

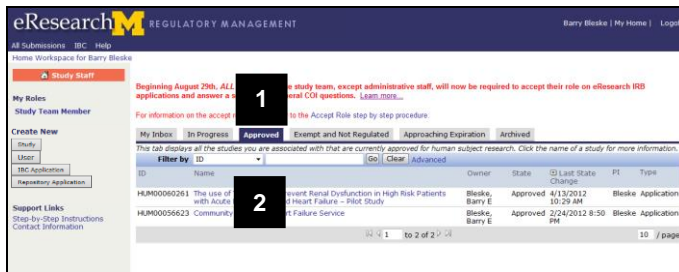
Creating an Adverse Event / ORIO

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.

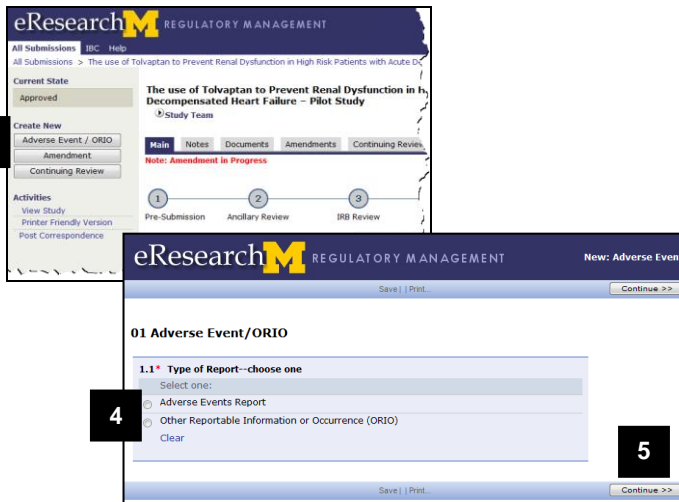
The basic steps for initiating an AE/ORIO report are the same regardless of the type of AE/ORIO being reported; however, the report form that opens and the information you are asked to provide will depend on the type of AE/ORIO indicated. The following procedure acts as a general guide for reporting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

eResearch Home Workspace



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

eResearch Study Workspace



3. Click **Adverse Event / ORIO**.
4. Click the radio button to choose the **Type of Report**.
5. Click **Continue**.

Report of Adverse Event Page

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.

End of AE/ORIO

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).

- Notes:**
- Once submitted, an AE/ORIO can no longer be edited unless reviewers require changes.
 - A message indicating **AE/ORIO(s) in Progress** displays in the application workspace.