



## Streamlyne IRB Tip Sheet

### *Creating and submitting an amendment*

1. 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 tip sheet will only cover the differentiators specific to creating and submitting an amendment.
2. The recommended way to initiate an amendment is from within the existing, active protocol: Protocol Actions > Request an Action > Create Amendment.

Form fields and options:

- Buttons: Show, Create Amendment
- Form Header: Hide, Create Amendment
- \* Summary: [Text Input Box]
- \*Amend:  General Info,  Add/Modify Notes & Attachments,  Funding Source,  Areas of Research,  Protocol References & Other Identifiers,  Special Review,  Protocol Organizations,  Protocol Personnel,  Subjects,  Others,  Questionnaire
- Button: create

3. Provide a summary of the purpose and content of the amendment in the Summary field. In the **Amend** section, check all boxes for sections you wish to amend. Only protocol sections with checked boxes will open for editing. Those not selected will remain read-only. If making changes to any approved documents (protocol, consent form(s), recruitment materials, etc.) click on the **Add/Modify Notes & Attachments** box.
4. Click the Create button. Streamlyne will open a new Amendment document. You will be able to make edits in the areas you selected in Step 3.
5. Make all applicable changes to the information displayed on the protocol document as needed.
6. Click on the **Questionnaire** to complete the Amendment Questionnaire. You **MUST** complete this before submitting the amendment. Once all required questions are answered, the IRB Protocol Amendment tab at the top with show Complete.
7. When ready to submit, click Protocol Actions > Request an Action > Submit for Review.
8. Complete the required fields of **Submission Type** (Amendment) and **Submission Review Type** (e.g., Full Board, Minimal Risk).
9. For Minimal Risk and Expedited (federally funded) protocols, a Checklist will display. Select all categories that apply to your study.
10. Click the Submit button to submit your amendment into the IRB workflow.