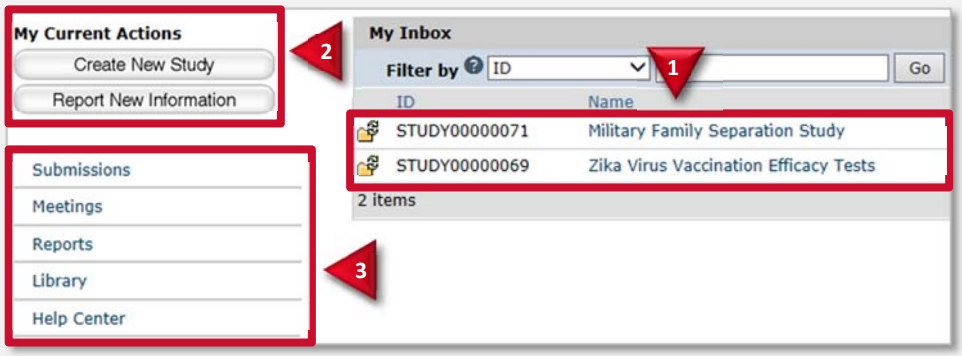
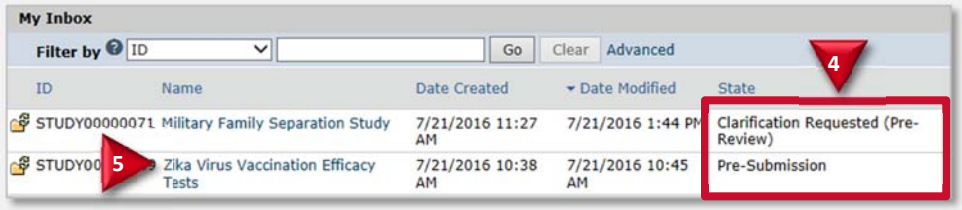
UNIVERSITY of HOUSTON
DIVISION OF RESEARCH

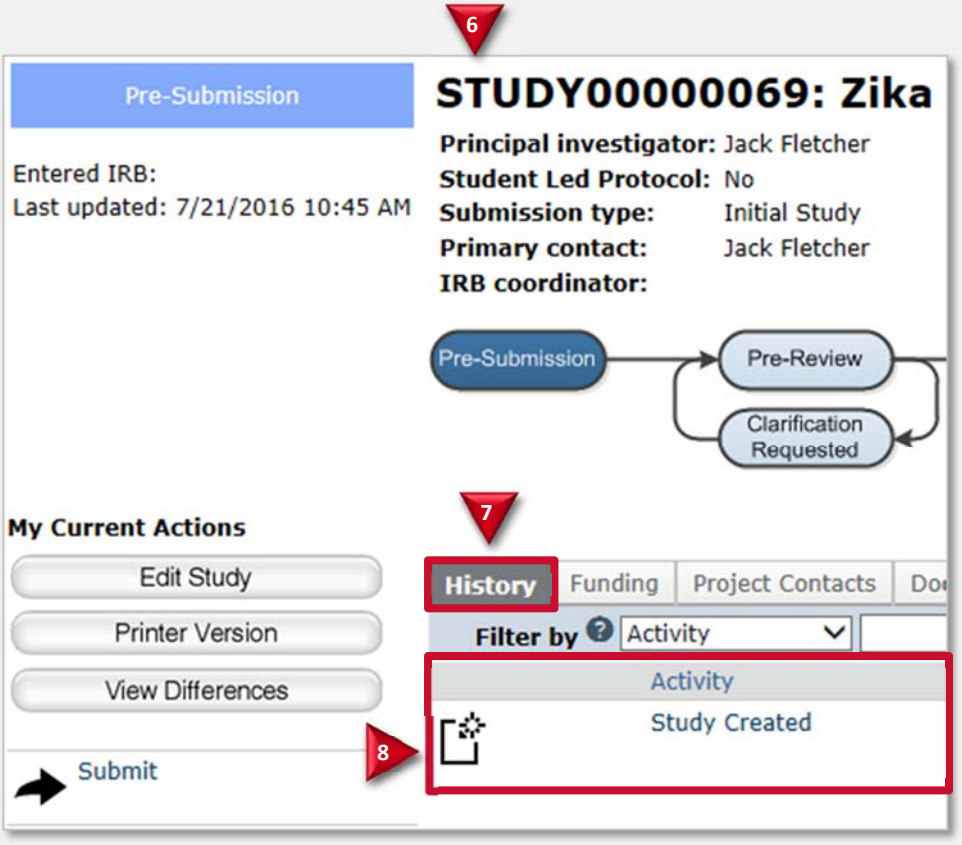
IRB Principal Investigator Quick Reference

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?

