



Streamlyne IRB Tip Sheet

Submitting an Event

Notifying the IRB (to submit an event)

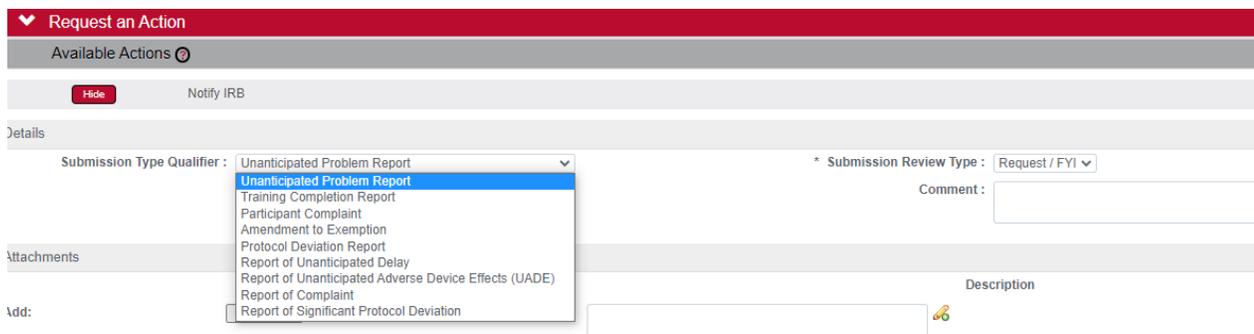
This process applies to all instances in which the PI needs to notify the IRB Committee of an event that occurred that may require further review or scrutiny by an IRB Administrator and/or IRB Committee. The most common occurrences are adverse events, unanticipated problems or protocol deviations. However, there are a variety of events that may be applicable.

Access the protocol through IRB Actions > Notify the IRB on a Protocol. Clicking this menu option will display all the protocols that qualify for this action.

Navigation	Main Menu > IRB > IRB Actions > Notify IRB on a Protocol
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Instructions:

1. Locate the protocol that you would like to notify the IRB about by logging into SL, going to Main menu at the top, then irb, then all my protocols. Open the study by clicking edit next to the appropriate study.
2. Click on the Protocol Actions tab on the left side of the screen and click > Request an Action.
3. Under Available Actions, click show next to Notify IRB.



4. In the **Submission Type Qualifier** field, use the dropdown to select unanticipated problem report.

Note **Submission Review Type** will default to FYI and cannot be changed.

5. In the **Comment** field, enter information regarding the reason for the notification.
6. In the Attachments subsection, upload an attachment (the completed event report form) by clicking the Browse button.
7. In the **Description** field enter a description of the attachment if needed.
8. **Click the add button.**  This is very important. If you do not click add, the attachment will not be saved.
9. Repeat Steps 7 through 9 until all necessary attachments are added.
10. Click the Submit button to finalize the Notify IRB action. 