

How to Create and Submit a Reportable New Information report to the Safety Subcommittee

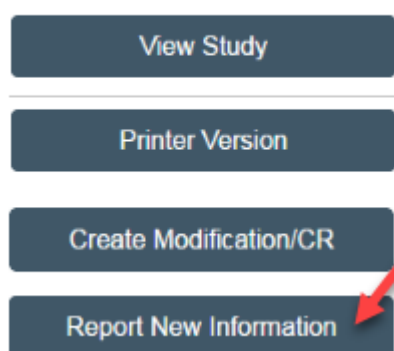
In UVMClick, RNI is synonymous with:

- Major and Minor Deviations
- Adverse Events
- Unanticipated Problems (UAP)
- Research participant complaints
- Quality Assessment Reports

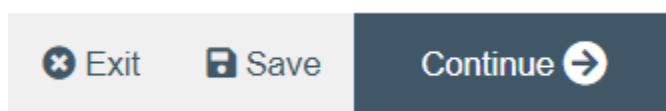
Create a new RNI Submission from an existing Study (preferred)

1. From the Dashboard tab > “My Inbox” or the IRB tab > “All Submissions” screen, *navigate to the appropriate protocol and click on the name to open it*. For more details about this process, please see the user guide called “Searching for a Protocol or Submission”.
2. Click “**Report New Information**” on the left side of the main study page.

Next Steps



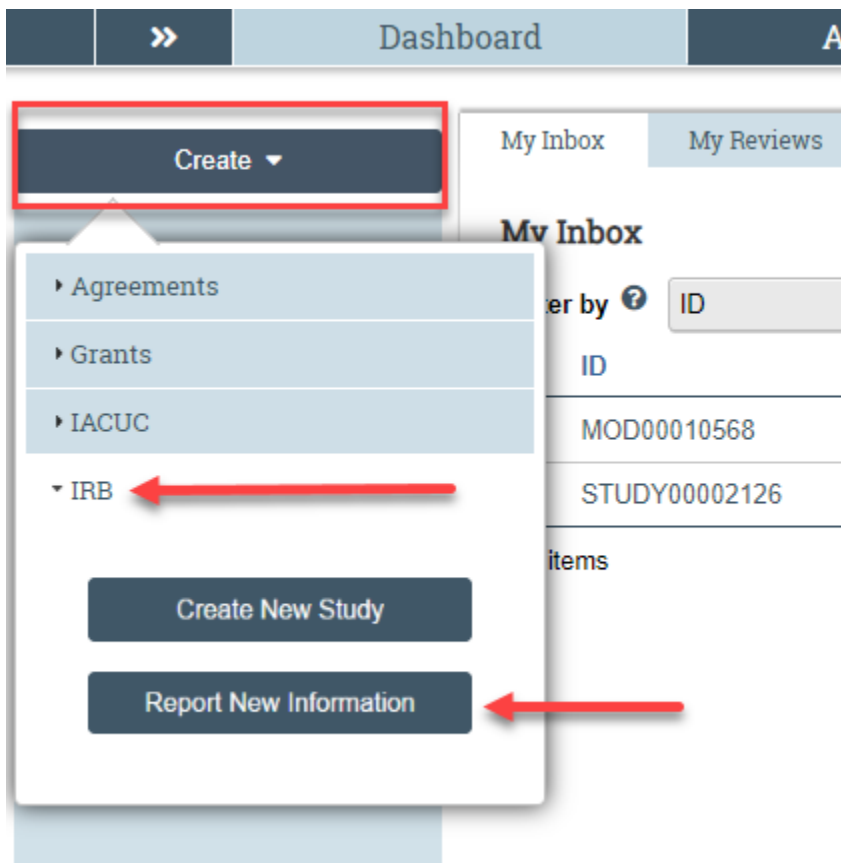
3. Answer all questions and hit “**Continue**” at the bottom, right corner of the page. Those questions with a red asterisk are required, but as much information as possible should be provided.