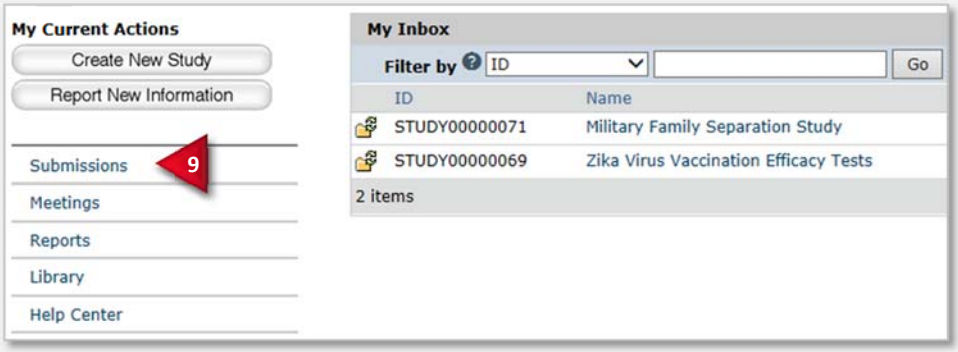
4. Review the state of submissions in your inbox. The state gives a clue as to what to do next. For example, "Pre-Submission" means you haven't submitted the study. You can finish and submit it for review.

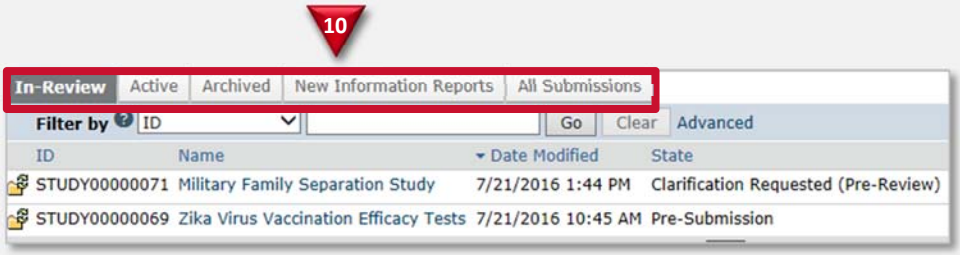
Open a Submission

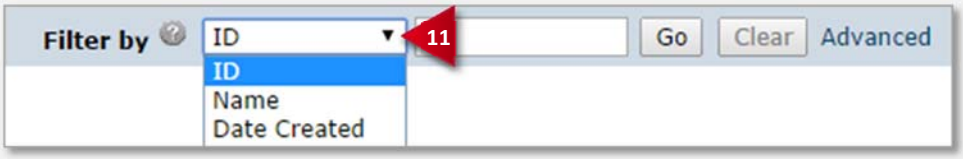
5. From your inbox, click the submission name.
6. The submission workspace opens.

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.







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

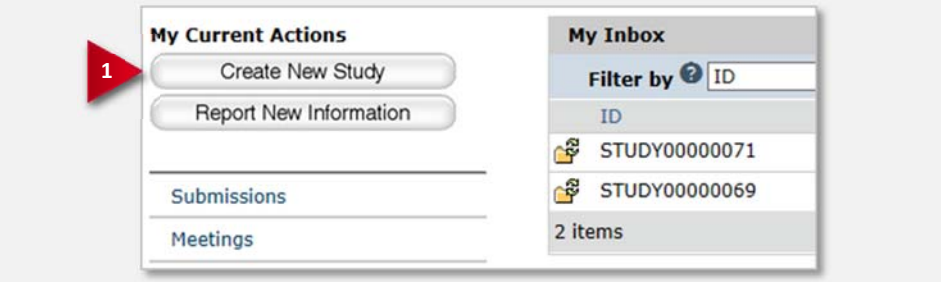
13. Click Help for operators you can type in the text box.

