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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 19.)

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>&quot;Sorry, you entered an invalid CaneID or password&quot;</td>
<td>CaneID Help Desk (305-285-6565) for help resetting your password or re-enabling your CaneID account.</td>
</tr>
<tr>
<td>&quot;We were unable to match your CaneID to an active eProst account&quot; and you already have an eProst account</td>
<td>Research IT Help Desk (305-243-9662) for assistance with re-enabling your eProst account.</td>
</tr>
<tr>
<td>&quot;We were unable to match your CaneID to an active eProst account&quot; and you do not yet have an eProst account</td>
<td>Research IT Help Desk (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 17.

Note for committee members: You can view the list of all submissions to be reviewed for a committee meeting as described in Locating Meeting Agenda Items on page 6.

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 10.
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.

**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></td>
<td>State</td>
<td>Explanation</td>
</tr>
<tr>
<td>IRB committee member or designated reviewer</td>
<td>Non-Committee Review</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>
</tr>
<tr>
<td>Committee Review</td>
<td>Committee Review</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 Preparing Comments for a Meeting on page 14.</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>
</tbody>
</table>
Locating Meeting Agenda Items

As a committee member, you can get a meeting agenda listing the studies and other submissions to be reviewed in an upcoming meeting. You can get the agenda in two forms:

- As a web page with links to the studies
- As a printable document

The procedures below describe how to access both forms of the agenda in two alternative ways:

- From an agenda notification e-mail you receive
- By navigating to the agenda within the IRB system

To access the agenda from an e-mail you receive:

1. Open the e-mail informing you about an IRB meeting agenda.
   The notification content should resemble this:

   **Notification of Meeting Agenda**

<table>
<thead>
<tr>
<th>To:</th>
<th>Your Name</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Link:</strong></td>
<td>IRB Committee meeting on 10/31/2012 11:06 AM</td>
</tr>
<tr>
<td><strong>Title:</strong></td>
<td>IRB Committee meeting on 10/31/2012 11:06 AM</td>
</tr>
<tr>
<td><strong>Description:</strong></td>
<td>The agenda for this meeting has been generated or updated and is available at the follow link: Agenda for IRB Committee meeting on 10/31/2012 11:06 AM(0.01)</td>
</tr>
</tbody>
</table>

2. Click the appropriate link:
   - To access the meeting workspace web page containing links to the studies, click the link next to Link (shown above). The meeting workspace and its important links are shown below.
   - To open or save the printable document, click the link next to Description (shown above).
   **Note:** The most up-to-date agenda is in the web page format.

3. If prompted, log in to the IRB system.

   **Tip:** For more details about opening the document or using the web page, see the procedure below about navigating to the agenda.
To access the agenda by navigating to it:

1. Click IRB and then IRB Meetings in the upper left corner.

2. From the list of meetings shown in the center of the page, click the name of the meeting to view.

   The meeting workspace displays the list of agenda items in the center of the page, resembling this:

   **IRB Committee 1**
   
   **Meeting Date & Time:** 10/31/2012 11:06 AM
   **Agenda:** Agenda for IRB Committee 1 meeting on 10/31/2012 11:06 AM(0.01)
   **Minutes:** Not yet created.
   **Report:** Expedited Studies Approved in the last 45 days

<table>
<thead>
<tr>
<th>Agenda Items</th>
<th>Attendees</th>
<th>History</th>
</tr>
</thead>
<tbody>
<tr>
<td>STUDY00000202</td>
<td>Comparison of calcium effects from supplements vs. foods on osteoporosis patients</td>
<td></td>
</tr>
<tr>
<td>STUDY00000206</td>
<td>Effectiveness of motivation techniques for long-term exercise habits</td>
<td></td>
</tr>
<tr>
<td>STUDY00000203</td>
<td>Effects of low-light environments on mood and behavioral disorders</td>
<td></td>
</tr>
<tr>
<td>STUDY00000190</td>
<td>Occupational choice influences - a survey</td>
<td></td>
</tr>
</tbody>
</table>

3. Click the appropriate link:
   - To access a study directly from the agenda items list, click the link to the study (shown above).
   - To open or save the printable document, click the link in the page header next to Agenda (shown above). The agenda is in Microsoft Word format.

