

# Reportable New Information (RNI)

\*Please note a terminology change: this was formerly called an Event Report (ER).

## Prior to the Submission

Prior to submitting your RNI in Huron, you should first complete the **HRP-206-Template: RNI Supplemental Information Form**. This editable Word document can be found in Huron Library [IRB > Library > Templates].

## Navigation

1. Make sure you are on the IRB tab.
2. Select “Submissions” in the sub-navigator to see your IRB submissions.
3. Select the “Active” tab.
4. Open the study with the RNI.

The screenshot displays the IRB system interface for The Ohio State University. The top navigation bar includes 'Dashboard', 'IRB', and 'Settings'. A sub-navigator below it contains 'Submissions', 'Meetings', 'Reports', 'Library', 'Help Center', and 'Central Actions'. The 'IRB' section is active, showing a list of studies. The 'Active' tab is selected, and the first study in the list, 'STUDY20240302 An Open-Label Study of the Efficacy of Re-Retreatments with Ritumimab', is highlighted. Red circles with numbers 1-4 indicate the navigation steps: 1 on the IRB tab, 2 on the Submissions sub-navigator, 3 on the Active tab, and 4 on the first study row.

ID	Name	Date Modified
STUDY20240302	An Open-Label Study of the Efficacy of Re-Retreatments with Ritumimab	3/6/2025 6:56
STUDY20250150	2/27 Second Tish Testing	3/4/2025 1:02
STUDY20240318	ACE Inhibitors and Statins	2/27/2025 1:30 PM
RNI00000080	ADH Withdrawal test	2/27/2025 1:22 PM

## Study Workspace

1. Once inside the study workspace, you will select “Report New Information” to open the RNI SmartForm.

**STAGE**

**THE OHIO STATE UNIVERSITY**  
ENTERPRISE FOR RESEARCH, INNOVATION AND KNOWLEDGE

**Dashboard** IRB Settings  
Submissions Meetings Reports Library Help Center Central Actions

IRB > An Open-Label Study of the Efficacy of Re-Retreatments with Ritumimab

**Approved**

Entered IRB: 12/10/2024 2:03 PM  
Initial approval: 3/6/2025  
Initial effective: 3/6/2025  
Effective: 3/6/2025  
Approval end: 3/5/2026  
Last updated: 3/6/2025 6:56 PM

### STUDY20240302: An Open-Label Study of the Efficacy of Re-Retreatments with Ritumimab with Ritumimab

**Principal Investigator:** Mary Kivel  
**Submission type:** Initial Study  
**Primary contact:** Mary Kivel  
**PI proxies:**

**IRB office:** Office of F  
**IRB coordinator:** Nicola He  
**Letter:** Cor  
**Regulatory authority:** 2018 Rec

**Next Steps**

- View Study
- Printer Version
- Create Modification/CR
- 1** Report New Information

**Ohio State Review Type:** Biomedical Sciences IRB

```
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[Modifications Required]; D1 --> D;
```

**History** Funding Contacts Documents Follow-on Submissions Reviews Snapshots Training

**Filter by** Activity

Activity	Author
Letter Sent	Hottel, Nicola

# RNI SmartForm

## Reportable Information

1. **RNI short title:** Select a brief title for this RNI submission that distinguishes it from other submissions. You can use any unique title shorter than 50 characters.

The short title identifies the RNI throughout the IRB system, such as in your inbox and in the IRB's list of submissions to review. Format the short title to list the general RNI category followed by a brief description in parenthesis.

For example:

- Protocol deviation (missed blood collection)
  - Consent issue (wrong version of consent used)
  - Harm (participant suffered ischemic stroke)
  - Breach of confidentiality (data emailed to unauthorized person)
2. **Data you became aware of the information:** Use the date selector to indicate when you became aware of the information. Please note that this is not the date of form submission, nor the date the reporting event took place.

The screenshot shows the 'Creating New: IRB Submission' form. At the top left is the Ohio State University logo and name. Below it is the navigation breadcrumb: 'You Are Here: An Open-Label Study of the Eff... > \_IRBSubmission'. The main heading is 'Creating New: IRB Submission'. Below that is the section 'Reportable New Information'. There are three numbered steps: 1. 'RNI short title: (uniquely identify this new information report) ?' with a text input field containing 'Consent issue (wrong version of consent used on 2/25/2025)'. 2. '\* Date you became aware of the information:' with a date selector showing '2/25/2025'. 3. 'Identify the categories that represent the new information: (check all that apply) ?' with a table header showing 'Name' and 'Description'.

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AND KNOWLEDGE

You Are Here: An Open-Label Study of the Eff... > \_IRBSubmission

### Creating New: IRB Submission

#### Reportable New Information

1. **RNI short title:** (uniquely identify this new information report) ?
2. **\* Date you became aware of the information:**
3. **Identify the categories that represent the new information:** (check all that apply) ?  

Name	Description
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3. **Identify the categories that represent the new information (check all that apply).** There are multiple categories in this section. Read through each category and select **all** that apply to your new information report.