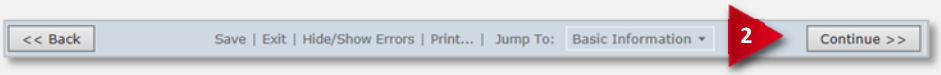
14. Click **Go** to apply the filter.

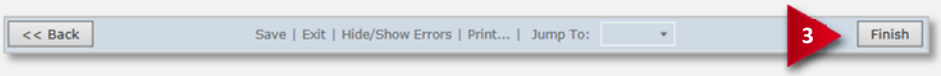
15. To combine multiple filter criteria, click **Advanced** and then click **Add Another Row**.

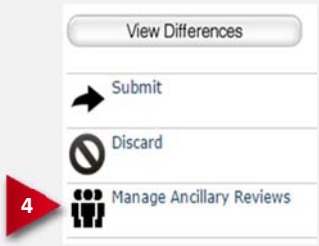
Create Study and Submission Approvals

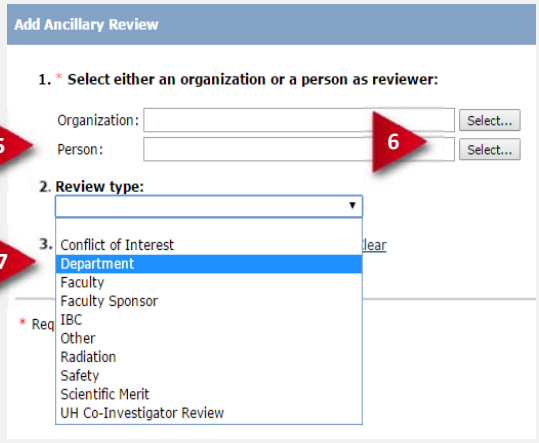
Before you begin, gather files and information about your protocol such as: supporting information (drug and device information, recruitment materials, etc.), financial interest status for each study team member, and contact information for collaborating sites involved in the study.

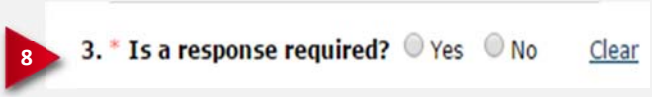


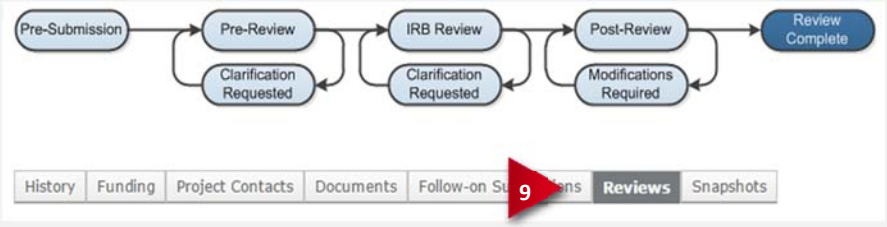












Create a Study

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.

