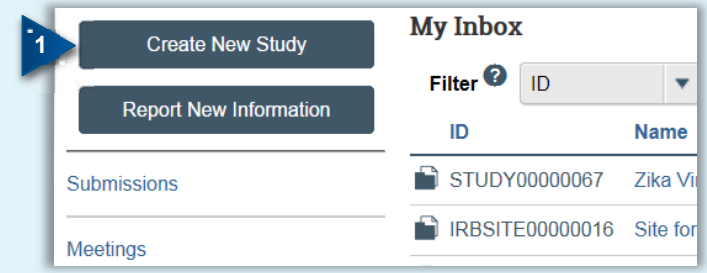
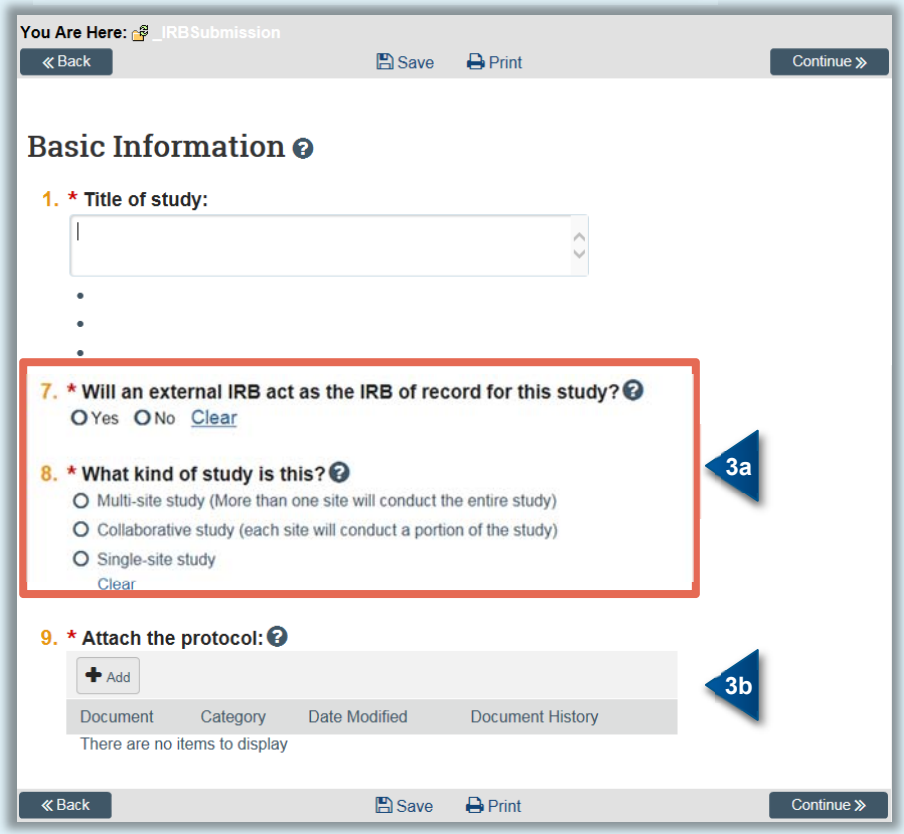
PittPRO | Pitt Protocol Review Online

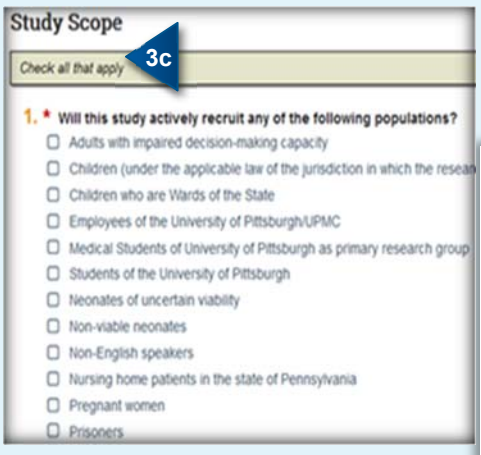
Click® IRB
Researcher's Quick Reference

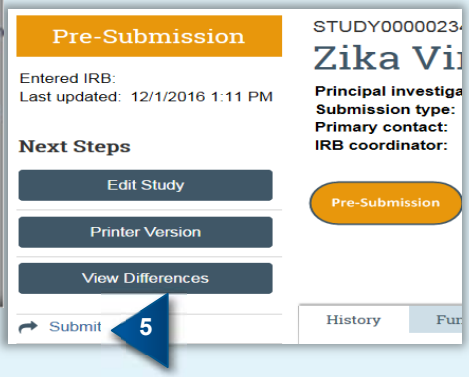
Create and Submit a New Study

Before you begin, gather files and information about your study. For more details on documents you may want to attach to a study, see the Checklist of Information to Attach.









