



PACS IRB
Researcher's Guide

February 2025

Table of Contents

Navigation and Basic Tasks.....	3
Create and Submit a Study.....	6
Create and Submit a New Single-Site External Study	7
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	12
Report CR Data for a Single-Site External Study.....	13
Create and Submit Reportable New Information	14
Checklist of Information to Attach	15
Search Your Solution.....	16

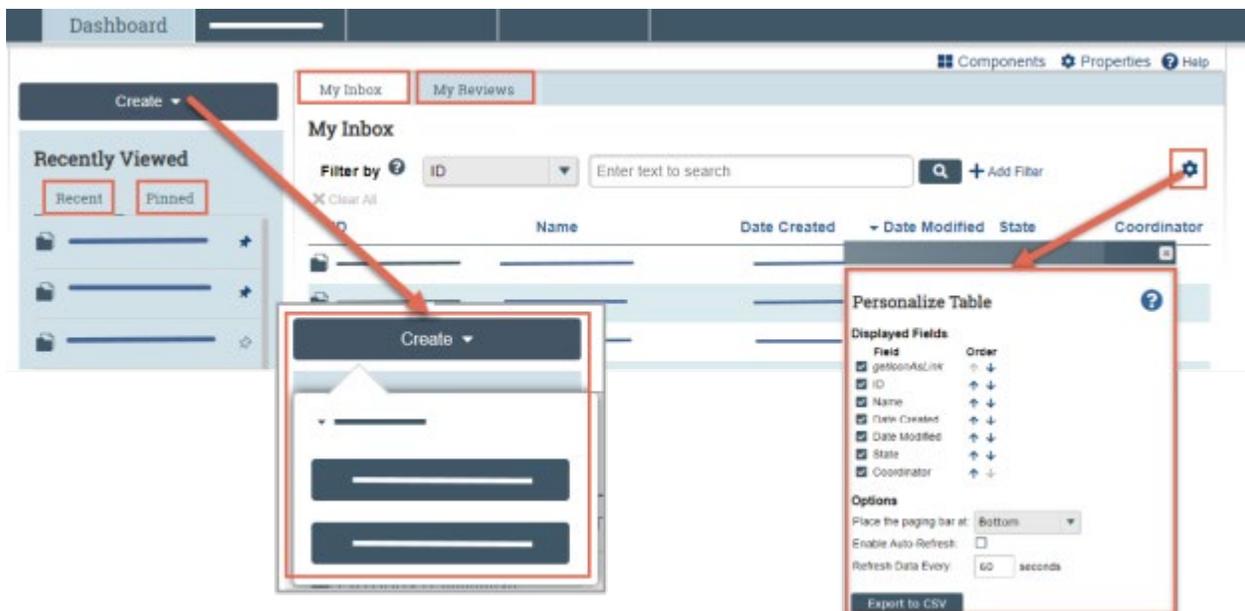
Navigation and Basic Tasks

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

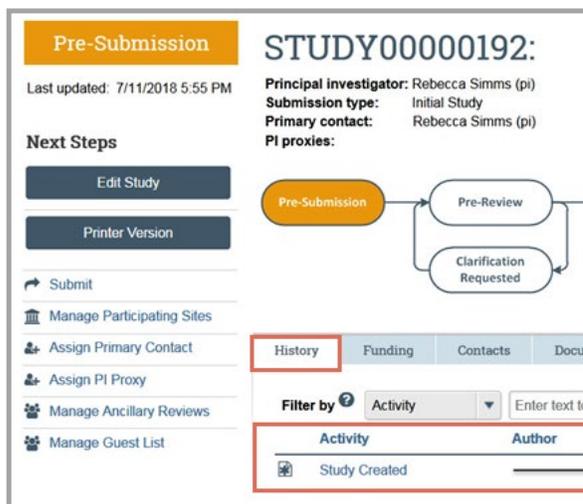
1. Review the state of submissions in My Inbox.
The state gives a clue as to what to do next. For example, "Pre-Submission" means you haven't submitted the study. You can open it, and then finish and submit it for review.

