

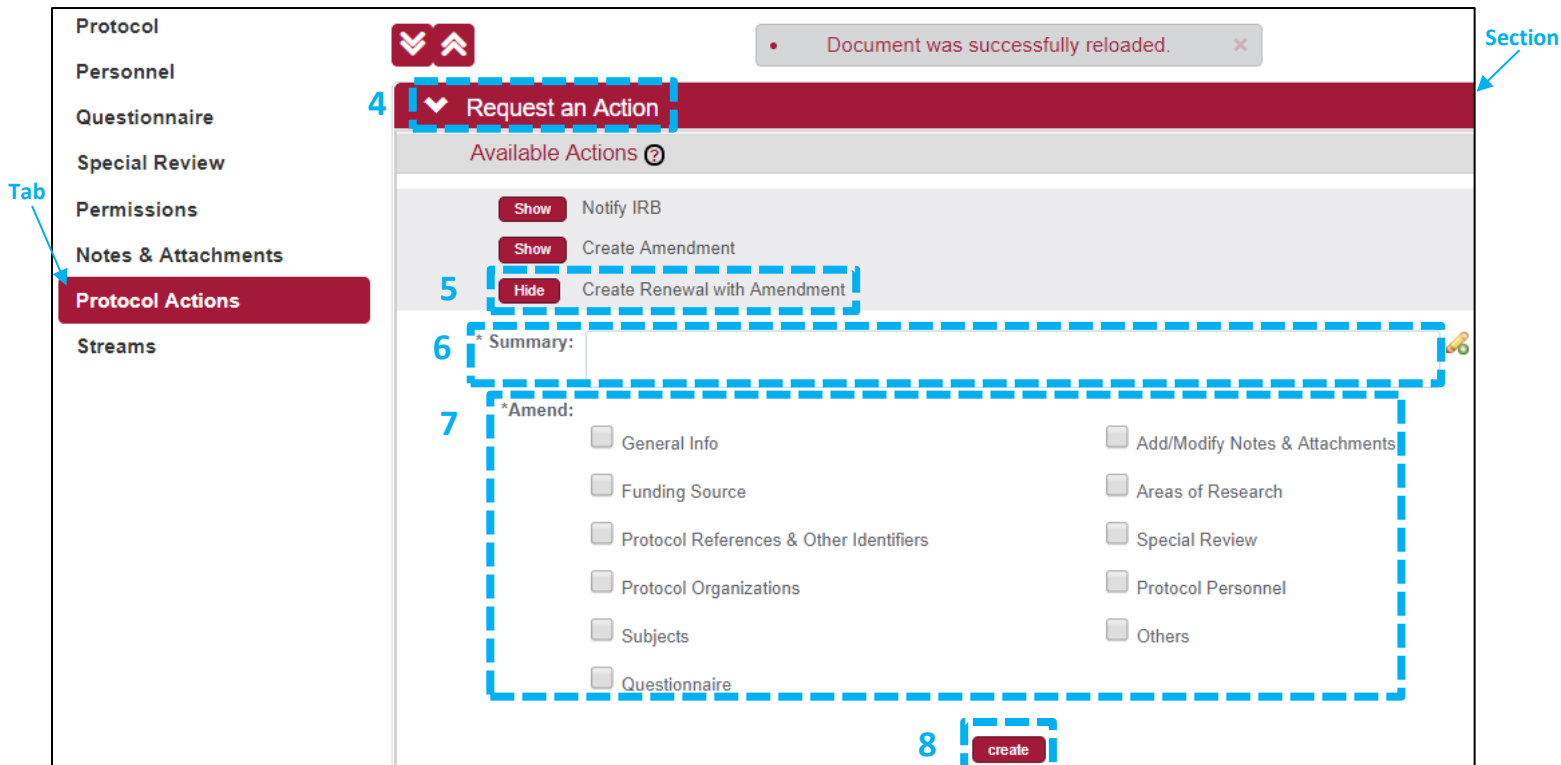
IRB: HOW TO CREATE AN IRB RENEWAL WITH AMENDMENT OR WITHOUT AMENDMENT

If you need to renew an existing approved Expedited or Full Board IRB protocol, this is done via the Create Renewal with/without Amendment feature in Streamlyne. Follow the steps below to create and submit a renewal. If your protocol expires and you have not renewed it, you need to stop work until it is renewed.

