Creating an Adverse Event / ORIO

Important Information

- Study teams are required to submit Adverse Events (AEs) and Other Reportable Information and Occurrences (ORIOs) via the eResearch system. ORIOs include audits, other reports, protocol deviations, protocol violations, facility/data accidents, and complaints (which includes lapses in approval).

eResearch Home Workspace

1. Click to display approved studies.
2. Click the Name of the study to view the approved study workspace.

eResearch Study Workspace

3. On the Study Workspace, click to create a new Adverse Event/ORIO.
### Adverse Event Form

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>Enter a title for your Adverse Event / ORIO&lt;br&gt;&lt;br&gt;Note: To make tracking the adverse event easier, include the HUM # of the original study in the title. Once approved, the adverse event is accessed through the approved study workspace.</td>
</tr>
<tr>
<td>5.</td>
<td>Select <strong>Adverse Events Report</strong> or <strong>Other Reportable Information and Occurrence (ORIO)</strong>.</td>
</tr>
<tr>
<td>6.</td>
<td>Click <strong>Continue &gt;&gt;</strong>.</td>
</tr>
<tr>
<td>7.</td>
<td>Select the <strong>Type of Adverse Event or ORIO</strong> which you are reporting.</td>
</tr>
<tr>
<td>8.</td>
<td>Indicate whether this report includes follow-up to previous reported events</td>
</tr>
<tr>
<td>9.</td>
<td>Click <strong>Continue &gt;&gt;</strong>.</td>
</tr>
</tbody>
</table>
**Previous Adverse Events**

Note: If you select Yes to this question (1-1.2), you will be required to indicate the previous reported events which this report follows.

**Adverse Event Form**

10. Fill out the required fields in the form. For Adverse Events, you will be required to click **Add** and fill out the Adverse Event Detail form.
11. Fill out the required fields in the **Adverse Event Detail** form.

12. Click **OK**.

   **Note:** To report multiple adverse events of the same type within one form, click **OK and Add Another**.

13. Fill out the remaining fields in the **Adverse Event Form**.

14. Click **Continue >>**.
15. Optional, enter the names of the documents in the box below as they should appear on the IRBMED approval, if the study sponsor requires that the IRBMED approval letter contain a list of supporting documents.

16. Click [Continue >>].

17. Click [Submit Adverse Event] from the end of the submission or workspace.

Note: If you are not ready to submit the Adverse Event, you can still go back and edit it.

You can withdraw the Adverse Event after it has been submitted by clicking [Withdraw Adverse Event] from the Study Workspace.

18. Click [OK].