

## How to Create and Submit a Reportable New Information (Safety) Report for an External IRB

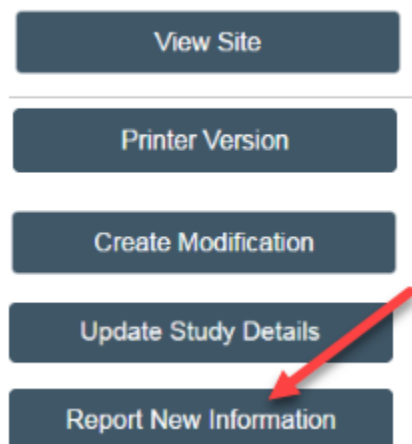
In UVMClick, Reportable New Information (RNI) is synonymous with:

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

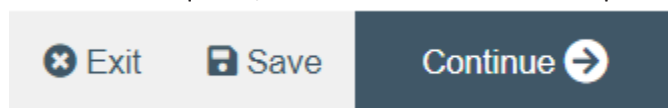
### Create a new RNI Submission from an existing Study (preferred)

1. From the Dashboard tab > “My Inbox” or the IRB tab > “External IRB” or “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 left side of the main study page.

#### Next Steps



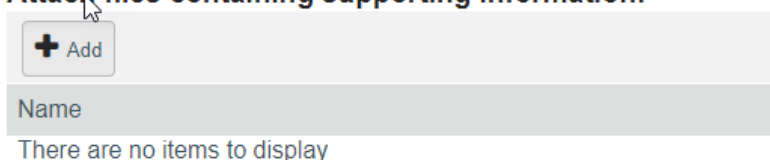
3. Answer all questions and hit “**Continue**” at the bottom, right corner of the page. Those questions with a red asterisk are required, but as much information as possible should be provided.



- 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.

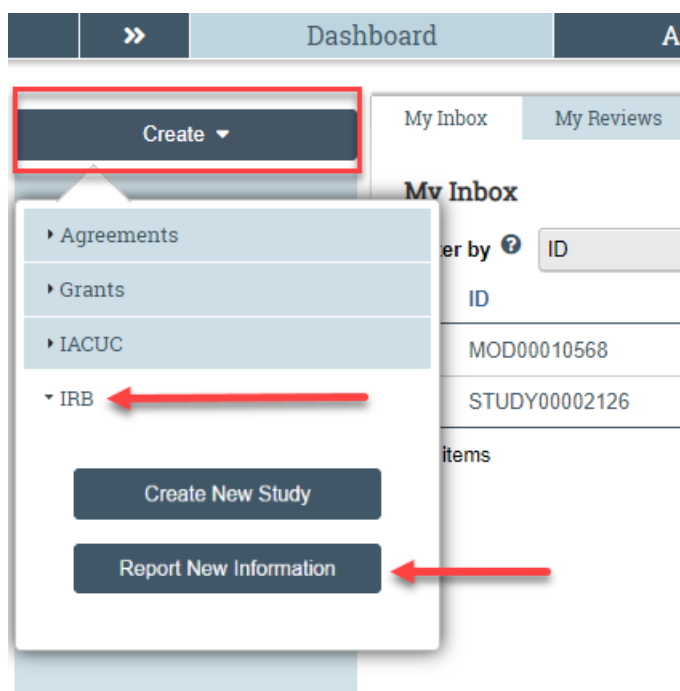
**\*\*TIP\*\*** The UVM IRB does not require submission of all protocol amendments for External IRB studies, unless they require local context review. Because of this, the protocol and consent form(s) will be those submitted at the time of initial review. Please attach the currently approved protocol and consent(s) for review in the supporting documents section of the RNI. The Committee needs these documents to assess relatedness of the RNI to the study.

### 23. Attach files containing supporting information:



## 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.”**



- 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

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

- Answer all questions and hit "Continue" at the bottom, right corner of the page as described above.
- 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:

- 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.*
- Click the activity on the left side of the main RNI page that says "Submit RNI"

**Pre-Submission**

Last updated: 11/14/2022 1:17 PM

Reported by: John Smith

Submission type: Reportable New Information

IRB office: CHRMS (Medical)

IRB coordinator:

**Next Steps**

**RNI00000472: Incorrect Consent used**

**Pre-Submission** → **Pre-Review** → **IRB Review** → **Post-Review** → **Review Complete**

**Pending sIRB Review**

**Activity**

Activity	Author	Activ
Reportable Information Opened	Smith, John Doe	11/14/2

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

- 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: 11/14/2022 1:31 PM  
Last updated: 11/14/2022 1:31 PM

**Next Steps**

[View RNI](#)

[Printer Version](#)

- + Add Related Submission
- 💬 Add Comment
- 📄 Copy Submission
- ← Withdraw
- 🗑️ Discard

## RNI00000472: Incorrect Consent used

**Reported by:** John Smith  
**Submission type:** Reportable New Information

**IRB office:** CHRMS (Medical)  
**IRB coordinator:**

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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 --> F([Pending sIRB Review])
    F --> E
  
```

History | **Documents** | Related Submissions

Filter by Activity  🔍 [+ Add Filter](#) [✕ Clear All](#)

Activity	Author	Act
🔄 RNI Submitted	Smith, John Doe	11/14
📄 Reportable Information Opened	Smith, John Doe	11/14