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The University of Georgia

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# **IRB Staff Administration Guide**

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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 highlights the current state of the study (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:

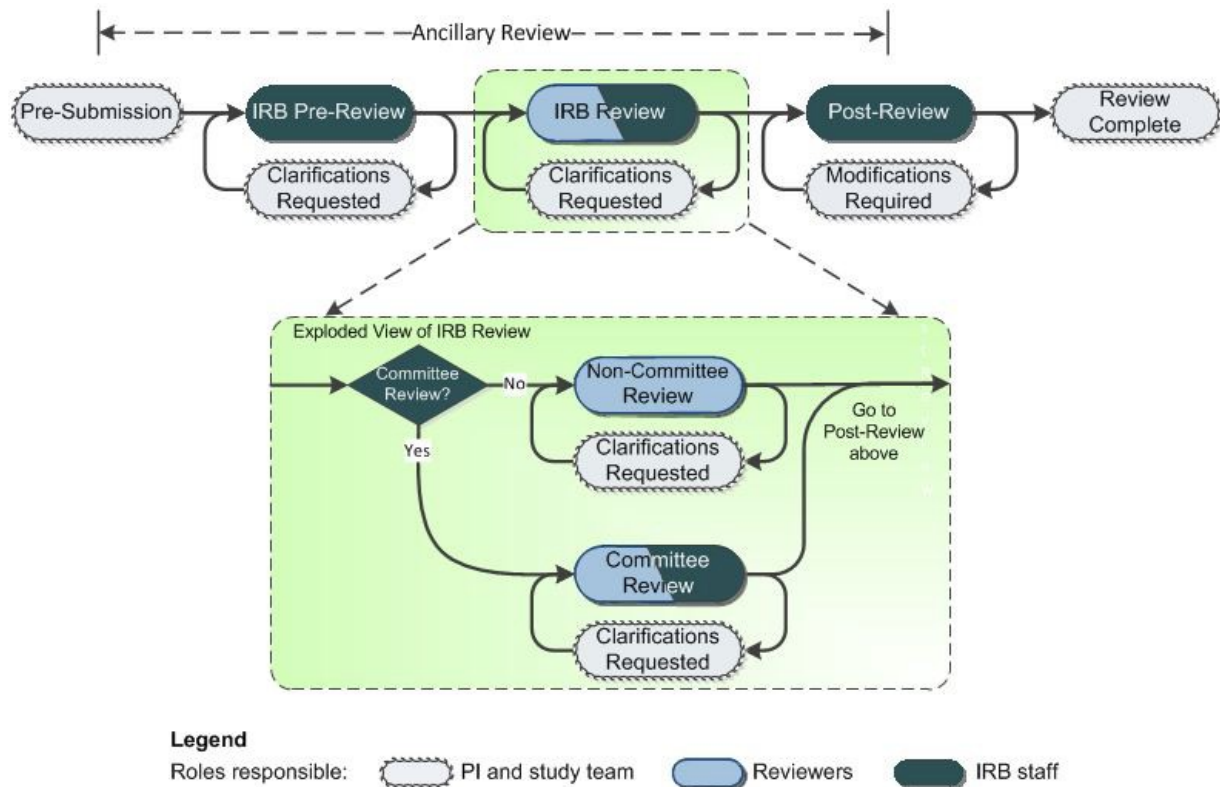
- n Initial submissions (studies)
  - n Follow-on submissions:
    - o Modifications and continuing reviews (either combined or separate) for approved studies
    - o New information reports (often called RNI for reportable new information) for approved studies or active research in general

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

- n Studies include optional ancillary reviews that can be conducted concurrently with the IRB's reviews.
  - n Follow-on submissions do not include ancillary review. Follow-on submissions may skip certain review states as well.
  - n Each type of follow-on submission has its own set of determinations that differs from the study determinations.

## 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](#).

Notable information about several states is identified below.

**IRB Review:** IRB review is not a single state, but a collection of other states. 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 13](#).

