**Logging In**

The IRB system is secure, which means only authorized individuals have access to it. When you log in to the system, you get a personalized view of the information and possible actions pertinent to you.

<table>
<thead>
<tr>
<th>To log in</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Click the <strong>Login</strong> link located at the top right corner of your screen.</td>
</tr>
<tr>
<td>2. Enter your CAS (CaneID) username and password. <strong>Tips:</strong> If you do not know your CAS/CaneID user name or password, contact the Cane ID Help Desk for assistance. (See <strong>Contacting Support</strong> on page ##.)</td>
</tr>
<tr>
<td>3. Click <strong>Login</strong> (or press Enter).</td>
</tr>
</tbody>
</table>
Navigation and Basic Tasks

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>Where</th>
<th>Where</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>My Inbox</strong></td>
<td>Studies assigned to you for action, such as a study you are:</td>
<td>Click the My Inbox link in the top right navigation header.</td>
</tr>
<tr>
<td></td>
<td>• Preparing to submit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Assigned to review</td>
<td></td>
</tr>
<tr>
<td><strong>IRB In-Review tab</strong></td>
<td>Studies the IRB has not reviewed or for which it has not communicated a decision</td>
<td>Click IRB in the top left navigation area and select the In-Review tab.</td>
</tr>
<tr>
<td><strong>IRB Active tab</strong></td>
<td>Studies approved by the IRB and currently in progress</td>
<td>Click IRB in the top left navigation area and select the Active tab.</td>
</tr>
<tr>
<td><strong>IRB All Submissions tab</strong></td>
<td>All studies, continuing reviews, modifications, and reportable new information (RNI) entered into the system that you have permissions to view</td>
<td>Click IRB in the top left navigation area and select the All Submissions tab.</td>
</tr>
<tr>
<td><strong>IRB New Information Reports tab</strong></td>
<td>Reportable new information (RNI) submissions, possibly related to one or more studies</td>
<td>Click IRB in the top left navigation area and select the New Information Reports tab.</td>
</tr>
</tbody>
</table>

**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**.
When you first log in, you will be on the My Inbox page. This topic lists where to find submissions and the basic tasks you will perform.

**Where do I find?**

From the My Inbox page, you will find:

1. **Submissions** that require you to take action.
2. **Actions** you can perform, such as create a new study.
3. **Shortcuts** that provide access to other items such as all the submissions you can view.

**What do I do?**

4. Review the state of submissions in your inbox. The state gives a clue as to what to do next. For example, “Pre-Submission” means you haven’t submitted the study. You can finish and submit it for review.

**Open a Submission**

5. From your inbox, or from the Submissions page, click the submission name.

**View History**

6. From the submission workspace, click the **History** tab.

7. The history tab lists the activity taken on a submission including any comments, attachments, or correspondence added.
**Find Previous Submissions**

8. Click the **Submissions** shortcut.

9. Click the tab to see submissions you can access:
   - **In-Review**: Submissions undergoing IRB review.
   - **Active**: All approved submissions as well external IRB, non-human research, human research not engaged, lapsed, and suspended submissions.
   - **Archived**: All closed, disapproved, discarded, and terminated submissions.
   - **New Information Reports**: All Reportable New Information (RNI) submissions, in any state.
   - **All Submissions**: All submissions, in any state.

**Filter Data**

Many pages contain tables that you can filter to show specific data.

10. Select the column to filter by.

11. Type the beginning characters for the items you want to find. You can also type a % symbol as a wildcard before the characters. Examples:
   - 71 shows all items beginning with 71
   - %71 shows all items containing 71

12. Click the Help icon for operators you can type in the text box.

13. Click **Go** to apply the filter.

14. To combine multiple filter criteria, click **Add Filter**.
Create and Submit a New Study

You can prepare a new study for IRB review by entering information into a series of online forms. The number of forms included may change based on the answers you provide. The forms tell you where to attach files to provide supporting information.

The simplest approach is to follow the forms in order, answering the questions and clicking Continue to save your information and move to the next form. When you reach the end of the series of forms, click the Finish button.

NOTE: A continuing review, modification or RNI (reportable new information) submission can be handled similarly to a study. For differences, see Submitting Continuing Reviews and New Information on page ##.

Before you begin, gather files and information about your study such as

- Supporting information files (for a list, see Checklist of Information to Attach on page ##)
- Financial interest status for each of your study team members
- Contact information and IRB oversight information for external sites involved in the study

For more details on documents you may want to attach to a study, see the Checklist of Information to Attach.