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:

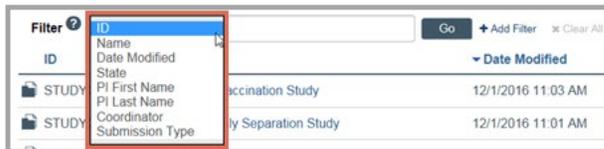
- **All Submissions:** All submissions, in any state.
- **Archived:** All closed, disapproved, discarded, and terminated submissions.

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 (irt)

To filter data

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

1. Select the column to filter by.



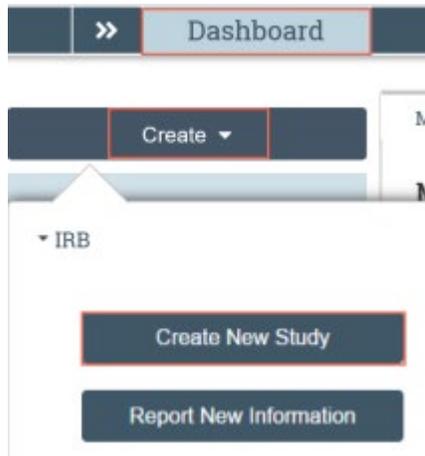
2. Type the beginning characters for the items you want to find. You can also type a % symbol as a wildcard before the characters. Examples:
 - 71 shows all items beginning with 71
 - %71 shows all items containing 71
3. Click Help for operators you can type in the text box.
4. Click **Go** to apply 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?

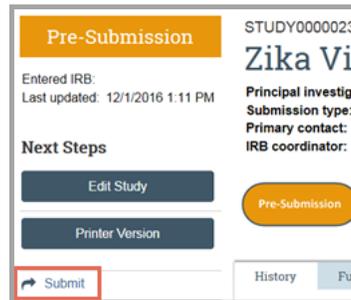
Will an external IRB act as the IRB of record for this study?
 - b. **Attach the protocol:** the study protocol is the only mandatory document to include.
 - c. **Local Site Documents:** add consent forms, recruitment materials and other documents specific to your study.
 - d. **Study-Related Documents:** if the study is a multi-site study for which you are serving as the sIRB, use this page to add templates for consent forms, recruitment materials, and other that participating sites will need to access.
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.

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**.

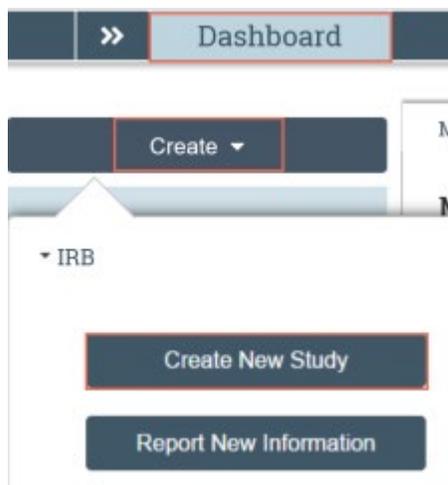
Your study has been submitted and has moved to the Pre-Review state. You can log off the system.

Create and Submit a New Single-Site External Study

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 (Externally reviewed MSS are covered in the IRB Multi-Site Study Guide.)

What kind of study is this?

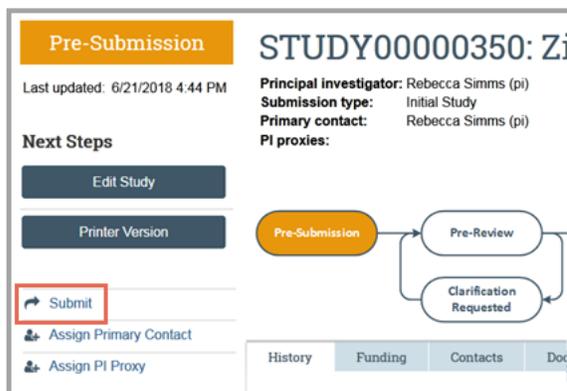
Will an external IRB act as the IRB of record for this study?

- b. **External IRB:** Specify which institution will serve as the external IRB.
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.

To submit the external study 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**.