**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.

**Post-Review and Modifications Required:** The Post-Review state gives the IRB staff the opportunity to:

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

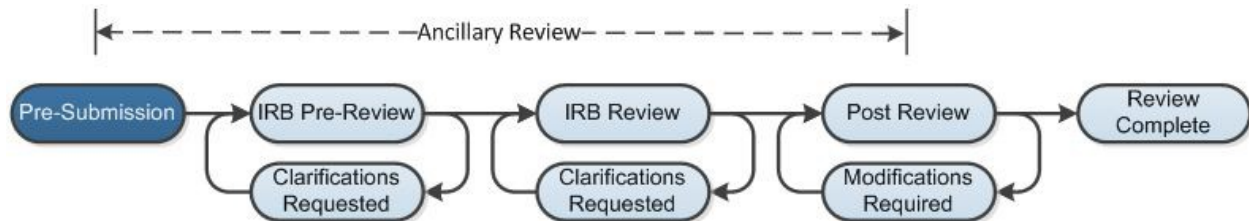
Sending the letter transitions the submission to the state determined by the IRB, such as Approved. If the convened IRB decided to require modifications to the study before approving it, the submission moves to the Modifications Required state. The study team can then update the submission and resubmit it.

The IRB coordinator can choose to review the changes personally or send them to non-committee or committee review, as appropriate. Once the changes are accepted, the submission returns to the Post-Review state. The IRB staff can then prepare a new letter reflecting the final state determined by the IRB, such as Approved.

## Ancillary Review Overview

The study review process optionally includes ancillary reviews. Ancillary reviews allow individuals, departments, and other organizations to give feedback on the study in parallel with the IRB review. The system does not prevent a study from being reviewed or approved by the IRB with ancillary reviews outstanding. The decisions about how, when, or whether to interrupt the IRB review process to wait for ancillary reviews is 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.



## Initiating Ancillary Reviews

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

- n Study team members can add ancillary reviewers to a study before submitting the study for IRB review.
- n IRB staff can add ancillary reviewers after the study has been submitted for IRB review.
- n Both can add individuals and organizations as reviewers.

Organizations must be set up in advance with 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 his department, to be included in all new studies he creates. If your standard process includes ancillary reviews, performing these setup steps is critical. For instructions, see the online help.

When the 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 coordinator can add ancillary reviewers at any time after the study is submitted and before the study transitions from Post-Review to its final state, such as Approved. The additional reviewers receive notifications when the coordinator adds them.

## Notifications and Ancillary Review Feedback

Ancillary reviewers are set up as required or optional by the person adding them to a research profile or an individual study. A required ancillary reviewer has the study in My Inbox, while an optional reviewer does not. 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 coordinator can add the reviewer's comments into the system using the Manage Ancillary Reviews activity to update the review. The IRB coordinator can also modify the optional/required setting of a reviewer on the study.

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

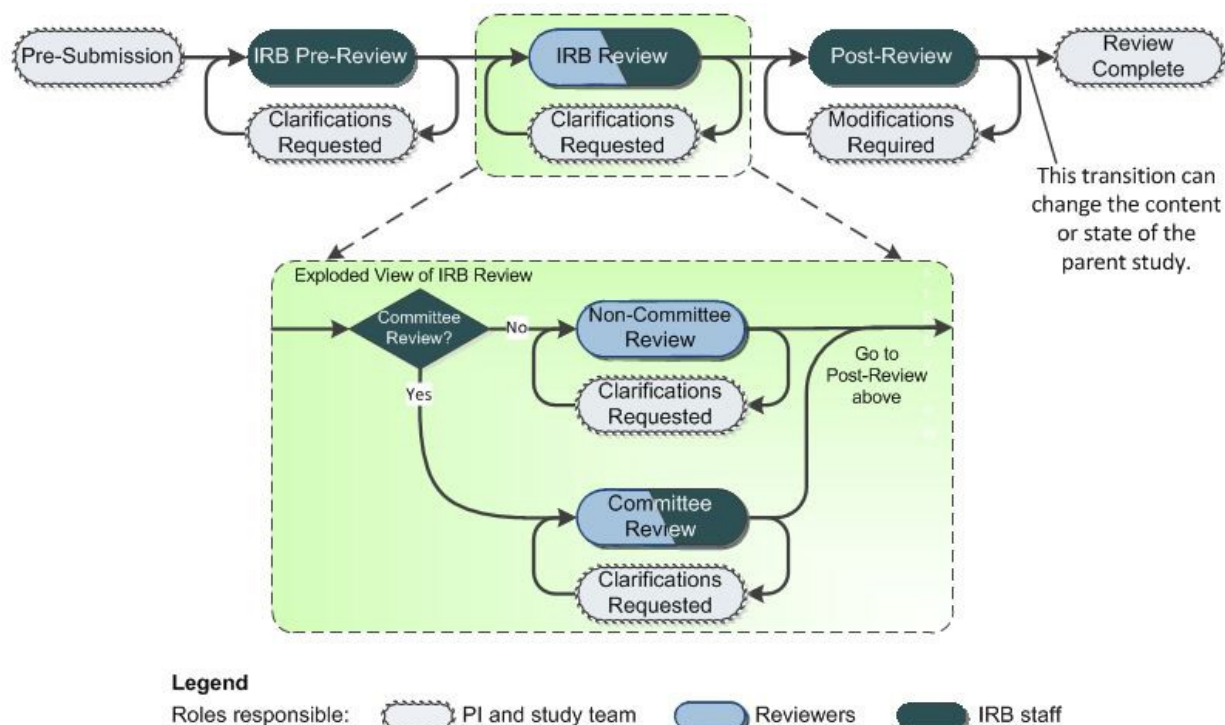
## Decisions Regarding Ancillary Review Feedback