Tips: If you regularly create studies with a similar set of team members, you can save time by defining the default team members to be added to each study you create. For instructions, see the online help.

Similarly, you can save time by defining the default list of ancillary reviewers to be added to each study you create. For instructions, see the online help.

Create a Study

1. From the My Inbox page, click Create New Study.
   a. If you do not see the Create New Study button, click the My Inbox link (upper right).

   TIP: When you create a study, you are assigned to be the primary contact who receives all communications from the IRB on behalf of the study team. (The principal investigator you specified also receives the communications.) You can change the primary contact later as described in Changing the Primary Contact on page ##.

2. Complete the pages. Click Continue to move to the next page.

   TIP: A red asterisk (*) precedes each question that requires an answer. If you cannot answer a required question at this time, or if you need to stop and continue at a later time, see the tips in the online help. If you do not answer a required question initially, you must return and answer it before you can submit the study for review.
3. Pay attention to the following:
   a. **Basic Information page questions**: Use the questions pictured to the left to indicate whether the study will be locally or externally reviewed, and whether it is a single- or multiple-site study.
   b. **Basic Information page protocol**: The study protocol is the only mandatory document to include.
   c. **Local Site Documents**: add consent forms, recruitment materials and other documents specific to your study.
   d. **Study Related Documents**: if the study is a multi-site study for which you are serving as the single IRB, use this page to add templates for consent forms, recruitment materials, and other documents that participating sites will need to access.

4. On the final page, click **Finish**. You are taken to the study workspace. You can continue to edit the study (Edit Study button) until you submit it. See **Editing a Study** on page 7.

   **Important!** The study has not been submitted for review yet.

**Editing a Study**

You can continue to make changes to a study until you submit it for IRB review. You can also make changes if the IRB requests clarifications (except during committee review) or requires modifications.

5. From **My Inbox**, click on the name of the study to open it.

   **NOTE**: If the study does not appear in your inbox, see **Accessing a Study on page ##**.

6. Click **Edit Study** on the left.
7. Make changes as appropriate. When updating a study document previously submitted to the IRB, revise it in tracked-changes format and replace the original document with the tracked-changes version. When the IRB approves the document, all tracked changes will be accepted and comments removed in the watermarked PDF version.

8. Exit the study  
**TIP:** Choose one of these ways to exit:  
- Click the *Exit* link. If prompted to save the study, click Yes.  
- Click *Continue* on each form, and then click the *Finish* button on the final form

### Checking the Study for Errors

Checking the study for errors and omissions helps you include all the relevant information, which is critical for receiving timely review of your study.

- **Automatic system error checking** identifies any omitted answers to required questions on the form when you click Continue. A red asterisk precedes each blank or question that requires an answer. Keep in mind that the system cannot catch every omission while you edit the study if you skip questions that cause more forms to be added to your study.

- **Visually inspecting the forms** to see what you may have missed, especially:
  - Questions that are relevant to your study but are not required for all studies
  - Documents that should be attached (see Checklist of Information to Attach on page ##)

To perform a visual inspection, open the study and look
through the forms in order. To open the study, see Editing a study on page ##.

- **Using the Hide/Show Errors option** to find and correct all errors before submitting the study. The system automatically checks for errors when the PI attempts to submit the study. However, if you are filling out the forms on behalf of the PI, it is best to check the study for errors before the PI attempts to submit it, using the steps below.

**To use Hide/Show Errors to find and correct errors:**

9. Open the study as explained in Editing a Study on page ##.

10. From the top navigation area, click Hide/Show Errors.

   a. The Error/Warning Messages pane appears at the bottom of the window, listing all the current errors and where to find them.

11. For one of the errors listed, click the link in the Jump To column to go to the form containing the error.

12. Click Continue to identify the specific questions on the form with errors.

13. Fill in the missing information.

14. Click Refresh in the Error/Warning Messages pane to update the list of errors.

15. Continue correcting errors until no errors are listed.
Submit a Study for Review

After entering all required information into the forms and attaching files, the principal investigator must submit the study for IRB review.

