ZOT IRB

Reviewer's Guide

October 2022

Table of Contents

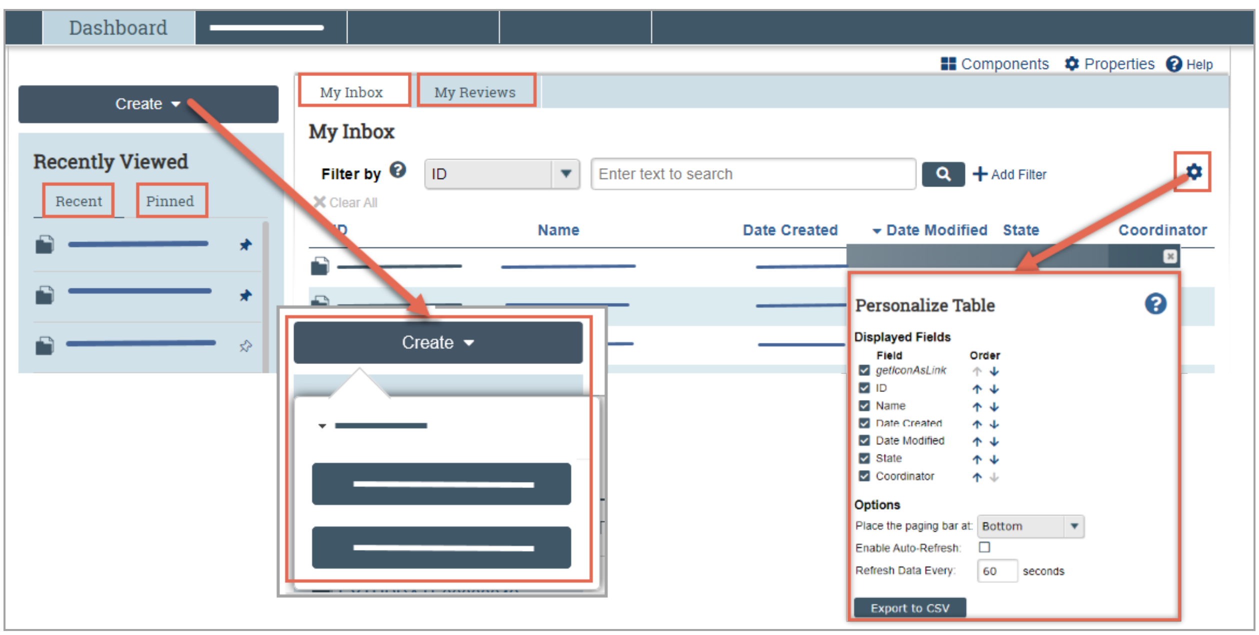
Navigation and Basic Tasks

When you first log in, you will be 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

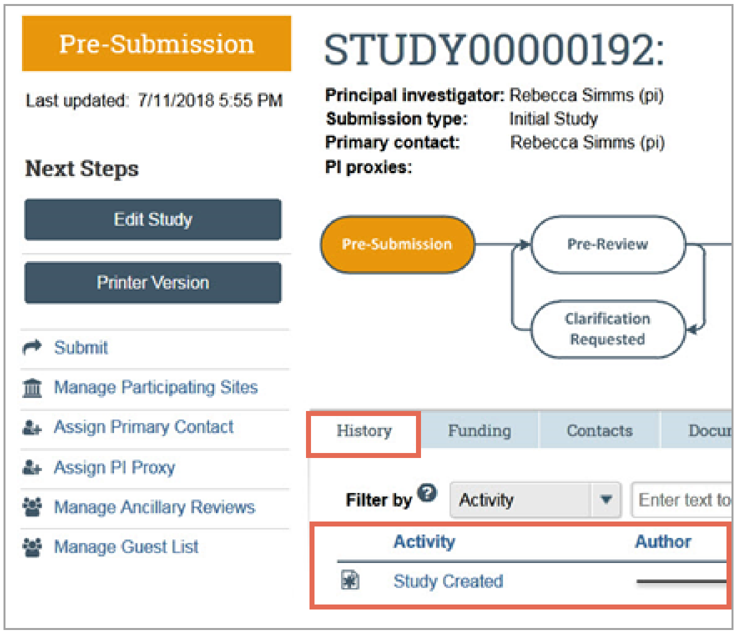
1. Review the state of submissions in My Inbox.
   The state gives a clue as to what to do next. For example, Committee Review means a study is scheduled or in-review by an IRB committee.