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. 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**: Upload the Study Protocol, Exempt forms, or Emergency Use Protocol.
   c. **Study Scope page**: This section allows you to limit the number of questions displayed based on the research to be conducted (populations, waivers, PHI, data security, etc.).
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 a Study for Review

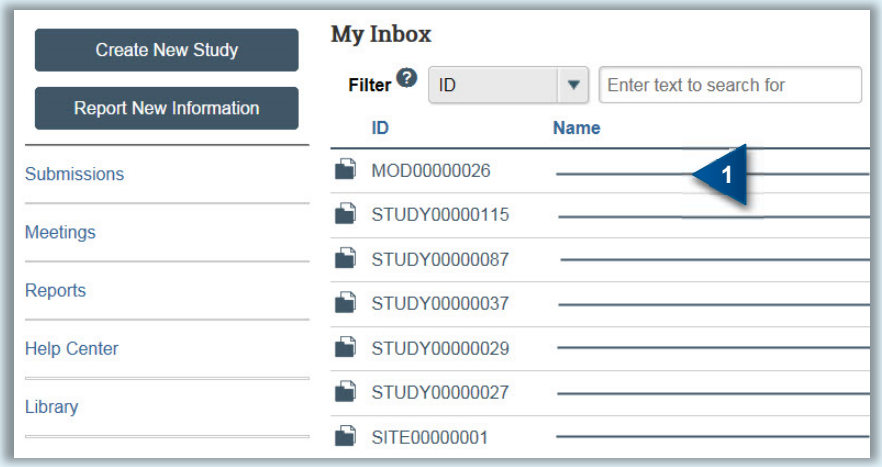
5. From the study workspace, click **Submit**.
6. Click **OK** to agree to the terms.

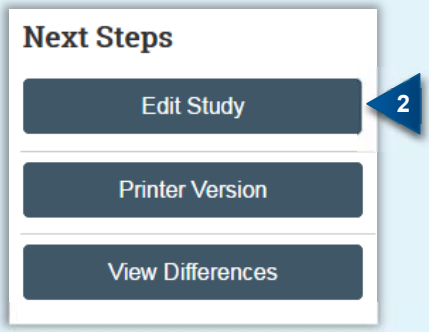
You can log off the system. Your study has been submitted for review.

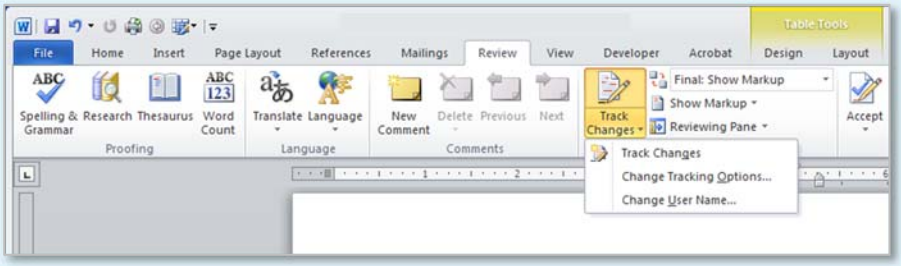
The study will be sent for a local Scientific Review which may not be required based on your funding source review process or department policies. Once scientific merit has been established, the study is then sent for IRB Review and in parallel, Ancillary Reviews if needed.

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.







Change Study Documents

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**.

