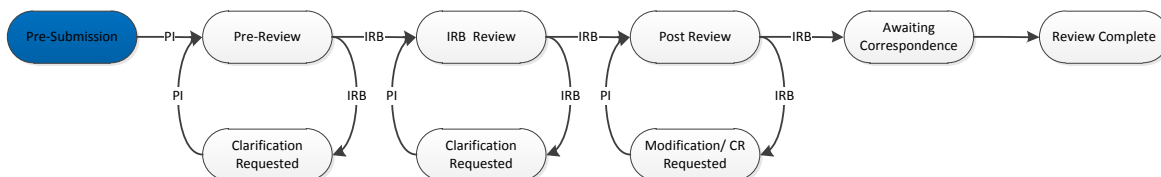




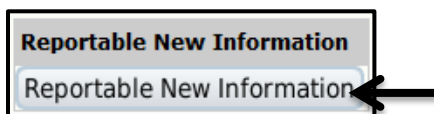
Job Aid Title	Reportable New Information (RNI)
Relevant Users	Principal Investigator (PI), Additional Contact, Study Staff
Covered Topics	<ul style="list-style-type: none"> ○ How to create a new reportable information ○ How to edit a reportable information



1. Please consult the Investigator’s Manual for the list of Reportable New Information categories. If no categories apply, the information may be reportable at time of continuing review.

2. Create a Reportable New Information (RNI)

- In the study workspace, click on the **Reportable New Information** button



- Item 1 displays a list of studies associated with the same PI. Select all studies to which this reportable information applies. Fill out the required information and then click **Continue** in the top or bottom right-hand side of the screen.

- Identify the appropriate categories for the reportable new information. If no categories apply, the information may be reportable at time of continuing review. If



you pick a category that is not an exact match to your information, be sure to explain how the information is different and why you are submitting.

- Answer the three specific questions regarding the reportable event. If you answer yes to questions 2 or 3, you **must** submit a separate Modification request in addition to submitting the Reportable New Information.

- To attach supporting documentation for the Reportable New Information, select the **Add** button under attachments.

- Click the **Finish** button in the top or bottom right-hand side of the screen to close.

3. Edit RNI

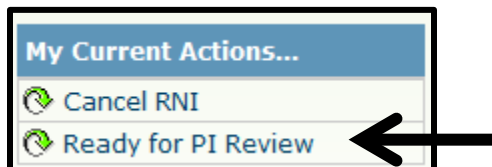
- Use the **Save** and **Exit** buttons at the top of the screen to prepare a submission that is not yet ready for the IRB.
- Select **Edit Reportable Event** to re-open the submission and to complete as required.



4. Submitting the RNI

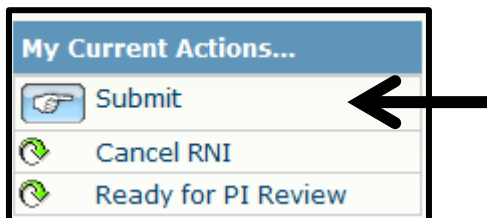
- **For Study Staff:**

- After clicking 'Finish' in the RNI submission, select **Ready for PI Review** under **My Current Actions** in the submission workspace. **The PI is the only member of the study team that may submit the RNI to the IRB office.**

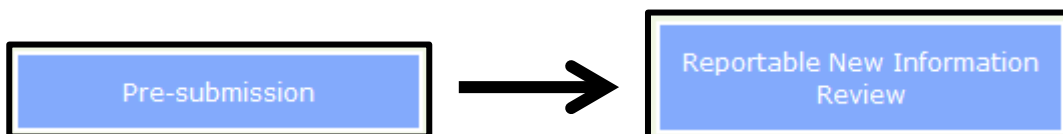


- **For the PI:**

- After clicking 'Finish' in the RNI submission, select **Submit** under **My Current Actions** in the submission workspace.



!Note: You will know that the RNI has been submitted successfully when the submission's 'state' has changed from **Pre-Submission** to **Reportable New Information Review**.



TIPS

- *If you are reporting a protocol deviation, explain why the deviation did or did not put the subject at increased **risk** of harm. It is not sufficient to confirm that no harm occurred.*