



Reportable New Information

Human Research Protection Program

(Last Updated: 12/14/2023)



This PowerPoint will guide you through how to submit Reportable New Information form in Huron.

Getting started

1. Navigate to the **IRB workspace**
2. Select **Submissions** tab
3. Select **All Submissions** tab
4. Note: **Filter by** allows you to sort through your studies by name, PI first and last name, and submission type.
5. Open your study by selecting the **folder symbol** or the **name** of the study.

The screenshot shows the IRB workspace interface. At the top, there is a navigation bar with tabs: Dashboard, Admin, COI, IRB (highlighted with a red box and callout 1), and Settings. Below this is a secondary navigation bar with options: Submissions (highlighted with a red box and callout 2), Meetings, Reports, Library, Institutional Profiles, Help Center, and Central Actions. The main content area is titled 'IRB' and contains a search bar (callout 3) and a filter bar (callout 4). The filter bar includes a 'Filter by' dropdown set to 'ID', a search input field, and buttons for '+ Add Filter' and 'x Clear All'. Below the filter bar is a table of studies. The first row is highlighted with a red box and callout 5, showing a folder icon, the ID 'STUDY2023-0039', the name 'New Study 9.19.2023', the date '12/14/2023 3:51 PM', a state toggle, and the PI names 'Denise' and 'Puga'.

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name
STUDY2023-0039	New Study 9.19.2023	12/14/2023 3:51 PM	<input type="checkbox"/>	Denise	Puga	



Reportable New Information

1. Select Reportable New Information

Approved

Entered IRB: 12/1/2022 11:25 AM
Initial approval: 12/1/2022
Initial effective: 12/1/2022
Effective: 12/9/2022
Approval end: 11/30/2023
Last updated: 4/6/2023 10:44 AM

Next Steps

View Study

Printer Version

Create Modification/CR

1

Report New Information



Reportable New Information

- When completing the **Reportable New Information** page:
 - All questions marked with a red asterisk (*) require a response.
- Complete the **Reportable New Information Page**
 - Note: If the original study is a multi-site study, the question, “Participating Sites” will appear for the user to choose any, if applicable, sites that the RNI pertains to.



Important additional guidance on how to complete the Reportable New Information form can be found on the next few slides.

The screenshot shows a web form titled "Creating New: IRB Submission" with a breadcrumb "You Are Here: Test > _IRBSubmission". The form is for "Reportable New Information" and includes the following sections:

- 1. RNI short title:** (uniquely identify this new information report) with a text input field.
- 2. * Date you became aware of the information:** with a date picker.
- 3. Identify the categories that represent the new information:** (check all that apply) with a table of categories and descriptions.

Name	Description
<input type="checkbox"/> Risk	Information that indicates a new or increased risk, or a safety issue. For example: <ul style="list-style-type: none">a. New information (e.g., an interim analysis, 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.b. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk.c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.d. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.e. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.f. Any changes significantly affecting the conduct of the research.
<input type="checkbox"/> Harm	Any harm experienced by a subject or other individual that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures. <ul style="list-style-type: none">a. A harm is "unexpected" when its specificity or severity is inconsistent with risk information previously approved by the IRB in terms of nature, se characteristics of the study population

At the bottom right, there are buttons for "Exit", "Save", and "Continue".



If revisions are required

If the study or consent requires revision, a separate modification request must be created and submitted for review. For example, if participant over-enrollment took place, a modification must be submitted to increase maximum participant enrollment.

Note: Instructions on how to submit a modification can be found [here](#).

The screenshot shows a mobile application interface for reporting information. The title bar is orange and says "Reportable Information". The form contains the following questions:

- 4. * Briefly describe the new information: [Text input field]
- 5. * Does this information indicate a new or increased risk, or safety issue? [Radio buttons for Yes/No, Clear link]
- 6. * Does this study need revision? [Radio buttons for Yes/No, Clear link]
- 7. * Does the consent need revision? [Radio buttons for Yes/No, Clear link]

A red-bordered box at the bottom contains an information icon and the text: "If revisions are required, describe them above and submit a study modification for review."

Link Related Studies

If the new information affects multiple studies, you may link other protocols to the Reportable New Information form. To do so:

1. Click the ellipsis [...], this will generate a list of all studies you are currently listed on.
2. Select the studies that are affected by the new information.
3. Select **OK**

8. Related studies and modifications:

... 1

ID	Short Title	Investigator	State	IRB Office
STUDY2023-0012	Test	Denise Puga	Approved	IRB 1 ✕

Select One or More IRB Submission Projects 2

Filter by ID Go Clear Advanced

Deselect All

Total Selected: 1 ⏪ 1-5 of 5 ⏩

ID	Name	Organization	PI first name	PI last name	IRB office
<input type="checkbox"/> STUDY2023-0025	adf	Vice President For Research	Jyothi	Naidu	IRB 1
<input type="checkbox"/> STUDY00000021	Scope	Vice President For Research	Jane	Seawright	IRB 1
<input type="checkbox"/> STUDY2023-0011	stage	Vice President For Research	Jane	Seawright	IRB 1
<input checked="" type="checkbox"/> STUDY2023-0012	Test	Vice President For Research	Denise	Puga	IRB 1
<input type="checkbox"/> STUDY00000010	Testing	Vice President For Research	Jane	Seawright	IRB 1

Total Selected: 1 ⏪ 1-5 of 5 ⏩

3 OK Cancel



Corrective and Preventive Action Plan

When a deviation from the IRB-approved protocol or an unanticipated problem has occurred in a study, it is the responsibility of the principal investigator to report the event to the IRB. In addition, steps must be taken to protect the welfare and safety of subjects, and ensure that the event does not reoccur in the future. When an unanticipated problem or noncompliance has occurred, it is important to develop a corrective and preventive action plan (CAPA) to protect study participants.

Action item:

- ▶ If you are reporting an instance of noncompliance or an unanticipated problem, please download and complete the CAPA template found [here](#) and attach it to your submission as a supporting document. Instructions on how to attach a supporting document in Huron can be found on the next page.
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How to attach Supporting Documents

Upload a written description of the reportable new event or any other supporting document that describes the event.

1. Click **+Add** in Question 9 of the Reportable New Information page
2. Click **Choose File** to locate the desired document from your desktop
3. Click **OK**

9. Attach files containing supporting information:

1 **+ Add** Drag and drop files to upload

Name

There are no items to display

Add Attachment 2

1. * File to attach:

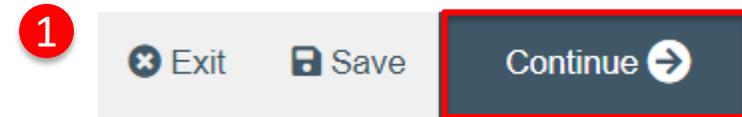
2. Name: (if not supplied, the file name will be shown) ?

3. Version number:



Submitting the Reportable New Information to the IRB

1. Click **Continue** to be directed to the **Final Page**
2. From the Final Page, click **Finish**
3. From the study workspace, click **Submit RNI**
4. Click **OK**



Edit RNI

Printer Version