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

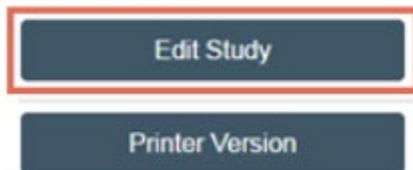
Change Study Documents

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.

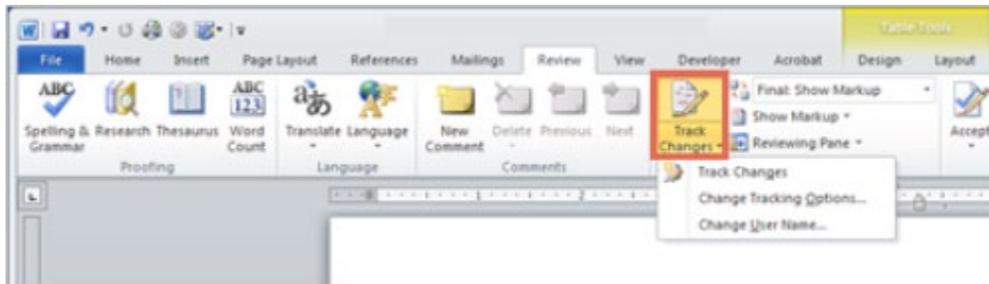
To change study documents

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. 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.



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.

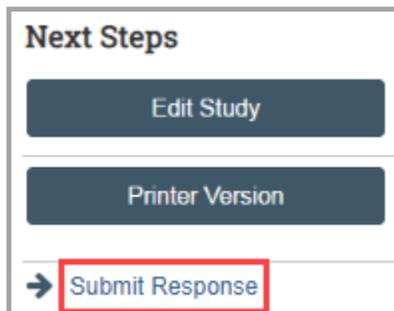


2. Click the **History** tab and review the Clarification Requested activity.
Note: If the reviewer attached a document, a link to open it appears on the History tab.



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.

IRB

The screenshot shows the IRB Submissions interface. On the left, there are two buttons: 'Create New Study' and 'Report New Information'. The main area has a navigation bar with tabs: 'In-Review', 'Active' (highlighted with a red box), 'New Information Reports', 'External IRB', and 'Relying Sites'. Below the tabs is a 'Filter by' dropdown set to 'ID' and a search box with the text 'Enter text to search for'. A table below shows a list of submissions with columns: ID, Name, Date Modified, State, PI First Name, PI Last Name, and Coordinator First Name. One submission is visible with ID 'STUDY00000411', Date Modified '7/23/2018 5:41 PM', State 'Pre-Submission', PI First Name 'Rebecca', PI Last Name 'Simms', and Coordinator First Name '(pi)'. The 'Active' tab and the 'Create Modification/CR' button in the next screenshot are highlighted with red boxes.

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

Next Steps

The screenshot shows the 'Next Steps' section with four buttons: 'View Study', 'Printer Version', 'Create Modification/CR' (highlighted with a red box), and 'Report New Information'.

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**.

6. Complete the pages. Click **Continue** to move through the pages and **Finish** on the last page.
7. From the workspace, click **Submit**.
8. Click **OK** to agree to the terms.
9. Type your login credentials and click **Submit**.

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

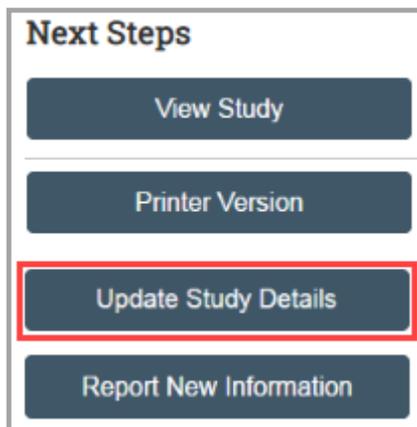
To find your modifications and CRs, go to the Submissions page (In the Top Navigator, click IRB and then Submissions), and then the Follow-On Submissions tab.

