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IRB Process Overview

The IRB system treats all types of submissions—studies and follow-on submissions—very similarly. You perform the same activities and follow the same process for each, with small exceptions. The questions asked are different for each type of submission, but the workflow is almost the same.

At the highest level, all submission types use the following IRB process workflow:

The system shows the diagram above when you view an individual study and shows the current state of the study in dark blue (Pre-Submission in this case). Pre-Submission indicates that the principal investigator has not yet submitted the study for review.

IRB Submission Types

The IRB system accepts these types of submissions:

- Initial submissions (studies)
- Follow-on submissions:
  - Modifications and continuing reviews (either combined or separate) for approved studies
  - New information reports (often called RNI for reportable new information) for approved studies or active research in general

All submission types follow a very similar workflow. Some differences include:

- Each type of follow-on submission has its own set of determinations that differs from the study determinations.
- Studies, modifications, and continuing reviews include optional ancillary reviews that can be conducted concurrently with the IRB's reviews. RNI submissions do not include ancillary review.
- RNI submissions may skip certain review states.
Study Process Overview

The basic process for a study—or initial submission—is shown in the following diagram. The exploded view shows what occurs during the IRB review process.

The legend indicates who can take major actions during each state within the process. Keep in mind that the diagram does not show all possible paths that a submission may take. The diagram shows the most likely path through the review process with common options identified.

Studies include optional ancillary reviews that can be conducted concurrently with the IRB's reviews. For more ancillary review information, see Ancillary Review Overview on page 5.

Before IRB review activities can begin, the submission must be assigned to an IRB coordinator, as described in Assigning Ownership of a Study on page 16.

Notable information about several states is identified below.

**IRB Pre-Review and Clarifications Requested**: In the Pre-Review state, the IRB coordinator answers questions about oversight agencies, special populations, etc., that apply to the study. Instead of asking the study team to answer the questions, the IRB staff takes responsibility for reviewing the submission information and answering them. Answering these questions before a committee review can save the committee's time if information is found to be missing or inconsistent. The IRB coordinator can send the study back to the study team for clarifications if needed, which lets the study team change the study.

**IRB Review**: IRB review is not a single state, but a collection of other states.
Post-Review and Modifications Required: The Post-Review state gives the IRB staff the opportunity to:

- Mark selected documents attached to a submission as approved to create final copies
- Prepare a letter to inform the study team about the IRB’s decision
- Send the letter

Sending the letter transitions the submission to the state determined by the IRB, such as Modifications Required or Approved. If the IRB decided to require modifications to the study before approving it or considering it Not Human Research, etc., the submission moves to the Modifications Required state to allow the study team to respond.

When the study team submits modifications, the IRB coordinator, director, or committee chair can choose to review the modifications personally. The IRB coordinator and director can also send them to non-committee or committee review, as appropriate. If the modifications are not acceptable, the submission is sent back to the Modifications Required state. If the modifications are acceptable, the submission returns to the Post-Review state and receives its final determination (for example, Approved) when the letter is sent.

The system purges all individual comments from committee review (everything submitted through the Add Review Comments activity) when the letter reflecting the final state is sent.

Ancillary Review Overview

The review process for studies, modifications, and continuing reviews optionally includes ancillary reviews. Ancillary reviews allow individuals, departments, and other organizations to give feedback on the submission in parallel with the IRB review. The system does not prevent a submission from being reviewed or approved by the IRB with ancillary reviews outstanding. Decisions about how, when, and whether to interrupt the IRB review process to wait for ancillary reviews are left to your IRB policies and staff.

Ancillary reviews can occur at any time from the Pre-Submission to Post-Review states, as illustrated here, or in the case of JHS/UMH, after the study has been approved by the IRB.

Initiating Ancillary Reviews

Both study team members and IRB staff can add ancillary reviewers to a study, modification, or continuing review as follows:

- Study team members can add ancillary reviewers to a submission before submitting it for IRB review.
- IRB staff can add ancillary reviewers before or after it has been submitted for IRB review.
- Both can add individuals and organizations as reviewers.
- The system will also automatically add required ancillary committees, based on the study team’s answers to questions within the SmartForm. Although you have the option of adding reviewers to the list of ancillary reviewers by clicking Manage Ancillary Reviews, we recommend instead relying on the system to automatically determine which ancillaries are required. The ancillaries added by the system automatically will take precedence over ancillaries added via the Manage Ancillary Reviews activity.
Organizations must be set up in advance with specific ancillary reviewers or no one will receive the ancillary review notification for the organization. A PI's research profile can be set up with a set of default ancillary reviewers, such as her department, to be included in all new studies (but not modifications or CRs) she creates. If your standard process includes ancillary reviews, performing these setup steps is critical. For instructions, see the online help.

For example, when a study is created, any ancillary reviewers identified in the PI's profile gain access to the study. When the PI adds more ancillary reviewers, they also gain access. When the study is submitted for IRB review, the reviewers receive notifications.

