Staff Guide

May 2025

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About this Document

This document covers information and tasks relevant to single-site studies, including initial single-site study submissions, external single-site study submissions, and single-site follow-on submissions (modifications, continuing reviews, and reportable new information).

For information related to multi-site studies under single IRB of record review, please see the *IRB Multi-Site Study Guide*, found in the Help Center of your IRB system.

Overview of IRB

The IRB system provides a mechanism for creating and tracking studies that require IRB overview. IRB supports the following submission types:

Submission Type	Description
Initial Submissions	
Study	Documents the details of a study that require oversight by an Institutional Review Board. Studies include external studies, single-site studies, and multi-site or collaborative studies.
Site	Documents the study details specific to a particular institution, such as local team members and institution-specific consent forms.
Follow-on Submissions	
Modification	Changes or updates to approved studies. The modification submission consists of a form that lists modification details along with the updated study pages.
Continuing Review (CR)	A review of an approved study. The continuing review submission consists of a form on which the researcher records any changes, accidents or other problems that have occurred since the study was approved, or since the previous continuing review.
Reportable New Information (RNI)	A report of new information about an approved study or active research.

Access to a study is based on the role a user is assigned in the IRB system and the role a user plays in relation to a particular study. For example, Study Staff is a system-wide role, whereas PI is a role in relation to a study; a user with the Study Staff role must be explicitly assigned the role of PI. For additional information on roles, see the *IRB Deployment Guide*.

User Role	Typical Activities
Registered User	Users authorized to create submissions.
PI	The Principal Investigator (PI) listed on the submission. While others assist the PI in developing and editing the submission, only the PI (or designated PI proxies) can submit the study or follow-on submissions to start the review process.

User Role	Typical Activities
Study Staff	Individuals involved in developing the study and listed on the submission as study team members. The study team always includes a PI but can also include a PI proxy, other co-investigators, science contributors, and administrative staff.
IRB Coordinator	Individuals who guide submissions through the review process. The coordinator reviews a newly submitted study for completeness, determines the level of review it needs, and ensures correspondence with the PI is completed in a timely manner.
IRB Director	An individual with IRB oversight responsibilities. Can perform the same actions as coordinators, but is typically less involved with the day-to-day processing of submissions.
Committee Member	Individuals on an IRB committee who are responsible for reviewing submissions.
Committee Chair	An IRB committee member assigned to chair the committee.
Committee Administrator	An individual responsible for managing committee meetings. See the *Meeting Management Guide* for tasks this person performs.
Site Manager	An individual who has system-wide access. This includes full access to security and system settings, and all data, workspaces, activities, and actions in the system.

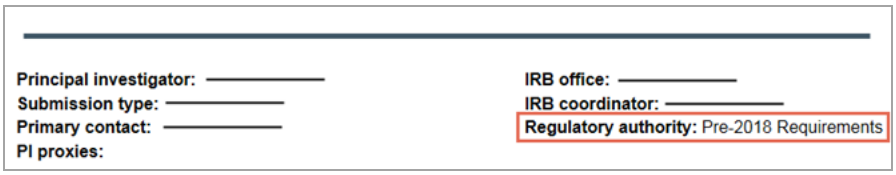
Common Rule Requirements

Studies in the IRB system may fall under the Pre-2018 or 2018 Common Rule requirements, based on the dates they were created and reviewed, the agencies providing regulatory oversight, and other factors. Institutions can evaluate which Common Rule requirements are applied to a study. There are several ways to do this:

- For new studies, the Common Rule effective date listed in the IRB settings page determines which rule is applied to the study, based on the study's Pre-Review submission date. For example, if the effective date in the settings is January 19, 2018, studies with a Pre-Review submission date before that date will fall under the Pre-2018 requirements, and studies with a Pre-Review submission date on or after the effective date will fall under the 2018 requirements. For more information on editing this setting, see the *IRB Deployment Guide*.
- For new external studies, the study team can record which Common Rule requirements are applied during creation of the study.
  Note: The decision of which Common Rule requirements the study falls under is made by the external IRB and the local study team should record the requirements communicated to them by the external IRB.
- For existing studies created before the effective date of the 2018 Common Rule requirements, all studies in a draft state or a state past Pre-Review will automatically have the Pre-2018 requirements applied. IRB coordinators and directors can move the study from the Pre-2018 rule to the 2018 rule as part of the continuing review process. When a Pre-Review for a CR is submitted, the IRB coordinator can specify whether the study should remain under the Pre-2018 requirements or be moved under the 2018 requirements.
- In the case of an error or discrepancy, the IRB Director or the Site Administrator can revert a study in a post-approval state from under the 2018 rule to under the Pre-2018 rule. If the study has any active follow-on submissions, they must be completed or discarded before the study can be reverted.

Note: The Common Rule requirements (Pre-2018 or 2018) applied to a study are also applied to any sites related to the study (in the case of external or multi-site studies) and to any follow-on submissions for which it is the parent study.

The Common Rule requirements applied to a study are displayed on the study workspace:



Agency Oversight

If the FDA or DOJ is selected in the Pre-Review form as an oversight agency for a study, the study will automatically fall under the Pre-2018 Common Rule requirements, even if the date of the study falls after the effective date setting of the 2018 requirements. This remains true even if other oversight agencies are selected in addition to the FDA or DOJ.

If, during a continuing review, you edit the Pre-Review form and change the study to fall under the 2018 requirements, the system will not allow the change if the FDA or DOJ remains selected. You must deselect these options in order to move the study under the 2018 requirements.

Exempt Categories

Some exempt categories are only available for studies under the Pre-2018 requirements, and some exempt categories are only available for studies under the 2018 requirements.

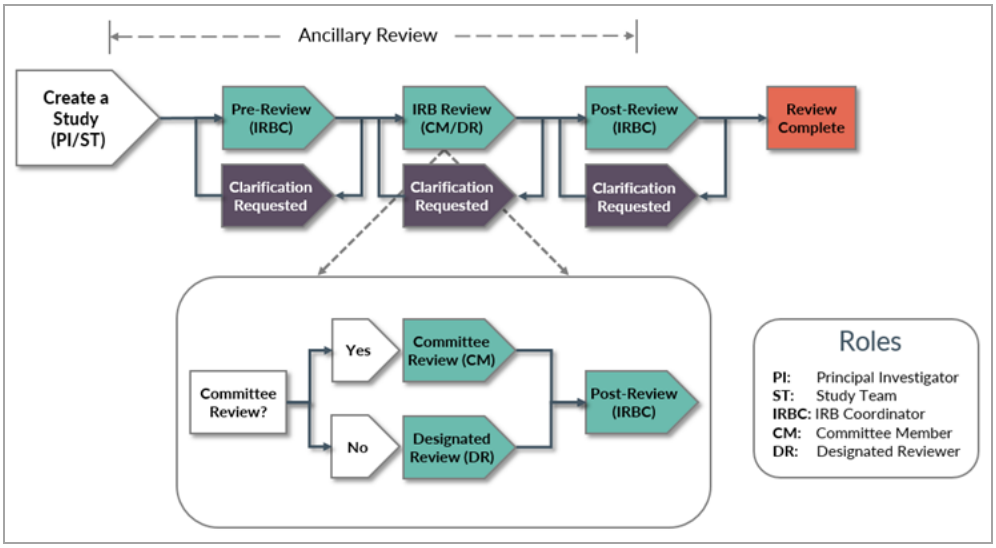
When you change a study under the Pre-2018 requirements to fall under the 2018 requirements, a Pre-2018 exempt category may still be displayed, but you will not be able to proceed with the change until it is deselected.

Overview of the Submission Review Process

The basic process for a study, or initial submission, is as follows:

1. The PI (and study team) creates a study, entering study information on a series of user-friendly pages in the IRB system. While the team is working on the study, it is in the **Pre-Submission** state, and when they finish working on it, the PI submits the study to the IRB for review.
2. The study first goes through **Pre-Review**, in which an assigned IRB coordinator reviews the study for completeness, ensuring it includes all the necessary information and documentation for the IRB committee member reviewers. At any point during Pre-Review, the IRB coordinator may request clarification or changes from the PI resulting in a back-and-forth exchange between the PI and IRB coordinator. The IRB coordinator also determines if the study should be reviewed by a designated reviewer or the full committee.
3. During **IRB Review**, the designated reviewer or the full committee will review the study.
    a. If it is being reviewed by a designated reviewer, that reviewer makes a determination about the study and submits the decision in the IRB system. Before making a decision, however, the reviewer may request clarification or changes from the PI, resulting in a back-and-forth exchange between the PI and designated reviewer.
    b. If a full committee reviews the study, a committee meeting occurs in which the committee makes a determination about the study. The committee may also request clarification before making a decision, but they can choose to make a determination without receiving a response. The IRB coordinator submits the decision in the IRB system on behalf of the committee. Submitting a determination in the system moves the study to Post-Review.
4. During **Post-Review**, the IRB coordinator prepares and sends the determination letter to the PI. If the study was approved, the IRB coordinator also creates a final, PDF version of the study documents and the review process is complete (Review Complete). If the committee determines modifications are needed for the study to be approved, the PI can make changes to the study. The IRB coordinator reviews the changes and decides if the study can be approved or must go back through an IRB review (by a designated member or the full committee).

The following diagram illustrates the submission review process, including the roles and states involved in the review, as well as the decision points that govern whether a submission undergoes committee or designated review.



Edit a Study As an IRB Coordinator

Depending on your institution's policy, the assigned IRB coordinator for a study may be allowed to edit the study on behalf of the study team. A system-wide setting must be enabled to allow this, as described in the *IRB Deployment Guide*.

When editing by the coordinator is enabled, the assigned IRB coordinator for any submission can edit the submission in the same states that the study team can (Pre-Submission, Clarification Requested, and Modifications Required). The PI or PI proxy must then submit the changes to the IRB.