- The RNI short title should be descriptive of the information being reported.
- Add supporting documents as needed, including but not limited to: redacted consent forms, laboratory reports or hospital admission summaries, communications with participants or sponsors, training logs, eligibility checklists etc. Redact any information that might identify a specific participant.
- 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...*
[Go to first error](#)
- You may either select **“Go to first error”** or 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.
- Please note, your RNI is *not submitted* at this point. See **“Submit the RNI to the IRB for Review”** below.

Create a new RNI Submission from your Dashboard

1. From the Dashboard tab, click on **“Create”** on the left side of the screen. Select **“IRB”** from the drop down menu and click on **“Report New Information.”**



2. Since you did not create the RNI from the Study record, you will have to link the associated Study/Studies in Question 22. To do so, start typing the Study's IRB number (STUDYxxxxxxx) into the free text field, or click on **“...”** for a pop up selection box. The RNI reporter's Studies will be visible in list format, and you can also search using various filters by typing in the free text box and clicking **“Go.”** After selecting the appropriate Study/Studies, click **“OK.”**

22. * Related studies and modifications:

There are no items to display

Select One or More IRB Submission Projects

Filter by ID Go Clear Advanced

Deselect All

ID	Name	Organization	PI first name	PI last name	IRB office
<input type="checkbox"/> STUDY00002124	Example Study Title	Med-General	John	Smith	CHRMS (Medical)

OK Cancel

3. Answer all questions and hit “**Continue**” at the bottom, right corner of the page as described above.
4. Please note, your RNI is *not submitted* at this point. See “Submit the RNI to the IRB for Review” below.

Submit the RNI to the IRB for Review

After completing the RNI Click Smart Form and hitting “**Continue**,” the status of the RNI submission will display as “Pre-Submission” and will remain visible in your “My Inbox” until submitted to the IRB for review.

To submit a completed RNI submission to the IRB for review:

1. From the Dashboard tab > “My Inbox” or the IRB tab > “All Submissions” screen, *navigate to the appropriate RNI and click on the name to open it.*
2. Click the activity on the left side of the main RNI page that says “**Submit RNI**”

Pre-Submission

Last updated: 10/13/2022 11:28 AM

Reported by: John Smith
Submission type: Reportable New Information

Next Steps

- Edit RNI
- Printer Version
- Submit RNI**
- Add Related Submission
- Add Comment
- Copy Submission
- Discard

RNI00000470: Unstamped Consent Form Used

Pre-Submission

Pre-Review

IRB Review

Post-Review

Review Complete

Clarification Requested

Action Required

History

Activity	Date	Author
Reportable Information Opened	10/13/2022 11:28 AM	John Smith

Note: A **Pre-Submission** status means the RNI has not yet been submitted to the IRB for review.

3. After clicking the “**Submit RNI**” activity, UVMClick will check for errors in the submission and then a verification text will appear. Read the text and click “**OK.**”

By signing below you are verifying that:

- The information you have submitted is complete and correct to the best of your knowledge.
- The information you have submitted has been done so in accordance with requirements in the [IRB Policies and Procedures Manual](#) found on the website.

OK

Cancel

The RNI has now been submitted and removed from your “My Inbox.” The status of the RNI is now “Pre-Review” indicating it is in the hands of the IRB for review. You will also note that the RNI is now in View Mode and no longer in Edit mode.

Pre-Review

Entered IRB: 10/13/2022 12:02 PM
Last updated: 10/13/2022 12:02 PM

Next Steps

View RNI

Printer Version

+ Add Related Submission

Add Comment

Copy Submission

Withdraw

Discard

Reported by: John Smith
Submission type: Reportable New Information

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graph LR; A[Pre-Submission] --> B[Pre-Review]; B --> C[IRB Review]; C --> D[Post-Review]; D --> E[Review Complete]; B --> B1[Clarification Requested]; B1 --> B; C --> C1[Clarification Requested]; C1 --> C; D --> D1[Action Required]; D1 --> D
```

History Documents Related Submissions

Filter by Activity

Enter text to search for

+ Add Filter X Clear All

Activity	Autho
RNI Submitted	Smith,
Reportable Information Opened	Smith,