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

- n Treating all ancillary reviewers as optional and not waiting for responses.
- n Letting the IRB review and approval proceed without the response of a required ancillary reviewer.
- n Letting the IRB review proceed, but waiting for an required ancillary reviewer response before approving the study.
- n 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 study back in the study team members' inbox).

## 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.

Unlike a study, a modification or CR does not include ancillary review.

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 modification is created, the system copies the approved study to create a draft study. The draft study contains 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**

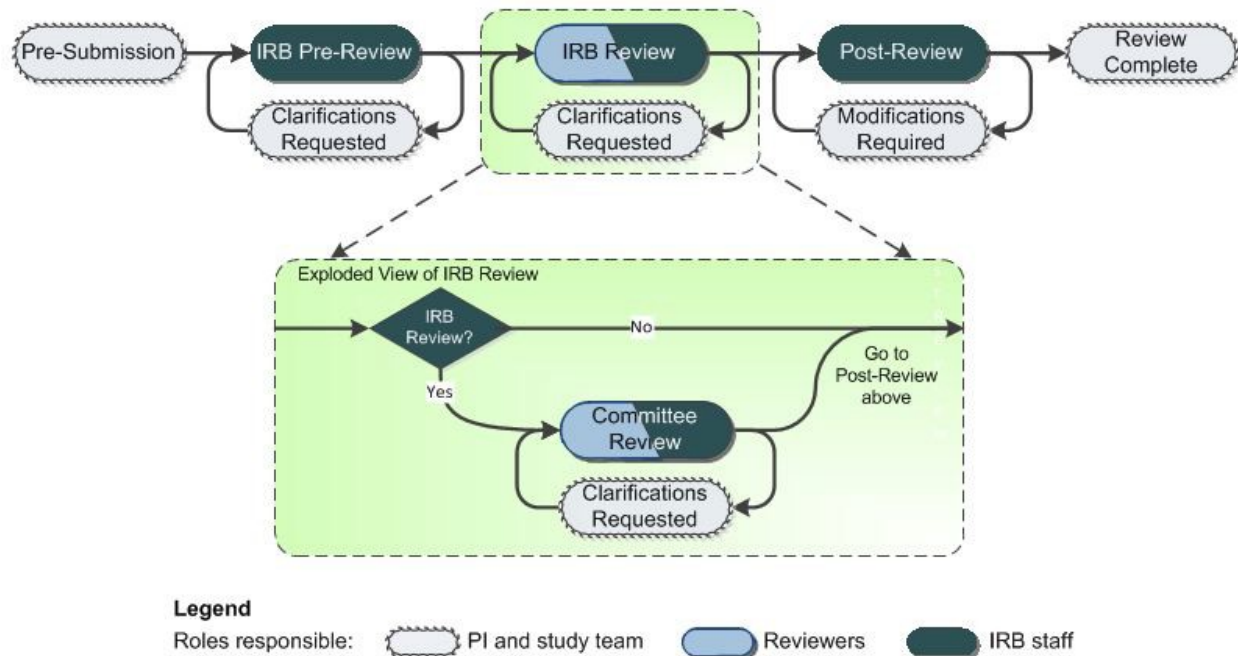
When a CR indicates that the top four research milestones listed on the form have been met, the parent study is closed automatically when the CR is approved. The top milestones indicate that all enrollment, interventions, and handling of subjects' private identifiable information is complete.

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.



## 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.



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.