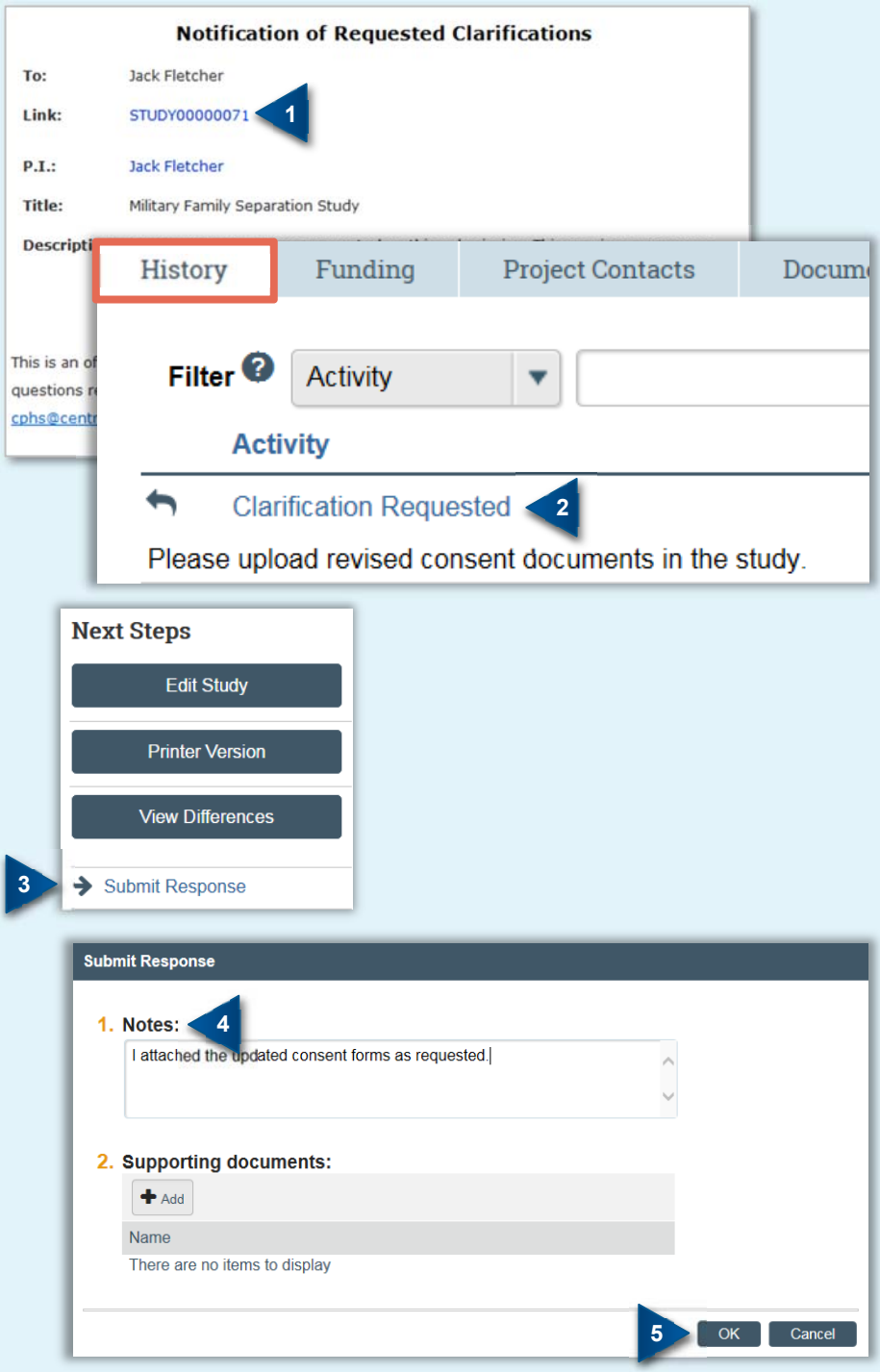
3. Add and update documents on study pages as needed and exit the study when done.

   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

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 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.

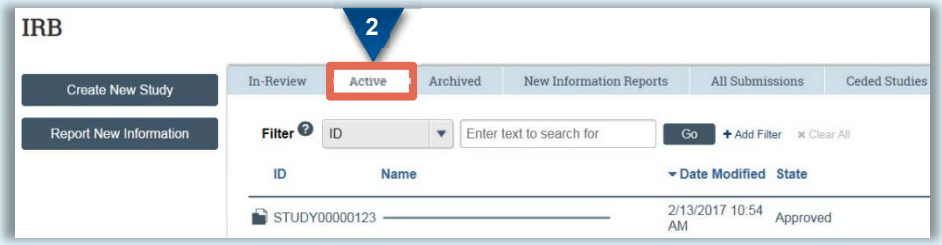
5. Click **OK**.

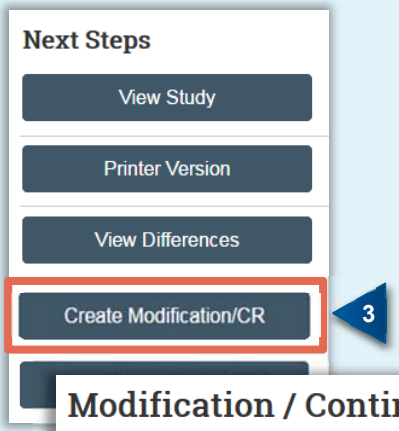
You can log off the system. The study has moved back to the reviewer's inbox to continue the review.