The IRB staff can add ancillary reviewers at any time before the study transitions from Post-Review to its final state, such as Approved. Any reviewers added after the study is submitted receive notifications when the IRB staff member adds them.

**Note:** Ancillary reviewers identified in the PI's profile are not automatically included in modifications and CRs created by the PI. Any ancillary reviewers must be added manually for each modification and CR.

**Notifications and Ancillary Review Feedback**

Ancillary reviewers are identified as required or optional by the person adding them to a research profile or an individual submission. A required ancillary reviewer receives the submission in My Inbox, where it remains until the review accepts the submission. An optional reviewer does not see the submission in My Inbox. Both required and optional reviewers receive a notification and can use the Submit Ancillary Review activity to provide feedback.

If any reviewer, required or optional, contacts the IRB to provide feedback, the IRB staff can add the reviewer's comments into the system using the Manage Ancillary Reviews activity to update the review. IRB staff can also modify the optional/required setting of a reviewer on the submission.

Ancillary review feedback is visible on the Reviews tab to everyone who can access the submission. For details, see the online help.

**Decisions Regarding Ancillary Review Feedback**

Depending on your IRB policies and the individual situation, the IRB staff may choose to use ancillary reviews in many different ways. For example:

- Treating all ancillary reviewers as optional and not waiting for responses.
- Letting the IRB review and approval proceed without the response of a required ancillary reviewer.
- Letting the IRB review proceed, but waiting for an required ancillary reviewer response before approving the submission.
- Pausing the IRB review process at any point until the required ancillary reviewers respond. This may involve forcing completion of the ancillary review by requesting clarifications or modifications from the study team (to officially put the submission back in the study team members' inboxes).
External IRB Process Overview

When the local IRB cedes authority over a study to an external IRB of record, the local IRB system tracks minimal information about the study throughout its life cycle. The basic process for reviewing and tracking an external IRB study locally is shown in the following diagram.

The legend indicates who can take major actions during each state within the process. Keep in mind that the diagram does not show all possible paths that a submission may take. The diagram shows the most likely path through the review process with common options identified.

Studies include optional ancillary reviews that can be conducted concurrently with the IRB’s reviews. External IRB studies have a shortened IRB review process, so all required ancillary reviews (except for JHS/UMH) should be completed prior to executing the Confirm External IRB activity. For more ancillary review information, see Ancillary Review Overview on page 5.

Notable information about several states is identified below.

**Pre-Submission:** During Pre-Submission, the PI typically identifies the study as being reviewed by a specific external IRB of record. In response, the forms greatly reduce the required information to submit the study to the local IRB, but add questions about the external IRB and its approval of the submission. The study team will be required to execute the Update Study Information activity, which requires them to enter basic information about the study (study team members, funding sources, drugs, devices, ancillary committee-related questions).

**Pre-Review and Clarifications Requested:** In the Pre-Review state, the IRB coordinator reviews the study, including the external IRB information provided by the PI. The IRB coordinator can send the study back to the study team for more information or clarifications if needed, which lets the study team change the study.

When all of the needed information is supplied, the coordinator confirms the external IRB as the IRB of record, and the study enters the External IRB state.

**External IRB:** The study remains in the External IRB state until the external IRB closes the study. The PI and IRB staff can add or update the approval letter and the last day of approval as the external IRB approves the study and extends the approval period. When the external IRB closes the study, the PI or IRB staff must close the study in the local system.
To enter the External IRB’s study ID number

1. From My Inbox, click the name of the study to open it.
   
   **Note:** If the study does not appear in your inbox, see Accessing a Study on page 15.

2. Click **Study Administration** on the left.

3. Enter the External IRB’s study ID number.

4. Click **OK**.

To update documents approved by an External IRB

In order for documents approved/watermarked by an external IRB to be available to the study team in the Documents tab and in Velos, the documents must be uploaded in eProst by an IRB staff member.

1. From My Inbox, click the name of the study to open it.
   
   **Note:** If the study does not appear in your inbox, see Accessing a Study on page 15.

2. Click **Edit Consent Forms** on the left.

3. Upload the approved, watermarked documents provided by the external IRB.

4. Click **OK**.
Modification / CR Process Overview

The basic process for either a modification or continuing review (CR)—or both combined—is shown in the following diagram. The exploded view shows what occurs during the IRB review process.

The legend indicates who can take major actions during each state within the process. Keep in mind that the diagram does not show all possible paths that a submission may take. The diagram shows the most likely path through the review process with common options identified.

Modifications and continuing reviews include optional ancillary reviews that can be conducted concurrently with the IRB's reviews. For more ancillary review information, see Ancillary Review Overview on page 5.

Because a continuing review often reminds the study staff to submit a modification, modifications and continuing reviews can be combined into a single submission or submitted separately. The beginning of the process prompts the PI to identify which submission type to create.

Modifications

When a study is approved, the system copies the approved study to create a draft study. When a modification is created, the draft study is updated with the proposed changes, while the approved study remains unchanged. When the modification is approved, the changes are published into the approved study.

