



eIRB

Researcher's Guide

January 2024 (implemented) / October 2022

Table of Contents

Navigation and Basic Tasks.....	3
Create and Submit a Study.....	6
Change Study Documents.....	9
Respond to a Clarification Request	10
Create and Submit a Continuing Review or Modification.....	11
Update Study Details for a Single-Site External Study	Error! Bookmark not defined.
Report CR Data for a Single-Site External Study.....	16
Create and Submit Reportable New Information	17
Checklist of Information to Attach	18
Search Your Solution.....	19

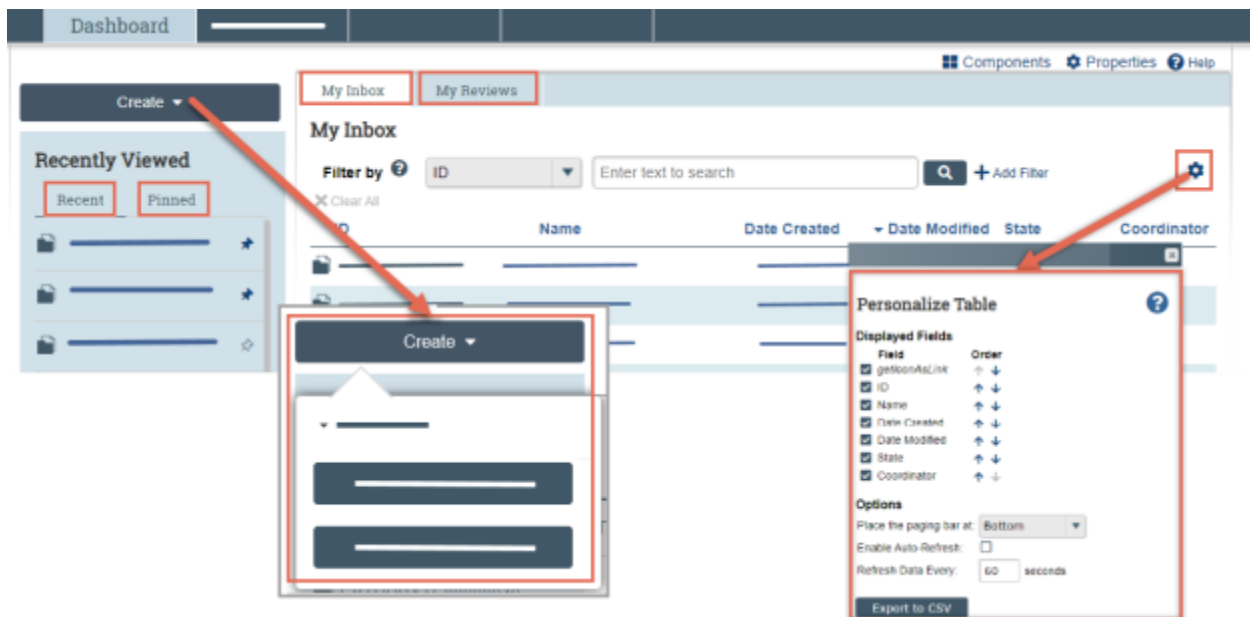
Navigation and Basic Tasks

When you first log in, you will be on on your Dashboard, which is the starting point for finding items and performing many basic tasks.

To find key items

From your Dashboard, you will see:

- **My Inbox:** Items that require you to take action.
- **My Reviews:** Items assigned to you to review. These are a subset of the items in My Inbox.
- **Create menu and buttons:** Actions you can perform. The menu will not show if you do not have access to any buttons.
- **Recently Viewed:**
 - **Recent:** The last several items you viewed. Scroll through this list to find an item you worked on recently.
 - **Pinned:** You can pin the items in Recently Viewed section for quick and easy access. This is where those pinned items are listed.
- **Personalize Table:** You can alter the tables displayed on the dashboard by using the Personalize Table gear icon.