Unlike a study, an RNI submission does not include ancillary review.

Unlike a modification or CR, an RNI submission:

- n Can be acknowledged and closed by an IRB coordinator with no further review if the coordinator does not deem it to be serious. Otherwise, the RNI is reviewed by a full committee. Non-committee review is not available for RNI submissions.
- n May 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.

As the result of a completed RNI review, the IRB may initiate follow-up steps to ensure the research meets all applicable standards.



## 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):

User Role	Information Visibility
Study staff, registered user	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.
IRB staff and committee members	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.
Ancillary reviewers and other reviewers who are not IRB committee members	Full access to submissions assigned to you for review.
Site manager	Full access to all submissions.

# 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:

- n 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 13](#).
- n Your inbox provides a helpful list of items that need your attention. For details, see [Locating Your To-Do List on page 10](#) and [Understanding My Inbox on page 14](#).
- n 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 15](#).

## 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 12](#).

To access studies or other submissions assigned to you:

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

Your Name **1** **My Inbox** Logoff

2. Identify the reason the study appears in My Inbox by looking at the State column. (For explanations, see [Understanding My Inbox on page 14](#).)

My Inbox					
Filter by ?		State	post	Go	Clear
		Advanced			
ID	Name	Date Created	Date Modified	State	Coordinator
STUDY00000249	Effects of high-dosage vitamin D supplements in low-light environments	9/10/2012 2:22 PM	9/24/2012 1:35 PM	Post-Review	Orlando Max

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 details, see [Viewing the Study Details on page 13](#).

## Navigation Elements Within a Study

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

- n Viewing the study contents and details, including all actions performed on it
- n 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 screenshot displays the Click Portal for Compliance interface. The **Header** at the top includes the Click logo and navigation links. The **Top Navigator** shows 'Home' and 'IRB'. The **Breadcrumb Navigator** shows the path 'IRB > Leukemia metastasis detection'. The main content area is titled 'STUDY00000224: Leukemia metastasis' and includes a 'Pre-Review' button, a timeline diagram showing the process from Pre-Submission to IRB Review, and fields for Principal investigator, Submission type, Primary contact, and IRB coordinator. The **Activities** section on the left lists actions like View Study, Printer Version, View Differences, Withdraw, Assign Primary Contact, and Add Comment. The **Shortcuts Area** at the bottom left lists My Inbox, Reports, and Help. The **Resource Tabs** at the top right include History, Project Contacts, Documents, and Snapshots. The **Activity History** table on the right shows a list of activities with columns for Activity and Author.

Activity	Author
Changes Submitted	Simms, Rebecca
Clarification Requested	Jones (irbc2), Lisa
IRB Coordinator Assigned	Jones (irbc2), Lisa
Assigned to Lisa Jones (irbc2)	
Department Approval Issued	Ing (dept-gas), Richard
Submitted	Simms, Rebecca
Study Created	Simms, Rebecca

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

- n **Header:** Provides links to your profile and to My Inbox, and lets you log in and log off
- n **Top navigator:** Provides links to the major sections of the system you are allowed to access
- n **Breadcrumb navigator:** Tracks your movement through the hierarchy of pages and enables you to quickly move back to a previous location
- n **Activities:** Lets you take appropriate actions—such as viewing the study—based on the study's current status
- n **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.

- n **Activity history:** Displays the actions taken previously on this study
- n **Shortcuts area:** Provides quick links to other frequently used areas of the system, and to documentation resources

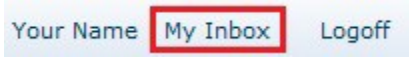
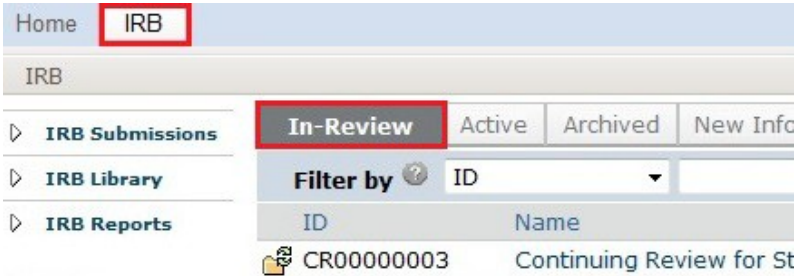
## Accessing a Study

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:

