Creating & Submitting an Amendment

The PI or the protocol creator can amend a protocol any time after initial approval. The review process for amendments is like the review process for initial submissions. This section will only cover the differentiators specific to creating and submitting an amendment.

The recommended way to initiate an amendment is from within the existing, active protocol: IRB Actions > Amend or Renew IRB Protocol. Clicking this menu option will display all protocols available to the user that currently qualify for an amendment or renewal.

Navigation	Main Menu > IRB > IRB Actions > Amend or Renew IRB Protocol

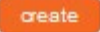| Actions	Protocol #	Protocol Type	Investigator	Title	Protocol Status	Approval Date	Expiration Date	Last Approval Date	Initial Submission Date	Lead Unit
perform action	1412000227	Expedited	Biochemistry Professor	Expedited Test	Expired	12/19/2014	12/18/2015		12/19/2014	105010
perform action	1502000810	Full Board	Biochemistry Professor	Boston College IRB Demo 3	Active - Open to Enrollment	05/01/2015	04/30/2016		02/03/2015	105010
perform action	1506002204	Expedited	Biochemistry Professor	America's Genetic Mutations: A Meta Data Analysis from 1980-2010	Active - Open to Enrollment	07/10/2015	07/09/2016		06/17/2015	105010

1. Locate the protocol that you would like to amend.

2. Click the corresponding perform action hyperlink.

Result Streamlyne will open the protocol to Protocol Actions > Request an Action panel. The Available Actions will display multiple options for you.
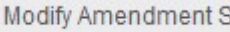
3. Click the Show button next to Create Amendment.

4. Describe the purpose and content of the amendment in the **Summary** field. If necessary, click on the edit button 🖉 to access a text editor with character count.

5. In the **Amend** section, check all boxes for sections you wish to amend. Protocol sections with checked boxes will be opened for editing. Those not selected will remain read-only.

6. Click the Create button.

Result Streamlyne will open a new Amendment document. You will be able to make edits in the areas you selected in Step 5.

7. If you would like to edit further sections in addition to those previously selected, navigate back to Protocol Actions > Request an Action > Available Actions.

8. Click the Show button next to Modify Amendment Sections.

9. Select the applicable sections and click the Update button.

10. Make all applicable changes to the information displayed on the protocol document as needed.
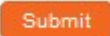
Note Your institution may have chosen to configure an Amendment Questionnaire – or a series of interview questions displayed only for amendments. If so, you MUST complete this questionnaire before submitting the document.

11. When ready to submit, navigate back to Protocol Actions > Request an Action> Submit for Review.

12. Click the Show button next to Submit for Review.

13. Complete the required fields of **Submission Type** (e.g., Amendment) and **Submission Review Type** (e.g., Full Board).

Notes For Exempt and Expedited protocols, a Checklist will display. Select all categories that apply to your amendment.

14. Click the Submit button to submit your amended protocol for the required workflow approvals.

Result   The delivered Data Validation routine will display any errors or warnings that pertain to this document. Be sure to complete the Questionnaire. If necessary, fix the errors and click the Submit button again to revalidate and submit.

Otherwise, the system will change the Document Status to Submitted to IRB.

Document Number : 32282	Document Status : Submitted to IRB	Copied from Document Header Id : 7490
Initiator:Last Updated : bioprofessor : 10:33 AM 07/18/2018	Submission Status : Pending	
Protocol # : 1501000500A001	Expiration Date : 03/17/2016	

See Understanding Streamlyne Amendments & Renewals for what Amendment details will be made available in the Summary & History section.