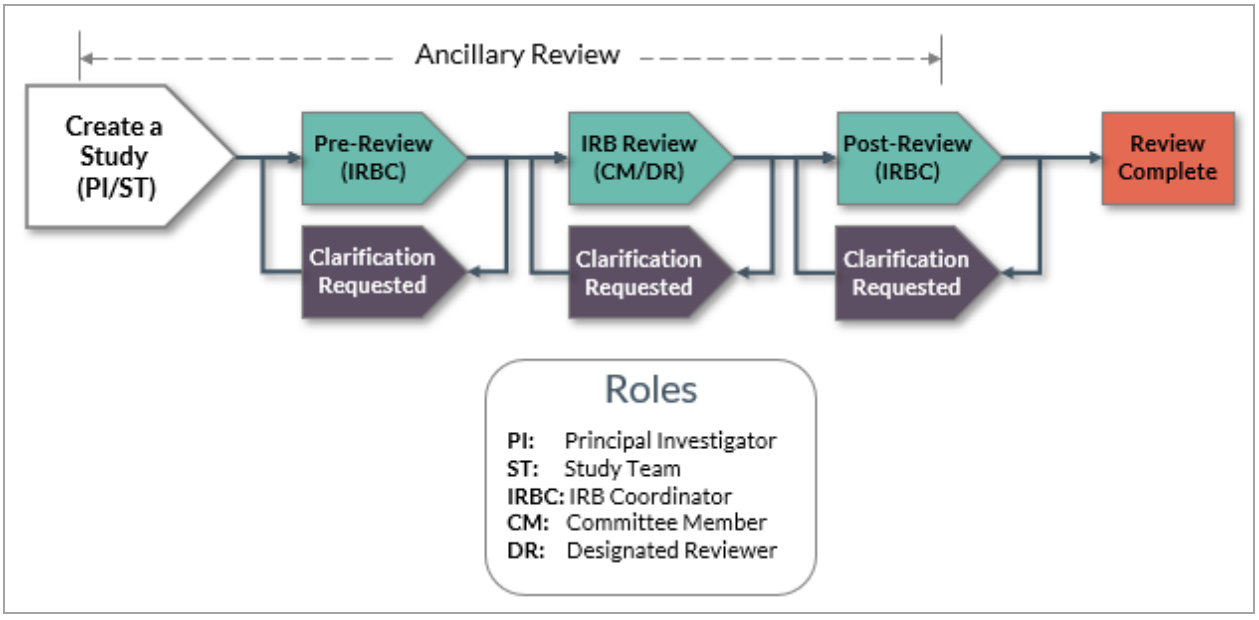
For example, suppose the assigned coordinator is completing the Pre-Review process and notices a small inconsistency in the submission. From talking with the PI, the coordinator knows what needs to be changed, and the PI prefers the coordinator make the change directly. The coordinator requests clarification (which opens the study for editing) and makes the change. The coordinator then uses the Add Comment activity to notify the PI of the change and request the change be submitted to the IRB for review.

Ancillary Review Process

Ancillary reviews allow individuals, departments, and other organizations to give feedback on the submission in parallel with the IRB review. Both PIs and the IRB staff can add optional or required ancillary reviewers, however, the system does not prevent a submission from being reviewed or approved by the IRB if an ancillary review is outstanding.

Ancillary reviews can be configured to block the workflow if the review is not completed or if the reviewer does not accept the submission when completing a required ancillary review. If necessary, the IRBC can bypass any workflow stoppage for this submission, effectively ignoring any outstanding required reviews for this submission. Refer to your IRB policies about how, when, and whether to interrupt the IRB review process to wait for ancillary reviews.

Ancillary reviews can occur in almost all states, starting from Pre-Submission when they can be initiated by the PI or an IRB director. A few end states are excluded, specifically Discarded and Closed—and for RNI, Complete and Acknowledged. The assigned coordinator is able to add ancillary reviewers in states after Pre-Submission.

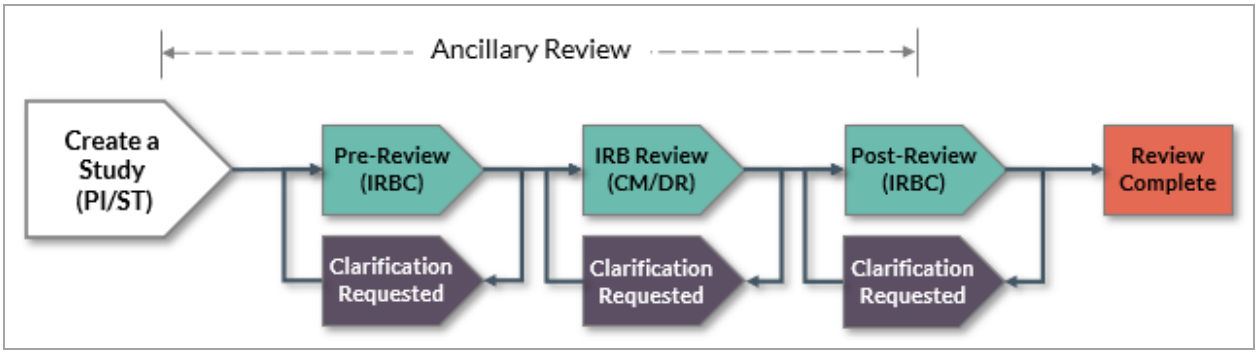


Continuing Review (CR) and Modification Process

Continuing reviews are submitted to close a study or extend the approval period. The IRB periodically reviews all approved studies involving human research. To start the review process, the study team submits a CR for the approved study in the IRB system. After that, the CR follows a similar review process to an IRB study and can also include ancillary reviews that are conducted concurrently with IRB reviews.

Note: Before closing a study via a CR, make sure to discard or approve any active modifications related to the study.

Modifications fall into the following categories: those that affect the study team membership, those that affect other parts of the study, or both. The study team submits a modification for any changes to the approved study; for example, to change the study team membership or update a consent form. Then, the modification follows a similar review process to an IRB study and can also include ancillary reviews that are conducted concurrently with IRB reviews.



When a modification is approved, the changes made in the modification are applied to the approved study. If an approved modification changes the determination of the parent study, the parent study's state will be updated according to the new determination.

A modification that is disapproved remains active until the modification is either approved (which applies the modifications to the study) or discarded (in which case, no modifications are applied to the study). No new modifications of the same type can be created until the disapproved modification is approved or discarded.

Modifications and continuing reviews can be created either separately or combined into a single submission. Combining them often makes sense. For example, suppose the study team wants to submit a consent form change about the same time that a continuing review is due. Both can be submitted and reviewed together, reducing the overhead for the study team, IRB staff, and reviewers.

Note: Only one CR can be open for a study at a time. Similarly, only one modification affecting a certain part of the study (study team membership or other parts of the study) can be open at once. A modification/CR submission counts as a CR and affecting one or more parts of the study, depending on what portions the modification includes. After an open follow-on submission has been closed (through approval, discarding, etc.), another submission covering that same scope can be opened.

Important!

There can be a situation where separate modification and CR submissions that are open concurrently can both affect the study's attached documents. This creates potential contention over the finalization and stamping of documents. Contention can occur when a CR (or a combined modification / CR submission) is open concurrently with a separate modification that includes other parts of the study (not limited to study team membership).

To handle potential conflicts in these situations, we recommend this approach:

- Approve the modification first before approving the CR (completing it through the To send determination letter on page 28 activity). This prevents contention.
- If you must approve the CR first, be aware that the modification will later overwrite the stamping of documents done by the CR. To correct this, make sure you finalize again in the modification all documents you finalized in the CR.

External IRB Process for a Single-Site Study

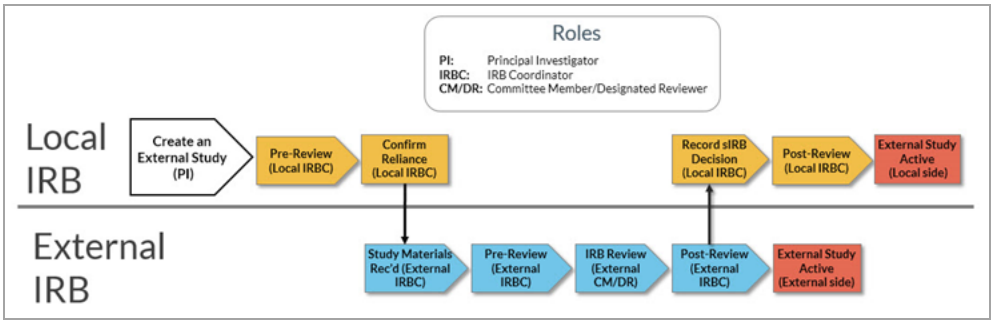
For a single-site study, when the local IRB cedes authority to an external IRB (or single IRB of record), the local IRB system tracks less information about the study throughout its life cycle. The basic process for reviewing and tracking a single-site external IRB study locally is shown below.
Note: Single-site external IRB studies do not use Huron's IRB Exchange. Rather, the local IRB communicates with the external IRB, then records the external IRB's determination using the Record sIRB Decision activity.

Note: For information on multi-site studies reviewed by an external IRB, see the *IRB Multi-Site Study Guide*.

1. During **Pre-Submission** when the study team is creating the study, they will indicate that they are using an external IRB. This causes subsequent pages to require less information for the local IRB to review and require information about the external IRB.
2. During **Pre-Review**, the assigned coordinator reviews the study, including the external IRB information, and can send the study back to the study team for more information or clarification as needed. When all the information has been supplied, the coordinator uses the **Confirm Reliance** activity to confirm that the external IRB is indeed overseeing the review process.
3. The study will move to the **Pending sIRB Review** state. If the study needs to be revised while in the Pending sIRB state, the assigned IRB coordinator or study staff can directly edit the study.
4. Once the external IRB communicates their decision, the local IRB coordinator records the decision using the **Record sIRB Decision** activity. The Record sIRB Decision activity is where you will record which Common Rule regulatory requirements apply to the study – Pre-2018 or 2018. Depending on the decision, and whether the coordinator needs to finalize documents and send an acknowledgement letter, the study moves to the Post-Review, Modifications Required, or Review Complete state:
    a. In the Modifications Required state, the coordinator or PI can respond to the external IRB.
    b. During Post-Review, the IRB coordinator can prepare and send the acknowledgement letter.
    c. Once the study is in the Review Complete state, the local IRB process is complete.

Note: All submissions reviewed by an external IRB are found on the **External IRB** tab.

The following diagram illustrates the review process for a single-site external submission.



Study, Modification, and CR States and Transitions

This table contains information on key transitions in the IRB review process that cause a submission to move from one state to another. The table lists the original state, the action required to change the state, the users that can perform this action, and the resulting state of the submission.

Note: To view the states and transitions available for a site connected to an externally-reviewed study, refer to the "pSite System Site States and Transitions" in the *IRB Multi-Site Study Guide*.