NOTE: IRB protocols approved as Exempt have no expiration date. If you significantly change the scope of the project then a brand new protocol must be submitted.

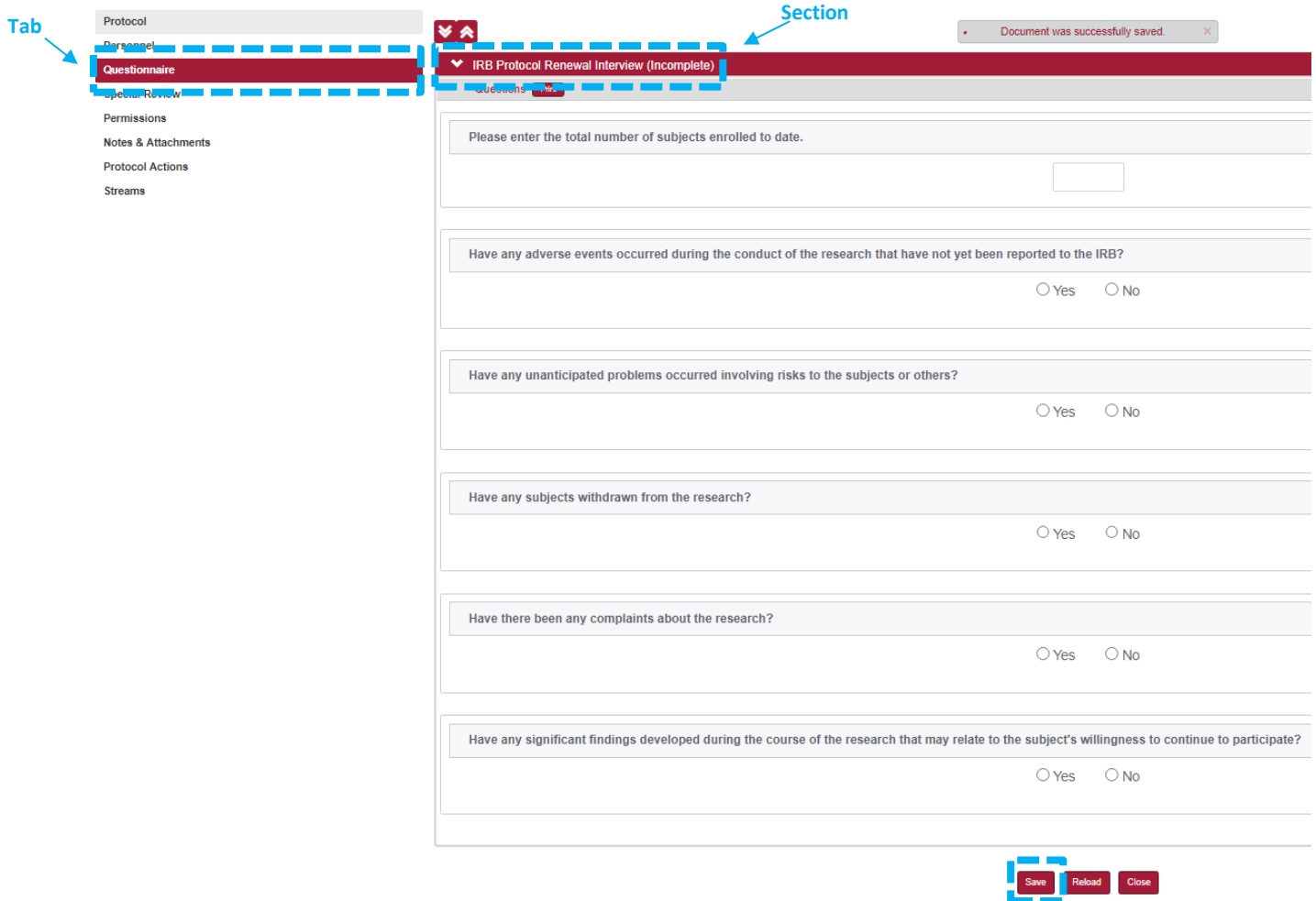
How to Renew AND Amend (modify) an Existing Expedited or Full Board IRB Protocol