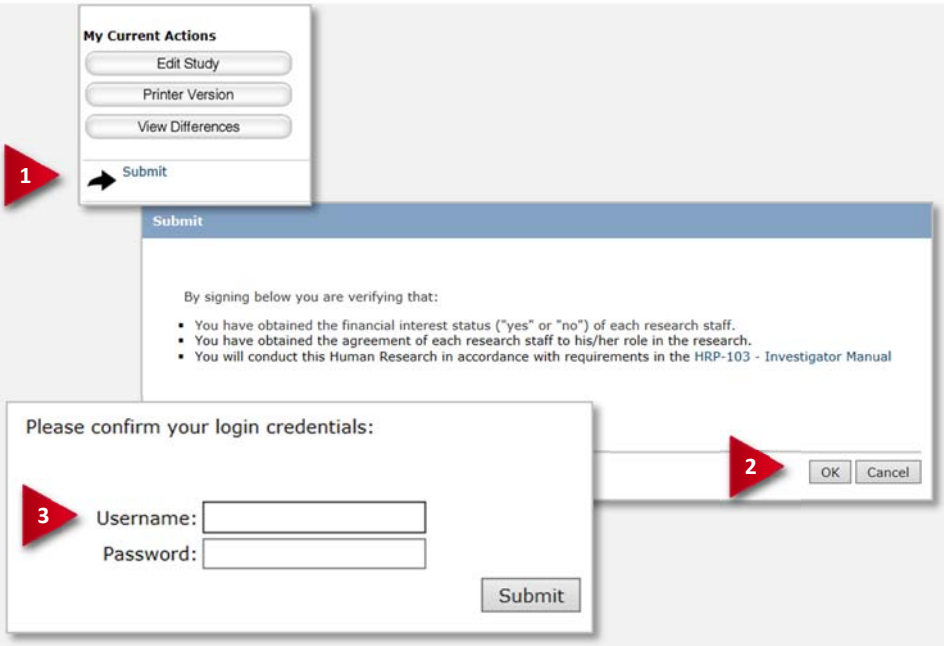
Manage Ancillary Reviews

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.



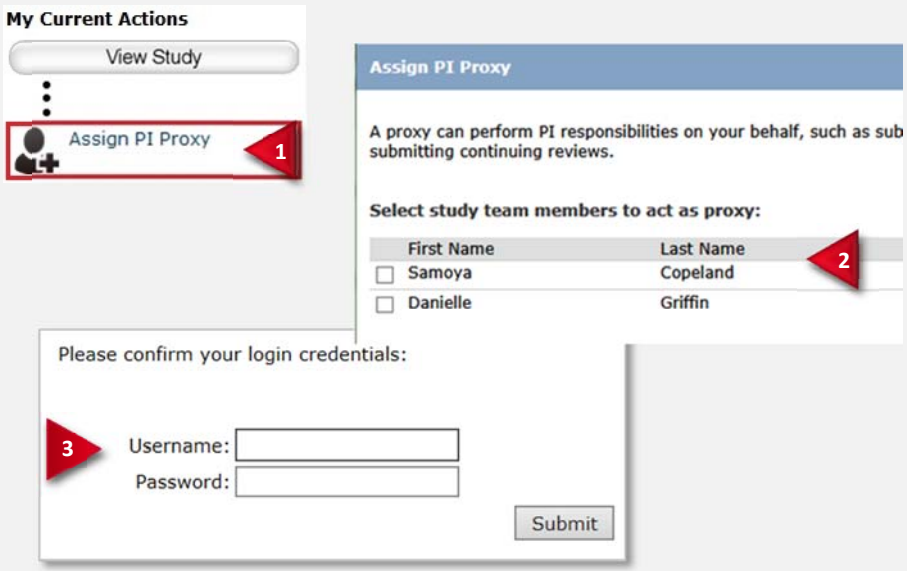
Submit a Study for Review

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.