In this state…	These roles…	Can perform these actions…	Changing the state to…
Pre-Submission	Investigator, PI Proxy	Submit	Pre-Review
Pre-Review	IRB Coordinator, IRB Director	Submit Pre-Review	Pre-Review Completed
		Request Pre-Review Clarification	Clarification Requested (Pre-Review)
Pre-Review Completed	IRB Coordinator, IRB Director	Assign Designated Reviewer	Non-Committee Review
		Assign to Meeting	Committee Review
Clarification Requested (Pre-Review)	Investigator, PI Proxy	Submit Response	Pre-Review
Committee Review	IRB Coordinator, IRB Director	Assign to Non-Committee Review	Non-Committee Review
	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit Committee Review	Post-Review
	Committee Member, IRB Coordinator, IRB Director	Request Clarification by Committee Member	Clarification Requested (Committee Review)
Clarification Requested (Committee Review)	Investigator, PI Proxy	Submit Response	Committee Review
	IRB Coordinator, IRB Director	Assign to Non-Committee Review	Non-Committee Review
Non-Committee Review	Designated Reviewer, IRB Coordinator, IRB Director	Assign to Committee Review	Committee Review
		Submit Designated Review	Post-Review
	Designated Reviewer	Request Clarification by Designated Reviewer	Clarification Requested (Designated Review)

In this state…	These roles…	Can perform these actions…	Changing the state to…
Clarification Requested (Designated Review)	Investigator, PI Proxy	Submit Response	Non-Committee Review
Post-Review	IRB Coordinator, IRB Director	Send Letter	Approved
			Modifications Required
			Deferred
			Human Research, Not Engaged
			Not Human Research
			Disapproved
Approved	IRB Coordinator, IRB Director	Close Study (Admin)	Closed
		Submit Committee Review	Post-Review
		Submit Designated Review	
	IRB Director	Terminate	Terminated
		Suspend	Suspended
Suspended	IRB Coordinator, IRB Director	Close Study (Admin)	Closed
	IRB Director	Terminate	Terminated
	Registered User	Continuing Review Closed	Approved
Deferred	Investigator, PI Proxy	Submit Response	Pre-Review
	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit Committee Review	Post-Review
Disapproved	Investigator, PI Proxy	Submit Response	Pre-Review
	IRB Coordinator, IRB Director	Submit Committee Review	Post-Review
		Submit Designated Review	
	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded

In this state…	These roles…	Can perform these actions…	Changing the state to…
Modifications Required	Investigator, PI Proxy	Submit Response	Modifications Submitted
	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded
Modifications Submitted	IRB Coordinator, IRB Director	Assign Designated Reviewer	Non-Committee Review
	Designated Reviewer, IRB Coordinator, IRB Director	Assign to Committee Review	Committee Review
	Committee Chair, Coordinator, IRB Director	Review Required Modifications	Post-Review
			Modifications Required
Lapsed	IRB Director	Suspend	Suspended
		Terminate	Terminated
	IRB Coordinator, IRB Director	Close Study (Admin)	Closed
	Registered User	Continuing Review Closed	Approved
Terminated	IRB Coordinator, IRB Director	Submit Committee Review	Post-Review
		Submit Designated Review	
External IRB	IRB Coordinator, IRB Director	Close Study (Admin)	Closed
All states prior to Post-Review	Study Staff	Withdraw	Pre-Submission
	Study Staff, IRB Coordinator, IRB Director	Discard	Discarded

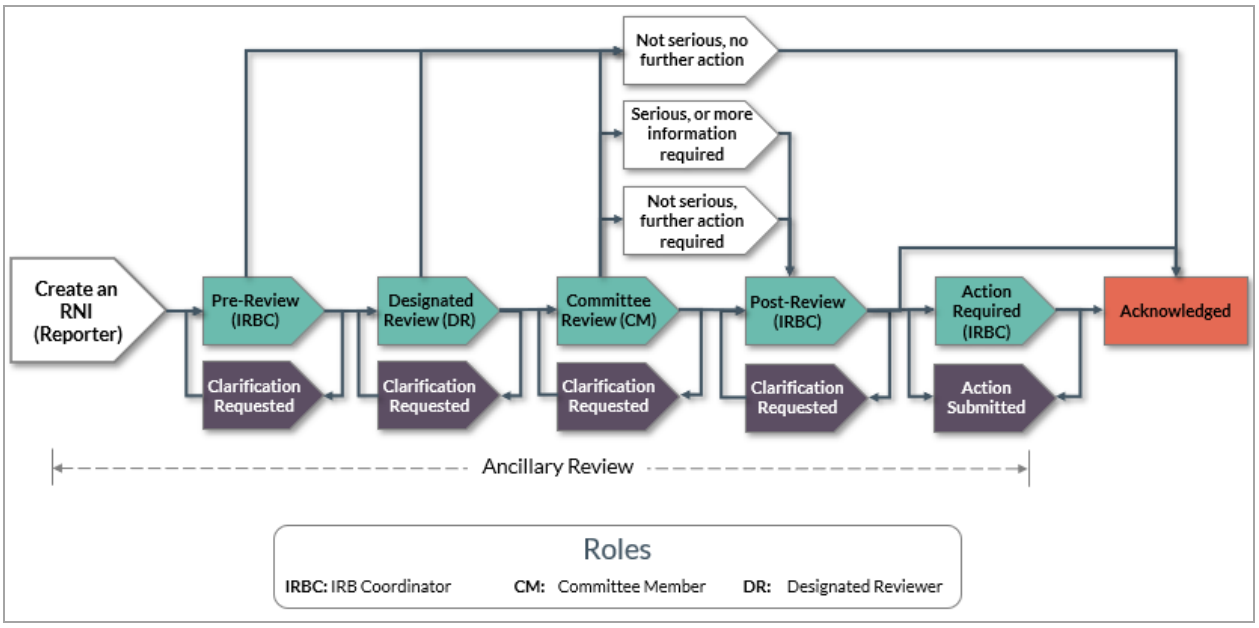
Reportable New Information (RNI) Process

The RNI workflow uses similar states to a study, but the IRB review process routes the submission differently depending on the significance of the determinations selected. For an RNI submission to be considered a serious issue, the determinations selected must include an unanticipated problem involving risks, serious or continuing non-compliance, or suspension or termination of IRB approval. This reduces the IRB's time spent handling insignificant issues.

1. The review process starts with a pre-review that enables the coordinator to make the final determinations regarding any RNI submission that is not considered serious.
    a. If the RNI submission is not considered a serious issue and is not marked as Additional review required, the submission transitions directly to **Acknowledged**.
    b. Otherwise, the coordinator can assign the submission to a designated reviewer or to committee review.
2. The RNI designated reviewer starts from the determinations selected in pre-review and can modify them as needed.
    a. If the RNI submission is not considered a serious issue, the submission transitions directly to **Acknowledged**.
    b. Otherwise, the submission transitions to **Committee Review** so it can be assigned to a meeting.
3. The committee review starts from the determinations selected in the previous review and can be modified as needed.
    a. If the RNI submission is not considered a serious issue, and no further action is required, the submission transitions directly to **Acknowledged**.
    b. If the RNI submission is not considered a serious issue, but further action is required, the submission transitions to **Post-Review**.
    c. If the RNI submission is considered a serious issue, or if additional information is required before making a determination, the submission transitions to **Post-Review** regardless of whether further action is required.
4. If further action is required to resolve the reported issue, the committee can specify an action plan and assign a responsible party for carrying out the plan. If action is required, the submission transitions from **Post-Review** to **Action Required** when the letter is sent. The responsible party (and others) can respond using the **Submit Action Response** activity when the action has been completed. Then the completed action can be reviewed and verified in the **Action Submitted** state. Alternatively, the submission can be assigned to a designated reviewer or to committee review to verify the completed action.
5. When there is no further action required, and a letter is sent, the submission transitions to **Complete**.
6. Depending on how your IRB solution is configured, an RNI for a single-site external study may follow the workflow described above, or it may be routed directly to **Pending sIRB Review**. Once the external IRB communicates their decision, the local IRB coordinator uses the **Record sIRB RNI Decision** activity to record the decision.

    Note: If the external IRB decision is to recommend local review, select the **sIRB recommends local IRB Review** determination in the **Record sIRB RNI Decision** activity.

The following diagram illustrates the review process for an RNI.



Reportable New Information States and Transitions

This table contains information on key transitions in the RNI Review process that cause an RNI to move from one state to another. The table lists the original state, the action required to change the state, the users that can perform this action, and the resulting state of the RNI.

In this state…	These roles…	Can perform these actions…	Changing the state to…
Pre-Submission	Reporter, PI and PI proxies of related submissions, RNI editors§	Submit RNI	Pending sIRB Review*
			Pre-Review
Pre-Review	IRB Coordinator, IRB Director	Submit RNI Pre-Review	Acknowledged
			pSite Review*
			Pre-Review Completed
		Route for sIRB Review*	Pending sIRB Review*
		Request Pre-Review Clarification	Clarification Requested (Pre-Review)
Clarification Requested (Pre-Review)	Reporter, PI and PI proxies of related submissions, RNI editors§	Submit Response	Pre-Review

In this state…	These roles…	Can perform these actions…	Changing the state to…
Pre-Review Completed	IRB Coordinator, IRB Director	Assign Designated Reviewer	Non-Committee Review
		Assign to Meeting	Committee Review
Committee Review	IRB Coordinator, IRB Director	Assign to Non-Committee Review	Non-Committee Review
	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit RNI Committee Review	Post-Review
			Acknowledged
		Review Required Actions	Post-Review
			Action Required
	Committee Member, IRB Coordinator, IRB Director	Request Clarification by Committee Member	Clarification Requested (Committee Review)
Clarification Requested (Committee Review)	Reporter, PI and PI proxies of related submissions, RNI editors§	Submit Response	Committee Review
Non-Committee Review	Designated Reviewer, IRB Coordinator, IRB Director	Assign to Committee Review	Committee Review
	Designated Reviewer, Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Review Required Actions	Post-Review
			Action Required
	Designated Reviewer	Submit RNI Designated Review	Acknowledged
			Committee Review
		Request Clarification by Designated Reviewer	Clarification Requested (Designated Review)
Clarification Requested (Designated Review)	Reporter, PI and PI proxies of related submissions, RNI editors§	Submit Response	Non-Committee Review
Pending sIRB Review*	IRB Coordinator, IRB Director	Record sIRB Decision*	Pre-Review
			Action Required
			Complete
Action Required	Responsible party, IRB Coordinator, reporter, PI and PI proxies of related submissions, RNI editors§	Submit Action Response	Action Submitted
			Action Submitted (sIRB Review)*

In this state…	These roles…	Can perform these actions…	Changing the state to…
Action Submitted	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Review Required Actions	Post-Review
			Action Required
	IRB Coordinator, IRB Director	Assign to Committee Review	Committee Review
		Assign Designated Reviewer	Non-Committee Review
Action Submitted (sIRB Review)*	IRB Coordinator, IRB Director	Record sIRB Decision*	Complete
			Action Required
Post-Review	IRB Coordinator, IRB Director	Send Letter	Action Required
			Complete
	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit RNI Committee Review	Acknowledged
Complete	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit RNI Committee Review	Post-Review
			Acknowledged
Acknowledged	IRB Coordinator, IRB Director	Submit RNI Pre-Review	Pre-Review Completed
	Committee Chair, Committee Administrator, IRB Coordinator, IRB Director	Submit RNI Committee Review	Post-Review
	Designated Reviewer, IRB Coordinator, IRB Director	Submit RNI Designated Review	Committee Review
All states prior to Post-Review	Study Staff	Withdraw	Pre-Submission
	Study Staff, IRB Coordinator†, IRB Director†	Discard	Discarded

* This action or state applies to RNIs related to externally-reviewed studies only.

† IRB Staff can discard the RNI if it was not downloaded from the IRB Exchange.

