

IRB Principal Investigator Quick Reference

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Navigation and Basic Tasks

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, click the submission name.
6. The submission workspace opens.

View History

7. From the submission workspace, click the History tab.
8. The history tab lists the activity taken on a submission including any comments, attachments, or correspondence added.

My Current Actions

- Create New Study
- Report New Information

My Inbox

Filter by ID [] Go

ID	Name
STUDY00000071	Military Family Separation Study
STUDY00000069	Zika Virus Vaccination Efficacy Tests

2 items

Submissions

Meetings

Reports

Library

Help Center

My Inbox

Filter by ID [] Go Clear Advanced

ID	Name	Date Created	Date Modified	State
STUDY00000071	Military Family Separation Study	7/21/2016 11:27 AM	7/21/2016 1:44 PM	Clarification Requested (Pre-Review)
STUDY00000069	Zika Virus Vaccination Efficacy Tests	7/21/2016 10:38 AM	7/21/2016 10:45 AM	Pre-Submission

Pre-Submission

STUDY00000069: Zika

Principal investigator: Jack Fletcher
 Student Led Protocol: No
 Submission type: Initial Study
 Primary contact: Jack Fletcher
 IRB coordinator:

Entered IRB:
 Last updated: 7/21/2016 10:45 AM

```

    graph LR
      A[Pre-Submission] --> B[Pre-Review]
      B --> C[Clarification Requested]
      C --> B
    
```

My Current Actions

- Edit Study
- Printer Version
- View Differences
- Submit

History Funding Project Contacts Doc

Filter by Activity []

Activity
Study Created

Find Previous Submissions

9. Click the **Submissions** shortcut.
10. 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.

To find specific data in a table, see [Filter Data](#).

Filter Data

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

11. Select the column to filter by.
12. 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
13. Click **Help** for operators you can type in the text box.
14. Click **Go** to apply the filter.
15. To combine multiple filter criteria, click **Advanced** and then click **Add Another Row**.

My Current Actions

Create New Study

Report New Information

Submissions **9**

Meetings

Reports

Library

Help Center

My Inbox

Filter by ID [] Go

ID	Name
STUDY00000071	Military Family Separation Study
STUDY00000069	Zika Virus Vaccination Efficacy Tests

2 Items



In-Review Active Archived New Information Reports All Submissions

Filter by ID [] Go Clear Advanced

ID	Name	Date Modified	State
STUDY00000071	Military Family Separation Study	7/21/2016 1:44 PM	Clarification Requested (Pre-Review)
STUDY00000069	Zika Virus Vaccination Efficacy Tests	7/21/2016 10:45 AM	Pre-Submission

Filter by ID [] Go Clear Advanced

- ID **11**
- Name
- Date Created



Filter by ID [71] Go Clear Advanced

13 **14** **15**

Create Study and Submission Approvals

Before you begin, gather files and information about your protocol such as: supporting information (drug and device information, recruitment materials, etc.), financial interest status for each study team member, and contact information for collaborating sites involved in the study.

The screenshot displays the IRB system interface. At the top left, the 'My Current Actions' panel features a 'Create New Study' button (1) and a 'Report New Information' button. Below it are links for 'Submissions' and 'Meetings'. To the right, the 'My Inbox' panel shows a 'Filter by ID' dropdown and a list of two items: 'STUDY00000071' and 'STUDY00000069'. At the bottom of the inbox, it says '2 items'. Below these panels is a navigation bar with '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To: Basic Information', and a 'Continue >>' button (2). A second navigation bar below it has '<< Back', 'Save | Exit | Hide/Show Errors | Print...', 'Jump To:', and a 'Finish' button (3). On the left side, a vertical menu includes 'View Differences', 'Submit', 'Discard', and 'Manage Ancillary Reviews' (4). The 'Add Ancillary Review' form is shown with a dropdown for 'Review type' (7) where 'Department' is selected. The form also has 'Organization:' (5) and 'Person:' (6) fields with 'Select...' buttons. Below the form is a question: '3. * Is a response required?' with radio buttons for 'Yes' and 'No', and a 'Clear' link (8). At the bottom, a navigation bar includes 'History', 'Funding', 'Project Contacts', 'Documents', 'Follow-on Studies', 'Reviews' (9), and 'Snapshots'. A review workflow diagram is also visible, showing stages: Pre-Submission, Pre-Review (with Clarification Requested), IRB Review (with Clarification Requested), Post-Review (with Modifications Required), and Review Complete.