To identify what action is needed

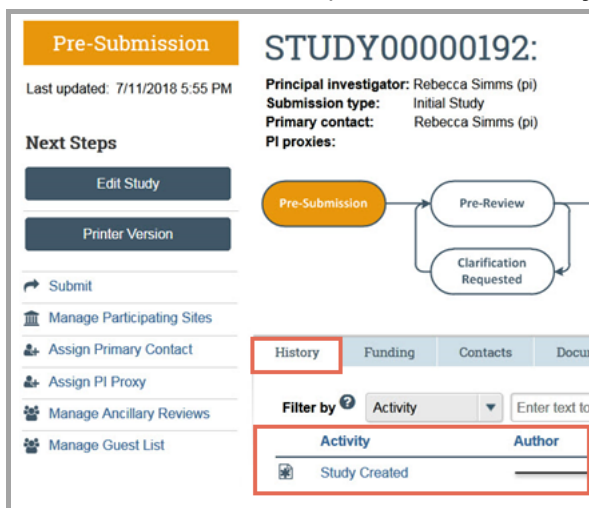
1. Review the state of submissions in My Inbox.
The state gives a clue as to what to do next. For example, "Pre-Submission" means you haven't submitted the study. You can open it, and then finish and submit it for review.

To open a submission

1. From My Inbox, or from the Submissions page, click the submission name.
2. The submission workspace opens.

To view history

1. From the submission workspace, click the **History** tab.






2. The history tab lists the activity taken on a submission including any comments, attachments, or correspondence added.

To find previous submissions

1. In the Top Navigator, click **IRB** and then **Submissions**.
2. Click the tab to see submissions you can access:
 - **In-Review:** Submissions undergoing IRB review.
 - **Active:** All approved submissions as well external IRB, non-human research, human research not engaged, lapsed, and suspended submissions.
 - **New Information Reports:** All Reportable New Information (RNI) submissions, in any state.
 - **External IRB:** All studies managed by an external IRB.
 - **Relying Sites:** All participating sites relying on the local IRB as the single IRB of record.

Click the ellipsis to see:

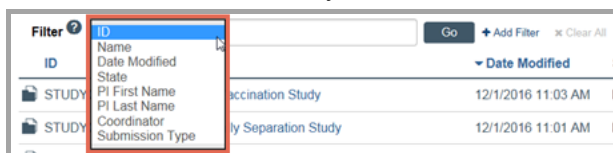
- **All Submissions:** All submissions, in any state.
- **Archived:** All closed, disapproved, discarded, and terminated submissions.

In-Review Active New Information Reports External IRB Relying Sites ...							
Filter by 							
ID	Enter text to search for  						
ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name	Coordinator Last Name
STUDY00000412	Endovascular vs Open Repair of Aneurysms	7/24/2018 7:31 AM	Clarification Requested (Pre-Review)	Rebecca	Simms (pi)	Orlando	Max (int)

To filter data

Many pages contain tables that you can filter to show specific data.

1. Select the column to filter by.



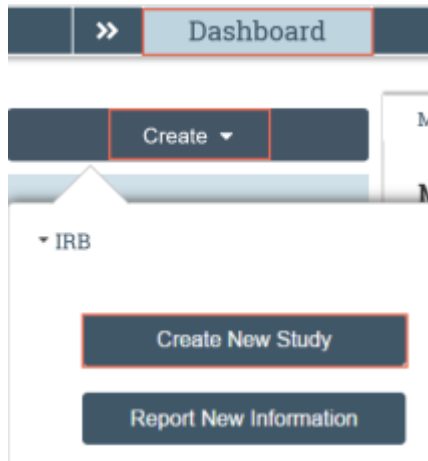
2. Type the beginning characters for the items you want to find. You can also type a % symbol as a wildcard before the characters. Examples:
 - 71 shows all items beginning with 71
 - %71 shows all items containing 71
3. Click Help for operators you can type in the text box.
4. Click **Go** to apply the filter.
5. To combine multiple filter criteria, click **Add Filter**.

Create and Submit a Study

Before you begin, gather files and information about your study. For more details on documents you may want to attach to a study, see the [Checklist of Information to Attach](#).