3

3. Identify the categories that represent the new information: (check all that apply) ?

Name	Description
<input type="checkbox"/> Risk	<p>Information that indicates a new or increased risk, or a safety issue. For example:</p> <ul style="list-style-type: none"> <li>a. New information (e.g., an interim analysis, data and safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk or uncovers a new risk.</li> <li>b. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.</li> <li>c. Protocol violation that caused harm to subjects or others or that indicates subjects or others might be at increased risk of harm, even if no harm occurred.</li> <li>d. Subject complaint that indicates an increased risk of harm or the risk of a new harm.</li> <li>e. Any changes made to the research significantly affecting its conduct.</li> </ul>
<input type="checkbox"/> Harm	<p>Any harm experienced by a subject or other individual that, in the opinion of the investigator, is unexpected and possibly, probably or definitely related to the research procedures.</p> <ul style="list-style-type: none"> <li>a. A harm is "<b>unexpected</b>" when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB (e.g., investigator's brochure, research protocol, consent form, or other available information) in terms of nature, severity, frequency, and characteristics of the study population.</li> <li>b. A harm is "<b>related</b>" to the research procedures if, in the opinion of the investigator, the research procedures likely caused the harm.</li> </ul>
<input type="checkbox"/> Protocol deviation	<p>Deviation, violation, or unintentional change to the protocol or procedures that <b>may</b> increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data. Examples may include:</p> <ul style="list-style-type: none"> <li>a. Research activities or interventions not conducted in accordance with the protocol</li> <li>b. Dosing error</li> <li>c. Over-enrollment of study participants</li> <li>d. Enrollment of an ineligible participant</li> <li>e. Research activities conducted by individual(s) not approved as study personnel</li> </ul>
<input type="checkbox"/> Consent issue	<p>Deviation from approved consent procedure(s). Examples may include:</p> <ul style="list-style-type: none"> <li>a. Consent obtained using an incorrect/unapproved version</li> <li>b. Consent and/or HIPAA research authorization improperly documented or obtained</li> <li>c. Failure to obtain consent prior to research activities</li> <li>d. Conducted research activities prior to participant(s) providing consent</li> <li>e. Completed consent forms and/or HIPAA research authorization documents missing (e.g., signed forms lost, stolen, or damaged)</li> </ul>
<input type="checkbox"/> Audit	Report containing findings by a federal agency (e.g., FDA Form 483) or institutional auditor.
<input type="checkbox"/> Study Monitor report (e.g. sponsor or CRO)	
<input type="checkbox"/> Breach of confidentiality	Contact the appropriate HIPAA Privacy Officer ( <a href="https://go.osu.edu/privacyofficers">https://go.osu.edu/privacyofficers</a> ) and the Office of Technology and Digital Innovation ( <a href="mailto:security@osu.edu">security@osu.edu</a> ) to determine if additional reporting is necessary.
<input type="checkbox"/> Unapproved change	Unapproved change made to the research to eliminate an apparent immediate hazard.
<input type="checkbox"/> Incarceration	Incarceration of participant(s) in a study not approved by the IRB to involve prisoners.
<input type="checkbox"/> Complaint	Complaint that cannot be resolved by the research team.
<input type="checkbox"/> Suspension	Premature suspension or termination of the research by the sponsor, investigator, or institution.
<input type="checkbox"/> Unanticipated adverse device effect	Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
<input type="checkbox"/> Data sharing certification request (e.g. dbGaP)	

4. **Briefly Describe the New Information**

Describe **in detail** the new information being reported. Use complete sentences to describe the information and specify what occurred, where it occurred, and how the event fits into one or more categories of the categories in question three. Indicate if the reportable new information was expected or if this was unexpected; if the RNI was related or unrelated to the research; if any increased risk was involved; and the outcome of the event. Please also describe any corrective actions the study team has already taken to address the issue.

For medical events: include diagnosis, assigned intervention, dose levels and frequency of intervention, relevant history including preexisting medical conditions, diagnostic test results, laboratory assessments, concomitant medications, and relevant dates. *Do not include participants' personally identifiable information.*

4 4. \* Briefly describe the new information: ?

At a recruitment event at the Martha Morehouse outpatient care facility on February 25, 2025, participants were enrolled using an outdated copy of the consent document. The outdated form does not accurately reflect the time between visits. The study team has reeducated the team members to access the current consent document on a shared drive location that is maintained by the RCO.

5. **Does this information indicate a new or increased risk, or safety issue?**

Select Yes if the information indicates an increase in the frequency or magnitude of a previously known risk or uncovers a new risk or safety issue.

6. **Does the study need revision?**

Indicate whether or not the study needs revision. If revisions are required, describe them in question four and submit a study modification for review.

7. **Does the consent need revision?**

If revisions are required to the consent form, describe them in question four and submit a study modification for review.

5 5. \* Does this information indicate a new or increased risk, or safety issue? ?  
 Yes  No [Clear](#)

6 6. \* Does this study need revision?  
 Yes  No [Clear](#)

7 7. \* Does the consent need revision?  
 Yes  No [Clear](#)

**i** If revisions are required, describe them above and submit a study modification for review.

- 8. Related Studies and Modifications:** Your study will already be populated and you can use the ellipses [...] to attach related studies and modifications.