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.

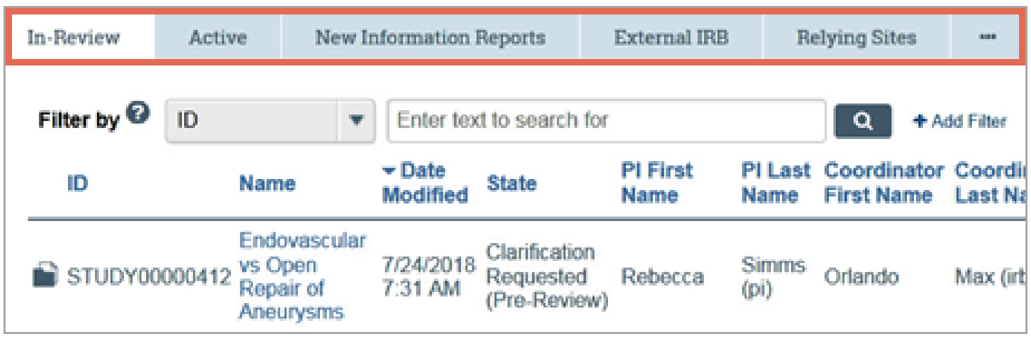


2. The history tab lists the activity taken on a submission including any comments, attachments, or correspondence added.

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.

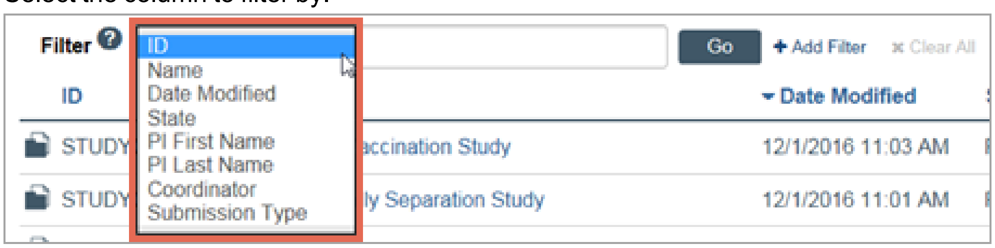
   Click the ellipsis to see:
   - **All Submissions:** All submissions, in any state.
   - **Archived:** All closed, disapproved, discarded, and terminated submissions.



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**.

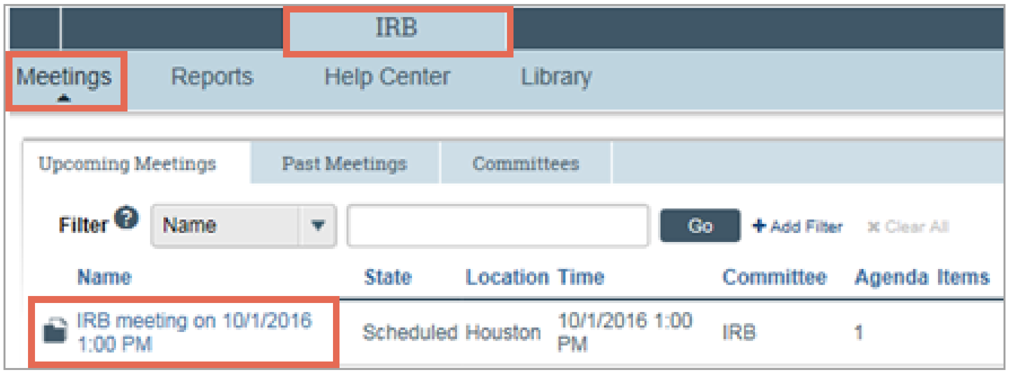
Find Important Documents

If you are an IRB committee member or reviewer, you may want to access meeting agendas, worksheets, or checklists.

To locate meeting agendas

As a committee member, you can access a meeting agenda from the agenda notification email or by navigating to it in the IRB system.

1. In the Top Navigator, click **IRB** and then **Meetings**.



2. From the list of meetings, click the name of the meeting.
   The meeting workspace displays the list of agenda items.
3. Click the agenda link for a printable agenda document.

