Submitting an Unanticipated Problem / Violation Report Form

1) Go to https://swarthmore.my.irbmanager.com/ and enter your login information.

2) At the bottom of the dashboard, your active studies are listed. If you do not see your study listed, please contact the IRB for additional support irb@swarthmore.edu.

3) Click on the blue link for the study you are reporting an unanticipated problem or a violation for.

4) Once you are in the study, please click “start x-form” under actions in the upper left corner.
   a. **NOTE:** If you’d like to see what the form looks like, including all questions, and potential values for dropdown type questions, click “Start xForm” under actions in the upper left. Click on the printer icon next to the form, which will give you a view you can print.

5) If you wish to fill out this form, choose the blue link for the “Unanticipated Problem / Violation Report”.

6) Enter your study information.

7) Once you’ve completed and submitted the form, the IRB personnel will begin the review process. You will be notified of the results via email.
   a. **NOTE:** The IRB should be notified within 48 hours from the time of an identified unanticipated problem, violation or adverse event. If the report was not submitted within this timeframe, please provide the IRB with a justification as to why we were not notified within 48 hours as detailed in your approval letter.

8) To view your submission once it has been accepted into IRBManager, click the link for the study from your dashboard. You will see the link in blue at the bottom of the page under “My Studies” (look for the appropriate unanticipated problem / violation report event).