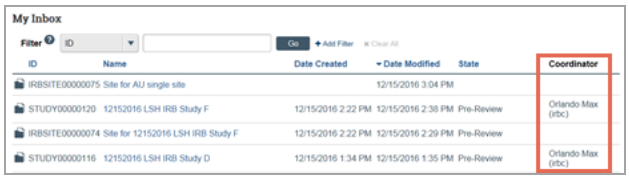
§ RNI editors are those assigned to the RNI using the Manage Editors activity. They can edit the RNI, submit it for review, submit a response to a clarification request, and submit an action response. For details, see Manage Editors for RNI on page 29.

Complete a Pre-Review

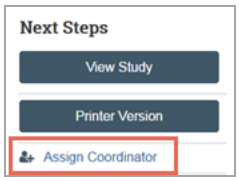
When a study is submitted to the IRB for review, it will appear in all coordinators' inboxes. The first step is to assign it to a specific coordinator to oversee through the review process. Next, the assigned IRB coordinator will check the study for completeness, ensuring all the information is there for the reviewers.

To assign a coordinator

1. From My Inbox, open the submission that does not have an assigned coordinator.



2. From the study workspace, click **Assign Coordinator**.



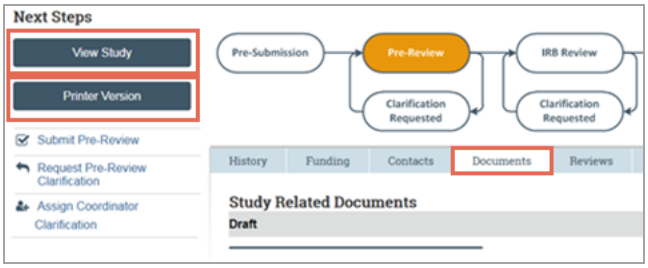
3. Select a coordinator to take ownership of the study.
4. Click **OK**.
   The submission will appear only in the assigned coordinator's inbox.

Note: If you assign a coordinator that is not yourself, the assigned coordinator will receive a notification.

To perform a Pre-Review

Review the submission and its documents. From the workspace, click the following:

- **View Study**: Opens the study. Click **Continue** to move through the pages.
- **Printer Version**: Shows the study in one scrollable page.
- **Documents** tab: Shows all attached study documents.



Note: You can also access these documents from the study pages and printer version.

Next Steps

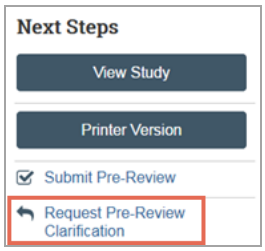
- If you have questions or change requests for the PI, see Request Clarification on a Submission on page 19.
- If you are finished reviewing the submission, see Submit a Pre-Review on page 20.

Request Clarification on a Submission

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

To request clarification

1. From the submission workspace, click **Request Pre-Review Clarification**.



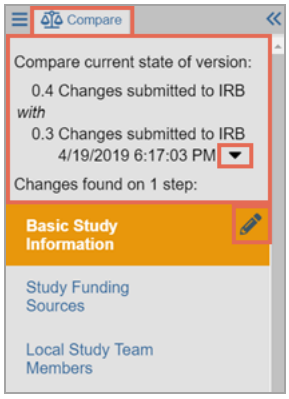
2. Type your request.
   Note: If you require more space for your request, add a document with the details in the Supporting documents section. In the text-box, instruct the PI to refer to the document.
3. Click **OK**.
   The PI will receive an email about your request. Once the PI responds to your request, you will receive an email and the submission will return to your IRB inbox so you can continue your review.

Compare Versions

After the study team submits their response to the clarification request at Pre-Review or Designated Review, you can compare versions to see the changes that were made.

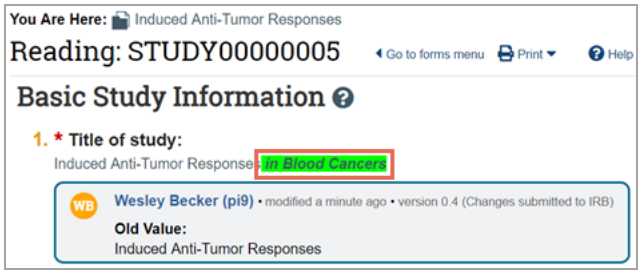
To compare

1. From the study Left Navigator, click **Compare**.
   The Compare section of the Left Navigator shows the versions you are comparing.



2. Click the down arrow to show the versions that you can compare against.
   a. Select a version to compare against the current version.
3. Click the Pencil icon to view the change made to the Basic Study Information page.

4. The change is shown within the SmartForm. The new information is highlighted in green.



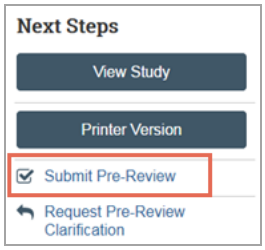
Submit a Pre-Review

After you have finished reviewing a submission for completeness, move it forward in the review process by submitting a pre-review.

Note: The Pre-Review form is editable in all states, including during a follow-on submission. However, if more than one follow-on submission is in progress for the parent study, the Pre-Review form is locked when a change is made to it.

To submit a Pre-Review

1. From the submission workspace, click **Submit Pre-Review**.



2. Complete the Submit Pre-Review page. Click the links to open and use a checklist.
   Note: If you select FDA or DOJ in the Regulatory Oversight section, the study will automatically fall under the Pre-2018 Common Rule requirements, even if it falls after the effective date setting of the 2018 requirements. The Regulatory Authority label on the study workspace will read: 2018 Requirements +FDA +DOJ, depending on your selection.
   Note: Broad consent is not a valid selection for studies falling under the Pre-2018 Common Rule requirements.
3. Indicate whether the study has any additional features.
4. Under Supporting documents, upload appropriate checklists based on the special determination and waivers selected.
5. Click **Yes** if you are ready to submit your review. If not, click **No** and you can return to this page later to submit.
6. When finished, click **OK**.
   Note: To correct a pre-review after you submit it, you can click **Submit Pre-Review** once more, make corrections, and click **OK** to resubmit.

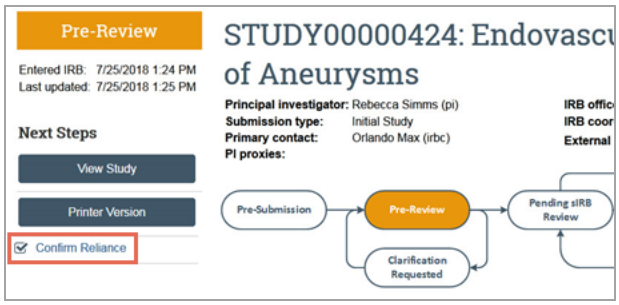
From here, you must decide whether to assign the study to a designated reviewer (non-committee review) or the committee to review.

Confirm Reliance with the External IRB

For a single-site external IRB study, you must confirm reliance on the external IRB before the submission can move forward in the review process. In the Top Navigator, click **IRB** and then **Submissions**. Click the **External IRB** tab, then open the study.

To confirm reliance

1. From the study workspace, click **Confirm Reliance**.



2. Complete the form.
3. Click **OK** to finish.
   If reliance is confirmed, the site enters a Pending sIRB Review state.

Record the sIRB Decision for an External Study

IRB staff records and edits the sIRB decision for an externally reviewed study.

To record sIRB decision

1. From the study workspace, click **Record sIRB Decision**.

2. Complete the form.
   Note: If you select FDA or DOJ in the Regulatory Oversight section, the study will automatically fall under the Pre-2018 Common Rule requirements, even if it falls after the effective date setting of the 2018 requirements.
   Note: Broad consent is not a valid selection for studies falling under the Pre-2018 Common Rule requirements.
3. Indicate whether the study has any additional features.
4. Under Supporting documents, upload appropriate checklists based on the special determination and waivers selected.
5. For **Do you need to finalize documents or send a letter?** , select **Yes** to send the item to Post-Review, and select **No** to send the item to Review Complete.
6. For **Are you ready to record the sIRB's decision?**, select **No** to note the sIRB determination without recording it and your selections will be saved.
7. Click **OK** to finish.

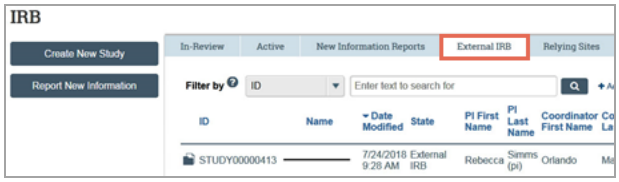
Update an Approved, Single-Site External Study

This section covers two scenarios when making an update to an approved, single-site study. Either the update originates with the local study, or the update originates with the external IRB, for example, when approval dates change.

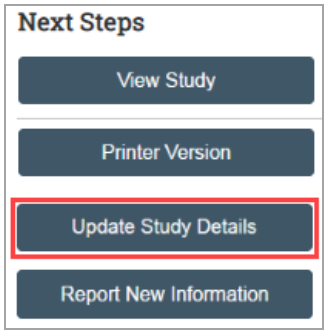
Both the local PI and local IRB coordinator can make updates to the external study. Depending on a setting described in the *IRB Deployment Guide*, the local PI can finalize updates to the study. If not, the PI can use the Add Comment activity to ask the IRB coordinator to finalize the update when the changes are complete.

Updates that originate with the local 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**.
6. Click **OK** to agree to the terms.
7. Type your login credentials and click **Submit**.
8. To review the local PI's updates, from the study workspace, click **View Differences** and reference the snapshot. If there is an error, the IRB coordinator can send a comment to the PI asking them to submit another update with corrected information.
   Note: Alternatively, the IRB coordinator can make another update with the correct information.

Updates that originate with the external IRB

1. After the external IRB notifies the local IRB of a change to the study, the local IRB coordinator runs the **Return to Post-Review** activity from the study workspace.
2. In Post Review, click the **Edit sIRB Decision** activity, then make the necessary changes. The activity presents the option to finalize documents, send a letter, or send the submission directly to Review Complete.

Report Continuing Review Data for an External Study

The local PI, PI proxies, and local IRB coordinator can report continuing review data for a single-site external study.

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**, ensure that you include an explanation for each unchecked item in the checklist on the Report Continuing Review Data page.
6. Click **OK**.

Manage Ancillary Reviews

PIs and IRB staff can invite other people or organizations, beyond IRB committee members, to review the submission. Ancillary reviewers can be assigned to a submission in almost any state, starting with Pre-Submission when they can be assigned by the PI or an IRB director. After Pre-Submission, the assigned coordinator can also assign reviewers.

Usually the reviewers are notified when they are added to the submission, and the submission appears in My Inbox for the reviewer if the ancillary review is required. However, in Pre-Submission state, the system waits until the submission moves forward to Pre-Review to send the notification and to show a required review in My Inbox.