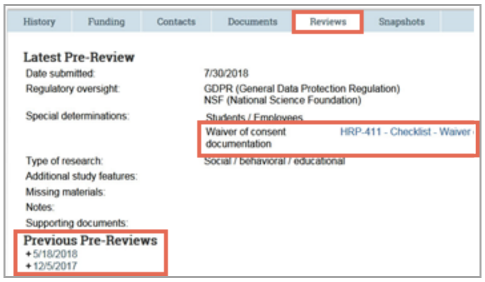
To locate reviewer checklists and worksheets

Several worksheets and checklists are provided in the system.

Note: Worksheets are for the reviewer's benefit only, but checklists must be completed and attached when submitting review comments.

Checklists uploaded by an IRB coordinator will be most relevant to your review. To find them:

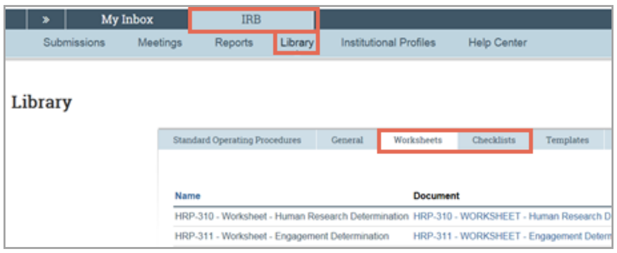
1. In the study workspace, click the **Reviews** tab.



2. Under Latest Pre-Review, click the link to download checklists relevant to your review.
3. Click to see previous reviews.

You can also find a list of all worksheets and checklists in the IRB Library.

1. In the top navigator, click **IRB** and then **Library**.



2. Click the **Worksheets** or **Checklists** tab, depending on the document you want to view.
3. Click a link to open or save the applicable document, which is in Microsoft Word format.

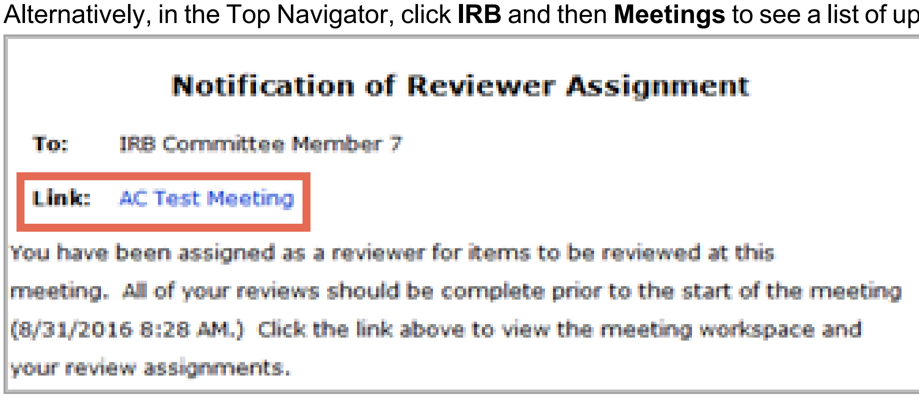
Open the Submission

You will receive an email when a study, site, or follow-on submission has been assigned to you to review and the submission will appear in your IRB inbox. As part of your review, you will want to access the necessary review checklists and worksheets, and the submission pages. Review comments and related files are not visible to study team members.

To open the submission (committee reviewer)

As a committee member, you can access a meeting agenda from the agenda notification email or by navigating to it in the IRB system.

1. Click the meeting link in your email to open it.
   Alternatively, in the Top Navigator, click **IRB** and then **Meetings** to see a list of upcoming meetings.

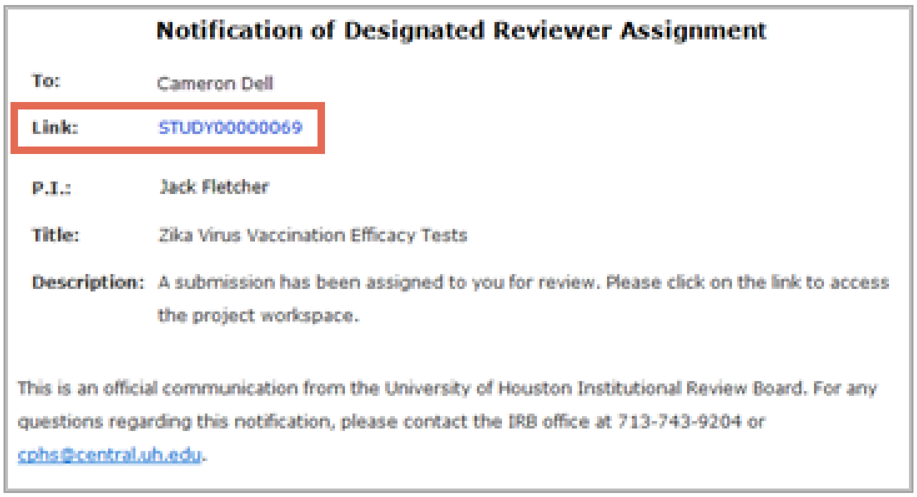


2. In the meeting workspace, you will see a list of all the protocols that are on the meeting agenda.

3. Click the agenda link for a printable agenda document.

To open the submission (designated reviewer)