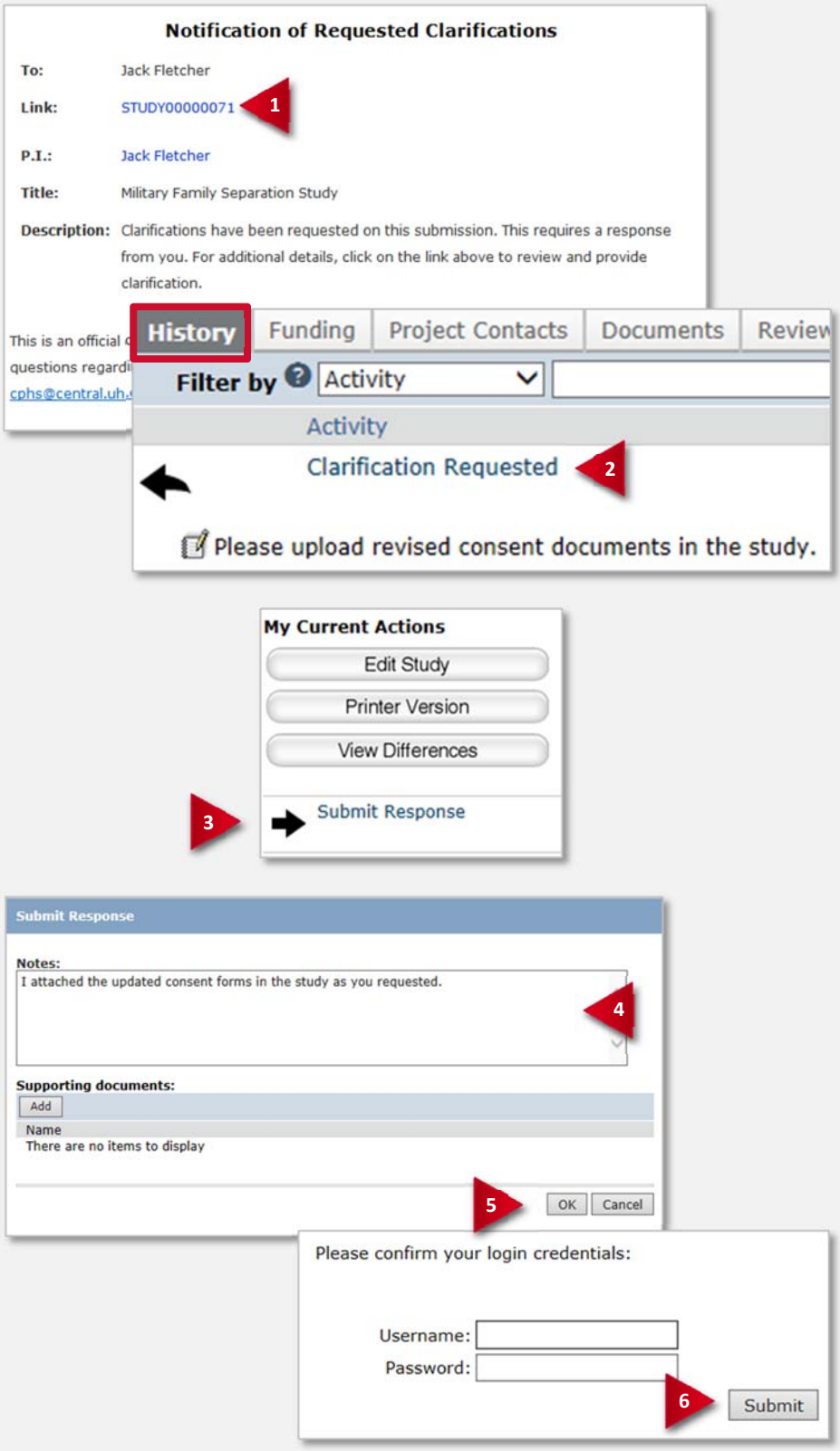
Assign PI Proxy

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.



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.

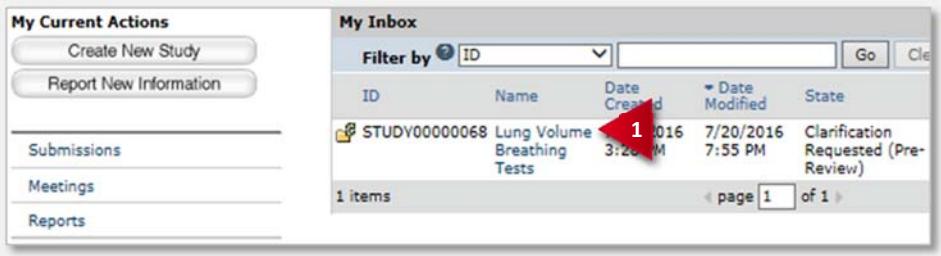
5. Click **OK**.

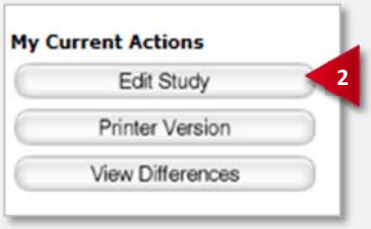
6. Type your login credentials and click **Submit**.

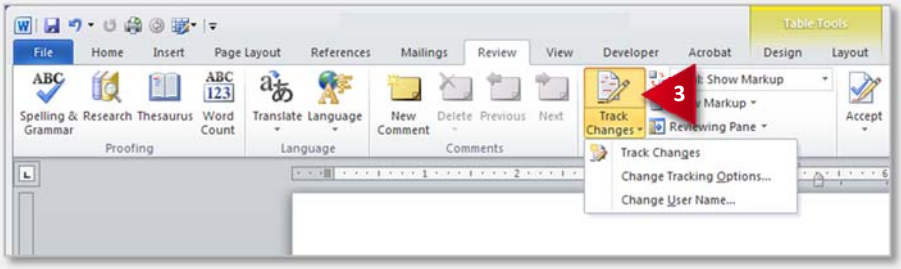
You can log off the system. The study has moved back to the reviewer's inbox to continue the review.