A modification can apply to the study team membership, to the other parts of the study, or to both. The system allows only one modification at a time to each part of the study. For example, you cannot open a modification of study team membership if the study already has an open modification applying to study team membership or to the entire study.
Study Closure through Continuing Review

When a CR indicates that the top four research milestones listed on the form have been met, the parent study is closed automatically when the CR is approved. The top milestones indicate that all enrollment, interventions, and handling of subjects' private identifiable information is complete.

In the Post-Review state for a study being closed, the study closure letter template is presented instead of the approval template. The letter, along with the closure e-mail notification that is sent, inform the PI of the study closure.

Combined and Separate Modifications and Continuing Reviews

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.

Caution for separate modifications and CRs:

In one situation, 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 Send Letter 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.

Pre-Review for Modifications and Continuing Reviews

Pre-review information is read-only for continuing review submissions and for modification submissions that are limited to study team membership changes. These types of submissions should not affect the pre-review information, so only the final question on the Submit Pre-Review form requires an answer.

For modifications and modification / CRs that include other parts of the study, the Submit Pre-Review form is fully editable, and the answers update the study's pre-review information when the modification is approved.
RNI Process Overview

The basic process for reportable new information (RNI) is shown in the following diagram. The exploded view shows what occurs during the IRB review process.

Unlike all other submission types, an RNI submission:

- Does not include ancillary review.
- Can be reviewed, acknowledged, and closed by an IRB coordinator or a designated reviewer if not deemed to be serious. If serious, a full committee must review the RNI to determine follow-up actions.

**Important!** For RNI submissions related to VA studies, a designated reviewer should always be used.

Unlike a modification or CR, an RNI submission can be associated with one or more studies, or with no study at all. For example, a research coordinator might allege that an investigator is conducting research that was never submitted to the IRB for review. It would not make sense to associate this RNI submission with a study within the system.
Document Change Process Overview

As a result of IRB reviews or changes to research, the study team may need to make changes to a study's documents.

We recommend using Track Changes functionality to easily identify changes for reviewers. When the documents are approved, the IRB software will automatically accept the changes and remove any comments in the final versions.

<table>
<thead>
<tr>
<th>Process</th>
<th>Recommended steps for using tracked changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study staff updates the original study documents.</td>
<td>Retrieve the documents from the Documents tab for the study. Edit the original documents with change tracking enabled and then replace the originals with the tracked-changes versions.</td>
</tr>
<tr>
<td>IRB reviewers review the study.</td>
<td>Use the review features in Word to toggle between showing the original and final versions of the document. No changes are made to the documents; documents remain in tracked-changes format.</td>
</tr>
<tr>
<td>IRB coordinator or director approves the documents using the Finalize Documents activity.</td>
<td>Finalizing the documents accepts the tracked changes and removes any comments to create a final version of the document. The draft version will still have the tracked changes. The draft and final documents appear on the Documents tab for the study.</td>
</tr>
</tbody>
</table>

Access to Studies by Role

Your access to a study is personalized based on your role in the system and the role you play in relation to the particular study. The following table summarizes the policies controlling the visibility of submissions (both studies and follow-on submissions):

<table>
<thead>
<tr>
<th>User role</th>
<th>Information visibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study staff, registered user</td>
<td>Access to submissions that include you on the study team or guest list. You cannot view the assigned reviewers or committee, or gain access to the reviewers’ comments.</td>
</tr>
<tr>
<td>IRB staff, IRB committee members</td>
<td>Access to all submissions. For studies that include you on the study team, you cannot view the assigned reviewers or committee, or gain access to the reviewers’ comments.</td>
</tr>
<tr>
<td>Ancillary reviewers, other reviewers who are not IRB committee members</td>
<td>Full access to submissions assigned to you for review.</td>
</tr>
<tr>
<td>Site manager</td>
<td>Full access to all submissions.</td>
</tr>
</tbody>
</table>
Performing Basic Administration Tasks

IRB staff members play a key role in preparing for reviews, moving a submission through the stages of review, and communicating the results to the study team. Here are a few keys to the process:

- Assigning each submission to an IRB coordinator is a crucial step to allowing further actions to be taken on the submission. Any IRB staff member can assign a coordinator, as described in Assigning Ownership of a Study on page 16.

- Your inbox provides a helpful list of items that need your attention. For details, see Locating Your To-Do List on page 13 and Understanding My Inbox on page 17.

- One of the more complex IRB processes is running a committee meeting. For a checklist to help you through the process, see Checklist of Committee Meeting Tasks on page 19.

Locating Your To-Do List

IRB studies that are assigned to you for action generally appear in My Inbox with a link to the study. You may also receive an e-mail with a link to the study. An e-mail indicates that you must take action or informs you of important changes, such as an IRB decision about your study.

Note: A continuing review, modification, or RNI (reportable new information) submission can be handled similarly to a study.