Check this list...	For...	How to find this list
My Inbox	Studies assigned to you for action, such as a study you are: <ul style="list-style-type: none"> <li>n Preparing to submit</li> <li>n Assigned to review</li> </ul>	Click the <b>My Inbox</b> link in the top right navigation header. 
IRB In-Review tab	Studies the IRB has not reviewed or for which it has not communicated a decision	Click <b>IRB</b> in the top left navigation area and select the <b>In-Review</b> tab. 
IRB Active tab	Studies approved by the IRB and currently in progress	Click <b>IRB</b> in the top left navigation area and select the <b>Active</b> 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 <b>IRB</b> in the top left navigation area and select the <b>All Submissions</b> tab. <b>Tip:</b> Try filtering this list by the study name or principal investigator. Next to Filter by, select <b>Name</b> or <b>Investigator</b> . Then type the beginning of the name and click <b>Go</b> .
IRB New Information Reports tab	Reportable new information (RNI) submissions, possibly related to one or more studies	Click <b>IRB</b> in the top left navigation area and select the <b>New Information Reports</b> 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.

## 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:**

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 12](#).
2. Click **View Study** on the left.

### ★ Tips:

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

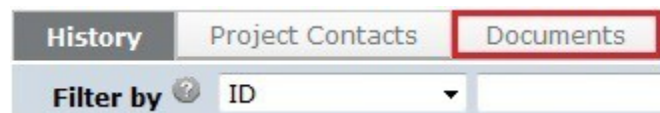
3. Use the Continue and Back buttons to view all of the forms.



**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:**

- n 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.
- n 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.



**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 your team 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.

Your Role	In My Inbox		Not in My Inbox
	State	Explanation	
Research Team			
Study team member or study's primary contact  <b>Note:</b> Any team member can make changes to the study, but the PI must personally submit the changes to the IRB.	Pre-Submission	Complete the study forms. The PI must submit it to the IRB to let the review begin.	Studies the IRB is reviewing
	Clarification Requested	Change the study to clarify as needed, and provide summary notes to the IRB when submitting the changes. <b>Note:</b> If the clarification was requested from Committee Review, you can only provide notes. You are not allowed to change the study.	Approved studies
	Modifications Required	Modify the study to meet IRB requirements and submit it with changes.	Closed studies
Reviewers and Committee Members			
IRB committee member or occasional reviewer	Non-Committee Review	You have been designated as the reviewer for this exempt or expedited study. You must complete a review checklist and notify the IRB coordinator that you have completed your part of the review. The IRB coordinator will communicate requests for additional information or modifications to the PI.	Studies assigned to other reviewers
	Committee Review	You may be part of the committee that will review this study. If so, review the study details in advance. You can request clarifications. Bring your notes and recommendations to the committee meeting.	Studies assigned to other committees
Ancillary reviewer	One of several	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.	Studies not yet submitted for review

## IRB Administrative Staff

IRB coordinator (IRBC)	Pre-Review	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.	Studies not yet submitted to the IRB
	Non-Committee Review	You have been designated as the reviewer for this exempt or expedited study. You must complete a review checklist and request clarifications, if needed. The IRB coordinator will communicate requests for additional information or modifications to the PI. If you request clarifications, the study comes back to you to finish the review after the clarifications are made.	Studies assigned to other reviewers
	Post-Review	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.	Studies being reviewed by individual reviewers
	Committee Review	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.	Studies assigned to other IRBCs
Committee chair	Committee Review	The study has been assigned to your meeting. The IRB director, IRB coordinator, or you must submit the committee's review decision.	Studies assigned to other committees

## Checklist of Committee Meeting Tasks

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

### Preparing for Each Meeting

- n Assign studies to the meeting (from the study workspace).
- n Assign reviewers to all the studies assigned to the meeting (from the meeting or study workspace).  
Note: Assignments made from the meeting workspace do not show up in the history tab of the study workspace; they can be found under the IRB Assignment Details.
- n Notify the reviewers (from the meeting workspace).
- n Prepare the meeting agenda (by generating, uploading, or editing and uploading an agenda).
- n Send the meeting agenda (to all committee members and any additional recipients).
- n Edit the meeting attendance before the meeting if you know who is planning to attend.
- n Prepare the meeting minutes by generating them.



**Tip:** The generated minutes document contains initial information about the studies as well as spaces to fill in the decisions and events of the meeting. We recommend taking notes directly



in the minutes document during the meeting to produce the final minutes.