To assign ancillary reviewers to a submission

1. From My Inbox or one of the tabs on the appropriate IRB page, click the name of the submission for which you want to assign an ancillary reviewer.
2. In the study workspace, click **Manage Ancillary Reviews**.
3. In the Manage Ancillary Reviews form, click **Add**.
4. On the Add Ancillary Review form, select an organization or person to do the review.
   Note: Ancillary reviewers must be assigned to an organization for the Organization option to be available.
5. Select the Review type.
6. Select whether this ancillary review is required.
   Note: Site-wide settings can specify states at which outstanding required ancillary reviews block the workflow.
7. If necessary, add the comments and any supporting documents.
8. Click **OK** to add the ancillary review or click **OK and Add Another** to add another ancillary review.

You return to the study workspace. The assigned ancillary reviewers receive email notifications (except in Pre-Submission state) with the relevant details such as review type, comments, and supporting documents.

To override blocking of ancillary reviews

Depending on the settings for your institution, if an ancillary reviewer does not accept a study or complete a required ancillary review, the submission can be blocked from moving forward. If an error message, "All required ancillary reviews must be completed and accepted before executing this activity," displays, the following actions can move the submission past the blockage:

- The reviewer completes the ancillary review.
- The reviewer accepts the submission.
- An IRB staff member overrides the blocking of ancillary review.

1. From My Inbox or one of the tabs on the appropriate IRB page, click the name of the submission for which you want to override the ancillary review.
2. In the study workspace, click **Manage Ancillary Reviews**.
3. Select the **Yes** option for the statement 'Allow the workflow to proceed despite incomplete required reviews.'
4. The next item appears, indicating you must provide a rationale for overriding the workflow stoppage. Provide the rationale for the override, then click **OK**.

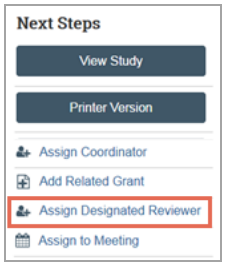
You return to the study workspace. The submission moves forward in the workflow.

Assign a Designated Reviewer

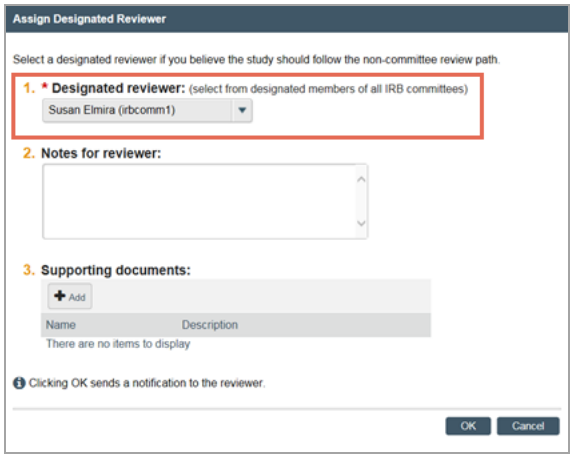
You can assign a study to one committee member to review or to a committee meeting for all committee members to review.

To assign a designated reviewer

1. From the study workspace, click **Assign Designated Reviewer**.



2. Select a committee member from the list.



3. To help the reviewer, you can add checklists or review documentation along with a note indicating this. This way, the reviewer doesn't have to search for them in the library.
4. Click **OK**.

   The reviewer will receive an email about the review and the study will appear in the reviewer's IRB inbox.

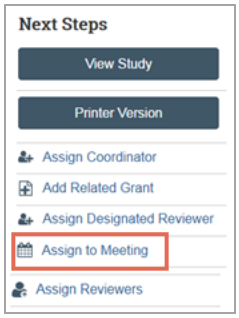
   Note: You can correct mistakes in an already-submitted designated review by clicking **Submit Designated Review**, making corrections, and clicking **OK** to resubmit.

Assign to Committee Review

You can assign a study to one committee member to review or to a committee meeting for all committee members to review.

To assign to a committee meeting

1. From the study workspace, click **Assign to Meeting**.

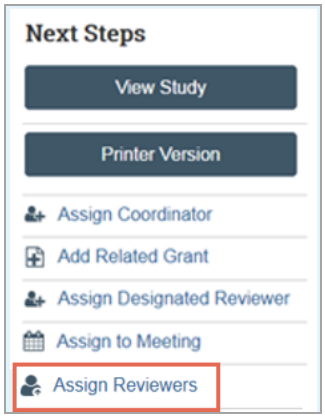


2. Select the upcoming IRB meeting for the office the study belongs to.
3. Click **OK**.
   The details will appear on the IRB Assignment Details tab.

To assign committee reviewers

After you assign a submission to a committee meeting, you can assign specific committee reviewers.

1. From the study workspace, click **Assign Reviewers**.



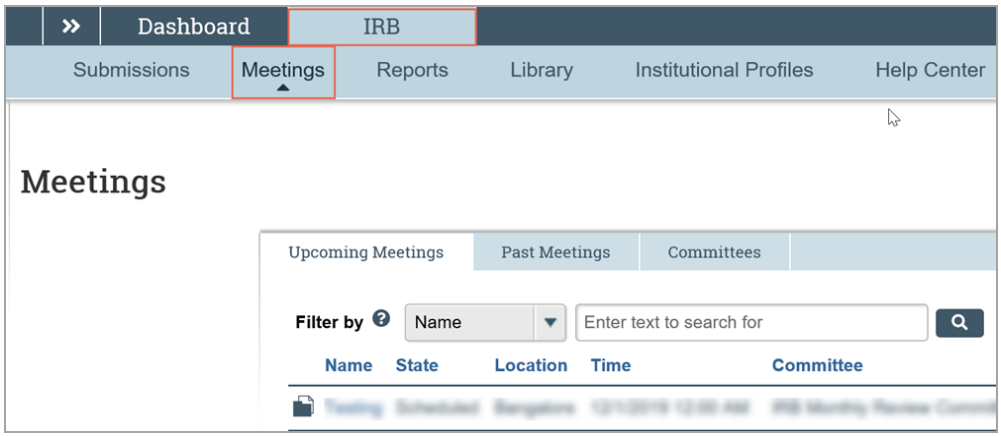
2. Click **Add**.
3. Click the ellipsis to select a reviewer, then click **OK**.
4. Select the reviewer's role.
5. Click **OK** to finish, or **OK and Add Another** to select an additional reviewer.

Submit a Committee Review

If the submission went through a committee review, the next step is to record the committee's determination for that submission. You may do this during or after the committee meeting. An IRB staff member, committee admin, or committee chair can submit the committee review.

To find the study

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



2. Click the **Past Meetings** tab and then the meeting name to open it.

To record decision for a submission

1. From the meeting workspace, in the Record Decision column, click the **Submit Committee Review** link.

2. On the Submit Committee Review page, pay attention to the following sections:
   a. **Determination**: Select the determination
   b. **Risk level**
   c. **Votes**: Fill in all votes regarding the determination.
   d. **Supporting Documents**: Include the final version of any relevant checklists.
   e. **Are you ready to submit this review**: Click **Yes** to move the submission to Post-Review, and click **No** to return and finish the review at another time.
3. Click **OK** when done.

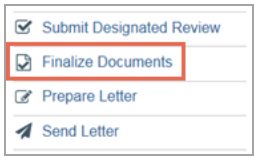
Note: To correct a committee review after you submit it, you can click **Submit Committee Review** once more, make corrections, and click **OK** to resubmit.

Post-Review Activities

After the designated member or committee review decision has been submitted for a submission, the next steps are to finalize the documents and prepare and send the determination letter to PI.

To finalize documents

1. From the study workspace, click **Finalize Documents**.

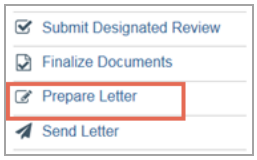


2. Select the documents to change to PDF and watermark.
3. Click **OK**.

The Documents tab on the study workspace will include links to the final versions of the documents.

To prepare determination letter

1. From the study workspace, click **Prepare Letter**.

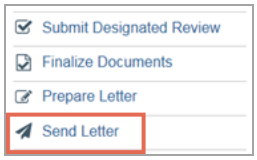


2. You have two options:
   a. To create a letter from a template, select the template from the list and click **Generate**.
   Note: You can open the draft letter, change it as needed, and then add the revised document.
   b. To add a letter, click **Upload** and then browse for the letter.
3. Click **OK** when done.

Until you send the letter, you can use the Prepare Letter activity to regenerate the letter again or upload revisions.

To send determination letter

1. From the study workspace, click **Send Letter**.



2. Review the determination and letter and then click **OK**.
   Note: You may want to verify the acuracy of the dates listed on the Send Letter page before clicking OK.

The letter is sent to the PI, PI proxy, and primary contact.

Manage Editors for RNI

IRB staff and the person who created the RNI can empower additional people to edit and take action on Reportable New Information (RNI) using the Manage Editors activity. The activity is available in any state.

There are two ways to get permissions to edit and perform additional actions on an RNI:

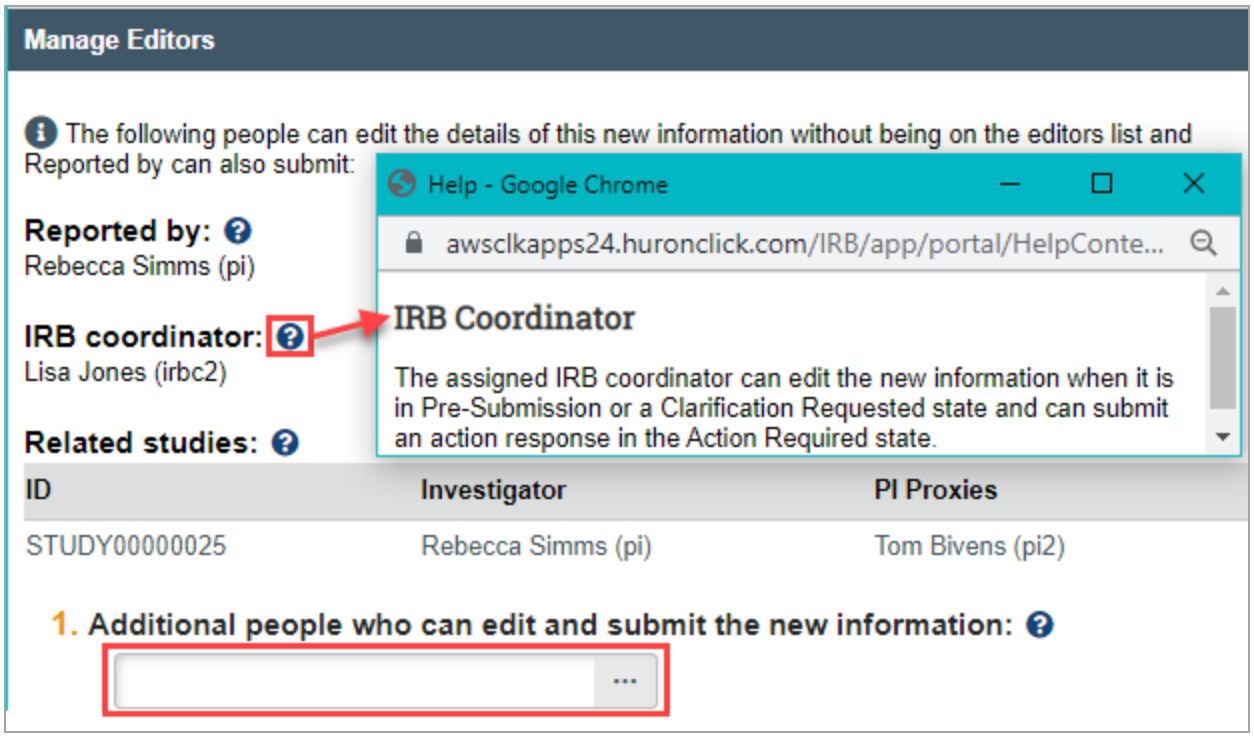
- **Be added as an editor via the Manage Editors activity**, which lets you:
  - Edit the RNI when it is in an editable state, submit it for review, submit a response to a clarification request, and submit an action response.
- **Have a relationship or assignment to the RNI.** The permissions vary based on the relationship, as defined in this table:

Relationship to RNI	Permissions
Reporter/creator of the RNI	Edit the RNI in any state when it is open to editing, submit the RNI for review, and submit a response to a clarification request
Assigned IRB coordinator	Edit the RNI in Pre-Submission, Action Required, or a Clarification Requested state and submit an action response
PIs and PI proxies of all related studies	Edit the RNI in Pre-Submission, Action Required, or a Clarification Requested state, submit the RNI for review, submit an action response, and submit a response to a clarification request
Responsible party for required actions	Edit the RNI in the Action Required state and submit an action response

The top of the Manage Editors activity form identifies the people who already have a relationship to the RNI (because you may not need to explicitly add them as editors). The activity form shows only relationships relevant to the current state of the RNI.

To manage editors

1. From the RNI workspace, click **Manage Editors**.
2. Notice those who already have permissions to edit the RNI and take actions on it in the current state, and use the help icons if needed to identify what actions they can take.



3. Under **Additional people who can edit and submit the new information**, type a name or click the ellipsis button, and select one or more people.
4. Click **OK** (and click **OK** again if necessary).

The people you added immediately receive the new permissions. The RNI appears in their inboxes during states when the RNI is editable.

Generate Standard Reports

The IRB system includes many standard reports regarding studies and Reportable New Information (RNI) to help you find relevant submissions and understand the overall operation of the IRB. In addition, your institution may create custom reports.

For information about the advanced reports that can help you monitor the performance of your IRB, see the *IRB Advanced Reports Guide*.

The reports provide links to the individual submissions, as well as sorting and filtering options.

Any user has access to reports, but the data in the reports is limited to the studies visible to the individual. For example, a Studies Involving Children report generated by a PI will include only the studies that person is allowed to see elsewhere in the system.

You can also see the reports on studies for which you are included on the study team or guest list. IRB coordinators, directors, and committee members generally have access to all report data.

To generate a standard report

1. In the Top Navigator, click **IRB**.
2. Click **Reports**.
   The list of standard study and RNI reports appears.

   > **Tip:** To find a custom report, click the **Custom Reports** tab.

3. Identify the report to generate and click the link.

The report appears, listing the relevant submissions.

> **Tip:** Try filtering the list by status. Next to Filter by, select **Status**. Then type the state to view, such as **Approved** for a study report or **Acknowledged** for an RNI report and press **Enter**.

Produce the AAHRPP Annual Report

The IRB system can complete a large portion of the AAHRPP annual report for you, while letting you fill in the information that is not stored in the IRB system.

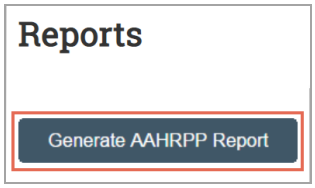
Note: IRB Settings Manager permissions are required to perform the initial setup. IRB director permissions are required to generate the report.

To update contact details to include in the report

1. Log in with IRB Settings Manager or Site Manager permissions.
2. In the IRB Settings SmartForm, update the IRB Office settings with appropriate organization and contact names to be included in the report. For detailed instructions, see the *IRB Deployment Guide*.

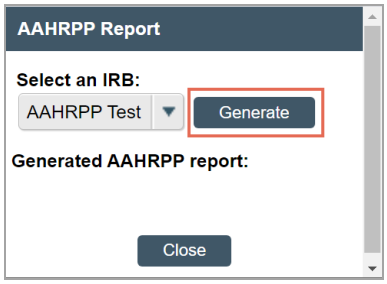
To generate the AAHRPP report

1. Log in with IRB director permissions.
2. In the Top Navigator, click **IRB**.
3. Click **Reports**.
4. Click **Generate AAHRPP Report**.

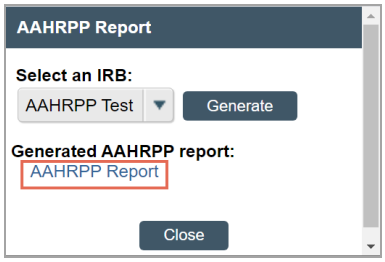


A new window opens.

5. Select the IRB office to include in the report.
6. Click **Generate**.
   A link to the generated report appears in the same window.



7. Click the link to save the report as a Microsoft® Word file.



8. Click **Close**.

To complete the generated report

1. Open the saved file.
2. Review the answers that are filled in, and edit the answers as necessary.
   Alternatively, you can add the information to the IRB system and regenerate the report.

AAHRPP Report Details

The following table identifies the data used to calculate numerical results generated for the AAHRPP annual report. All calculations use only submissions assigned to the selected IRB office. Calculations that are limited to a year's data reflect the previous calendar year.

Name of calculated field	Explanation
15. Number of open studies (excluding exempt) where **your organization serves as IRB/EC for external organizations**	Total number of initial, multi-site, non-external studies where your institution is the IRB of record (for all studies currently in Approved, Lapsed, or Suspended state and where the review type is not exempt).
19. Number of open studies reviewed by an internal IRB/EC with **Expedited Review**	Total number of initial, non-external studies currently in Approved, Lapsed, or Suspended state where the review type for the most recent review is Expedited.
20. Number of open studies reviewed by an internal **convened IRB/EC**	Total number of initial, non-external studies currently in Approved, Lapsed, or Suspended state where the review type for the most recent review is Committee.
24. Number of **exempt** determinations made in the most recent year **by an internal review process**	Total number of initial studies reviewed by your internal IRB/EC that are currently in Approved, Lapsed, or Suspended state where the initial approval date is within the previous calendar year and where the review type is Exempt. This includes studies from all Exempt categories, including limited review.
25. For **exempt** determinations in the most recent year, what is the median number of calendar days from submission to exempt determination	Median elapsed time in days from entering the Pre-Review state for the first time to initial study approval or initial effective date, whichever is later (for all studies currently in Approved, Lapsed, or Suspended state and where the initial approval date is within the previous calendar year). All exempt determinations are reached by an internal review process.
26. Number of **exempt** determinations made in the most recent year **by an external review process**	Total number of initial studies reviewed by your external IRB/EC that are currently in Approved, Lapsed, or Suspended state where the initial approval date is within the previous calendar year and where the review type is Exempt. This includes exemption determinations made using the limited IRB review procedure within the US Common Rule.
28. Number of open studies (excluding exempt) reviewed by **external IRBs/ECs**	Total number of initial studies currently in the External IRB state in the most recent year.

32. For new studies reviewed in the most recent year by the **expedited procedure**, what is the median number of calendar days from submission to approval	Median elapsed time in days from entering the Pre-Review state for the first time to initial study approval or initial effective date, whichever is later (for all studies currently in Approved, Lapsed, or Suspended state, where the initial approval date is within the previous calendar year and where the review type is expedited).
33. For new studies reviewed in the most recent year by the **convened IRB/EC**, what is the median number of calendar days from submission to...	**Review:** Median elapsed time in days from first transition into Pre-Review state to the oldest scheduled date of any meeting to which the study was assigned when Submit Committee Review was performed on it (for all studies currently in Approved, Lapsed, or Suspended state and where the initial approval date is within the previous calendar year).
	Approval: Median elapsed time in days from first transition into Pre-Review state to initial study approval or initial effective date, whichever is later (for all studies currently in Approved, Lapsed, or Suspended state and where the initial approval date is within the previous calendar year).
34. Your organization's review of certain **events**	Number of RNI submissions that reached the Acknowledged or Completed state in the previous calendar year with a determination* of "**Serious non-compliance**"
	Number of RNI submissions that reached the Acknowledged or Completed state in the previous calendar year with a determination* of "**Continuing non-compliance**"
	Number of RNI submissions that reached the Acknowledged or Completed state in the previous calendar year with a determination* of "**Unanticipated problem** involving risks to subjects or others"

* RNI submissions can be assigned multiple determinations.

Note: The contact information in the first two pages of the report is completed for you if you have entered it in the system as described in Produce the AAHRPP Annual Report on page 32.

Tag Submissions

As an IRB staff member, you can add tags, or keywords, to any type of IRB submission so that you can later report on those submissions. For example, you could tag submissions with "Phase III" to identify submissions in that clinical trial phase.

You can associate tags to any type of submission in any state.

Note: IRB Data Managers can update and add to the list of tags that can be associated with a submission, as described in the *IRB Deployment Guide*.

To tag a submission

1. From My Inbox, click the name of the submission you want to open.
2. Click **Manage Tags**.
3. Under Associate Tags, start typing the name of the desired tag or click the ellipsis.
4. Select tags from the list and click **OK**. If you want to use a tag that is not in the list, contact your site administrator to add it.
5. Click **OK** again to associate the tags with the submission.

> **Tip:** You can find the tagged submissions by searching for the tag text in the search box on the IRB Submissions page.

Generate a Report of Submissions with Tags

As an IRB staff member, you can add tags, or keywords, to any type of submission so that you can later report on those submissions. Once tagged, an IRB staff member or user with the Global IRB Viewer role can run the Submissions with Tags standard report and filter the report to show only submissions that have specific tags.

