Reportable New Information (RNI)

WORK INSTRUCTIONS:

1. Log into the Click Portal and click on the IRB tab in the top navigation menu.
2. Click the Approved tab to locate all approved studies.
3. Click the Name of the study.
4. Under My Current Actions, select the Report New Information button to create a RNI.
5. Enter the required information on the first page of the SmartForms.
6. Click the Continue button at either the top or bottom-right of the form.
7. Navigate through any additional SmartForms and complete all of the required fields
   • Click the Help icon ( ) for more information about a question or field
8. Click the Hide/Show Errors link in the navigation bar at the top or bottom of the SmartForm page
   to display any unanswered questions
   • Use the Jump To: link to navigate directly to SmartForm pages that are missing information
   • Submissions with any incomplete information will be redirected to the study team for updates
9. When all of the required fields have been completed, click the Finish button in the footer of the last
   SmartForm page to be redirected to the Study Workspace.

Your submission has not yet been submitted for review.

10. Use the Add Related Submission activity to notify the IRB if you are also submitting a
    modification to the approved study as a result of the RNI.
11. The **Principal Investigator** (or **PI Proxy**) must click the **Submit** activity located under **My Current Actions** on the left side of the **Study Workspace**. Read the statement, and then click **OK** to submit the study for review.

- The system will check the study to ensure that all required questions have been answered on the **SmartForms**. If any items have been missed, you will be prompted to answer them.

- If the submission is successful, the page will refresh and the submission will transition from the **Pre-Submission** state to the **Pre-Review** state.