Create a Study

1. From the My Inbox page, click Create New Study.
2. Complete the pages. Click Continue to move to the next page.
3. 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.

Manage Ancillary Reviews

Once you have completed your protocol, use this activity for Department Chair and/or Dean approval.

4. From the study workspace, click the Manage Ancillary Review activity on the left and click the Add button.
5. In the Person field, start typing in the name of the Department Chair, Dean, or Faculty Sponsor you want to send the protocol to for approval
6. Alternatively, you can also click the Select button and search for the person
7. Select Department in Review type if you are seeking Department approval. Select Faculty Sponsor if the PI is a student.
8. Indicate that the review is required and click OK
9. You can keep see if the review was completed or not under the Reviews tab of the study workspace

Submit a Study

Once you have received approval from Department Chair or Dean, you ready to submit the protocol to the IRB.

My Current Actions

- Edit Study
- Printer Version
- View Differences
- Submit**

Submit

By signing below you are verifying that:

- You have obtained the financial interest status ("yes" or "no") of each research staff.
- You have obtained the agreement of each research staff to his/her role in the research.
- You will conduct this Human Research in accordance with requirements in the HRP-103 - Investigator Manual

Please confirm your login credentials:

Username:

Password:

Submit

Submit a Study for Review

1. From the study workspace, click **Submit**.
2. Click **OK** to agree to the terms.
3. Type your login credentials and click **Submit**.

You can log off the system. Your study has been submitted to the IRB.

Assign PI Proxy

The PI can assign a PI Proxy who can perform all PI actions on a study on the PIs behalf. A proxy must be a member of the study team.

My Current Actions

- View Study
- ...
- Assign PI Proxy**

Assign PI Proxy

A proxy can perform PI responsibilities on your behalf, such as submitting continuing reviews.

Select study team members to act as proxy:

First Name	Last Name
<input type="checkbox"/> Samoya	Copeland
<input type="checkbox"/> Danielle	Griffin

Please confirm your login credentials:

Username:

Password:

Submit

Assign PI Proxy

1. From the study workspace click **Assign PI Proxy**
2. Select one or more team members to act as proxy. Click **OK**.
3. Type your login credentials and click **Submit**.

Note: Only the PI can assign PI Proxies.

Respond to Clarification Requests

If a reviewer has questions or requires you to change your submission, you will receive an email indicating this. Review the request details and then respond to the request.

Notification of Requested Clarifications

To: Jack Fletcher

Link: [STUDY00000071](#)

P.I.: Jack Fletcher

Title: Military Family Separation Study

Description: Clarifications have been requested on this submission. This requires a response from you. For additional details, click on the link above to review and provide clarification.

This is an official communication from the IRB. If you have any questions regarding this notification, please contact the IRB at cphs@central.uh.edu.

History Funding Project Contacts Documents Review

Filter by Activity

Activity

Clarification Requested

Please upload revised consent documents in the study.

My Current Actions

Edit Study

Printer Version

View Differences

Submit Response

Submit Response

Notes:

I attached the updated consent forms in the study as you requested.

Supporting documents:

Add

Name
There are no items to display

OK Cancel

Please confirm your login credentials:

Username:

Password:

Submit

Review the Request Details

1. Click the submission ID link 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 protocol 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**.
6. Type your login credentials and click **Submit**.

You can log off the system. The study has moved back to the reviewer's inbox to continue the review.