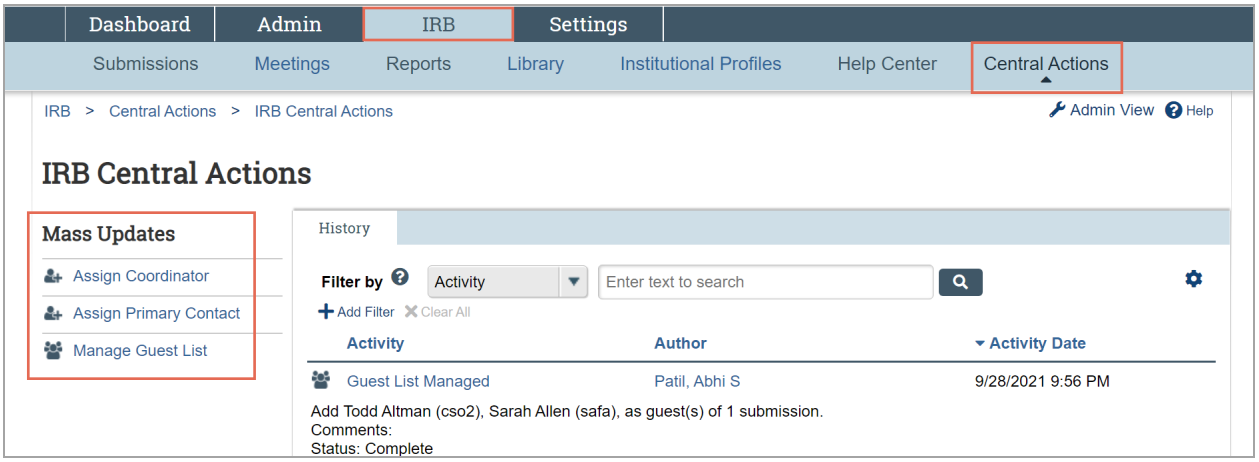
To generate a report of submissions that have certain tags

1. Click **IRB** on the Top Navigator then click **Reports** on the Sub-Navigator.
2. On the **Standard Reports** tab, click the **Submissions with Tags** link.
3. In the Filter by area, click the drop-down menu and select **IRB Tags**.
4. Type the beginning characters for the tag 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
5. Click the search icon  to apply the filter.

Mass Update Administrative Assignments

Mass update activities can update administrative assignments on multiple projects in a single run. This is much more efficient than methods that affect only one project at a time, such as selecting personnel in a SmartForm or running activities from the project workspace.

Mass update activities reside on the IRB Central Actions workspace.



When planning a mass update, remember:

- Mass update activities support only administrative assignments that do not require additional reviews and approvals.
- The security and business rules governing mass update activities, such as who can be assigned, and how that will impact a project, are the same as for single-project assignment activities.
- As mass updates can have extensive impacts, only users with the Site Manager or IRB Data Manager role can run them.
- To run a mass update activity, a data manager must also have at least one role with Read rights on the targeted projects, for example, Global IRB Viewer.

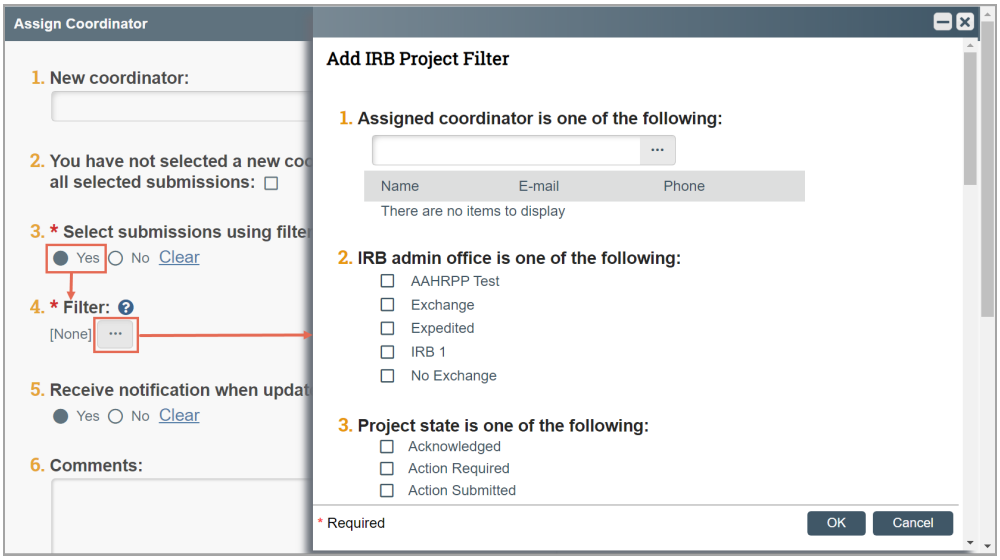
IRB mass update activities support these assignments:

To make this assignment	Run this activity
Replace coordinator	▪ Assign Coordinator
Replace primary contact	▪ Assign Primary Contact
Add or remove guests	▪ Manage Guest List

To run a mass update activity

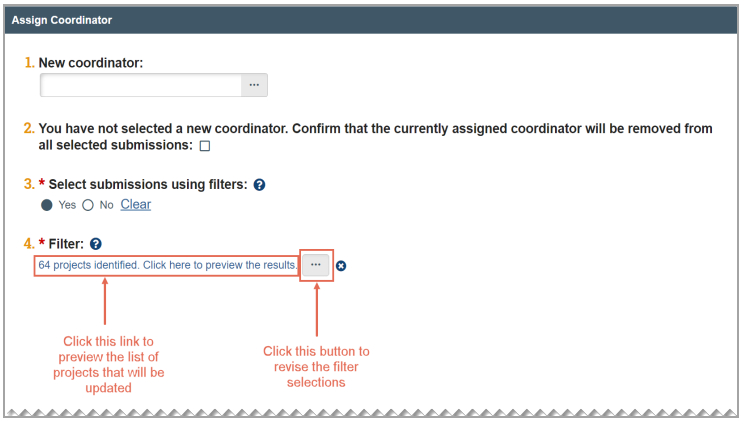
1. Select the appropriate type of activity for the assignment.
2. Select the personnel to perform the activity upon.

3. Select the projects to affect. You can do so in two ways:
   - Filter projects by specified attributes. This option lets you define a set of filters to apply.



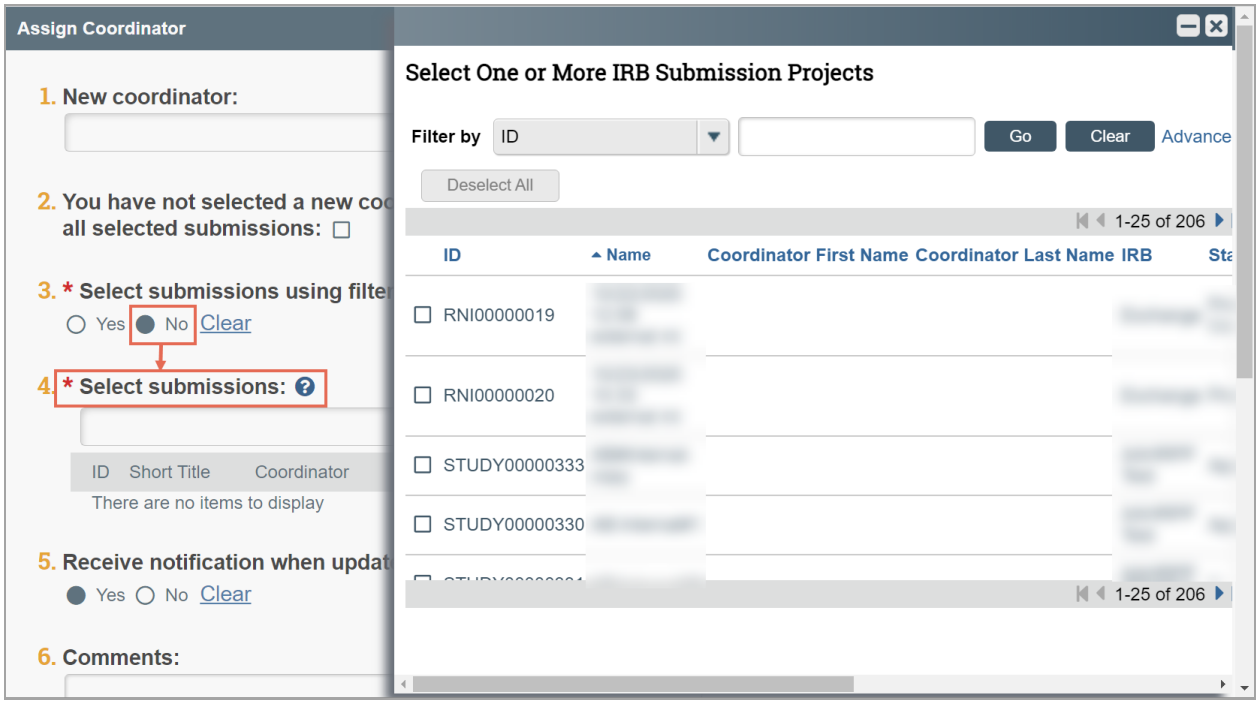
You can select more than one item for each filter.

Once you OK a set of filter selections, the activity form reports how many projects satisfy your filter criteria. You can then preview the list of projects to verify they're the ones you intended. If not, you can modify the filters and preview until you are satisfied with the returned list.



Executing the activity updates the specified administrative assignments on every project satisfying your filter criteria. Use filtering when you need to update assignments for many projects.

- Select projects from a list. This is the standard selection mechanism used throughout IRB, and offers the standard search features.



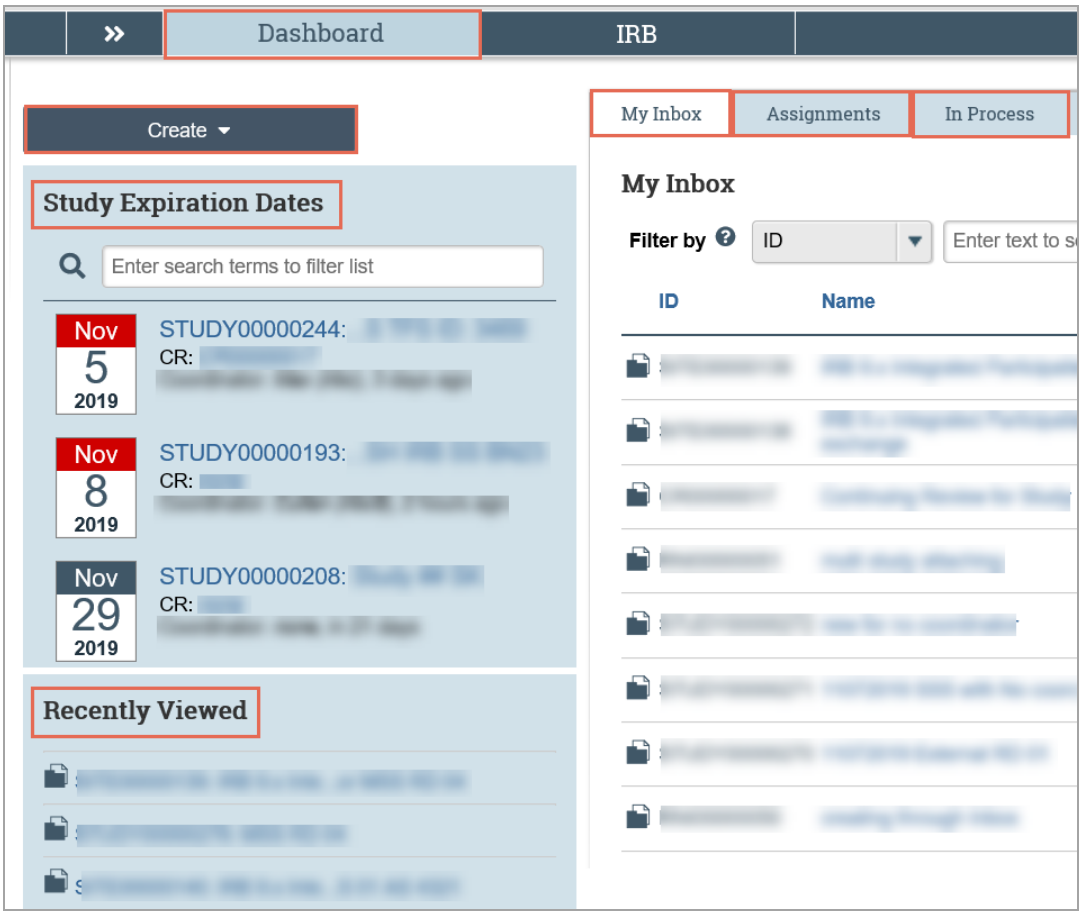
  Selecting projects from a list is a good approach when you need to update assignments for only a few projects.