Update Study Details for a Single-Site External Study

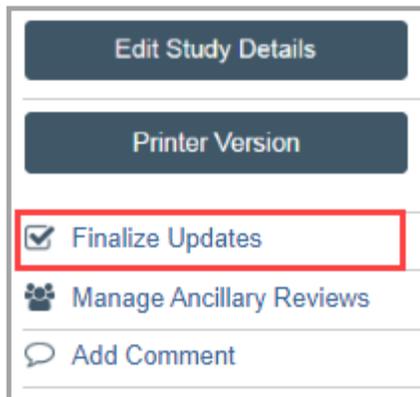
Use Update Study Details to make changes to an approved, single-site external study based on what the external IRB approved. The resulting External Update will be found in the study's Follow-on Submissions tab.

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.
5. From the study workspace, click **Finalize Updates** if it is available. If it is not, skip to the Tip box below.



6. Click **OK** to agree to the terms.
7. Type your login credentials and click **Submit**.
Your updated study details have been submitted.

Tip: You might not be able to finalize the updates yourself, depending on your institution's policies. If Finalize Updates is **not** available, follow these steps instead:

1. Click **Add Comment**.
2. In the **Comment** box, ask the IRB office to finalize the updates.
3. Select the **IRB Coordinator** checkbox to send a notification to them.
4. Click **OK**.

You can log off the system.

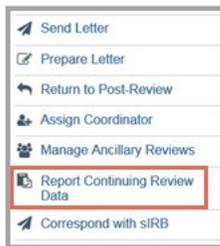
To find your External Update, go to the Submissions page (in the Top Navigator, click IRB and then Submissions), and then click the External IRB tab. You can also find the External Update by clicking the Follow-on Submissions tab in the study's workspace.

Report CR Data for a Single-Site External Study

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 an explanation for each item left unchecked in question 2 of the Report Continuing Review Data page.
6. Click **OK**.

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

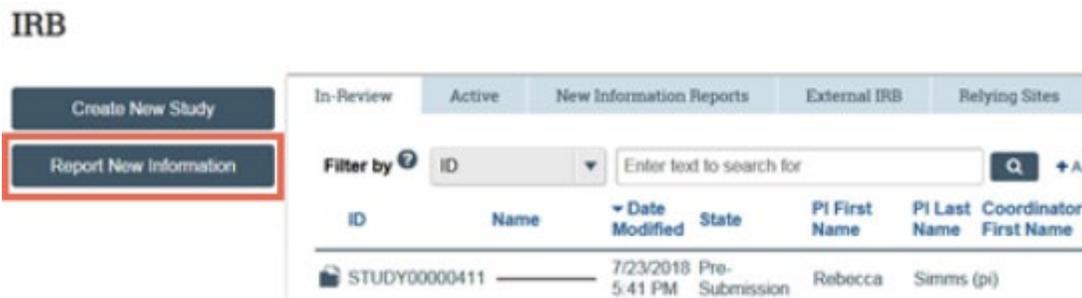
Create and Submit Reportable New Information

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 external RNI, the IRB system generates and displays the correspondence letter. You can download letter under the **IRB Review** tab in the IRB Exchange UI and under the **Participating Site** tab in the RNI summary section. 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
- HHS (Department of Health and Human Services) 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
 - HHS-approved consent document
 - 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:

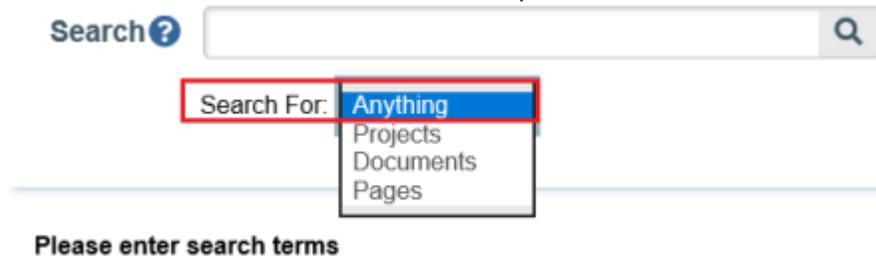
- **Projects**— Projects are the day-to-day items you use to manage your research in a Huron solution. They include items such as funding proposals, studies, protocols, agreements, and disclosures. You can search for any project in your solution using properties on the project, including its name, ID, 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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