Change Study Documents

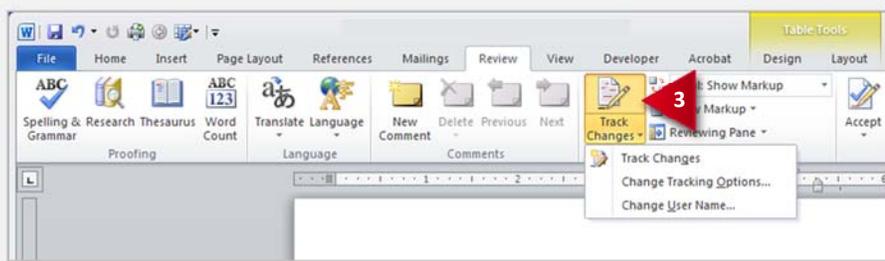
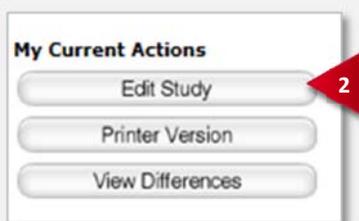
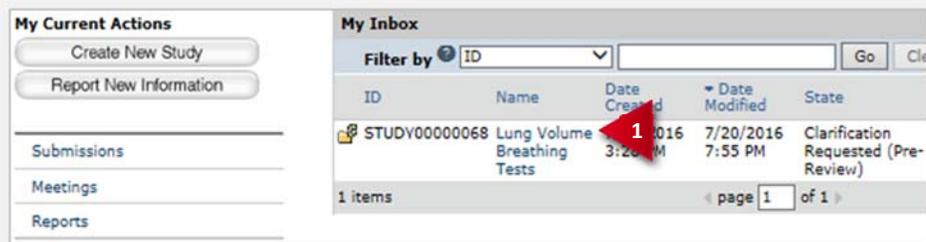
You can update your study documents any time prior to submitting the study to the IRB for review. Once it is in the review process, you will only be able to update documents if the IRB coordinator or a committee member requests clarification to it. In this case, the study will appear in your inbox.

Change Study Documents

1. From your inbox, open the study you want to edit.
2. If the study is not in your inbox, contact the IRB coordinator assigned to your study.
3. From the submission workspace, click **Edit Study**.
4. 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.



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.

Create a CR or Modification

1. From your inbox, click the **Submissions** shortcut.
2. On the IRB page, click the **Active** tab and open the approved study. Click the **Create CR/Modification** button.
3. Select whether the submission is a CR, a modification, or a combination and then complete the pages.
Click **Continue** to move through the pages and **Finish** on the last page.
4. From the workspace, click **Submit**.
5. Click **OK** to agree to the terms.
6. Type your login credentials and click **Submit**.

IRB

Submissions **1**

Meetings

Reports

Library

Help Center

In-Review **2** Active Archived New Information Reports

Filter by ID

ID	Name	Date Modified	State
STUDY00000069	Zika Virus Vaccination Efficacy Tests	7/25/2016 10:37 PM	Approved

Modification / Continuing Review / Study Closure

What is the purpose of this submission? **3**

Continuing Review

Modification and Continuing Review

Modification/Update

[Clear](#)

Submit **4**

By signing below you are verifying that:

- You have obtained the financial interest status ("yes" or "no") of each research staff.
- You have obtained the agreement of each research staff to his/her role in the research.
- You will conduct this Human Research in accordance with requirements in the HRP-103 - Investigator Manual

5 OK Cancel

Please confirm your login credentials:

Username:

Password:

6 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 **Active** tab and open the approved study.
3. On the study workspace, click **Report New Information**.
Note - you can also create Reportable New Information directly from My Inbox.
4. Complete the Reportable New Information page and 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.

The screenshot shows the IRB system interface with several key elements:

- IRB Dashboard:** A sidebar on the left contains navigation links: Submissions (1), Meetings, Reports, Library, and Help Center.
- Study List:** A table at the top right shows study details. The 'Active' tab is selected. A table lists studies with columns for ID, Name, Date Modified, and State. One study is listed: ID: STUDY00000069, Name: Zika Virus Vaccination Efficacy Tests, Date Modified: 7/25/2016 10:37 PM, State: Approved. A red arrow (2) points to the 'Active' tab.
- My Current Actions:** A central box contains buttons for View Study, Printer Version, View Differences, and Report New Information (3).
- Reportable New Information Page:** A form titled 'Reportable New Information' is shown. It includes a '<< Back' button, a 'Save | Print.' button, and a 'Continue >>' button (4).
- Submit RNI:** A button labeled 'Submit RNI' (5) is located below the form.
- Agreement:** A section titled 'By signing below you are verifying that:' contains two bullet points:
 - The information you have submitted is complete and correct to the best of your knowledge.
 - The information you have submitted has been done so in accordance with requirements in the HRP-103 - Investigator Manual
 Below this are 'OK' and 'Cancel' buttons (6).
- Login Confirmation:** A box titled 'Please confirm your login credentials:' contains fields for 'Username:' and 'Password:', and a 'Submit' button (7).

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