How to Create a New Reportable Event: Protocol Deviation/Violation

ePirateTraining
When you Login to ePirate, click on the “Dashboard” tab in the upper left hand corner of the screen.
Click on the IRB Studies tab, then click on the name of the research study for which you need to submit a Reportable Event: Protocol Deviation.
Click on “New Reportable Event” on the left side of the study workspace screen.
Provide a brief name for the event and then select “Protocol Deviation/Violation”. Red asterisks indicate there must be an answer provided. Click “Continue” to go to the next page and also to finish the remainder of the application.
Complete all relevant Information until you get to the Final Page. When you click Finish on the Final Page, you will be taken back to the workspace.

Please note that clicking “Finish” does not submit your reportable event, it just means you’re finished working on the application at that moment.
When the application is complete, the Principal Investigator must click “Submit Reportable Event” on the left side of the workspace screen for the application to arrive in the IRB’s queue.
Once the Reportable Event has been submitted, you will note that the State of the study changes from “Pre Submission” to “IRB Staff Review”.

The UMCIRB office has now received your Reportable Event for review.