To access a study that does not appear in My Inbox, see Accessing a Study on page 15.

To access studies or other submissions assigned to you:

1. Click the My Inbox link in the top right navigation header.

2. Identify the reason the study appears in My Inbox by looking at the State column. (For explanations, see Understanding My Inbox on page 17.)

3. Open the study by clicking the link in the Name column.

   The study workspace opens.

   To view the details of the study, click View Study on the left. For instructions, see Viewing the Study Details on page 16.
Navigation Elements within a Study

Once you open a study, you see the study workspace. The workspace is your access point for:

- Viewing the study contents and details, including all actions performed on it
- Performing actions on the study

The figure below identifies the key workspace elements that help you find your way around the IRB system and perform actions on the study.

The key elements shown (from top to bottom) are:

- **Header**: Provides links to your profile and to My Inbox, and lets you log in and log off
- **Top navigator**: Provides links to the major sections of the system you are allowed to access
- **Breadcrumb navigator**: Tracks your movement through the hierarchy of pages and enables you to quickly move back to a previous location
- **Activities**: Lets you take appropriate actions—such as viewing the study—based on the study’s current status
- **Resource tabs**: Gives access to collected study information, such as the study team membership, documents attached to the study, and older versions of the study.
- **Activity history:** Displays the actions taken previously on this study
- **Shortcuts area:** Provides quick links to other frequently used areas of the system, and to documentation resources

## Accessing a Study

You may want to open a specific study to view or update its contents, submit it for review, review it, or take other actions on the study.

**Note:** Your access to a study is personalized based on your role in the system and the role you play in relation to the particular study. In addition, the actions you can take on a study are personalized.

To open a study, click its name when you find it in a list of studies.

To find a list that includes the study, try these suggestions:

<table>
<thead>
<tr>
<th>Check this list...</th>
<th>For...</th>
<th>How to find this list</th>
</tr>
</thead>
</table>
| My Inbox           | Studies assigned to you for action, such as a study you are:  
- Preparing to submit  
- Assigned to review | Click the **My Inbox** link in the top right navigation header.  
[Your Name] **My Inbox** Logoff |
| IRB In-Review tab  | Studies the IRB has not reviewed or for which it has not communicated a decision | Click **IRB** in the top left navigation area and select the **In-Review** tab. |
| IRB Active tab     | Studies approved by the IRB and currently in progress | Click **IRB** in the top left navigation area and select the **Active** tab. |
| IRB All Submissions tab | All studies, continuing reviews, modifications, and reportable new information (RNI) entered into the system that you have permissions to view | Click **IRB** in the top left navigation area and select the **All Submissions** tab.  
**Tip:** Try filtering this list by the study name or principal investigator. Next to Filter by, select **Name** or **Investigator**.  
Then type the beginning of the name and click **Go**. |
| IRB New Information Reports tab | Reportable new information (RNI) submissions, possibly related to one or more studies | Click **IRB** in the top left navigation area and select the **New Information Reports** tab. |
Assigning Ownership of a Study

Before an IRB coordinator can take action on a study, the study must be assigned to the coordinator. Any coordinator or the IRB director can take ownership of the study or assign it to another coordinator. The study can be reassigned at any point to handle vacations, changes in workloads, etc.

When a study is first submitted to the IRB, all IRB coordinators see the study in My Inbox. After a coordinator is assigned, only the assigned coordinator sees the study in My Inbox, only when the IRB needs to take action.

To assign a coordinator:
1. Open the study.
2. Click Assign Coordinator on the left.
3. Select yourself or another coordinator.
4. Click OK.

The coordinator gains access to activities that are reserved for the assigned coordinator and can move the study through the IRB process.

Note: Follow-on submissions (Modifications, Continuing Reviews, and RNIs) are automatically assigned to the IRB coordinator who reviewed the parent study. If the parent study has no IRB coordinator assigned to it, the IRB Director will assign the submission to a coordinator.

Viewing the Study Details

As a reviewer or IRB staff member, you often need to view all the information submitted as part of the study.

To view the details of a study:
4. From My Inbox, click the name of the study to open it.
   Note: If the study does not appear in your inbox, see Accessing a Study on page 15.
5. Click View Study on the left.

Tips:
- For a continuing review or modification, click View Modification / CR instead.
- For a new information report, click View RNI instead.

7. Use the Continue and Back buttons to view all of the forms.

Tip: Clicking Continue from the Supporting Documents page (the last page of the forms) exits the study.
To view the documents submitted as part of the study, you have these options:

- While viewing the details of the study (as instructed above), click the name of each document when you encounter it on the various forms. Documents are listed in tables throughout the forms.
- When you have opened the study workspace (as in step 1 above), you can view a list of all the attached documents in one place by clicking the Documents tab.

**Tip:** If the study team updated the documents, they may contain tracked changes. You can use the review features in Word to toggle between showing the original and final versions of the document. When the IRB approves the documents, all tracked changes will be accepted and comments removed in the final versions.