- 1) Login to Streamlyne.
UADA: streamlyne.uada.edu **UAF:** streamlyneinfo.uark.edu **UALR:** ualr.edu/streamlyne
- 2) Locate the protocol you need to renew. You can search under: **Main Menu > IRB >** and click **All My Protocols** or search using the IRB Protocol lookup feature.
- 3) Once you've located the protocol, click the **edit** link to open it in edit mode.
 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 Renewal with Amendment**. If you only need to renew with no changes go to page 3 for instructions.
- 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 renewal with amendment. Now the protocol and the sections you selected under Amend are open for editing.



The screenshot displays the Streamlyne web interface for editing a protocol. On the left is a sidebar with a 'Tab' label pointing to the 'Protocol Actions' tab. The main content area has a 'Section' label pointing to the 'Request an Action' header. Below this header is a list of 'Available Actions': 'Notify IRB', 'Create Amendment', and 'Create Renewal with Amendment'. The 'Create Renewal with Amendment' action is highlighted with a blue dashed box and callout 5. Below the actions is a 'Summary' text area with a callout 6. Underneath is an 'Amend' section with a list 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. Callout 7 points to this list. At the bottom right is a 'create' button with callout 8. A notification at the top says 'Document was successfully reloaded.'

8) Navigate to the **Questionnaire Tab > IRB Protocol Renewal Interview (incomplete)** section. You will need to fill out (and **save** at the bottom of the page) the questions prior to submission of the renewal.



The screenshot shows a web interface for an IRB protocol renewal. On the left, a sidebar menu is labeled 'Tab' and includes options like 'Protocol', 'Personnel', 'Questionnaire', 'Supervisor Review', 'Permissions', 'Notes & Attachments', 'Protocol Actions', and 'Streams'. The 'Questionnaire' option is highlighted. The main content area is labeled 'Section' and shows the 'IRB Protocol Renewal Interview (Incomplete)' section. It contains several questions with radio button options for 'Yes' and 'No':

- Please enter the total number of subjects enrolled to date.
- Have any adverse events occurred during the conduct of the research that have not yet been reported to the IRB?
- Have any unanticipated problems occurred involving risks to the subjects or others?
- Have any subjects withdrawn from the research?
- Have there been any complaints about the research?
- Have any significant findings developed during the course of the research that may relate to the subject's willingness to continue to participate?

At the bottom right of the form, there are three buttons: 'Save', 'Reload', and 'Close'. A notification at the top right of the page states 'Document was successfully saved.'

