members from the protocol team. **NOTE:** To change the PI, select "Other Parts of the Protocol".

Other Parts of the Protocol: Select this amendment type if you want to change any other part of the approved protocol.

NOTE: You can submit one or both amendment types for review at any given time, providing there is not already an open amendment of the same type. The list below your amendment type selection shows the active amendments and their amendment types.

CREATE AMENDMENT, CR or AMENDMENT/CR SUBMISSION (FOLLOW-ON SUBMISSIONS)

Click "CONTINUE" to move to the next page(s) for completion. The number of pages to complete will depend upon the submission and amendment types that were selected.

CONTINUING REVIEW: Complete the three SmartForm pages associated with the CR. Depending on your answers, additional questions may appear for you to complete.

AMENDMENT INTRODUCTION: Complete this page describing the proposed changes to the protocol and if the changes will alter the biosafety level of the protocol.

AMENDMENT DETAILS: This page will take you directly to the page(s) in the approved protocol that you will change. For instance, if you selected "*Protocol Team Member Information*", you will be taken only to the "*Protocol Team Members*" page in your approved protocol.

If you selected "*Other Parts of the Protocol*", the entire approved protocol will become available and you will be able to navigate to the page/question(s) that you want to change.

When you are done making changes, click "**Exit** "(making sure to "**Save**" before doing so) or **"Finish"** on the final page. The submission workspace appears. **This does NOT submit the form.**

Notice your Amendment and/or CR has its own ID. It will begin with "SAMEND", "SAMENDCR" or "CR" followed by a series of numbers.

NOTE: You can continue to edit the submission until you submit it for review.

IMPORTANT! You must click "Submit" on the Amendment/CR workspace to send the follow-on submission to the IBC.

Once submitted, the Amendment/CR will move to the Specialist Review stage of the process. Monitor your email and the DASH Research Safety protocol workspace for requests for clarification or other updates to your IBC Amendment/CR submission. You should see a graphic illustration of the workflow showing your protocol is in the Specialist Review stage, as shown below:
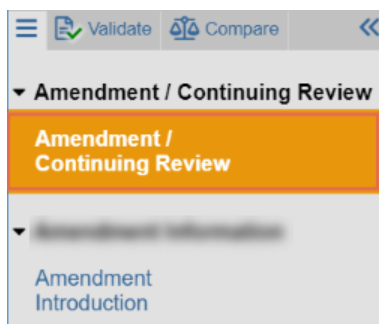
CONVERT AN AMENDMENT OR CR

A PI or protocol team member can convert a follow-on submission to another submission type before it is approved. Once the follow-on submission is submitted, you are only able to convert the submission when it is in an editable state, such as "Clarification Requested".

You can convert a follow-on submission to any other type provided there are no open submissions of the same type. For example, an Amendment can only be converted to an Amendment/CR if there are no open CRs for the protocol.

STEP 1: Open Existing Follow-On Submission: From the Dashboard "My Inbox", open the follow-on submission.

STEP 2: On the left side of the workspace, click the "**Edit...**" button.

STEP 3: Click the Amendment/Continuing Review page on the left-hand side.

STEP 4: Change the submission type and click "**Save**". The SmartForm will change according to your submission type.
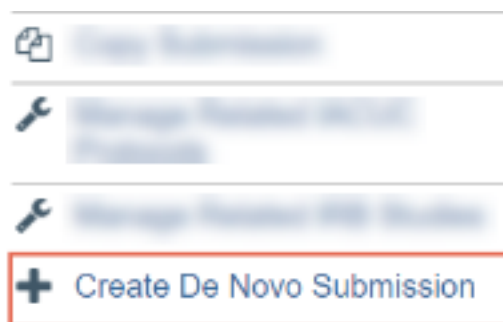
CREATE A DE NOVO SUBMISSION

A De Novo submission creates a copy of the existing protocol. Once created, you will need to go into the SmartForms to make any necessary changes to the protocol before submitting to the IBC.

A new submission ID, approval date and expiration date is created with a De Novo submission.

NOTE: A CR cannot be submitted in parallel with a De Novo submission.

NOTE: Amendments can still be submitted to the parent (original) protocol, **HOWEVER**, the De Novo submission will not include those changes.

STEP 1: On the left side of the approved protocol workspace, click "**Create De Novo Submission**".

STEP 2: Read the statement and select "**Yes**" to indicate you are ready to create this De Novo submission.

STEP 3: Click "**OK**".

STEP 4: On the "**History**" tab, click the De Novo submission ID you just created to navigate to the submission workspace. Make any necessary changes to the protocol. When ready, remember to "**Submit**" the protocol to submit it to the IBC office for review.

AFTER SUBMISSION

LOCATING YOUR AMENDMENT/CR:
After creating your Amendment/CR, you can see in the breadcrumb trail at the top of the protocol workspace that it is "housed" under the parent study. You can click on the title of the parent protocol to navigate back to that protocol.

Within the Safety module, go to the "**Submission**" tab. From there, navigate to your "Active" protocol. Open the parent protocol, then click on the "**Follow-on Submissions**" tab to see your Amendment/CR.

REQUEST FOR CLARIFICATION: You may receive a request for clarification from the IBC Administrator via a system-generated email notification which will link back to your protocol workspace. Revise the amendment/CR/protocol and reply to the request for clarification within the system. Please refer to the guidance document for responding to requests for clarification on the IBC website.

APPROVAL: At the time of approval, the IBC office will send you an approval letter via a system-generated email notification. *Activities associated with this approved Amendment/CR or De Novo submission may now begin*. Changes to a protocol after approval can only be made via an Amendment/CR submitted in DASH Research Safety.