

Steps for Filling out eIRB for a LOCAL (INTERNAL) EVENT:

1. PI determines or is instructed to self-report an Unanticipated Problem (UP) or Reportable Event (RE) to the IRB because of an event that occurred at our local study site.
2. In eIRB, the study team member selects “New Reportable Event” on the left side of the eIRB page.
 - a. For Question 1.0—the unique code, please ensure that “Atlanta VAMC” is part of the event title to indicate to the IRB that this is a VA study or event.
 - b. For Question 2.0—the Reportable Event Submission Type is “Event at an Emory-affiliated site”
 - c. **Press Continue**
3. Under Event at Emory-affiliated site
 - a. Please answer questions 1.0, 2.0 & 3.0 based on the specifics of the event.
 - b. For Question 4.0—Was this event anticipated in terms of the frequency, duration, and severity given (a) the research procedures that are described in the protocol-related documents, such as the protocol, informed consent document, or Investigator's Brochure; and (b) the characteristics of the subject population being studied?
 - i. Please click “YES” if the event was anticipated or “NO” if it was not anticipated.
 - c. For Question 5.0—What is the relationship of the event to the study
 - i. Answer is based on the PI’s determination
 - d. For Question 6.0—Was the event considered serious due to being associated with or the cause of any of the following:
 - i. Answer based on the specifics of the event
 - e. **Click Continue**

From here you will either be directed to the next page of the smart form in order to give specifics of the event (meaning the event is truly reportable) OR you will be directed to page that says:

“In order for an event occurring at an Emory-affiliated site to be promptly reportable, it must be (a) an unanticipated problem involving risk to participants or others, (b) a death that is possibly, probably, or definitely related to the research, (c) anticipated events occurring with a greater frequency, duration, or severity than what is described in the protocol related documents, or (d) any other information that suggests the research places participants or others at greater risk of harm than was previously known.

Your answers to questions on the previous pages indicated that these conditions were not met, and this event is not reportable to the IRB.

If you think you have reached this page in error (the event is reportable) and wish to edit the report, click Finish below to return to the Reportable Event workspace. Then modify your Reportable Event and submit.

Otherwise, if you will not be reporting this event, click Finish below, and then click Withdraw on the left hand side of the workspace to cancel the report.”

If you have been directed to this page then your event is not reportable (based on the answers provided). Use the “Reportable Event Assessment Form” to track the event so that if questioned it is documented why the event is not reportable to the IRB.

*If your event does not meet the threshold for the 5 business day reporting but your sponsor is requiring a report to the IRB anyway for acknowledgment, click “Finish” and then have the PI submit the event. You must also log a comment in the history section of the Reportable Event uploading the documentation from the sponsor requiring this submission to be reviewed.

If you have been directed to continue filling out the smart form, this event did meet the criteria for reporting to the IRB within the 5 business day timeframe.

Under the Event at Emory-affiliated site 2

- a. Please answer Question 1.0 regarding how the event exceeded the expected frequency, duration, or severity from what is described in the protocol related documents if applicable.
- b. For Question 2.0, please clarify if the event increased risks to subjects
- c. For Question 3.0, the PI should answer whether the consent form needs to be changed to inform subjects of new information regarding the event.
 - i. If YES—upload information regarding this change AND submit an amendment with the updated document.
- d. For Question 4.0—upload a document with the specific details of the event
- e. For Question 5.0—explain whether or not a breach of confidentiality occurred with this event
- f. For Question 6.0—indicate what other entities have been notified of this event
- g. **Click Continue**

4. Click FINISH

- h. The PI must submit the report to the IRB. The 5 day reporting clock does not stop until the PI submits this to event to the IRB.
- i. The IRB will review the event and be in touch regarding determinations and/or clarifications.

ONCE eIRB is FILLED OUT, SEND AN EMAIL TO: VAReportableEvents@atlaref.org WITH THE PI’S NAME AND STUDY eIRB NUMBER TO ALERT THE RESEARCH OFFICE THAT AN UP/RE HAS BEEN SUBMITTED TO THE IRB.