To create a study

1. From the Dashboard, click the **Create** menu and then select **Create New Study**.



2. Complete the pages. Click **Continue** to move to the next page.
3. Pay attention to the following pages:
 - a. **Basic Study Information:** use the following questions to indicate whether the study is a single - or multiple-site study or will be locally or externally reviewed.
What kind of study is this?
Will an external IRB act as the IRB of record for this study?
 - b. **Attach the protocol:** include the Sponsor Protocol (if applicable) and the DH Protocol.
 - c. **Local Study Team Members** - If you are adding study team members:
 - For those affiliated with DH, use the drop-down feature in the eIRB section Local Study Team Member, item 1, to add a study team member.
 - For those **NOT** affiliated with DH (including those who are affiliated with Dartmouth College or those who have a dual affiliation (DH and Dartmouth College but are working under their Dartmouth College affiliation for this study), use HRP-220 - FORM - Non-DH Study Staff Form and upload this form to Local Study Team Members, item 2 ("External team member information").
 - Non-DH Affiliates **DO NOT** need access to the eIRB system to be added as a study team member on a DH research study.
 - d. **Local Site Documents:** add consent forms, recruitment materials and other documents specific to your study at the DH site.
 - e. **Study-Related Documents:** if the study is a multi-site study, use this page to add templates for consent forms, recruitment materials, and other that participating sites will be using.

- f. **ALL STUDY DOCUMENTS SHOULD BE IN WORD.** Many features of the eIRB system do not function when Adobe pdf-version documents are uploaded.

4. On the final page, click **Finish**.

Important! Clicking **Finish** does not send the study to the IRB office. It remains in the Pre-Submission state. When the study is ready for IRB review, the PI or PI proxy must submit it using the steps that follow.

You are taken to the study workspace. You can continue to edit the study (Edit Study button) until you submit it.

Note! There are some additional steps needed before clicking "Submit"

- 1) All submissions must "Push to OnCore" **PRIOR** to being submitted to the IRB for review. This is an important step as the Clinical Trials Office (CTO) reviews the submission for any additional items that might be needed, for example, data use agreements, sponsor contract negotiation (which could include the subject injury language to include in the informed consent form document, among others).
- 2) All IRB submissions that involve data from DH records must adhere to the following process: Check out the Research Data Handbook (https://synergy.dartmouth.edu/wp-content/uploads/2023/11/Research-Data-Handbook_v1.5_2023-10-28.pdf) and then, complete the Research Data Request Form (https://synergy.dartmouth.edu/wp-content/uploads/2023/11/DH_Research_Data_Request-Form_2023-11-091.docx)

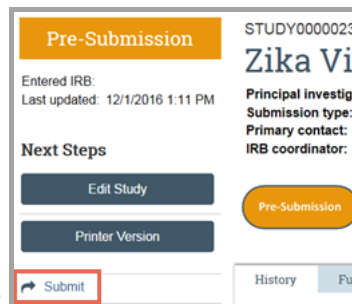
Know that if you are accessing certain types of data or there are other concerns, additional review will be required. Please refer to the [Research Data Handbook](#) for more information.

Once this has been done, make any necessary revisions to your IRB submission and append the Research Data Request Form to your submission.

Depending on the nature of your research, there may be additional review required by other DH offices.

To submit a study for review

Tip: Only the study's PI or an assigned PI proxy can submit it for review.



1. From the study workspace, click **Submit**.
2. Click **OK** to agree to the terms.
3. Type your login credentials and click **Submit**.

Your study has been submitted and has moved to the Pre-Review state. You can log off the system.

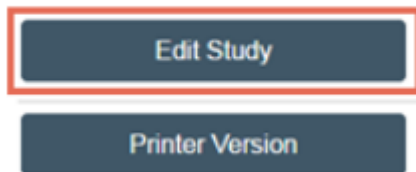
Change Study Documents

You can update your study documents any time **prior to submitting the study** to the IRB for review. Once it is in the review process, you can only update documents if the IRB coordinator or a committee member requests clarification, or if you are submitting a modification to the study.