Tips:

- Make sure you attach all applicable information to the study, as identified in Checklist of Information to Attach on page 17.
- Check for missing information before attempting to submit the study, as described in Checking the Study for Errors on page 8. Any errors or omissions not corrected are shown when attempting to submit the study and must be corrected before you can submit it for review.
- Identify any person or organization outside the IRB who needs to review the study. Add them to the list of ancillary reviewers by clicking Manage Ancillary Reviews.

To submit the study for IRB review:

**Important! Only the principal investigator can complete the following steps. Once a study is initially submitted, the PI may designate a proxy who will be able to submit follow-on submissions and clarifications on their behalf**

16. From the study workspace, click **Submit**.

17. Click **OK** to agree to the terms.

You can log off the system. Your study has been submitted to the IRB.
Create and Submit a New External Study

An external study contains two projects. Once you complete the study form, a study and site are created. You must submit the site for the external study submission process to be complete.

Create an External Study

1. From the My Inbox page, click Create New Study.
2. Complete the pages. Click Continue to move to the next page.
3. Pay attention to the following:
   a. Basic Information page questions: Use the questions pictured to the left to indicate whether the study will be locally or externally reviewed, and whether it is a single- or multiple-site study.
   b. External IRB page: specify which institution will serve as the external IRB.
4. On the final page, click Finish. You are taken to the study workspace. You can continue to edit the study (Edit Study button) until you submit it.

Submit the External Site for Review

5. From the study workspace, click the site link to navigate to the associated site.
6. From the site workspace, click the Edit Site button.
7. Complete the pages and click Finish. Pay attention to any required information.
8. From the site workspace, click Submit.
9. Click OK to agree to the terms. You can log off the system. Once an IRB coordinator confirms reliance on the external IRB, your study will be submitted.
Checklist of Information to Attach (New Studies)

Be prepared to attach several files to your study. While editing the study, several forms provide places to attach related files. In some cases, a template file is provided directly on the form for download, such as for the protocol.

When attaching each file, name it as you want it to appear on the IRB approval letter.

Attach the information listed below (if relevant to your study) to the location identified.

**Protocol: (Basic Information page)**

- Investigator protocol
- Complete sponsor protocol
- Site supplement to sponsor protocol
- HHS (Department of Health and Human Services) protocol

**Funding information: (Funding Sources page, with each source)**

- Grant applications

**Drug details: (Drugs page, with each drug, or on main Drugs page if not specific to one drug)**

- Package insert
- Investigator brochure
- Verification of each IND number (one of these):
  - Sponsor protocol with the IND number
  - Communication from the FDA or sponsor with the IND number

**Device details: (Devices page, with each device, or on main Devices page if not specific to one device)**

- Product labeling/device instructions
- Investigator brochure
- Verification of each IDE or HDE number (one of these):
  - Sponsor protocol with the IDE / HDE number
  - Communication from the FDA or sponsor with the IDE / HDE number

**Recruitment and consent details: (Local Site Documents page)**

- Consent documents:
  - Consent forms
  - HHS-approved consent document
  - For non-written consent, a script of the information provided orally to the subjects
- All recruitment material to be seen or heard by subjects, such as:
  - Advertisements, including printed, audio, and video
  - Recruitment materials and scripts
- Supporting document and other attachments:
  - Evaluation instruments and surveys
  - Ancillary committee forms
  - Completed checklist of meeting Department of Energy requirements
- Foreign-language versions of materials for subjects (only after the English version has been approved)

**All other relevant documents: (Study-Related Documents page)**

- Consent document templates for use by participating sites
- Recruitment materials templates for use by participating sites
- Other supporting documents needed by participating sites
What to Expect After Submitting

Submitting information to the IRB initiates a series of activities that may include:

- Review within your department
- Pre-review by an IRB staff member
- Review by the IRB committee or a designated reviewer
- Communication of the IRB decision to the investigator

Any of these may lead to a request for the study team to take further action, such as providing clarifications or modifying the study. Whenever the study team needs to act, the PI receives an e-mail notification, and the study appears in My Inbox for all study team members when they log in to the IRB system.

Important! Make sure the appropriate person is listed as the primary contact to receive e-mail notifications and see the study in My Inbox (along with the PI and any PI proxies, who also receive these). By default, the person who created the study is the primary contact. See Changing the Primary Contact below.

Checking the status of your study

You can see a diagram showing the state of your study within the IRB review process by opening the study.

You can easily open your study from one of the following lists (depending on its status):

- My Inbox
- IRB In-Review Studies
- IRB Active Studies

For Instructions about opening your study from these lists, see Accessing a study on page ##.

