

How to Create and Submit an RNI (Safety)


In UVMClick, Report New Information (RNI submission) is synonymous to

- Safety
- Adverse Event
- Noncompliance
- Unanticipated Problem(UAP)

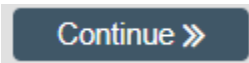
Please Note: Many of the IRB Forms have transitioned into our UVMClick online smartforms. The Safety form has been retired and transitioned into an online smartform.

Create a new RNI Submission

1. From “My Inbox” or the IRB>Submissions screen, navigate to the appropriate protocol and click on the name to open it.
2. Click **Report New Information**.



3. Answer all questions and hit Continue. Those questions with a red asterisk are required.



- If you miss any required fields, there will be a message at the top of the screen
**Could not submit the form due to one or more errors:
Please review the page and correct any errors...**
- Scroll through the page. Missing fields will display the following red text:
This is a required field; therefore, you must provide the required information.

Enter all missing information and click the Continue button.

Submit the RNI to the IRB Office for Processing

After completing the RNI online form, the status of the RNI submission will display as “Pre-Submission” and will remain visible in your “My Inbox until submitted to the IRB Office for processing.

To submit a finished RNI submission to the IRB Office for their review and processing,

1. Make sure the RNI is open
2. Click the activity on the left that says **“Submit”**

The screenshot shows the RNI submission interface for RNI00000017: _IRBSubmission. The status is 'Pre-Submission'. The 'Next Steps' section includes buttons for 'Edit RNI', 'Printer Version', 'Submit RNI' (highlighted with a red box and arrow), and 'Add Related Submission'. A flowchart on the right shows the process flow: Pre-Submission (highlighted) leads to Pre-Review, which can lead to IRB Review or Clarification Requested. IRB Review can lead to Clarification Requested, which then loops back to Pre-Review. Below the flowchart are tabs for 'History', 'Documents', and 'Related Submissions'. A green callout box contains the text: 'Note: A Pre-Submission status means the RNI has not yet been submitted to the IRB Office'.

When clicking the **Submit** activity certification text will appear. Read the text and click **OK**.

The screenshot shows the 'Submit RNI' certification screen. It features a dark blue header with the text 'Submit RNI'. Below the header, it says 'By signing below you are verifying that:'. There are two bullet points: 'The information you have submitted is complete and correct to the best of your knowledge.' and 'The information you have submitted has been done so in accordance with requirements in the IRB Policies and Procedures Manual found on the website.' At the bottom right, there are two buttons: 'OK' and 'Cancel'. A red arrow points to the 'OK' button.

The status of the RNI is no longer “Pre-Submission”. It has changed to “Pre-Review” indicating it is in the hands of the IRB Office for processing. You will also note that the RNI is now in View Mode and no longer in Edit mode.

The screenshot shows the RNI submission interface for RNI00000017: _IRBSubmission. The status is 'Pre-Review'. The 'Next Steps' section includes buttons for 'View RNI' (highlighted with a red box and arrow) and 'Printer Version'. A flowchart on the right shows the process flow: Pre-Submission leads to Pre-Review (highlighted), which can lead to IRB Review or Clarification Requested. IRB Review can lead to Clarification Requested, which then loops back to Pre-Review.

The RNI has now been submitted and removed from your “My Inbox.” It now displays in the IRB Office “My Inbox” for review and processing.