Creating an Adverse Event / ORIO

Study teams are required to submit Adverse Events (AEs) and Other Reportable Information and Occurrences (ORIOs) via eResearch Regulatory Management (eRRM). AE/ORIO reports can also be created to follow-up on previously reported AEs/ORIOs.

AEs include any experience or abnormal finding that is harmful or increases the risk of harm to research participants. ORIOs include audits, other reports, protocol deviations, protocol violations, facility/data accidents, and complaints (which includes lapses in approval). See the eRRM Glossary for more details.

The basic steps for initiating an AE/ORIO report are the same regardless of the type of AE/ORIO being reported; however, the report form that opens and the information you are asked to provide will depend on the type of AE/ORIO indicated. The following procedure acts as a general guide for reporting an AE/ORIO of any type.

**eResearch Home Workspace**

1. Click to display approved studies.
2. Click the Name of the study to open the Study Workspace.

**eResearch Study Workspace**

3. Click
4. Click the radio button to choose the Type of Report.
5. Click Continue.
6. (Optional) Enter a title for your AE/ORIO report.  
**Note:** A default title is created and includes the HUM # of the original study, the type of report (i.e., AE or ORIO), and the date/time it was created. If you choose to edit the default title, it is recommended that you keep the HUM # and type of report in the title.

7. Click the appropriate radio button to select the Adverse Event type (or ORIO type, if applicable).

8. Click the radio button to indicate if the report includes follow-up to previously reported events.

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

9. Click **Continue**.

Depending on the type of AE or ORIO you are reporting, the applicable report form will open. Complete all required fields marked with an asterisk (*). After completing each page of the report, click **Continue** to save and move to the next page.

10. If you are not yet ready to submit the AE/ORIO, click **Finish** to save and exit the report.

**Note:** You will be taken to the AE/ORIO Workspace from where you can edit, submit, or withdraw the report.

11. If you are ready to submit the report, click **Submit Adverse Event** (or **Submit ORIO**, if applicable).

**Notes:**
- The system automatically validates that all required fields are complete.
- Any returned errors must be addressed before continuing.

12. Click **OK** in the Submit Adverse Event (or Submit ORIO, if applicable) window that opens (not shown).

**Note:** Once submitted, an AE/ORIO can no longer be edited unless reviewers require changes.