

Request Clarification on a Submission

If you have questions for the study team or require that they make a change to the submission, the assigned IRB coordinator will use the request clarification feature to route your questions and communicate back and forth with the team. Any questions for the study team should be entered in the "Review Comments" Notes section (see below).

Prepare Review Comments for a Committee Meeting

Primary and secondary reviewers should use this function to confirm that they have reviewed the submission and to attach any necessary checklists. If you would like to get feedback from the study team, add this in the Notes section and an analyst will follow up with the study team.

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**.

Next Steps



2. Type your notes for other committee members or the analyst.
3. Add any checklists or documents as necessary.
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**.

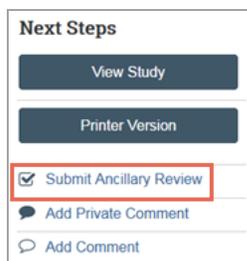
If you said Yes, the submission moves to the IRB coordinator's inbox so the coordinator can send a determination letter to the PI.

Submit an Ancillary Review

You may be assigned to review a submission as an ancillary reviewer. 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 study.
4. Under **Supporting documents**, add any documents related to your review.
5. When finished, click **OK**.

Your ancillary review responsibilities are complete.

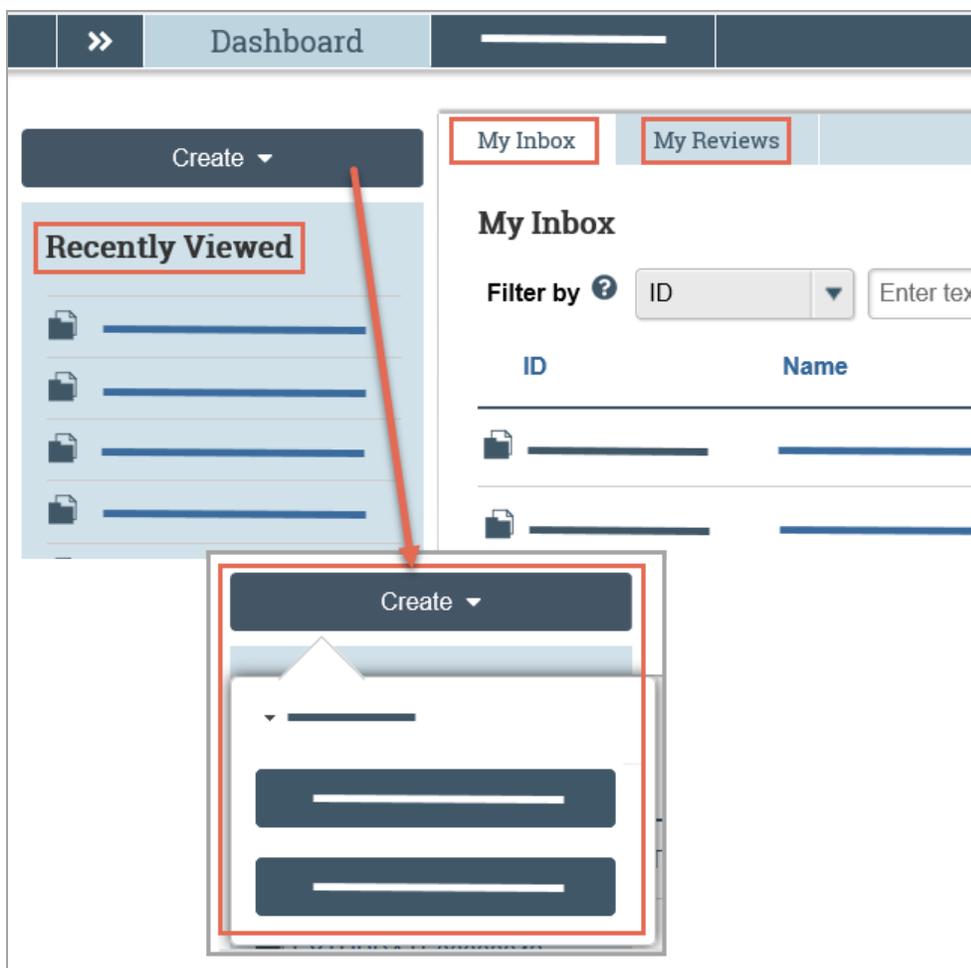
Navigation and Basic Tasks

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:** The last several items you viewed. Look here for an item you worked on recently.



▶ 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.

Pre-Submission STUDY00000192:
Last updated: 7/11/2018 5:55 PM
Principal investigator: Rebecca Simms (pi)
Submission type: Initial Study
Primary contact: Rebecca Simms (pi)
PI proxies:

Next Steps

Edit Study
Printer Version

Submit
Manage Participating Sites
Assign Primary Contact
Assign PI Proxy
Manage Ancillary Reviews
Manage Guest List

History Funding Contacts Docu

Filter by Activity

Activity	Author
Study Created	

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**.

Dashboard IRB

Submissions Meetings Reports

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	7/24/2019 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.

ID	Name	Date Modified
STUDY	...ccination Study	12/1/2016 11:03 AM
STUDY	...ly Separation Study	12/1/2016 11:01 AM

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**.

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