   **Tip:** Microsoft® Word documents open differently in different web browsers. If the document does not open promptly:
   - Click the Word icon if it is flashing at the bottom of your screen, and then click one of your open Word documents.

   ![Image of Word icon]

   - Check the bottom of the browser window to see if the document icon and name is shown there. If so, click the name to open it.
Locating Checklists for Reviewers

Several worksheets and checklists are provided in the system to guide your review process and document your decisions. They are intended for pre-reviewers, designated reviewers, and committee reviewers.

- **Worksheets** are for the reviewer’s benefit only.
- **Checklists** must be completed and attached when submitting your review comments to document your decisions.

**Tip:** First identify the pertinent documents using the topical list in Key Checklists and Worksheets on page 8. Then locate them using the procedure below.

**To locate the worksheets and checklists:**
1. Click IRB and then IRB library in the upper left corner.

2. Click the **Worksheets** or **Checklists** tab, depending on the document you want to view.
3. Click a link to open or save the applicable document, which is in Microsoft Word format.

**Tip:** Microsoft® Word documents open differently in different web browsers. If the document does not open promptly:

- Click the Word icon if it is flashing at the bottom of your screen, and then click one of your open Word documents.
- Check the bottom of the browser window to see if the document icon and name is shown there. If so, click the name to open it.

Key Checklists and Worksheets

Many checklists and worksheets for reviewers are available in the IRB Library to provide reminders, guide decisions, and help document decision criteria.

**Important!** Checklist information is required by regulations to document the findings that justify your determinations. Fill out the pertinent checklists and attach them when you submit the review form. For committee reviews, attach your individual checklists as described in Preparing Comments for a Meeting on page 14.

Worksheets also provide important guidance, but regulations do not require them to be retained.
The following table summarizes the pertinent checklists and worksheets, organized by the types of review decisions you must make.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Checklists (use and attach)</th>
<th>Worksheets (for reviewer’s use)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval criteria</td>
<td></td>
<td>▪ Criteria for Approval and Additional Considerations (HRP-314)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Additional Federal Criteria (HRP-318)</td>
</tr>
<tr>
<td>Type of review</td>
<td></td>
<td>▪ Pre-Review (HRP-308)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Review of Information Items (HRP-321)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Scientific or Scholarly Review (HRP-320)</td>
</tr>
<tr>
<td>Level of review</td>
<td></td>
<td>▪ Human Research (HRP-310)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Engagement (HRP-311)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Exemption (HRP-312)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Expedited (HRP-313)</td>
</tr>
<tr>
<td>Consent / recruitment</td>
<td>▪ Waiver or Alteration of Consent (HRP-410)</td>
<td>▪ Short Form of Consent (HRP-317)</td>
</tr>
<tr>
<td></td>
<td>▪ Waiver of Written Documentation of Consent (HRP-411)</td>
<td>▪ Advertisements (HRP-315)</td>
</tr>
<tr>
<td></td>
<td>▪ Waiver of Consent for Emergency Research (HRP-419)</td>
<td>▪ Payments (HRP-316)</td>
</tr>
<tr>
<td></td>
<td>▪ HIPAA Waiver of Authorization (HRP-441)</td>
<td></td>
</tr>
<tr>
<td>Special populations</td>
<td>▪ Pregnant Women (HRP-412)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Non-Viable Neonates (HRP-413)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Neonates of Uncertain Viability (HRP-414)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Prisoners (HRP-415)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Children (HRP-416)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>▪ Cognitively Impaired Adults (HRP-417)</td>
<td></td>
</tr>
<tr>
<td>Devices / drugs</td>
<td>▪ Non-Significant Risk Device (FDA) (HRP-418)</td>
<td>▪ Drugs (HRP-306)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Devices (HRP-307)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Criteria for HUD Approval and Additional Considerations (HRP-323)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Emergency Use (HRP-322)</td>
</tr>
<tr>
<td>Federal agencies / laws</td>
<td>▪ HIPAA Waiver of Authorization (HRP-441)</td>
<td>▪ Additional Federal Criteria (HRP-318)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ HIPAA Authorization (HRP-330)</td>
</tr>
</tbody>
</table>
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 17.
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.

   **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.
Requesting Clarifications to a Study

If a study is confusing or needs additional information to receive IRB approval, you can request clarifications. Requesting clarifications sends the study back to the study team so they can edit it.

