

IRB: HOW TO CREATE AN AMENDMENT (MODIFICATION) TO AN IRB PROTOCOL

If you need to create a modification to an existing approved Expedited or Full Board IRB protocol, this is done via the amendment feature in Streamlyne. Follow the steps below to create and submit an amendment to your protocol. Remember, the amendment must be approved before you begin work using the requested changes.

NOTE: If making significant changes to a protocol approved as Exempt, a brand new protocol must be submitted.

How to Create and Submit an Amendment to an existing Expedited or Full Board IRB protocol

1) Login to Streamlyne.

UADA: streamlyne.uada.edu **UAF:** streamlyneinfo.uark.edu **UALR:** ualr.edu/streamlyne

1) Locate the protocol you need to amend. You can search under: **Main Menu > IRB >** and click **All My Protocols** or search using the IRB Protocol lookup feature.

2) Once you've located the protocol, click the **edit** link to open it in edit mode.

3) Navigate to the **Protocol Actions** tab > **Request an Action** section. There will be a list of Available Actions.

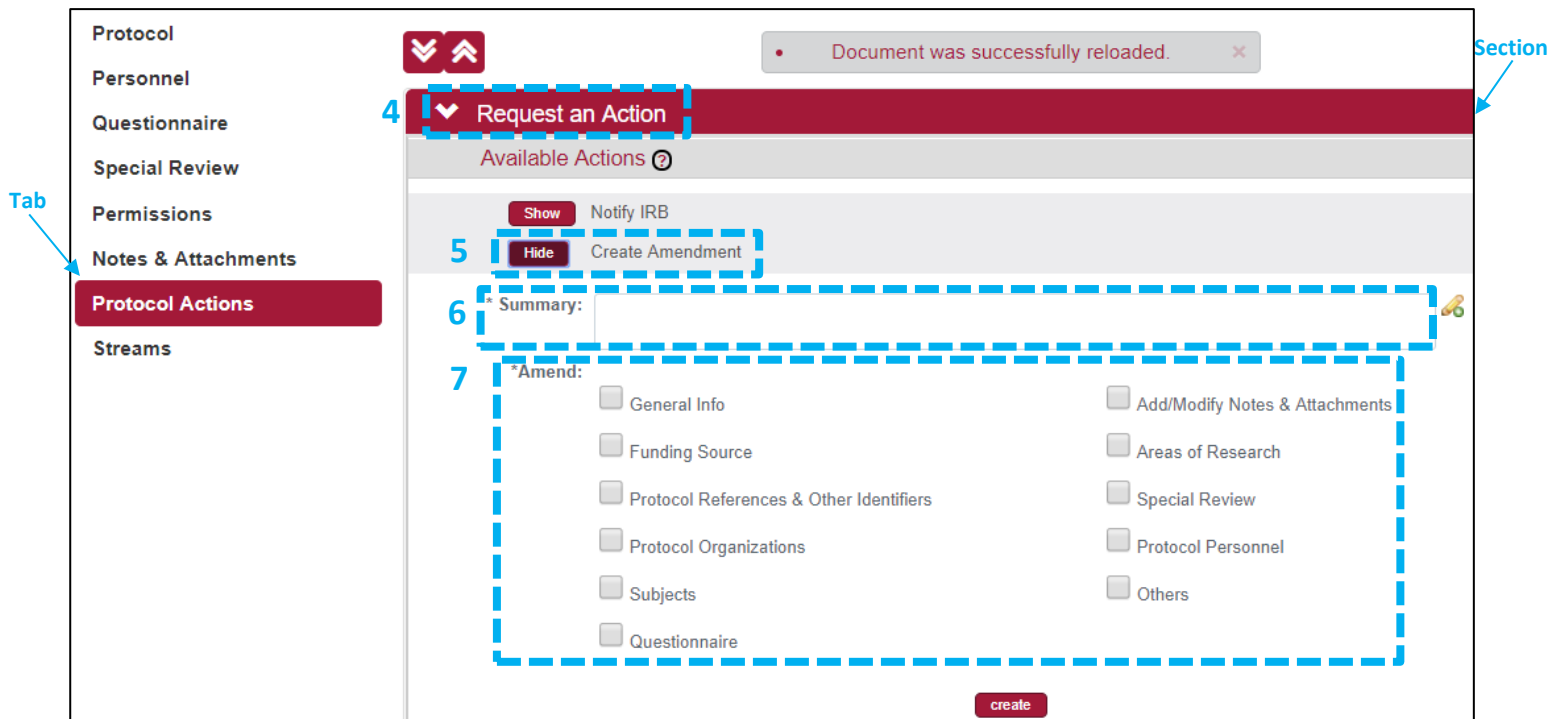
4) Click the **Show** button next to **Create Amendment**. If your protocol is up for renewal and you need to amend it, click the Show button next to Create Renewal with Amendment.

NOTE: You should only renew and amend if your protocol is up for annual review.

5) Enter a summary of the amendments you are making to the protocol in the **Summary** box.

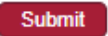
6) In the **Amend** section, check the box next to each section of the protocol that you need to amend. You can check multiple boxes if needed.

7) Next click the **create** button to create your amendment. Now the protocol and the sections you selected under Amend are open for editing.



The screenshot shows the Streamlyne web interface. On the left is a navigation sidebar with a 'Tab' label pointing to the 'Protocol Actions' tab. The main content area is titled 'Request an Action' (step 4) and contains an 'Available Actions' section. A 'Show' button next to 'Create Amendment' is highlighted with a dashed blue box and labeled '5'. Below this is a 'Summary' text box (step 6) and an 'Amend' section with a grid of checkboxes for protocol components: General Info, Funding Source, Protocol References & Other Identifiers, Protocol Organizations, Subjects, Questionnaire, Add/Modify Notes & Attachments, Areas of Research, Special Review, Protocol Personnel, and Others. A dashed blue box around this grid is labeled '7'. A 'create' button is at the bottom right. A notification at the top says 'Document was successfully reloaded.' A 'Section' label points to the 'Request an Action' header.

8) Once you have entered all your amendments you need to submit this amended protocol. Go to the **Protocol Actions** tab > **Request an Action** > and click the **Show** button **Show** next to **Submit for Review**.

- 9) Choose the **Submission Type** from the drop-down menu (there is only one option) and select the **Submission Review Type**. Select the same protocol/review type you originally selected. If the review type you selected has a Checklist, check the appropriate box(es). Then click the **Submit** button. 

NOTE: When you submit the amendment, it will re-route to anyone listed as a PI, COI or Supervisor and each person will have to approve before the protocol routes to the IRB Coordinator.