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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.

To log in:
1. Click the Login link located at the top right corner of your screen.
2. Enter your CAS (CaneID) user name and password.
   
   **Tips:** Press the Tab key after typing your user name to move to the Password box.
   
   If you do not know your CAS/CaneID user name or password, contact the Cane ID Help Desk for assistance. (See Contacting Support on page 12)
3. Click Login (or press Enter).

Login issues

<table>
<thead>
<tr>
<th>If you receive this error message...</th>
<th>...contact...</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Sorry, you entered an invalid CaneID or password”</td>
<td>CaneID Help Desk (305-285-6565) for help resetting your password or re-enabling your CaneID account.</td>
</tr>
<tr>
<td>“We were unable to match your CaneID to an active eProst account” and you already have an eProst account</td>
<td>Research IT Help Desk (305-243-2314 or 305-243-9662) for assistance with re-enabling your eProst account.</td>
</tr>
<tr>
<td>“We were unable to match your CaneID to an active eProst account” and you do not yet have an eProst account</td>
<td>Research IT Help Desk (305-243-2314 or 305-243-9662) for assistance with requesting an eProst account.</td>
</tr>
</tbody>
</table>
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 9.

**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.

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 6.
Understanding My Inbox

The list called My Inbox consists of two separate inboxes: your Study Staff Inbox and your Reviewer Inbox. The **Study Staff Inbox** contains studies or other submissions that require you (or your study team members) to take action. The **Reviewer Inbox** contains studies or other submissions that require your review. See the examples below to understand what you should and should not expect to appear in My Inbox.

<table>
<thead>
<tr>
<th>Your role</th>
<th>In My Inbox Explanation</th>
<th>Not in My Inbox</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ancillary reviewer or Department reviewer</td>
<td>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.</td>
<td>Studies not yet submitted for review</td>
</tr>
</tbody>
</table>

**Important note for JHS and UMH ancillary committee members only:** Since you may sometimes review submissions after they have already received IRB approval, the items requiring your review may not always be in your Inbox. To view a complete list of the submissions pending your review, go to the Custom Reports tab and run the report named “REPORT_Items_with_Ancillary_Reviews_Pending.” See Generating Reports on page 10.
Viewing the Study Details

As a reviewer, 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 9.
2. 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.

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:
- 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.

**Important!** Supplemental forms required by your ancillary committee can be found in the Documents tab, unless the study is going to an **External IRB** (such as WIRB). For External IRB studies, please go to the History tab, and look for the “Study Information Updated” activity. Click on the activity name and the documents will be listed at the top of the Activity Details page. (This page may take a few moments to load).

**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.
Viewing Changes to a Study

When a study changes based on reviewer requests, you may want to:

- View the changes submitted for a particular request
- View the differences between two versions of a study

To view changes submitted for a clarification request:

1. From My Inbox, click the name of the study to open it.
2. Click the **History** tab.
3. Click the **Changes Submitted** activity link to see any notes or documents added to the study.

To view the differences between two versions of a study:

1. From My Inbox, click the name of the study to open it.
2. Click **View Differences** on the left.
3. Next to Show Changes, select a version to compare the current study to.
4. Look for red and green changes in the current form.
   - Click the 🔖 arrow to show the details. The changes since the version you selected appear as follows:
     - Additions to text since that version are shown with green highlighting.
     - Deletions to text show in a light red box below the current text.
     - Additions and deletions of selectable items show the changes (such as old values) in a light red box after the current values that appear normally.
5. Next to Changed Steps, click the \( \Rightarrow \) arrow (or use the drop-down list) to view each of the other forms that have changed.

6. Exit the View Differences screen by clicking Close on the right.

**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.

### Submitting a Review Decision

After reviewing a study or other submission, you must record the decision in the system. Recording the decision completes the review and moves the study forward in the IRB process.

**Tip:** You can include comments when you record your decision. To avoid regulatory issues, it is best to phrase your comments as questions or requests for information. If you need the study team to answer a question before you can complete the review, request clarifications using the Add Comments activity or the Submit Ancillary Review activity. The IRB Staff will send the submission back to the study team for revisions/clarifications.

**Note:** The procedures below assume that the study team has completed any requested clarifications.

**To open the study:**
1. From My Inbox, click the name of the study to open it.
2. Choose the appropriate procedure below.

**To complete an ancillary (or department/division) review:**
1. Click Submit Ancillary Review on the left.
2. Select the review you are completing from the list.
3. Indicate whether you think the submission is acceptable as it is currently written.
4. (Optional) Add comments and attach documents related to the review.
5. Click OK.

The review comments are shown in the study.
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>
<tbody>
<tr>
<td>My Inbox</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>IRB In-Review tab</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>IRB Active tab</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>IRB All Submissions tab</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></td>
<td><strong>Tip:</strong> 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.</td>
<td></td>
</tr>
<tr>
<td>IRB New Information Reports tab</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>
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 9)
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.

Tip: Comments directly related to your ancillary review decision and requests for clarification/changes should be posted via the Submit Ancillary Review activity, rather than through the Add Comments activity. This helps ensure that your comments will be seen by the IRB staff as the submission moves through the review process.

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, there are a number of custom reports available to UM/JHS ancillary committee members and department/division reviewers.

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, ancillary reviewers, and IRB members have a higher level of access to 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.
## 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><strong>Shortcuts</strong>&lt;br&gt;My Inbox&lt;br&gt;Reports&lt;br&gt;Help</td>
<td>Click the <strong>Help</strong> 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><strong>Shortcuts</strong>&lt;br&gt;My Inbox&lt;br&gt;Reports&lt;br&gt;Help</td>
<td>Click the <strong>Study Submission Guide</strong> link in the Shortcuts area on the left.</td>
</tr>
<tr>
<td>Instructions for submitting a study for review.</td>
<td><strong>Shortcuts</strong>&lt;br&gt;My Inbox&lt;br&gt;Reports&lt;br&gt;Help</td>
<td>Click <strong>IRB</strong> and then <strong>IRB library</strong> in the upper left corner.</td>
</tr>
<tr>
<td>Document templates, checklists, and IRB procedures.</td>
<td><img src="image" alt="IRB Library" /></td>
<td>Click <strong>IRB Library</strong> in the upper left corner.</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 11</td>
</tr>
<tr>
<td>Training materials in the IRB Library</td>
<td>See Finding More Information on page 11</td>
</tr>
</tbody>
</table>
| For **regulatory** questions, contact the HSRO | E-mail: eprost@med.miami.edu  
  Phone: 305-243-3195 |
| For **technical** issues, contact Research IT | E-mail: eprost@med.miami.edu  
  Phone: 305-243-9662 or 305-243-2314 |
| For **login** problems, contact the Cane ID help desk | Phone: 305-284-6565, option 2 |