To request clarifications to a study:

1. From My Inbox, click the name of the study to open it.
2. Click Request Clarification... on the left.

   ![Request Clarification Button]

3. In the Request Clarification form, provide detailed questions or requests for changes.
   
   **Note:** You can also attach documents that explain, show the study text, or show screen captures of the problematic areas, or that show suggestions for resolving the problems.

4. Click OK to send the request to the study team.

Unless the study is in committee review, you will receive an e-mail notification when the study team submits their response to the clarification request.

Requests for clarifications are handled differently during committee review than during other types of review in that study team members are not solely in control of the submission:

- Committee members can continue to request clarifications after a request has been made. This allows multiple reviewers to communicate with the study team at once.

- Study team members cannot edit the study when the clarifications requested are from committee review, but they can submit comments back to the committee.

- The committee cannot record a decision for the submission when it is in the Clarifications Requested state. The options are:
  - The IRB coordinator can remove the submission from the agenda before the meeting and reassign it to a later meeting.
  - At the time of the meeting, the committee chair or administrator can use the Convene Meeting activity to return all submissions still in the Clarifications Requested state to the Committee Review state so their reviews can be recorded.
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 16.)
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 16.)
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.
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.
   - Click the Changes Submitted activity link to see any notes or documents added to the study.
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.

<table>
<thead>
<tr>
<th>Differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Added: Mayo Clinic</td>
</tr>
<tr>
<td>Changed: National Institute of Health</td>
</tr>
<tr>
<td>Location: Funding Source ID</td>
</tr>
<tr>
<td>New Value: 38978</td>
</tr>
<tr>
<td>Old Value: 38974</td>
</tr>
</tbody>
</table>
5. Next to Changed Steps, click the >> 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.

Preparing Comments for a Meeting

While reviewing a study, you can record your review comments within the IRB system. You can also upload required checklists and any review-related documents. This lets committee members view each other's comments before and during the meeting.

All of your comments and the files you attach will be purged from the system when the approval letter is sent. Your comments are never visible to the study team members.

To record your review comments:
1. Open the study. For details, see Accessing a Study on page 17 or Locating Meeting Agenda Items on page 6.
2. Click Add Review Comments on the left.
3. Type in notes, and upload any relevant reviewer checklists and other related documents.
4. Click OK.

Note: Before and during the committee meeting, you can go to the study’s Reviews tab as shown below to view your comments and comments from other reviewers.
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.

Note for committee members: An IRB staff member must submit the decision on behalf of the committee. If you are a reviewer of the study, record your comments and attach relevant files (such as reviewer checklists) as described in Preparing Comments for a Meeting on page 14.

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 as described in Requesting Clarifications to a Study on page 11.

There are several types of review, with procedures for each identified below:

- Designated review
- Committee review

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 a designated (or non-committee) review:

**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. Make sure it is corrected before you submit your review decision.

1. Click **Submit Designated Review** on the left.

2. If true, check the box to indicate that you do not have a conflicting interest. (For more details about conflicting interests, click the icon.)

3. Answer the relevant questions, paying special attention to each required question marked with a red asterisk (*).

4. (Optional) Add comments and attach documents related to the review.

5. If you have entered all the relevant information and are ready to submit the final IRB decision, answer Yes when asked if you are ready to submit this review.
   
   Otherwise, answer No, which enables you to return and perform Submit Designated Review again to update the information.

6. Click **OK**.

If you submitted the final decision, the IRB can now officially communicate the decision to the study team.

To complete a committee review: (usually completed by the IRB Staff)

**Important!** An IRB staff member must submit the decision on behalf of the committee. If you are a reviewer of the study, record your comments and attach relevant files (such as reviewer checklists) as described in Preparing Comments for a Meeting on page 14.

**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.

1. Click **Submit Committee Review** on the left.

2. Answer the relevant questions, paying special attention to each required question marked with a red asterisk (*).

3. (Optional) Add notes and attach documents related to the committee's review.

4. Click **OK**.

The IRB coordinator assigned to the study can now officially communicate the decision to the study team.
## 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. Your Name My Inbox Logoff</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. <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>
</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>
# 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&lt;br&gt;Study Submission Guide</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&lt;br&gt;Study Submission Guide</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&lt;br&gt;Study Submission Guide</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><strong>IRB</strong></td>
<td>Click <strong>IRB</strong> and then <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>
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