## **Conducting the Meeting**

We recommend assigning one person to display information for the committee during the meeting, while another person records the meeting minutes and decisions about each submission.

## Displaying information during the meeting:

- n From the meeting workspace:

1. Convene the meeting.
2. Under "Previous meetings with minutes for approval," click a previous meeting to go to its workspace. Then display its minutes to get approval, and return to the current meeting.
3. Click the Expedited Studies Approved link to display the report.
4. Click the name of a study to go to the study workspace.

Agenda Sent

**My Current Actions**

- Prepare Agenda
- Send Agenda
- Assign Reviewers
- Notify Reviewers
- Edit Meeting Attendance
- Confirm Attendance
- Decline Attendance
- Prepare Minutes
- Convene Meeting** (highlighted with red box and arrow 1)

### Biosafety Committee

**Meeting Date & Time:** 9/13/2012 2:00 PM

**Agenda:** Agenda for Biosafety Committee meeting on 9/13/2012 2:00 PM(0.01)

**Minutes:** Minutes for Biosafety Committee meeting on 9/13/2012 2:00 PM(0.01)

**Report:** 3 Expedited Studies Approved in the last 45 days

Agenda Items		
ID	Name	State
CR00000006	4 Continuing Review for Study STUDY00000029	Committee Re
STUDY00000224	Leukemia metastasis detection	Committee Re

#### Previous meetings with minutes for approval

ID	Name
Mee00000052	2 Biosafety Committee meeting on 8/21/2012 10:40 AM

- n From the study workspace:

1. To show information recorded during pre-review, use the Reviews tab.

**My Current Actions**

- View Study** (highlighted with red box and arrow 3)
- Printer Version
- View Differences

History Project Contacts **Documents** (highlighted with red box and arrow 2) IRB Assignment Details **Reviews** (highlighted with red box and arrow 1)

Draft  
Consent form  
Inv protocol

Category  
Consent Form  
IRB Protocol

2. To show attached documents, use the Documents tab.
3. To show study details in the forms, use View Study.

## Recording decisions, events, and notes:

- n Fill in the empty fields of the minutes document as you go through the meeting and review each study.

★ **Tip:** If you type notes into the Word document, save the file to your computer before you begin. Save frequently during the meeting.

- n Collect any notes or attachments that reviewers want to add to the studies. These can be added to a study using the Submit Committee Review activity.

## Wrapping Up After the Meeting

- n Perform Submit Committee Review to record decisions and information for each study reviewed, as listed in the minutes document. The IRB coordinator assigned to the study, the committee chairperson, or the committee administrator can submit the committee review.

★ **Important!** Don't miss this step. Correspondence cannot be prepared and sent to the investigator for a study until Submit Committee Review is complete.

- n Finalize the study's attached documents to create a permanent copy (optional).
- n Prepare a letter for each study reviewed to inform the study's investigator.
- n Send the letter to the investigator.
- n Upload the completed minutes document using Prepare Minutes.
- n Close the meeting.

- n For any previous meeting that had minutes approved, navigate to that meeting and mark the minutes approved.

## 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 update contact information to include in the report:**

1. Log in with site manager permissions.
2. Update the IRB Settings area with appropriate organization and contact names to be included in the report. For detailed instructions, see the *IRB Setup and Deployment Guide*.
3. Log off.

**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:

1. Right-click the box and select **Properties**.
2. 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.

# Finding More Information

To find this...	...look for this...	...and click...
More information about a question or form.		Click the question mark icon next to the question or form title.
The full online help system, with search and table of contents.	<b>Shortcuts</b> <a href="#">My Inbox</a> <a href="#">Reports</a> <a href="#">Help</a> <a href="#">Study Submission Guide</a>	Click the <b>Help</b> link in the Shortcuts area on the left.
The online help contains additional procedures and information for all users.		
Instructions for submitting a study for review.	<b>Shortcuts</b> <a href="#">My Inbox</a> <a href="#">Reports</a> <a href="#">Help</a> <a href="#">Study Submission Guide</a>	Click the <b>Study Submission Guide</b> link in the Shortcuts area on the left.
Document templates, checklists, and IRB procedures.	<a href="#">Home</a> <a href="#">IRB</a> <a href="#">IRB</a> <b>IRB</b> <a href="#">IRB Library</a>	Click <b>IRB</b> and then <b>IRB library</b> in the upper left corner.