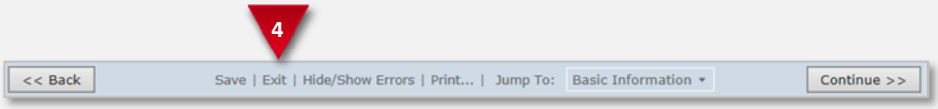
Change Study Documents

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.

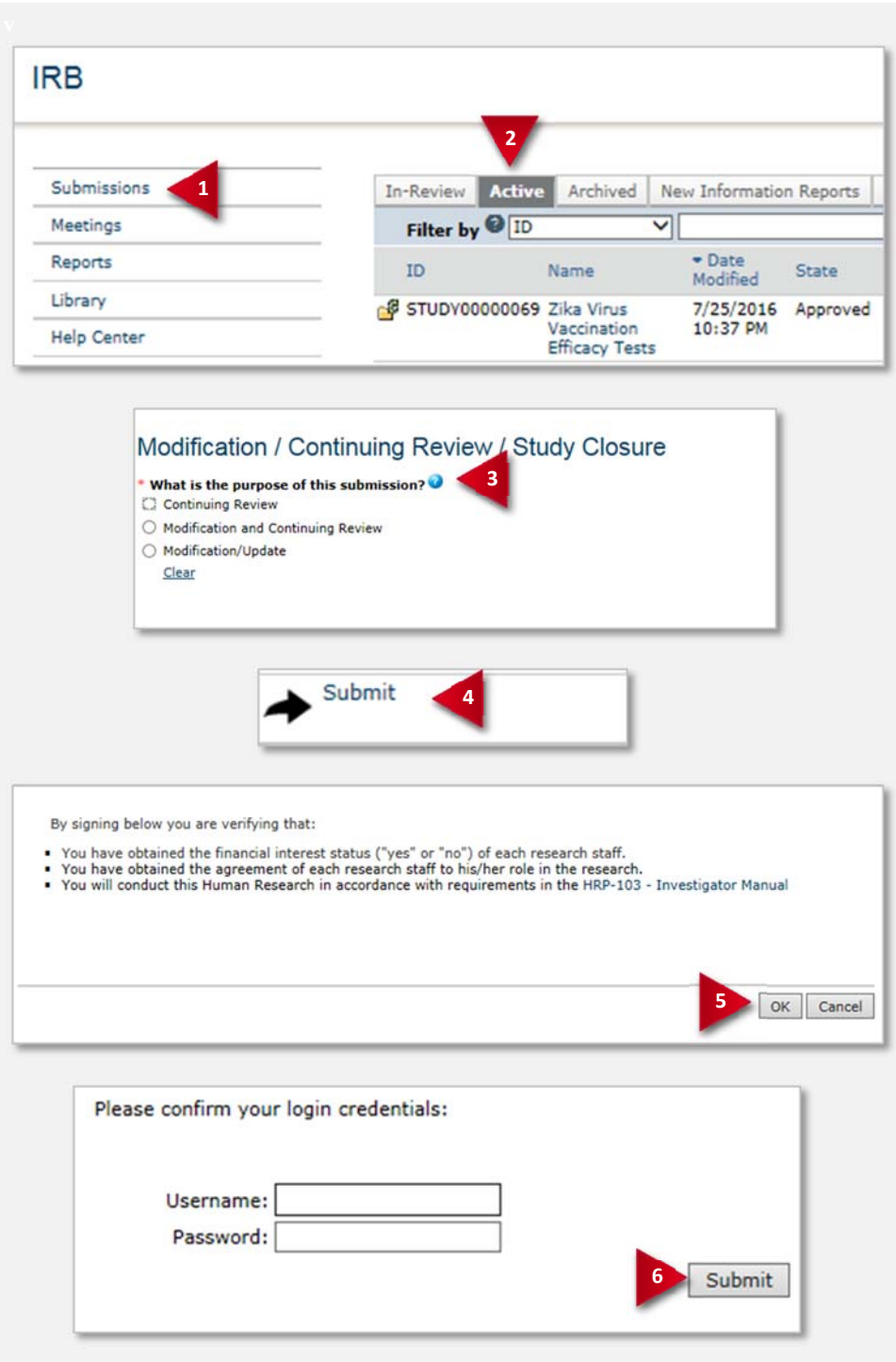
   Note: When updating a document previously submitted to the IRB, revise it using Word's Track Changes feature and then replace the original document with the tracked-changes version. When the IRB finalizes documents on approved studies, all tracked changes will be accepted and comments removed.