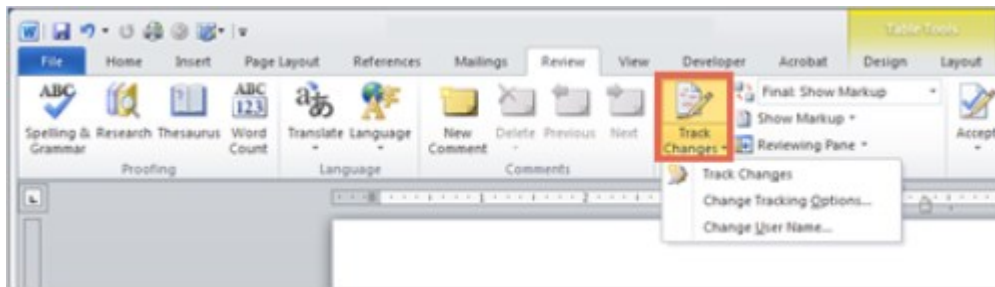
To change study documents

1. From My Inbox, open the study you want to edit.
If the study is not in your inbox, contact the IRB coordinator assigned to your study.
2. From the submission workspace, click **Edit Study**.

Next Steps



3. Add and update documents on study pages as needed and exit the study when done.
 - a. **Important!** When updating a document previously submitted to the IRB, revise it using Word's Track Changes feature and then replace the original document with the tracked-changes version. When the IRB finalizes documents on approved studies, all tracked changes will be accepted and comments removed.
 - b. If a study document is being updated, **do not add another new version**. Instead, **replace** the previous version with the new version.



If responding to a clarification request, see Respond to Clarification Requests see [Respond to Clarification Requests](#) to submit the changes back to the IRB.

Respond to a Clarification Request

If a reviewer has questions or requires you to change your submission, you will receive an email indicating this.

Review the request details and then respond to the request.

To review the request details

1. Click the submission ID link in the email to open it.
If you no longer have the email, see [Open a Submission](#) and then [View History](#) to see reviewer comments.

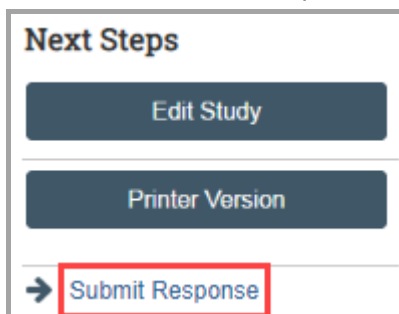


2. Click the **History** tab and review the Clarification Requested activity.
Note: If the reviewer attached a document, a link to open it appears on the History tab.



To submit response

1. On the submission workspace, click **Submit Response**.



2. In the Notes box, explain your response to the reviewer.

Note: If you responded to the reviewer's request in a document, you can add the document in the Supporting documents area.

3. Click **OK**.
4. Type your login credentials and click **Submit**.

You can log off the system. The study has moved back to the reviewer's inbox to continue the review.

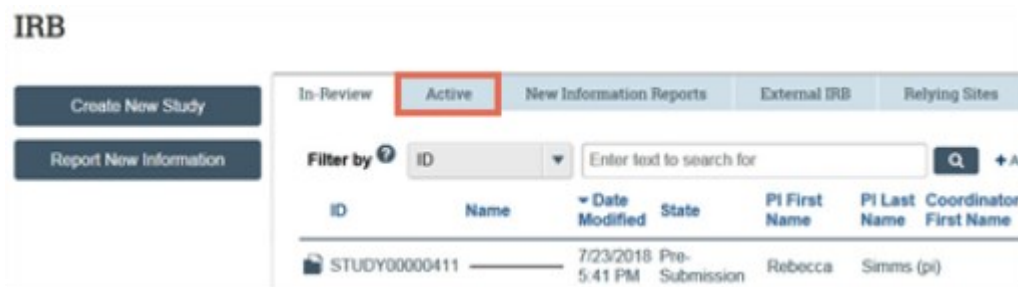
Create and Submit a Continuing Review or Modification

You can submit a Continuing Review (CR), a modification, or both combined:

- To close a study or extend your approval period, submit a CR.
- To change an approved study or the study team's members, submit a modification.

To create a CR or modification

1. In the Top Navigator, click **IRB** and then **Submissions**.
2. On the IRB page, click the **Active** tab and open the approved study.