To view the information entered for pre-review:

1. Open the study as instructed in step 1 above.
2. Click the **Reviews** tab.

**Tip:** If the information entered for pre-review is inaccurate, contact the study's IRB coordinator to request a change. The coordinator can change the pre-review information until the decision from designated or committee review is submitted.

### Understanding My Inbox

The list called My Inbox contains studies or other submissions that require you (or other IRB staff members) to take action. See the examples below to understand what you should and should not expect to appear in My Inbox.

**Tip:** Look at the State column in My Inbox, and see the explanation for that state in the table below.

<table>
<thead>
<tr>
<th>Your role</th>
<th>In My Inbox</th>
<th>Not in My Inbox</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>State</strong></td>
<td><strong>Explanation</strong></td>
<td></td>
</tr>
<tr>
<td>review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRB committee member or occasional reviewer</td>
<td>Non-Committee Review</td>
<td>Studies assigned to other reviewers</td>
</tr>
<tr>
<td></td>
<td>You have been designated as the reviewer for this exempt or expedited study. You must submit your final review before the IRB decision can be communicated to the study team. If you request clarifications, the study comes back to you to finish the review after the clarifications are made.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Committee Review</td>
<td>Studies assigned to other committees</td>
</tr>
<tr>
<td></td>
<td>You may be part of the committee that will review this study. If so, review the study details in advance. You can request clarifications. Record your notes and recommendations in the system before the meeting as described in the online help</td>
<td></td>
</tr>
<tr>
<td>Your role</td>
<td>In My Inbox</td>
<td>Not in My Inbox</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-------------</td>
<td>--------------------------------------</td>
</tr>
<tr>
<td><strong>State</strong></td>
<td><strong>Explanation</strong></td>
<td></td>
</tr>
<tr>
<td>Ancillary reviewer</td>
<td>One of several</td>
<td>You have been selected as a reviewer (either by name or representing a specific organization). The IRB can begin its review before you submit your review. The IRB may or may not wait for your input before completing its review of the study.</td>
</tr>
<tr>
<td>Committee chair</td>
<td>Committee Review</td>
<td>The study has been assigned to your meeting. The IRB director, IRB coordinator, or you must submit the committee’s review decision.</td>
</tr>
</tbody>
</table>

**IRB administrative staff**

<table>
<thead>
<tr>
<th>IRB coordinator (IRBC)</th>
<th>Pre-Review</th>
<th>Newly submitted studies appear in all coordinators' inboxes until a coordinator is assigned. (See the Coordinator column of My Inbox.) The assigned coordinator must submit a pre-review and assign the study to designated review or a committee.</th>
<th>Studies not yet submitted to the IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post-Review</td>
<td>The IRB decision has been made. You must prepare correspondence and send it to notify the investigator of the decision. You can also finalize study documents to create a permanent record.</td>
<td>Studies being reviewed by individual reviewers</td>
</tr>
<tr>
<td></td>
<td>Committee Review</td>
<td>You can assign the study to a particular meeting, remove it from a meeting agenda and reassign it to another, and assign specific reviewers. The IRB director, IRB chair, or you must submit the committee’s review decision.</td>
<td>Studies assigned to other IRBCs</td>
</tr>
</tbody>
</table>

My Inbox will contain all of the items you currently own, plus those items that do not yet have an owner. As other IRB staff members take ownership of these submissions, they will be removed from your inbox.
Add Comments/Add Private Comments

Add Comments

Anyone who has "read" access to a study may add comments to the study and read comments posted by others. These comments will be visible only in the History Log of the study/submission. The system will NOT send an email notification to notify others that you have posted a comment.

To add comments:
1. Open the study by clicking the study's name. (For instructions about finding the study, see Accessing a Study on page 15.)
2. Click Add Comment from the My Current Actions list on the left. A new window opens.
3. Enter your comments. You may also upload supporting documents.
4. Click OK.

Add Private Comments

IRB staff and committee members may also post private comments that are not visible to anyone outside of the HSRO/IRB. These comments will be visible only in the History Log of the study/submission. The system will NOT send an email notification to notify others that you have posted a comment.

To add private comments:
1. Open the study by clicking the study's name. (For instructions about finding the study, see Accessing a Study on page 15.)
2. Click Add Private Comment from the My Current Actions list on the left. A new window opens.
3. Enter your comments. You may also upload supporting documents.
4. Click OK.
Checklist of Committee Meeting Tasks

The checklists below identify the major steps for preparing for, conducting, and completing a committee meeting. The checklists assume you have already created the committee and the meeting.

Most steps are performed by the committee chair or committee administrator in the meeting workspace unless otherwise specified.

Preparing for Each Meeting

Well in advance of the meeting:

☐ Assign studies (Modifications/CRs/RNIs) to the meeting (from the item's workspace).

☐ Assign reviewers to the items assigned to the meeting (from the meeting or study workspace). Reviewers will be notified when you send out the agenda.