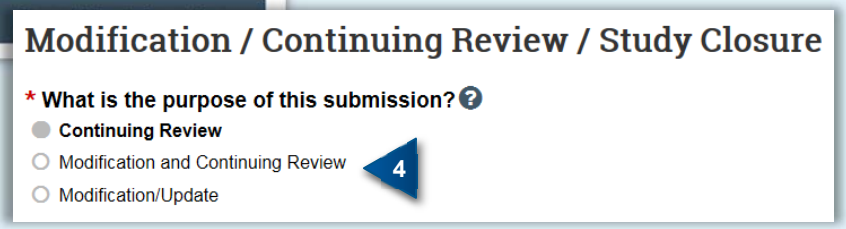
Create and Submit a CR or Modification

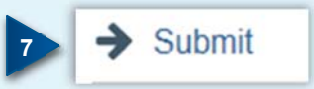
You can submit a Continuing Review (CR), a modification, or both combined:

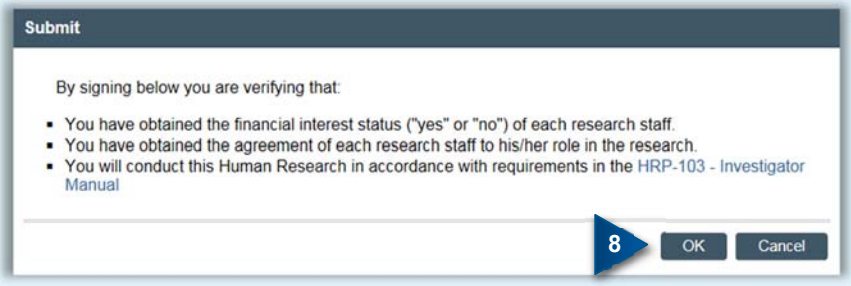
- To close a study or extend your approval period, submit a CR.
- To change an approved study or the study team's members, submit a modification.











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.
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:

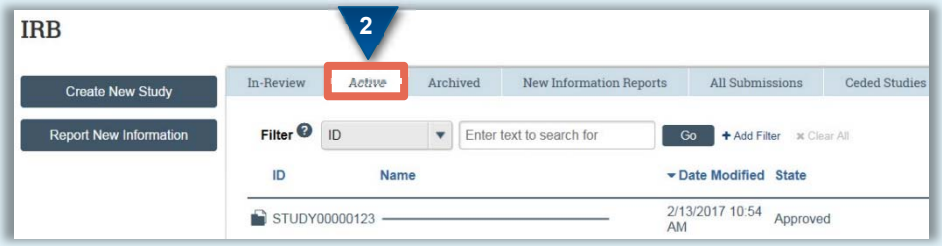
   Modification scope. To make changes to any part of the study except for study team members, select **Other parts of the study**.
6. Complete the pages. Click **Continue** to move through the pages and **Finish** on the last page.
7. From the workspace, click **Submit.**
8. Click **OK** to agree to the terms.

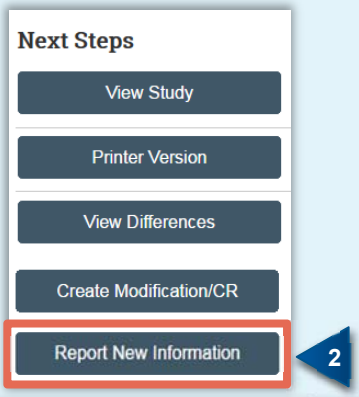
You can log off the system. Your modification or CR has been submitted to the IRB.

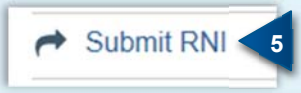
To find your modifications and CRs, go to the Submissions page (click the Submissions shortcut), and then the Follow-On Submissions tab.

