

Steps for Filling out eIRB for an EXTERNAL EVENT:

1. PI determines or is instructed to report an External Adverse Event or Unanticipated Problem for subjects enrolled by investigators at sites other than AVAMC sites.
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 non-Emory-affiliated site”
 - c. **Press Continue**
3. Under Event at non-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 unanticipated 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?
 - i. Please click “YES” if the event was unanticipated or “NO” if it was not unanticipated.
 - c. For Question 5.0—What is the relationship of the event to the study
 - i. Answer is based on the PI’s determination YES or NO
 - d. For Question 6.0—Was the event considered serious due and suggest an increase in risk?
 - i. Answer based on the specifics of the event YES or NO
 - 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 that occurs at a non-Emory-affiliated site to be reportable, it must be (a) an unanticipated problem involving risks to participants or others or (b) any other event that places subjects 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 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.

4. Under the Event at non-Emory-affiliated site 2
 - a. Please answer Question 1.0 by uploading the event description as specified in eIRB. Be sure to include the information requested by the system in this explanation.
 - b. For Question 2.0 provide the number of subjects enrolled study wide.
 - c. For Question 3.0 provide the number of subjects enrolled locally.
 - d. For Question 4.0—explain whether revisions of study documents are necessary based on this new information.
 - a. If YES—upload changes summary and submit an amendment if modify the documents (if not already submitted).
 - e. **Click Continue**

5. **Click FINISH**
 - f. The PI must submit the report to the IRB. The 5 day reporting clock does not stop until the PI submits this event to the IRB.
 - g. 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.