☐ Prepare the agenda.

☐ Send the agenda to committee members and any additional recipients.

Note: If you change the agenda after you have sent it out, use the Notify Reviewers action to inform reviewers of the change.

Just before the meeting:

☐ Edit the meeting attendance if you know who is planning to attend.

☐ Remove any items in the Clarification Requested (Committee Review) state from the agenda if the missing clarifications warrant delaying a committee decision. Reassign the submissions to a later meeting.

Tip: Items in the Clarification Requested (Committee Review) state that remain on the agenda will transition back to the Committee Review state when the meeting is convened.

Conducting the Meeting

We recommend dedicating one person to fill out the Submit Committee Review forms and record the non-submission information such as meeting start and end times.

During the meeting, it may be helpful to display study information and committee member review comments in the course of discussion. See tips for navigating to study information below.

Meeting administration:

☐ Record meeting times, attendance, and other non-submission items.

Tip: You may wish to record this information using the meeting minutes template. To do so, prepare the meeting minutes, save the generated document to your computer, and then use it to record the information. When you prepare the final minutes (as instructed below), copy and paste the items recorded during the meeting into the final version of the minutes.

☐ Convene the meeting. Note: Convene Meeting returns agenda items in the Clarifications Requested (Committee Review) state to Committee Review.

☐ (Optional) Under "Previous meetings with minutes for approval," click a previous meeting to go to its workspace. Then you can display its minutes, approve them, and return to the current meeting.
Click the **Expedited Submissions Approved** link to display the report.

**Tip:** To keep a permanent record of the approved expedited submissions reviewed during the meeting, export the report to Excel and save it to your computer. Later, copy and paste the information from the report into the minutes.

---

**Tips for navigating to study information:**

From the meeting workspace:

- To show study information, click the name of a study in the agenda items list.

From the study workspace:

- To show study details in the forms, use View Study (Modification/CR/RNI).
- To show attached documents, use the Documents tab.
- To show information recorded during pre-review and comments from individual committee members, use the Reviews tab.
Recording decisions, events, and notes:

- From the individual reviewer checklists, reviewer comments, and committee discussion, fill out all relevant checklists to reflect the final committee opinion and reasoning. These files will be attached in the Submit Committee Review activity.
- Perform Submit Committee Review (or Submit RNI Committee Review for an RNI) to record decisions and information for each submission reviewed. Attach the relevant checklists. Note: The IRB coordinator assigned to the study can also submit the committee review.

**Important!** Don’t miss the Submit Committee Review or Submit RNI Committee Review step. Correspondence cannot be prepared and sent to the investigator for a study until this step has been completed.

**Tip:** If there is not enough time to completely fill out the committee review form during the meeting, finish it as soon as possible after the meeting. You can complete some of the form and select “No” to the question “Are you ready to submit this review?” The system will save what you have entered so you can update and submit it later.

Wrapping Up After the Meeting

- If you haven’t yet submitted the final committee review for each study, do so now to move to the next steps.

**Tip:** From the meeting workspace, look at the Record Decision column for the agenda items. The column will indicate Submit Committee Review or Submit RNI Committee Review if the action has not yet been completed.

- Prepare the minutes. The minutes will contain the committee decisions for each study.
- Open and save the minutes on your computer. Add the meeting times, attendance, and any other non-submission items to the minutes. Note: If you used the minutes template to record information during the meeting, simply cut and paste the information from that document into the minutes.
- Perform Prepare Minutes again to upload the revised minutes.
- Follow your internal processes to obtain the appropriate approvals of the meeting minutes.
- Inform the IRB coordinator(s) that they can send correspondence to the investigators. For each study, the assigned coordinators:
  - Finalize the study’s attached documents to create an approved, stamped copy (optional).
  - Prepare a letter to inform the study’s investigator about the IRB’s decisions.
  - Send the letter to the investigator.
- Send the minutes to the committee members.
- Close the meeting.
- After the period for receiving comments from committee members has passed, perform Approve Meeting Minutes.

**Tip:** Until you perform this action, the minutes are listed in the next meeting’s workspace with the approve activity available there as well.
Generating 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.

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—studies for which the person is included on the study team or guest list. IRB coordinators, directors, and committee members generally have access to all report data.

To generate a report:
1. Click IRB in the top navigator.
2. Click IRB Reports on the left.
   
   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 click Go.

Producing 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:** Site manager permissions are required to perform the initial setup step. IRB director permissions are required to generate the report.

To generate the AAHRPP report:
1. Log in with IRB director permissions.
2. Click IRB in the top navigator.
3. Click IRB Reports on the left.
4. Click Generate AAHRPP Report on the left.

**My Current Actions**

   Generate AAHRPP Report

A new window opens, providing a link to the generated report.

5. Click the link and choose to save the report as a Microsoft® Word file.
Important! The report is not stored in the IRB system, so save the file in an appropriate location for later retrieval if you need to keep a permanent copy.