1. Click the submission ID link in your email to open it.
   If you no longer have the email, see Open a Submission Open a Submission and then View History View History.



2. On the **History** tab, read any Assigned to Designated Reviewer comments.

Review a Submission

You will receive an email when a study, site, or follow-on submission has been assigned to you to review and the submission will appear in your IRB inbox. As part of your review, you will want to access the necessary review checklists and worksheets, and the submission pages. Review comments and related files are not visible to study team members.

To review the submission pages

Review the submission and attached documents using the following tools:

1. Click **Review Study** and review each section. You can scroll through the submission or use the Left Navigator to jump to specific sections of the form.

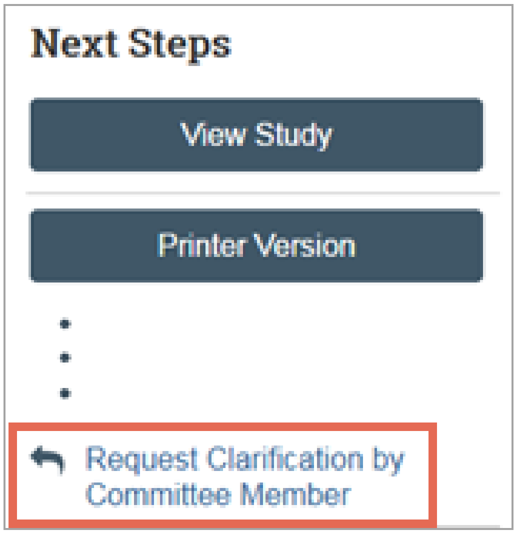
2. To see what changed between this and a previous version, look in the Compare section of the Left Navigator.
3. After reviewing each section, select the check-box at the bottom to indicate you have reviewed it.
4. The section turns green, and a green check mark appears in the Left Navigator.
5. If the submission is edited later, the green check mark is removed and a pencil icon is added, indicating to review that section again.
   Note: This **Review Tracker** feature does not stop a submission from moving forward in the review process.
6. Click the **Reviews** tab to access reviews completed by other committee members or reviewers.

Request Clarification

If you have questions for the study team or require they make a change to the submission, use the request clarification feature to communicate back and forth with the team. When all questions have been answered or changes made, you can submit your review.

To request clarification

1. From the submission workspace, click **Request Clarification by…**



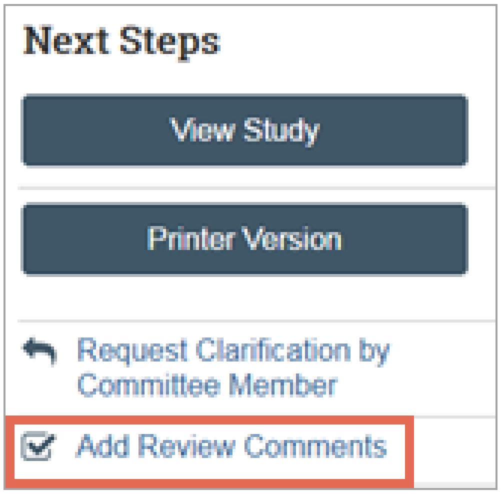
2. Type your clarification request.
3. Click **OK**.
   The PI will receive an email about your request.

Prepare Review Comments for a Committee Meeting

If the committee plans to review a study, site, or follow-on submission, then you may want to record your review comments in the IRB system for other committee members to view before and during the meeting. Review comments and related files are not visible to study team members and are purged from the system when the approval letter is sent.