3. Click the **Create Modification/CR** button.



4. Select whether the submission is a CR, a modification, or a combination.
5. Pay attention to the following question:
Modification scope:

- To make changes to any part of the study except for study team members, select **Other parts of the study**.
 - Also use the **Other parts of the study** modification type when changing the PI. Please be sure to revise any study documents that may list the PI by name and these will need to be revised.
- To make changes (add or remove) a study team member, choose **Study team member information**.
 - **Important!** If you are adding study team members:
 - For those affiliated with DH, use the drop-down feature in the eIRB section Local Study Team Member, item 1, to add a study team member.
 - For those **NOT** affiliated with DH (including those who are affiliated with Dartmouth College or those who have a dual affiliation (DH and Dartmouth College but are working under their Dartmouth College affiliation for this study), use HRP-220 - FORM - Non-DH Study Staff Form and upload this form to Local Study Team Members, item 2 ("External team member information").
 - Non-DH Affiliates **DO NOT** need access to the eIRB system to be added as a study team member on a DH research study.
- 6. Include a comprehensive explanation for **WHY** the modification is being submitted, for example, if submitting a new recruitment flyer, explain that the study needs to recruit more participants. If changes are being made to the study's informed consent form (ICF), explain that there was a change in drug risk and the ICF needs to be revised.
- 7. Complete the pages. Click **Continue** to move through the pages and **Finish** on the last page.
- 8. From the workspace, click **Submit**.
- 9. Click **OK** to agree to the terms.
- 10. Type your login credentials and click **Submit**.

You can log off the system. Your modification or CR has been submitted.

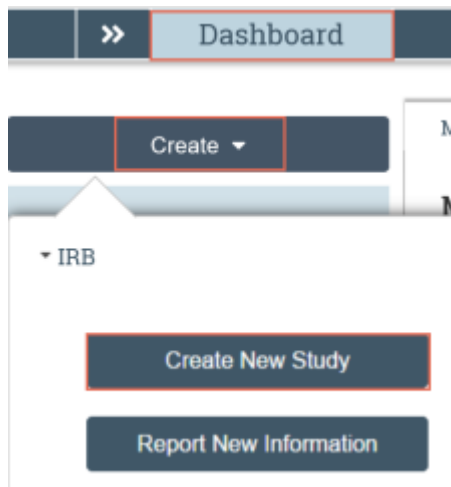
To find your modifications and CRs, go to the Submissions page (In the Top Navigator, click IRB and then Submissions), and then the Follow-On Submissions tab.

Create and Submit a New Single-Site External Study (when another IRB is providing review for the DH site)

External IRB study forms require less information than normal, but do require information about the external IRB.

To create an external single-site study

1. From the Dashboard, click the **Create** menu and then select **Create New Study**.



2. Complete the pages. Click **Continue** to move to the next page.
3. Pay attention to the following pages:
 - a. **Basic Study Information:** use the following questions to indicate whether the study is a single-site and that an external IRB will act as the IRB of record.
What kind of study is this?
Will an external IRB act as the IRB of record for this study?
 - b. **External IRB:** Specify which institution will serve as the external IRB. If the External IRB that you wish to use does not auto-populate in the text box, contact the DH IRB office -> irb@Hitchcock.org
 - c. Please refer to the Investigator Manual (HRP-103) for additional information on how to submit a study for External IRB review.
4. On the final page, click **Finish**.

You are taken to the study workspace. You can continue to edit the study (Edit Study button) until you submit it.

Note! There are some additional steps needed before clicking "Submit"

- 1) All submissions must "Push to OnCore" **PRIOR** to being submitted to the IRB for review. This is an important step as the Clinical Trials Office (CTO) reviews the submission for any additional items that might be needed, for example, data use agreements, sponsor contract negotiation (which could include the subject injury language to include in the informed consent form document, among others).

- 2) All IRB submissions that involve data from DH records must adhere to the following process: Check out the Research Data Handbook (https://synergy.dartmouth.edu/wp-content/uploads/2023/11/Research-Data-Handbook_v1.5_2023-10-28.pdf) and then, complete the Research Data Request Form (https://synergy.dartmouth.edu/wp-content/uploads/2023/11/DH_Research_Data_Request-Form_2023-11-091.docx)

Know that if you are accessing certain types of data or there are other concerns, additional review will be required. Please refer to the [Research Data Handbook](#) for more information.

