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.

**eResearch Home Workspace**

1. Click **Approved Studies** to display a list of approved studies
2. Click the **Name** of the study to view more detail.

**eResearch Study Workspace**

3. On the Study Workspace, click the **New Adverse Event/ORIO** button.
4. Enter a title for your Adverse Event / ORIO

**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 work-space.

5. Select whether you are reporting an **Adverse Event (AE)** or **Other Reportable Information and Occurrence (ORIO)** and continue to the next screen.

6. Select the **Type of Adverse Event or ORIO** which you are reporting.

**Note:** New to the eResearch 1.5 release, you can report multiple adverse events of the same type within the same submission.

7. Indicate whether this report includes follow-up to previous reported events and continue to the next screen.

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

9. Fill out the required fields in the Adverse Event Detail form.

10. Click the OK button to complete the Adverse Event Detail form or click the OK and Add Another button to report multiple adverse events of the same type within one form.
11. Fill out the remaining fields in the Adverse Event Form.

12. Click the Finish button.

Note: When you click the Finish button, the AE is submitted automatically and you will be returned to the Study Workspace.

13. Click the Submit Adverse Event button.

Note: If you are not ready to submit the Adverse Event, you can still go back and edit it. You can also withdraw the event by clicking the Withdraw Adverse Event button.

14. Click the OK button.