To add review comments

1. From the submission workspace, click **Add Review Comments**.



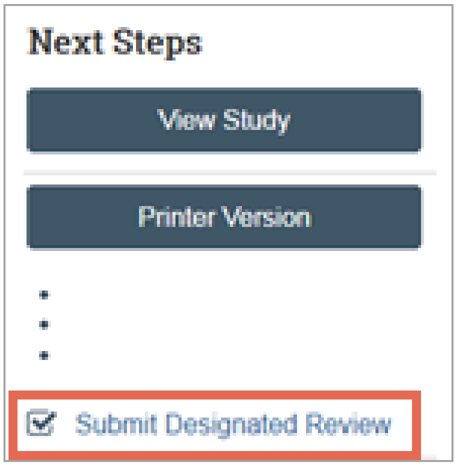
2. Type your notes for other committee members.
3. Add any checklists or documents you want to share with other committee members.
   Note: You can access the appropriate checklist to upload by clicking the **Library** link and downloading the document from the **Checklists** tab.
4. Click **OK**.
   The review comments and attachments will appear on the Reviews tab of the submission workspace.

Submit a Designated Review

You may be assigned to perform a designated review, a process which doesn't involve other committee members. After reviewing the assigned submission, you must record your decision in the IRB system. Recording your decision completes the designated review and moves the submission forward in the review process. (For committee meeting decisions, an IRB staff member will record the decision on behalf of the committee.)

To submit designated review

1. From the submission workspace, click **Submit Designated Review**.



2. Complete the Submit Designated Review page. Use the worksheets to support your determination and selections.
   Note: Different determinations and exempt categories are available based on whether the study falls under the Pre-2018 or 2018 Common Rule requirements.
3. For a study that falls under the 2018 Common Rule requirements, indicate whether continuing review is required.
4. Under Supporting documents, add any documents related to your review such as a completed checklist.
5. Select the check-box in question 7 affirming that you do not have a conflict of interest.
6. Click **Yes** if you are ready to submit your review. If not, click **No**, and the information you entered will be saved. You can submit your review later.
7. When finished, click **OK**.

If you said Yes, the submission moves to the IRB coordinator's inbox so the coordinator can send a determination letter to the PI.

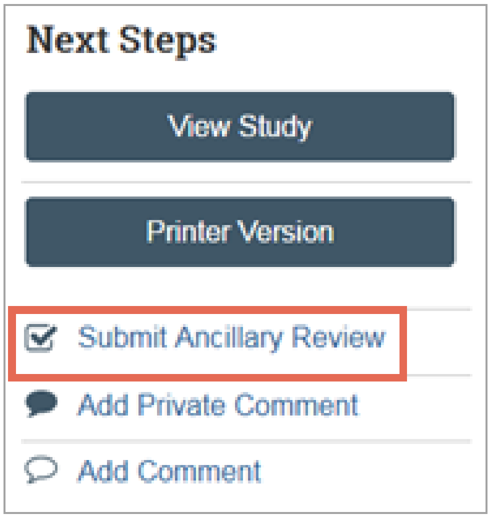
Submit an Ancillary Review

You may be assigned to review a submission as an ancillary reviewer. You will receive a notification. The submission will also appear in your inbox if it is a required ancillary review.

After reviewing the submission, you must record your decision in the IRB system. This step completes the ancillary review but does not change the state of a submission.

To submit ancillary review

1. From the submission workspace, click **Submit Ancillary Review**.



2. Complete the Submit Ancillary Review page.
3. Indicate whether you accept or do not accept the proposed submission.
4. Under **Supporting documents**, add any documents related to your review.
5. When finished, click **OK**.

Your ancillary review responsibilities are complete.

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.

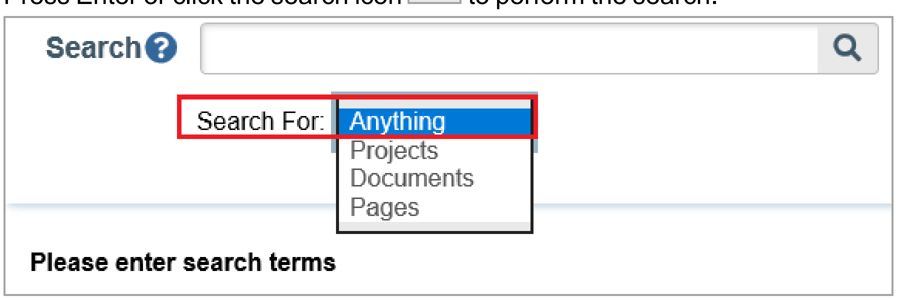
After your initial search, you can further refine results using the following filter options:

- **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.

Published by Huron Consulting Group Inc.
9170 NE Turing Court
Suite 100
Hillsboro, OR 97006