Once this has been done, make any necessary revisions to your IRB submission and append the Research Data Request Form to your submission.

Depending on the nature of your research, there may be additional review required by other DH offices.

To submit the external study for review

1. From the study workspace, click **Submit**.

The screenshot shows the 'Pre-Submission' study workspace. On the left, under 'Next Steps', there are buttons for 'Edit Study', 'Printer Version', and 'Submit' (which is highlighted with a red box). Below these are links for 'Assign Primary Contact' and 'Assign PI Proxy'. The main content area shows study details for 'STUDY00000350: Zi'. It lists the Principal investigator as Rebecca Simms (pi), Submission type as Initial Study, Primary contact as Rebecca Simms (pi), and PI proxies. A workflow diagram shows the process: Pre-Submission (orange oval) leads to Pre-Review (white oval), which leads to Clarification Requested (white oval), which loops back to Pre-Review. At the bottom, there are tabs for History, Funding, Contacts, and Documents.

2. Click **OK** to agree to the terms.
3. Type your login credentials and click **Submit**.

You can log off the system. Your study has been submitted.

Modification of an External IRB Study

There are two activities that can be used to modify an External IRB study:

- (1) **Create Site Modification:** Create Site Modification allows the PI to edit only site (DH) information. The PI can select to modify either Study Team Members, or Other Parts of the Study.
 - a. If Study Team Members is selected – The DH IRB either accepts the site updates, or requests a pre-review clarification. The site update does not go through sIRB review as it is only a local (DH) review.
 - b. If Other Parts of the Study is selected – The DH IRB either accepts the site updates, or request a pre-review clarification.
- (2) **Update Study Details:** Update Study Details allows the PI to edit only the **overall** study information. This will include updates to funding, study scope, or study related documents and template.

Whatever you do, **DO NOT** finalize study updates. This makes it challenging for the IRB staff to see what changed and also changes our review process. However, feel free to leave a comment for us so that we know that it was submitted!

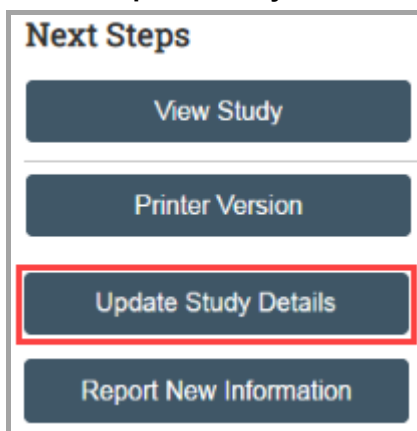
Things to keep in mind for a successful modification of your External IRB study:

1. In the Modification Summary, provide a description of **WHY** the change is occurring. The eIRB system will let us know what has changed. What we don't know is **WHY** the change is occurring.
2. **Replace** older versions of the same document with the latest version. Don't just add more documents. The eIRB system is a great document management system. When you receive a new IB, for example, replace the previous one with the most recent version. The system will keep track – just click on “history” (found to the right of the document name).
 - a. Again, Word documents work best in the eIRB system.
3. As soon as you receive a change from the Sponsor or Reviewing IRB, create a modification in eIRB. When multiple Reviewing IRB updates are submitted in one modification, it is challenging for IRB staff to ascertain what is still active, what has been superseded, as well as which consent forms are the most recent.
 - a. For all studies, **with the exception of studies reviewed by the NCI CIRB**, the DH study team may not implement the modification at the DH site until the DH IRB has reviewed the modification.

To update study details for an external study

1. In the Top Navigator, click **IRB** and then **Submissions**.
2. Click the **External IRB** tab and open the study.

Note: The active external studies are in the External IRB state.
3. Click the **Update Study Details** button.



4. Summarize the updates, click **Continue**, then make changes to the study.

Important! The eIRB system will not permit the study team to finalize the updates yourself, according to this institution's policies. Follow these steps instead:

5. Click **Add Comment**.
6. In the **Comment** box, ask the IRB office to finalize the updates.
7. Select the **IRB Coordinator** checkbox to send a notification to them.
8. Click **OK**.