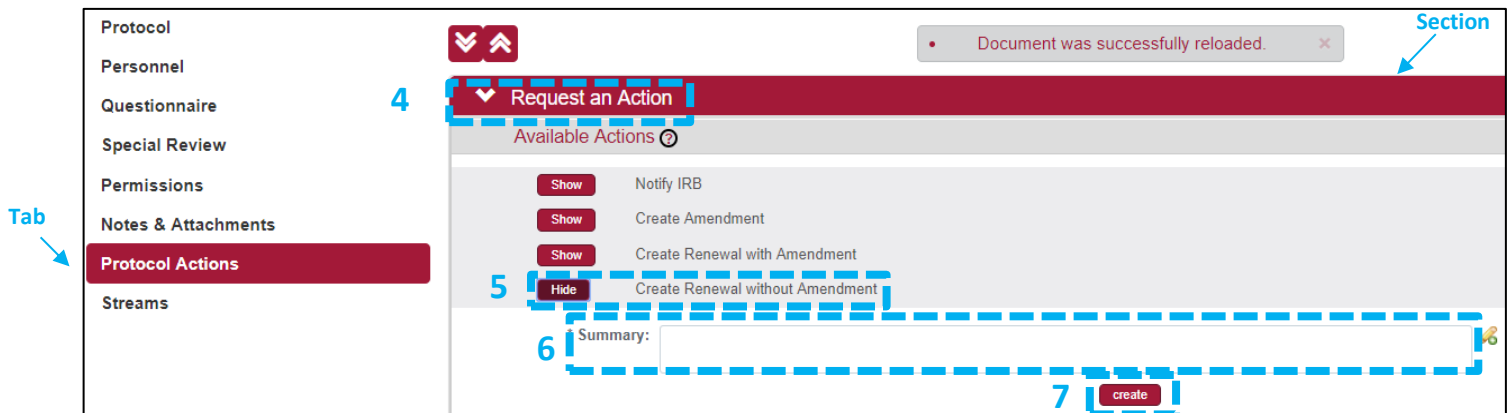
9) Once you have entered all your amendments you need to submit this amended protocol. Go to the **Protocol Actions** tab > **Request an Action** > and click the **Show** button **Show** next to **Submit for Review**.

10) Choose the **Submission Type-Continuing Review/Continuation with Amendment** from the drop-down menu. 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.

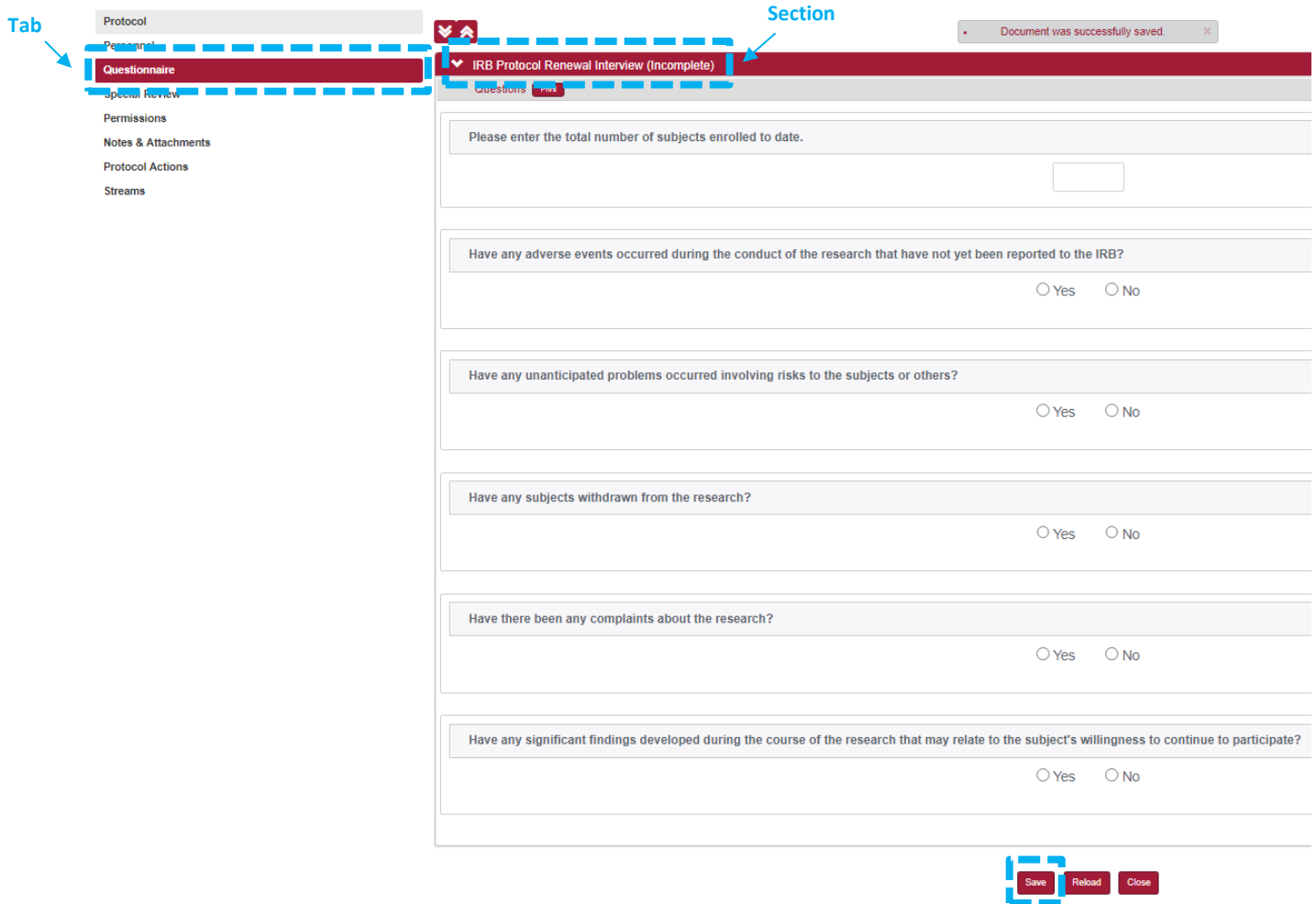
NOTE: When you submit any renewal, it will re-route to anyone listed as a PI, COI or Supervisor and each person will have to approve before the protocol routes to the IRB Coordinator.