Changing the Primary Contact

The study's primary contact for receiving communications from the IRB can be changed at any time. For example, it may help to provide a contact person in addition to the PI if the PI does not check e-mail frequently.

The primary contact can also edit the study just as a study team member can.

Notes:

- To change the primary contact, you must be a member of the study team or the IRB coordinator assigned to the study.
- By default, the person who created the study in the system is the primary contact.
- The PI and any PI proxy continue to receive notifications regardless of the primary contact assignment.
have the same primary contact as the initial study. To change the primary contact on these submissions, do so in the initial study.

To change the primary contact:

1. Open the study by clicking the study's name. (For instructions about finding the study, see Accessing a Study on page 10.)

2. Click Assign Primary Contact from the My Current Actions list on the left. A new window opens.

3. Click Clear to remove the current contact.

4. Begin typing the name of the new contact. A list of matching names appears.

5. Select the correct name using the mouse or down arrow key.

6. Click OK.

Note: If the primary contact is also engaged in the research, make sure the list of team members within the study includes the person.

Managing the Guest List

By default, the Principal Investigator, Primary Contact, and Study Team Members have the ability to view details of the study. If you wish to grant read-only access to individuals outside of this group, you may use the Manage Guest List activity to add these individuals to your Guest List.

To add a user to your guest list:

1. Open the study by clicking the study's name. (For instructions about finding the study, see Accessing a Study on page 10.)

2. Click Manage Guest List from the My Current Actions list on the left. A new window opens.

3. Begin typing the name of the new contact. A list of matching names appears.

4. Select the correct name using the mouse or down arrow key.

5. Click OK.
Assign PI Proxy

A proxy can perform certain responsibilities on behalf of the Principal Investigator, such as submitting the study to the IRB, modifying the study, and submitting continuing reviews.

**Important!**

- Only the principal investigator can assign a PI Proxy
- The PI Proxy must be a UM faculty member and a study team member on the study

To select a PI Proxy:

1. Open the study by clicking the study's name. (For instructions about finding the study, see Accessing a Study on page 10.)

2. Click **Assign PI Proxy** from the My Current Actions list on the left. A new window opens.

3. Select the study team member(s) who will serve as proxy.

4. Click **OK**.
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 10.)

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**.
Change Study Documents

You can update your study documents any time prior to submitting the study to the IRB for review. Once it is in the review process, you can only update documents if the IRB coordinator or a committee member requests clarification, or if you are submitting a modification to the study.

1. From your inbox, open the study you want to edit.
   If the study is not in your inbox, contact the IRB coordinator assigned to your study.

2. From the submission workspace, click Edit Study.

3. Add and update documents on study pages as needed and exit the study when done.

   Note: When updating a document previously submitted to the IRB, revise it using Word’s Track Changes feature and then replace the original document with the tracked-changes version. When the IRB finalizes documents on approved studies, all tracked changes will be accepted and comments removed.

   If responding to a clarification request, see Respond to Clarification Requests to submit the changes back to the IRB.
Respond to Clarification Requests

At any state during the review process, the IRB may request clarifications to the study content. Similarly, the official IRB determination may be that the study requires changes before research can begin.

Both situations require the study staff to take similar actions. If a reviewer has questions or requires you to change your submission, the PI, any PI proxy, and the study’s primary contact will receive an email indicating this. The study also appears in My Inbox for each member of the study team.

Important!

- Any study team member can update the study, but only the PI can submit the response to the IRB.
- Failure to respond promptly slows the review and approval process for your submission. In some cases, your submission may be rescheduled for review at a later IRB meeting because the committee requires your response before making a decision.

### Review the Request Details

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

2. Click the History tab and review the “Clarification Requested” activity.
   - **Note:** If the reviewer attached a document, a link to open it appears on the History tab.

### Submit Response

3. On the submission workspace, click Submit Response.

4. In the Notes box, explain your response to the reviewer.
   - **Note:** If you responded to the reviewer’s request in a document, you can add the document in the Supporting documents area.

5. Click OK.

You can log off the system. The study has moved back to the reviewer’s inbox to continue the review.
Create and Submit a CR or Modification

You can submit a Continuing Review (CR), a modification, or both combined:

- To close a study or extend your approval period, submit a CR.
- To change an approved study or the study team’s members, submit a modification.