You can log off the system.

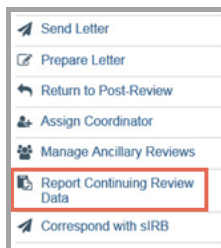
To find your External Update, go to the Submissions page (in the Top Navigator, click IRB and then Submissions), and then click the External IRB tab. You can also find the External Update by clicking the Follow-on Submissions tab in the study's workspace.

Report CR Data for a Single-Site External Study (when another IRB is providing review for the DH site)

The local PI, PI proxies, and local IRB coordinator can report continuing review data for a single-site external study, so ask the IRB coordinator for help if the need arises.

To report continuing review data for an external study

1. In the Top Navigator, click **IRB** and then **Submissions**.
2. Click the **External IRB** tab and open the study.
Note: The active external studies are in the External IRB state.
3. Click **Report Continuing Review Data**.



4. Complete the Report Continuing Review Data activity.
5. In **Supporting Documents**, be sure to include HRP-509 - TEMPLATE - Continuing Review Supplement, if any boxes were left unchecked in the eIRB SmartForm. By uploading this form, you will provide the IRB with additional information about the study.
6. Click **OK**.

You can log off the system. Your information has been saved.

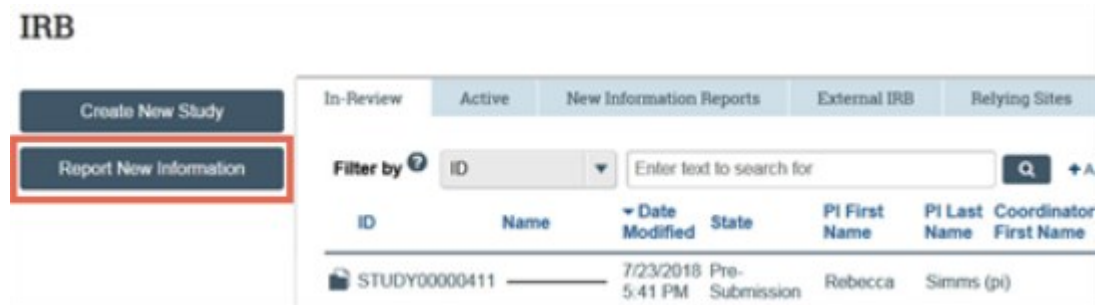
Create and Submit Reportable New Information

You can report any adverse events or new information about a study as soon as you become aware of it.

To create reportable new information (RNI)

1. In the Top Navigator, click **IRB** and then **Submissions**.
2. Click the **Report New Information** button.

Note: You can also open an active study and report new information from the study workspace.



3. Complete the Reportable New Information page. Pay attention to the following question:
 - **Related studies and modifications:** Select any studies or modifications that the RNI applies to.

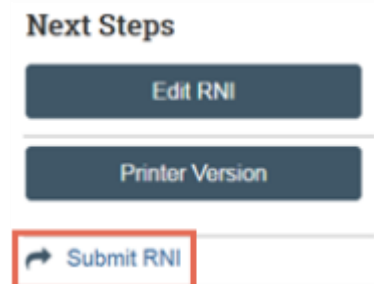
Notes:

- To relate a modification to the RNI, first add the parent study. You cannot relate sites, external studies (unless the external study is part of a multi-site study), or other follow-on submissions to an RNI.
- 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 new information, submit it for review, and submit a response to a clarification request.

4. Click **Continue**.
5. If applicable, select the IRB office and then click **Finish**.

To submit an RNI

1. From the RNI workspace, click **Submit RNI**.



2. Click **OK** to agree to the terms.

3. Type your login credentials and click **Submit**.

You can log off the system. The RNI has been submitted to the IRB. After reviewing the RNI, the IRB may require specific actions be taken and assign a responsible party to do so.

Checklist of Information to Attach

While editing the study, several forms provide places to attach related files. In some cases, a template file is provided directly on the form for download, such as the protocol.

When attaching each file, name it as you want it to appear on the IRB approval letter.