How to Renew an Existing Expedited or Full Board IRB Protocol with No Amendments

1. Login to Streamlyne.
UADA: streamlyne.uada.edu **UAF:** streamlyneinfo.uark.edu **UALR:** ualr.edu/streamlyne
2. Locate the protocol you need to renew. You can search under: **Main Menu > IRB >** and click **All My Protocols** or search using the IRB Protocol lookup feature.
3. Once you've located the protocol, click the **edit** link to open it in edit mode.
4. Navigate to the **Protocol Actions** tab > **Request an Action** section. There will be a list of Available Actions.
5. Click the **Show** button next to **Create Renewal without Amendment**. If you need to make changes to the protocol as well as renewing it, go back to page 1 for instructions.
6. Enter a summary for the renewal you are submitting in the **Summary** box.
7. Next click the **create** button to create your renewal without an amendment



8. Navigate to the **Questionnaire Tab > IRB Protocol Renewal Interview (incomplete)** section. You will need to fill out (and **save** at the bottom of the page) the questions prior to submission of the renewal.



The screenshot displays the 'IRB Protocol Renewal Interview (Incomplete)' section. The left sidebar contains a 'Questionnaire' tab, which is highlighted with a blue dashed box and labeled 'Tab'. The main content area, labeled 'Section', contains the following questions:

- Please enter the total number of subjects enrolled to date. (Input field)
- Have any adverse events occurred during the conduct of the research that have not yet been reported to the IRB? (Radio buttons: Yes, No)
- Have any unanticipated problems occurred involving risks to the subjects or others? (Radio buttons: Yes, No)
- Have any subjects withdrawn from the research? (Radio buttons: Yes, No)
- Have there been any complaints about the research? (Radio buttons: Yes, No)
- Have any significant findings developed during the course of the research that may relate to the subject's willingness to continue to participate? (Radio buttons: Yes, No)

At the bottom right of the form, there are three buttons: 'Save', 'Reload', and 'Close'. A notification at the top right of the page states 'Document was successfully saved.' with a close button.

- Go to the **Protocol Actions** tab > **Request an Action** > and click the **Show** button **Show** next to **Submit for Review**.
- Choose the **Submission Type-Continuing Review/Continuation without Amendment** from the drop-down menu. 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.