4. Once you've selected the desired projects, click **OK** on the activity form to run the activity.
   As the data manager who ran the mass update, you receive an email notification when it completes.
5. Review the activity history when the update completes.
   - To examine the filtering criteria that were used, click the activity name on the History tab, and on the resulting summary, click **View More Details**.
   - If the activity history shows skipped or failed updates, click the **Background processing results** link to open a spreadsheet with additional details. This spreadsheet also serves as an audit trail for which projects were affected.

Manage Submissions from Your Dashboard

When you first log in, you will be on the Central Staff Dashboard. In addition to all the features of the General Dashboard as seen by reviewers and researchers, the Central Staff Dashboard has features designed to help you track deadlines and manage workloads of team members ensuring that the tasks are completed on time.

This topic focuses on project management features as highlighted in the screenshot below:



To find key items for submission and workload management

From your Dashboard, you will see:

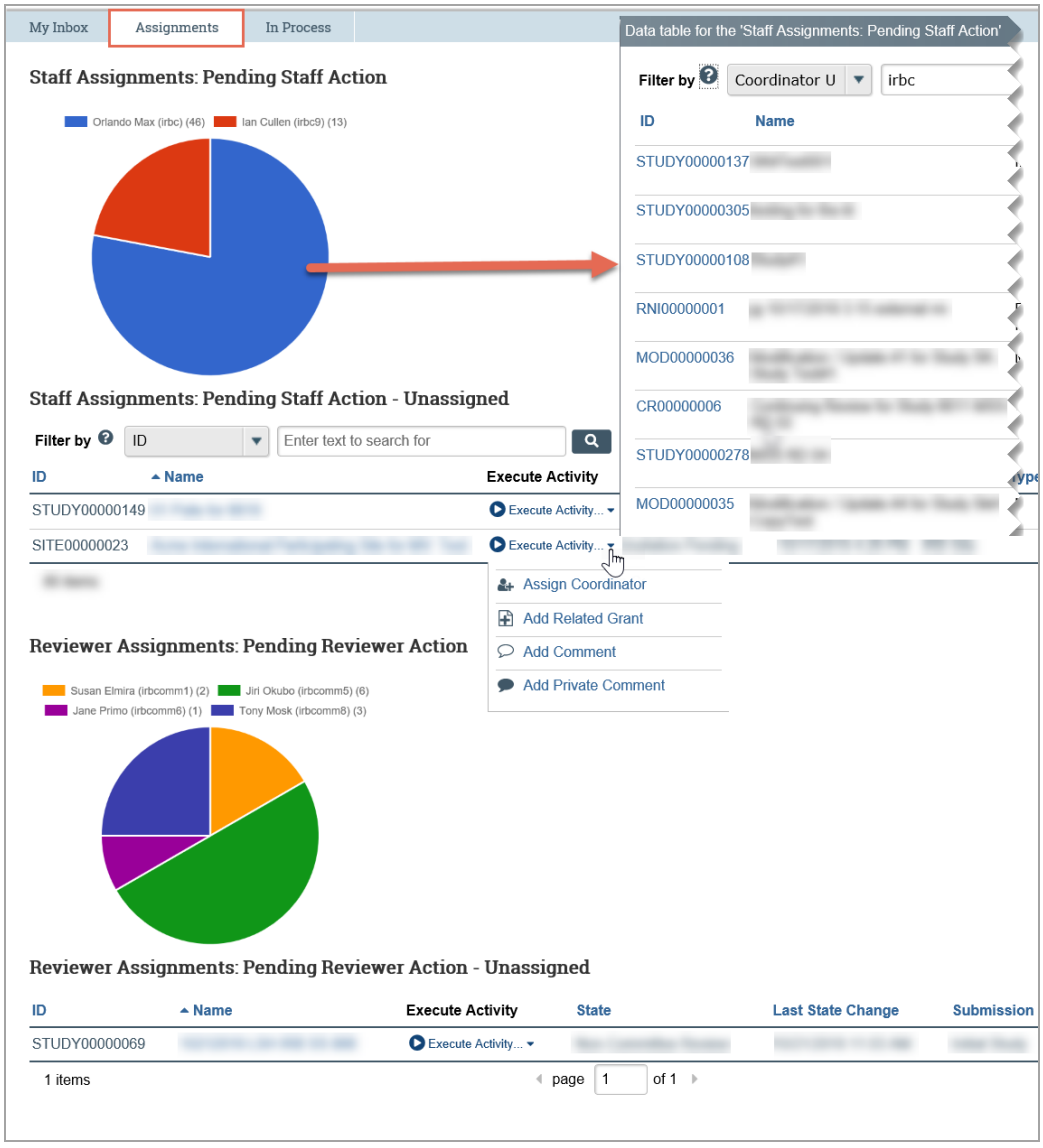
- **Create menu and buttons:** Actions you can perform. The menu will not show if you do not have access to any buttons.

- **Study Expiration Dates:** Shows the studies about to expire, as well as those that have expired or been suspended. Studies appear 60 days before their expiration date (last day of approval period).
  The study expiration dates icon's header is one of three colors, which designate the nearness of a submission or completion deadline, as shown in the table below:

Type of Submission	Blue	Orange	Red	Disappears when
Study	The study expiration date is between 60 and 15 days away.	Today is 15 days or less before the expiration date.	Today is the expiration date or it is within 6 days after the expiration date.	Either: ◦ The expiration date has been extended beyond 60 days ◦ 6 days have passed since the expiration date.

  You can search for a submission by typing any part of its ID or name in the text box and pressing Enter. Click the submission link to open its workspace.
- **Recently Viewed:** Shows the last several items you viewed. Look here for an item you worked on recently.
- **My Inbox:** Items that require you to take action.

- **Assignments tab:** Shows who is assigned to the submissions. Different options to view assignments in this view are:
  - **Staff Assignments: Pending Staff Action:** Shows who is assigned to submissions.
  - **Staff Assignments: Pending Staff Action - Unassigned:** Shows the list of submissions that are unassigned.
  - **Reviewer Assignments: Pending Reviewer Action:** Shows the submissions of reviewers that are assigned.
  - **Reviewer Assignments: Pending Reviewer Action - Unassigned:** Shows the list of submissions that are unassigned for reviews.

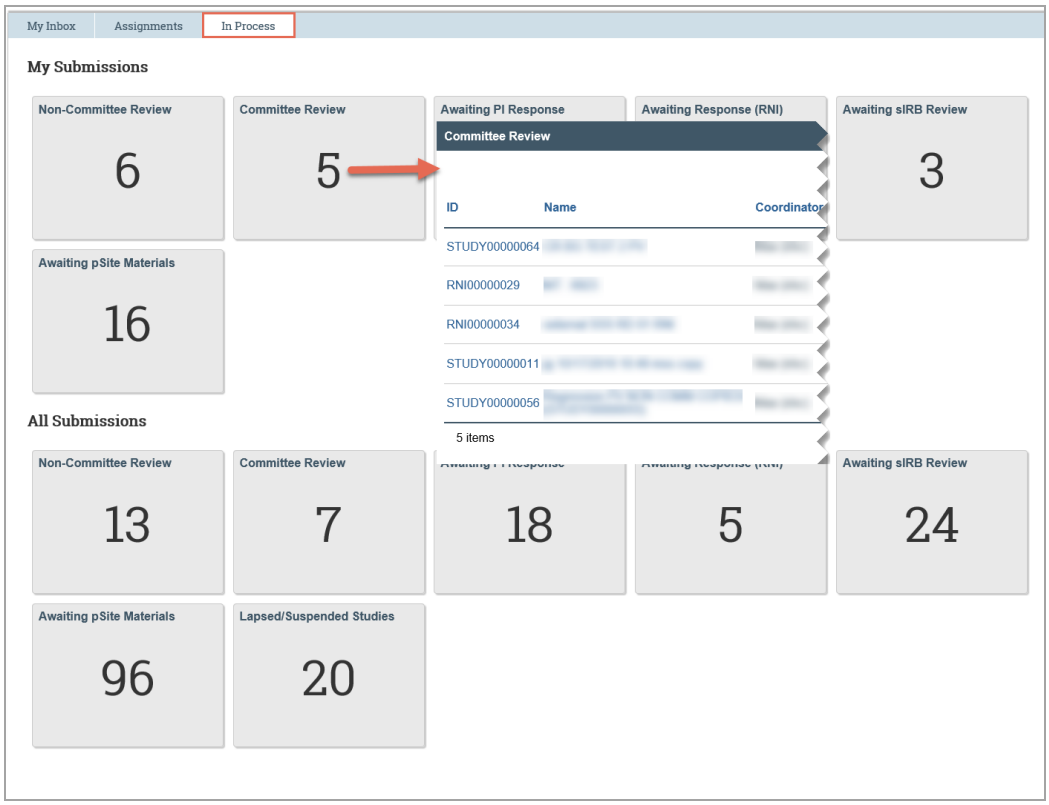


Pie charts show at a glance whether workloads are imbalanced so you can adjust assignments to keep submissions on schedule. Click a segment to view a related table listing the submissions that person is assigned to.

> **Tip:** Click a user's name to remove them from the pie chart and view a smaller set of users.

The tables show a list of unassigned submissions. From the table you can access and edit submission data, and even execute activities. For example, to assign a user to a submission, click **Execute Activity** for the submission you want to assign, then select the appropriate **Assign…** activity and select the desired user.

- **In Process tab:** Groups submissions by state. Different options in this view are:
  - **My Submissions:** Submissions by state.
  - **All Submissions:** All the submissions by state.



The number on a tile tells you how many submissions are there in that category. Click on a tile to view a related table listing those submissions. From the table you can access and edit submission data, and execute activities.

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