1. From your inbox, click the Submissions shortcut.
2. On the IRB page, click the Active tab and open the approved study.
3. Click the Create CR/Modification button.
4. Select whether the submission is a CR, a modification, or a combination.
5. Pay attention to the following question:
   **Modification scope.** To make changes to any part of the study except for study team members, select Other parts of the study.
6. Complete the pages. Click Continue to move through the pages and Finish on the last page.
7. From the workspace, click Submit.
8. Click OK to agree to the terms.
9. Type your login credentials and click Submit.

You can log off the system. Your modification or CR has been submitted to the IRB.

To find your modifications and CRs, go to the Submissions page (click the Submissions shortcut), and then the Follow-On Submissions tab.
Create and Submit Reportable New Information

Report any adverse events or new information about a study as soon as you become aware of it.

Create an RNI

1. From your inbox, click the Submissions shortcut.
2. Click the Report New Information button.
   Note: You can also open an active study and report new information from the study workspace.
3. Complete the Reportable New Information page. Pay attention to the following question:
   a. Related studies and modifications: Select any studies or modifications that the RNI applies to.
   Note: You cannot relate sites, external studies (unless the external study is part of a multisite study), or follow-on submissions (except for modifications, which can be added by adding the parent study) to an RNI.
4. Click Continue when done.
5. From the RNI workspace, click Submit RNI.
6. Click OK to agree to the terms.
7. Type your login credentials and click Submit.

You can log off the system. The RNI has been submitted to the IRB. After reviewing the RNI, the IRB may require specific actions be taken and assign a responsible party to do so.
Responding to Action Required

After reviewing a new information report (or adverse event), the IRB may require specific actions to be taken in response to the reported issue. A responsible party is assigned to complete the action.

The system sends e-mail to notify the responsible party, the submitter of the RNI (reportable new information), as well as the PIs, PI proxies, and primary contacts of all related studies. The RNI also appears in My Inbox for the responsible party.

To view the action plan and respond to the IRB

1. From My Inbox, click the name of the RNI submission to open it.
2. View the details of the RNI submission and the action plan, as described here:
   a. **Read the letter:** Click the letter link near the top of the page on the right side. The letter typically contains the action plan and a summary of the IRB’s decisions.
   b. **Review the action plan:** Click the Action Plan tab and read the action plan listed there, plus any history of the action plan that might be helpful.
   c. **Review the RNI submission details:** If you aren’t already familiar with the details of the information report, read it by clicking View RNI on the left side.
3. Take action inside or outside the system to complete the action.
Tip: You can add related studies to the RNI submission to indicate that the information report applies to the studies. From the RNI submission, click Add Related Submission on the left.

If the action plan requires a change to a study, create a modification and submit it for review as mentioned in Submitting Continuing Reviews and New Information on page 14. Then return to the RNI and add the modification using Add Related Submission. The study being modified must be added as a related submission before the modification can be added.

4. Click Submit Action Response to indicate that the action plan is complete. The Submit Action Response form gives you space to type notes and attach a file. Summarize the actions taken to resolve the reported issue and complete the action plan.