6. Click Close to dismiss the window.

To complete the generated report:
1. Open the saved file.
2. Review the answers that are filled in, and adjust the answers as necessary if the IRB system does not contain complete data (or add the information to the IRB system and regenerate the report).
3. Answer the questions that are blank, saving the file often.

Tip: To mark a check box:
   a. Right-click the box and select Properties.
   b. Under Default value, select Checked.

4. Scroll through every page, being sure to answer each question.
5. Follow the checklist located at the end of the document, verifying the report contents and creating a PDF file to send to AAHRPP.
Administration of Ongoing Studies

Study Administration

IRB Staff Members can execute the Study Administration activity. This activity enables you to:

- Enter/correct study expiration dates
- Enter/correct study closure dates
- Enter study ID numbers for External IRB studies
- Flag studies for emergency use, compassionate use, multiyear approval, eLane, capped IRB fees, and studies in which the ICF language is not consistent with contract language
- Update finalized (watermarked) study documents

To update the study:
1. Open the study by clicking the study's name. (For instructions about finding the study, see Accessing a Study on page 15.)
2. Click Study Administration from the My Current Actions list on the left. A new window opens.
3. Update applicable fields.
4. Click OK.

Update Pending Contingencies

This activity is to be used after a study has been approved, but there are items the HSRO/IRB is requesting that the study team complete within a certain timeframe. You will receive email reminders 10 days before an item/contingency is due and the day after the due date.

To add new pending items:
1. Open the study by clicking the study's name. (For instructions about finding the study, see Accessing a Study on page 15.)
2. Click Update Pending Contingencies from the My Current Actions list on the left. A new window opens.
3. Add contingencies by clicking the Add button. For each pending item, you will select a Type from the dropdown, enter a brief description, the date the request was made to the study team, and date due.
4. Click OK.

As the study team completes the items, use this activity to update the status.

To update existing pending items:
1. Open the study by clicking the study's name. (For instructions about finding the study, see Accessing a Study on page 15.)
2. Click Update Pending Contingencies from the My Current Actions list on the left. A new window opens.
3. Update contingencies. If the item has been completed by the study team, check the "completed" box and enter the date completed.
4. Click OK.
# Finding More Information

<table>
<thead>
<tr>
<th>To find this...</th>
<th>...look for this...</th>
<th>...and click...</th>
</tr>
</thead>
<tbody>
<tr>
<td>More information about a question or form.</td>
<td><img src="image" alt="Question Mark Icon" /></td>
<td>Click the question mark icon next to the question or form title.</td>
</tr>
<tr>
<td>The full online help system, with search and table of contents.</td>
<td><img src="image" alt="Quick Help" /></td>
<td>Click the Help link in the Shortcuts area on the left.</td>
</tr>
<tr>
<td>The online help contains additional procedures and information for all users.</td>
<td><img src="image" alt="Study Submission Guide" /></td>
<td>Click the Study Submission Guide link in the Shortcuts area on the left.</td>
</tr>
<tr>
<td>Instructions for submitting a study for review.</td>
<td><img src="image" alt="Study Submission Guide" /></td>
<td>Click the Study Submission Guide link in the Shortcuts area on the left.</td>
</tr>
<tr>
<td>Document templates, checklists, and IRB procedures.</td>
<td><img src="image" alt="IRB Library" /></td>
<td>Click IRB and then IRB library in the upper left corner.</td>
</tr>
</tbody>
</table>
## Appendix 1: Project States and what they mean