The PI, PI proxies, and primary contact of each related submission are notified at several points in the RNI workflow. In addition, the PI and PI proxies of each related submission can edit the RNI and submit it for review, along with submitting a response to a clarification request.

- 9. Attach supporting information. Include a corrective action plan, as applicable.** Use this entry field to upload your completed RNI Supplemental Form (HRP -216), which includes any corrective action plans or any additional information relevant to the RNI.

The screenshot shows two sections of the RNI SmartForm interface. Section 8, titled "8. Related studies and modifications:", features a search input field with a dropdown arrow and a table of related studies. The table has columns for ID, Short Title, Investigator, State, and IRB Office. A single entry is visible: ID "STUDY20240302", Short Title "An Open-Label Study of the Efficacy of Re-Retreatments with Ritumimab", Investigator "Mary Kivel", State "Approved", and IRB Office "Office of Responsible Research Practices". A blue plus icon is in the right margin. Section 9, titled "9. Attach supporting information. Include a corrective action plan, as applicable:", shows a "+ Add" button, a "Name" label, and a file upload area containing a document icon and the text "HRP-216 - Template- RNI Supplement Form.docx(0.01)".

## Final Page

- After you have completed the RNI SmartForm, you will come to the Final Page. You can check your submission for errors using the validate and compare features at the top of the left navigator.
- After you have corrected any errors, you are now ready to finish the RNI SmartForm. You will notice that the RNI SmartForm now has a finish button. Click finish and exit the SmartForm.

The screenshot shows the "Final Page" of the RNI SmartForm. At the top left is the The Ohio State University logo and name, with the tagline "ENTERPRISE FOR RESEARCH, INNOVATION AND KNOWLEDGE". The user is identified as "Hello, Mary Kivel". A navigation bar includes "Validate" and "Compare" buttons. The main content area displays "You Are Here: An Open-Label Study of the Eff. > Consent issue (wrong version o...". Below this, it says "Editing: RNI0000094" and "Final Page". A message states: "You have reached the end of the IRB new information form. Read the next steps carefully." Two numbered instructions follow: "1. Click Finish to exit the form." and "2. Important! To send the new information for review, click Submit RNI on the next page." At the bottom right, there are three buttons: "Exit", "Save", and "Finish". A red circle with the number "2" is placed over the "Finish" button.

# RNI Workspace

Before entering the RNI in the RNI SmartForm, you were in the Study Workspace. After completing the RNI SmartForm, a new RNI Workspace has been created as a follow-on to the original study. You can use the breadcrumb trail at the top of the page to navigate back to the Study Workspace.

## Submit RNI

1. After exiting the RNI SmartForm, you are now in the RNI Workspace. Your RNI is completed, but not yet submitted. You will notice that the current status is “Pre-Submission.” Click on “Submit RNI” in the left navigator, and a pop-up window will appear.
2. You will now be back in the study workspace. The RNI submission is complete but has not yet been sent to the IRB. If you look at the workflow map, you can see that the RNI is still in pre-submission.

The screenshot shows the RNI Workspace interface. At the top, there are navigation tabs: Dashboard, IRB, and Settings. Below these are sub-tabs: Submissions, Meetings, Reports, Library, Help Center, and Central Actions. The main content area displays the RNI title: "RNI00000094: Consent issue (wrong version of consent used on 2/25/2025)". It also shows the reported by (Mary Kivel), submission type (Reportable New Information), IRB office (Office of Responsible Research Practices), and IRB coordinator. A workflow diagram shows the process from Pre-Submission to Review Complete, with intermediate steps like Pre-Review, IRB Review, Post-Review, and Review Complete, and sub-steps like Clarification Requested and Action Required. A red circle with the number '1' highlights the "Submit RNI" button in the left sidebar.

The screenshot shows the "Submit RNI" pop-up window. It contains the following text:

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 [HRP-103 -General: Investigator Manual](#)

A red circle with the number '2' highlights the "OK" button at the bottom right of the window.

- After you submit your RNI, you will see that your RNI submission has now moved to “Pre-Review.”

Dashboard | IRB | Settings

Submissions | Meetings | Reports | Library | Help Center | Central Actions

IRB > An Open-Label Study of the Efficacy of Re-Retreatments with Ritumimab > Consent issue (wrong version of consent used on 2/25/2025)

**Pre-Review**

Entered IRB: 3/8/2025 5:37 PM  
Last updated: 3/8/2025 5:37 PM

**Reported by:** Mary Kivel  
**Submission type:** Reportable New Information **3**

**IRB office:** Office of Responsible Research Practices  
**IRB coordinator:**

**Next Steps**

- View RNI
- Printer Version
- Manage Ancillary Reviews
- Manage Editors
- Add Related Submission
- Add Comment
- Copy Submission

**RNI00000094: Consent issue (wrong version of consent used on 2/25/2025)**

Workflow Diagram:

```

    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

Activity	Author	Activity Date
RNI Submitted	Kivel, Mary	3/8/2025 5:37 PM
Reportable Information Opened	Kivel, Mary	3/8/2025 5:31 PM