GEORGETOWN UNIVERSITY

INSTITUTIONAL REVIEW BOARD

Electronic Research and Information Compliance (eRIC)

Investigator and Study Staff Manual Quick Reference

Reportable Events

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Reportable Events

Reportable events are used to report any of the following to the IRB:

- Internal Serious Adverse Event (SAE) – Initial Report
- Internal Serious Adverse Event (SAE) – Follow-up Report
- External Serious Adverse Event (SAE) – Initial Report
- External Serious Adverse Event (SAE) – Follow-up Report
- Data Safety Monitoring Report
- Protocol Violation
- Investigator Brochure

Investigators are required to report adverse events and/or unanticipated problems in order to assure protection of human subjects involved in research. All events that fall under the definition of reportable adverse events and unanticipated problems, as set forth in the Georgetown Policy Manual, must be reported to the IRB through the “Reportable Events” form in eRIC. Unanticipated problems that do not constitute reportable adverse events (i.e. stolen data) must be submitted through the “Amendments” form.

Creating and Submitting a New Reportable Event

1. In the approved study’s workspace, click the New Reportable Event button to start the application for the new reportable event.
2. Complete the first page of the application and select the type of reportable event.
3. Click the Continue button and complete the rest of the application. TIP: If this reportable event requires you to also submit an amendment to the study, please open a new amendment to be submitted.
4. A member of the study staff must submit the reportable event to the IRB using the Submit to IRB activity.
The table below outlines the essential steps for creating and submitting a new reportable event report.

In the approved study’s workspace, click the New Reportable Event button to start the reportable event report.

After selecting New Reportable Event, you are directed to the “Reportable Event Information” page. Please select the type of reportable event and fill in all required fields.
Fill in all required fields. Click continue to move to the next section.

Click “Choose the descriptor(s) that best describe this event” to designate the MEDdra term which best describes the event.
Type in a word or phrase to search for. Click “Find” to begin the search.

Making the search term more specific will shorten the list to choose from. In this example, there are 277 terms which relate to “Injury”.

In this second example, searching specifically for “Brachial Plexus” results in 5 event terms.
To choose the event term, click on the circle next to the name. Then click “OK”.

The event chosen will appear. Click “OK” to add to the application.

The added term will not be visible within the Adverse Event application.
Finish completing the required sections of the Adverse Event application. Click “Finish” to be taken back to the Adverse Event workspace.

When the adverse event report is ready for submission, click on the “Submit for Review” activity.

Click “OK” to submit for review. Any study member can submit an adverse event for review.
Once submitted, the submission will be logged in the history and the Current State will change.

Responding to Adverse Event Contingencies

To respond to Adverse Event Contingencies, navigate to your Inbox and click on the adverse event name.
To view the reviewer notes, click on “Edit Adverse Event” or the Reviewer Notes tab.

View the Reviewer Note in by expanding the Reviewer Note bar.
Click on the “Click here to respond” link to respond directly to the note.
Also, make the appropriate change within the adverse event application.
The response to the reviewer note will require a “type” of response and a typed “response”.

Declining to Make Requested Changes in Response to SAE Reviewer’s Contingencies is shown in the screenshot. Choosing the type “change request not completed” and providing an adequate explanation, the study team can indicate that the change was not made as requested.
To submit the response, navigate to the adverse event workspace. Click on the “Submit Changes” activity on the left.

Click “Ok” to submit the changes.
Once submitted, the submission will be logged in the history and the state will change.
Once approved, the adverse event determination will appear in the history and the Current State will change.