Attach the information listed below (if relevant to your study) to the location identified.

Protocol: (Basic Information page)

- Investigator protocol
- Complete sponsor protocol
- Site supplement to sponsor protocol

Funding information: (Funding Sources page, with each source)

- Grant applications

Drug details: (Drugs page, with each drug, or on main **Drugs page if not specific to one drug)**

- Package insert
- Investigator brochure
- Verification of each IND number (one of these):
 - Sponsor protocol with the IND number
 - Communication from the FDA or sponsor with the IND number

Device details: (Devices page, with each device, or on main **Devices page if not specific to one device)**

- Product labeling/device instructions
- Investigator brochure
- Verification of each IDE or HDE number (one of these):
 - Sponsor protocol with the IDE / HDE number
 - Communication from the FDA or sponsor with the IDE / HDE number

Recruitment and consent details: (Local Site Documents page)

- Consent documents:
 - Consent forms
 - For non-written consent, a script of the information provided orally to the subjects
- All material to be seen or heard by subjects, such as:
 - Evaluation instruments and surveys
 - Advertisements, including printed, audio, and video

- Recruitment materials and scripts
- Foreign-language versions of materials for subjects
- Supporting document and other attachments:
 - Conflict of Interest Committee's determination for each financial interest related to the research
 - Completed checklist of meeting Department of Energy requirements

All other relevant documents: (Study-Related Documents page)

- Consent document templates for use by participating sites
- Recruitment materials templates for use by participating sites
- Other supporting documents needed by participating sites

Search Your Solution

To help you work more efficiently, you can use search to locate a wide range of information in your solution. You can search for project data, documents, or content from specific pages on your site. The search results appear in a secondary window and display only those items you have permission to view. Results are ranked to show items where the search term is most prevalent at the top.

After your initial search, you can further refine results using the following filter options:


- **Projects**— Projects are the day-to-day items you use to manage your research in a Huron solution. They include items such as funding proposals, studies, protocols, agreements, and disclosures. You can search for any project in your solution using properties on the project, including its name, ID, and description. Depending on the solution, other properties are also available to search. When you select the Projects filter, the system will only display results that match search criteria in your project data.
- **Documents**— Documents are third-party files uploaded to your solution outside the context of a project. When you select the Documents filter, the system will only display results that match search criteria from documents. The search includes metadata on a document, such as its name and description. It also includes the contents of a document. From the results, you can click directly on the provided link to open a document.
- **Pages**— Pages organize information on your site into a hierarchy that you can use to view and manage your work. The Pages filter provides a way for you to search one type of page within your solution - content pages. Content pages are presented outside the context of a project. They supply supporting information for your solution, such as the Help Center, Reports, and Meetings. Dashboards and project workspaces are not included with this filter.

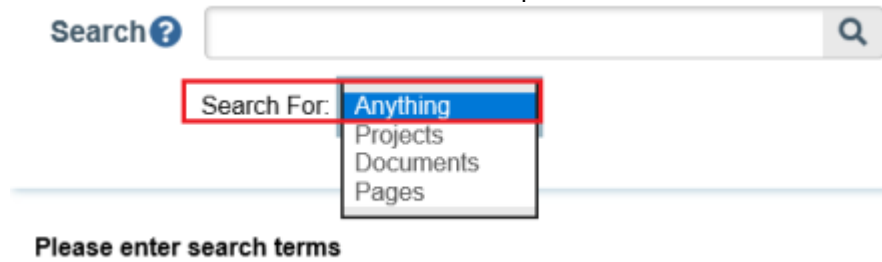
Note: Content on the site is updated periodically. If you are searching for something you just added, results might not be available immediately. Try your search again at another time.

To search your solution

1. In the Top Navigator, click **IRB**.
2. In the **Search** box, type your search criteria. You can use the following operators:
 - **And:** Finds all the specified words.
 - **Or:** Finds at least one of the specified words.
 - **Not:** Excludes the specified word. You cannot start a search with the Not operator.

- **Quotation marks:** Finds the exact phrase.

3. Press Enter or click the search icon  to perform the search.



The search results appear.

4. Click the **Search For** arrow to apply filter of your choice.

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