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.

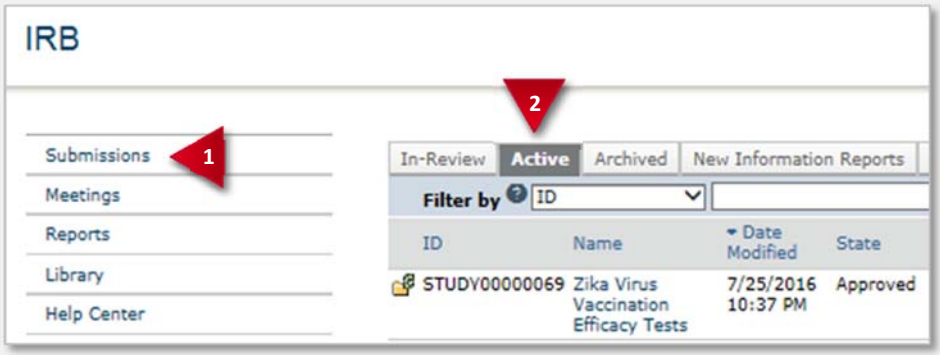
   Click **Continue** to move through the pages and **Finish** on the last page.
4. From the workspace, click **Submit.**
5. Click **OK** to agree to the terms.
6. Type your login credentials and click **Submit**.

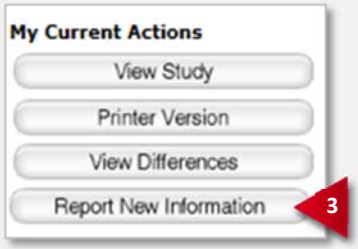
You can log off the system. Your modification or CR has been submitted to the IRB.

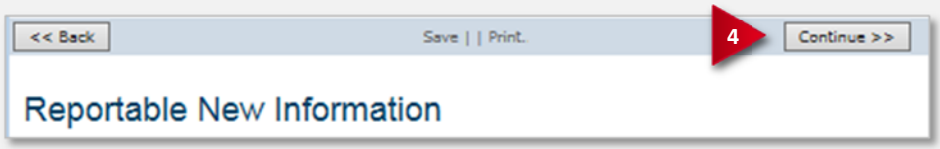
To find your modifications and CRs, go to the Submissions page (click the Submissions shortcut), and then the Follow-On Submissions tab.

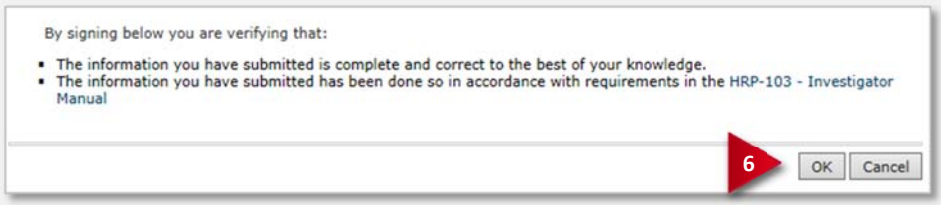
Create and Submit Reportable New Information

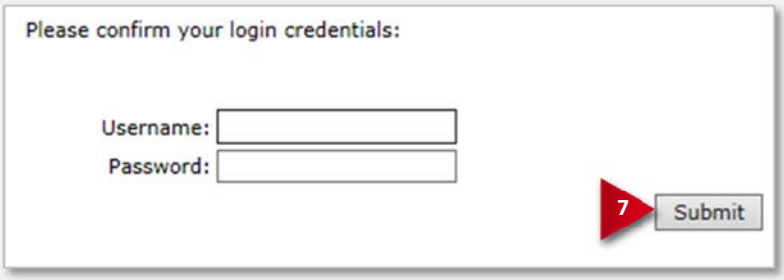
Report any adverse events or new information about a study as soon as you become aware of it.











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.

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