<table>
<thead>
<tr>
<th>Project State</th>
<th>Description</th>
<th>Pending Action by (and will be found in the inbox of)</th>
<th>Submission in this state can be found in the:</th>
<th>Can be edited by the Study Team?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-Submission</strong></td>
<td>Has not yet been submitted by the PI. Can also indicate the submission was previously submitted by the PI but later withdrawn (upon withdrawal, submissions return to the Pre-Submission state)</td>
<td>PI/Study Team</td>
<td>In-Review tab</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Disapproved</strong></td>
<td>Submission has been disapproved by the IRB</td>
<td>N/A</td>
<td>Archived tab</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Pre-Review</strong></td>
<td>Submission has been submitted by the PI</td>
<td>HSRO</td>
<td>In-Review tab</td>
<td></td>
</tr>
<tr>
<td><strong>Clarification Requested (Pre-Review)</strong></td>
<td>HSRO has requested clarifications or changes. Study Team must make the requested changes and execute the &quot;Submit Changes&quot; activity</td>
<td>PI/Study Team</td>
<td>All Submissions tab</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Pre-Review Completed</strong></td>
<td>HSRO has completed the pre-review and submission is ready to be sent to the IRB</td>
<td>HSRO</td>
<td>In-Review tab</td>
<td></td>
</tr>
<tr>
<td><strong>Non-Committee Review</strong></td>
<td>Submission is being reviewed by an IRB member</td>
<td>IRB</td>
<td>In-Review tab</td>
<td></td>
</tr>
<tr>
<td><strong>Committee Review</strong></td>
<td>Submission is/will be scheduled for review at an upcoming IRB meeting</td>
<td>IRB</td>
<td>In-Review tab</td>
<td></td>
</tr>
<tr>
<td><strong>Clarification Requested (Committee Review)</strong></td>
<td>IRB has requested clarifications or changes. Study Team must make the requested changes and execute the &quot;Submit Changes&quot; activity</td>
<td>PI/Study Team</td>
<td>All Submissions tab</td>
<td></td>
</tr>
<tr>
<td><strong>Post-Review</strong></td>
<td>Submission has been reviewed by the IRB and determination letter is being prepared</td>
<td>HSRO</td>
<td>In-Review tab</td>
<td></td>
</tr>
<tr>
<td><strong>Modifications Required</strong></td>
<td>Submission has been reviewed by the IRB but the IRB has requested changes (Modifications Required to Secure Approval). Study Team must make the requested changes and execute the &quot;Submit Modifications&quot; activity</td>
<td>PI/Study Team</td>
<td>All Submissions tab</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Modifications Submitted</strong></td>
<td>Changes have been submitted by the study team and changes now must be reviewed by IRB (committee, designated reviewer, or HSRO staff)</td>
<td>HSRO/IRB</td>
<td>In-Review tab</td>
<td></td>
</tr>
<tr>
<td><strong>Deferred</strong></td>
<td>Submission has been reviewed by the IRB but the IRB has requested changes</td>
<td>PI/Study Team</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Approved</strong></td>
<td>Submission has been approved by the IRB</td>
<td>N/A</td>
<td>Active tab</td>
<td></td>
</tr>
<tr>
<td>Project State</td>
<td>Description</td>
<td>Pending Action by (and will be found in the inbox of)</td>
<td>Submission in this state can be found in the:</td>
<td>Can be edited by the Study Team?</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------</td>
<td>-----------------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>External IRB</td>
<td>Submission is under the purview of an external IRB</td>
<td>N/A</td>
<td>Active tab</td>
<td></td>
</tr>
<tr>
<td>Lapsed</td>
<td>Study has lapsed in IRB approval and a continuing review is required</td>
<td>PI/Study Team</td>
<td>Active tab</td>
<td></td>
</tr>
<tr>
<td>Suspended</td>
<td>Submission has been suspended by the IRB, either for cause or due to lapse in IRB approval</td>
<td>PI/Study Team</td>
<td>Active tab</td>
<td></td>
</tr>
<tr>
<td>Closed</td>
<td>Study has been closed by the IRB, either through approval of a final report or through administrative closure</td>
<td>N/A</td>
<td>Archived tab</td>
<td></td>
</tr>
<tr>
<td>Discarded</td>
<td>Submission has been permanently discarded by the study team and will not be submitted/re-submitted</td>
<td>N/A</td>
<td>Archived tab</td>
<td></td>
</tr>
<tr>
<td>Terminated</td>
<td>Study has been closed by the IRB</td>
<td>N/A</td>
<td>Archived tab</td>
<td></td>
</tr>
<tr>
<td>Not Human Research</td>
<td>IRB has determined that the study does not meet criteria for human subject research</td>
<td>N/A</td>
<td>Archived tab</td>
<td></td>
</tr>
<tr>
<td>Human Research, Not Engaged</td>
<td>IRB has determined that UM is not engaged in the research</td>
<td>N/A</td>
<td>Archived tab</td>
<td></td>
</tr>
<tr>
<td>RNI Review</td>
<td>Applies only to RNI submissions. RNI has been submitted by the PI and is pending review by the HSRO/IRB</td>
<td>HSRO/IRB</td>
<td>In-Review tab and New Information Reports tab</td>
<td></td>
</tr>
<tr>
<td>Clarification Requested (RNI Review)</td>
<td>Applies only to RNI submissions. IRB reviewer has requested changes or clarifications. Study Team must make the requested changes and execute the &quot;Submit Changes&quot; activity</td>
<td>PI/Study Team</td>
<td>In-Review tab and New Information Reports tab</td>
<td>Yes</td>
</tr>
<tr>
<td>RNI Review Completed</td>
<td>Applies only to RNI submissions. IRB member has reviewed the RNI. Pending further action by the HSRO.</td>
<td>HSRO</td>
<td>In-Review tab and New Information Reports tab</td>
<td></td>
</tr>
<tr>
<td>Complete</td>
<td>Applies only to RNI submissions. Determination letter has been sent by the HSRO. Only applicable if the determination was that the RNI was unanticipated, required suspension or termination, was serious, or continuing.</td>
<td>N/A</td>
<td>New information Reports tab</td>
<td></td>
</tr>
<tr>
<td>Acknowledged</td>
<td>Applies only to RNI submissions. Determination letter has been sent by the HSRO.</td>
<td>N/A</td>
<td>All RNI Submissions tab</td>
<td></td>
</tr>
</tbody>
</table>