5. Click OK
The RNI submission is returned to the IRB to verify completion of the action plan.
<table>
<thead>
<tr>
<th>Project State</th>
<th>Description</th>
<th>Pending Action by (and will be found in the inbox of)</th>
<th>Submissions in this state can be found in the:</th>
<th>Can be edited by the Study Team?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Submission</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, submission return to the Pre-Submission state)</td>
<td>PI/Study Team</td>
<td>In-Review tab</td>
<td>Yes</td>
</tr>
<tr>
<td>Disapproved</td>
<td>Submission has been disapproved by the IRB</td>
<td>N/A</td>
<td>Archived tab</td>
<td>Yes</td>
</tr>
<tr>
<td>Pre-Review</td>
<td>Submission has been submitted by the PI</td>
<td>HSRO</td>
<td>In-Review tab</td>
<td>No</td>
</tr>
<tr>
<td>Clarification Requested (Pre-Review)</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>In-Review tab</td>
<td>Yes</td>
</tr>
<tr>
<td>Pre-Review Completed</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>No</td>
</tr>
<tr>
<td>Non-Committee Review</td>
<td>Submission is being reviewed by an IRB member</td>
<td>IRB</td>
<td>In-Review tab</td>
<td>No</td>
</tr>
<tr>
<td>Committee Review</td>
<td>Submission is/will be scheduled for review at an upcoming IRB meeting</td>
<td>IRB</td>
<td>In-Review tab</td>
<td>No</td>
</tr>
<tr>
<td>Clarification Requested (Committee Review)</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>In-Review tab</td>
<td>No</td>
</tr>
<tr>
<td>Post-Review</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>No</td>
</tr>
<tr>
<td>Project State</td>
<td>Description</td>
<td>Pending Action by (and will be found in the inbox of)</td>
<td>Submissions 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>Modifications Required</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 “Submit Modifications” activity</td>
<td>PI/Study Team</td>
<td>In-Review tab</td>
<td>Yes</td>
</tr>
<tr>
<td>Modifications Submitted</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>No</td>
</tr>
<tr>
<td>Deferred</td>
<td>Submission has been reviewed by the IRB but the IRB has requested changes</td>
<td>PI/Study Team</td>
<td>In-Review tab</td>
<td>Yes</td>
</tr>
<tr>
<td>Approved</td>
<td>Submission has been approved by the IRB</td>
<td>N/A</td>
<td>Active tab</td>
<td>No</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>No</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>No</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>No</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>No</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>No</td>
</tr>
<tr>
<td>Terminated</td>
<td>Study has been closed by the IRB</td>
<td>N/A</td>
<td>Archived tab</td>
<td>No</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>No</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>No</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>No</td>
</tr>
<tr>
<td>Project State</td>
<td>Description</td>
<td>Pending Action</td>
<td>Submissions 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>
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<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>No</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>No</td>
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<tr>
<td>Acknowledged</td>
<td>Applies only to RNI submissions. Determination letter has been sent by the HSRO</td>
<td>N/A</td>
<td>New Information Reports tab</td>
<td>No</td>
</tr>
</tbody>
</table>
## Finding More Information

<table>
<thead>
<tr>
<th>Resource</th>
<th>Description</th>
<th>How to access it</th>
</tr>
</thead>
<tbody>
<tr>
<td>Help for a field or page</td>
<td>More information about a question or form.</td>
<td>Click 🔄 next to the question or at the top of the form.</td>
</tr>
<tr>
<td>Help system</td>
<td>The full online help system, with search and table of contents. The online help contains procedures and information for all users.</td>
<td>1. Click the Help Center link on the left.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Submissions</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Meetings</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Reports</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><img src="image.png" alt="Help Center" /></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Library</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><img src="image.png" alt="Help Center" /></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Help with Search</strong> at the top of the page.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>IRB Help Center</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><img src="image.png" alt="Help with search" /></td>
</tr>
<tr>
<td>IRB Study Submission Guide</td>
<td>Instructions for submitting a study for review.</td>
<td>1. Click the Help Center link on the left.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. On the Guides tab, click the name of the guide to open it.</td>
</tr>
<tr>
<td>IRB Study Reviewer’s Guide</td>
<td>Instructions for reviewing an IRB submission.</td>
<td></td>
</tr>
<tr>
<td>IRB Staff Administration Guide</td>
<td>An overview of the IRB review and administration process.</td>
<td></td>
</tr>
<tr>
<td>IRB Library</td>
<td>Document templates, checklists, and IRB procedures.</td>
<td>Click the Library link on the left.</td>
</tr>
</tbody>
</table>

## Contacting Support

For additional answers to your questions, feel free to use the following resources

<table>
<thead>
<tr>
<th>Resource</th>
<th>How to access it</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation</td>
<td>See Finding More Information on page 5</td>
</tr>
<tr>
<td>Training materials in the IRB Library</td>
<td>See Finding More Information on page 5</td>
</tr>
<tr>
<td>For <strong>regulatory</strong> questions, contact the HSRO</td>
<td>E-mail: <a href="mailto:hsro@med.miami.edu">hsro@med.miami.edu</a></td>
</tr>
<tr>
<td></td>
<td>Phone: 305-243-3195</td>
</tr>
<tr>
<td>For <strong>technical</strong> issues, contact Research IT</td>
<td>E-mail: <a href="mailto:eprost@med.miami.edu">eprost@med.miami.edu</a></td>
</tr>
<tr>
<td></td>
<td>Phone: 305-243-2314</td>
</tr>
<tr>
<td>For <strong>login</strong> problems, contact the CaneID Help Desk</td>
<td>Phone: 305-284-6565, option 2</td>
</tr>
</tbody>
</table>