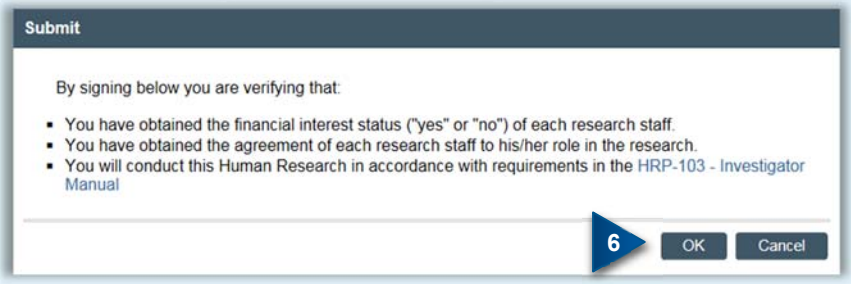
Create and Submit Reportable New Information

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:

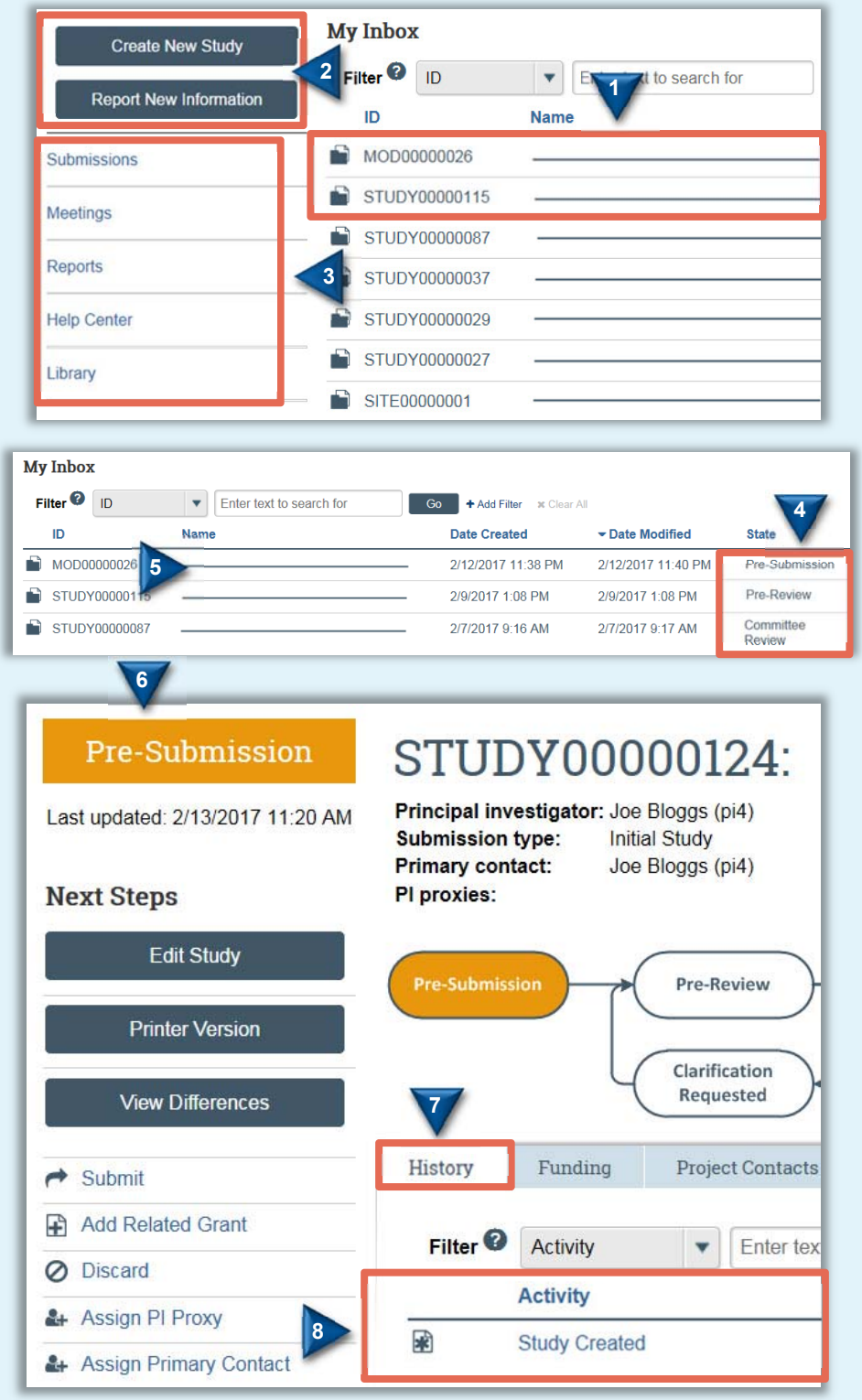
   a. **Related studies and modifications:** Select any studies or modifications that the RNI applies to.

   Note: You cannot relate sites, external studies (unless the external study is part of a multi-site 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.

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.

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?

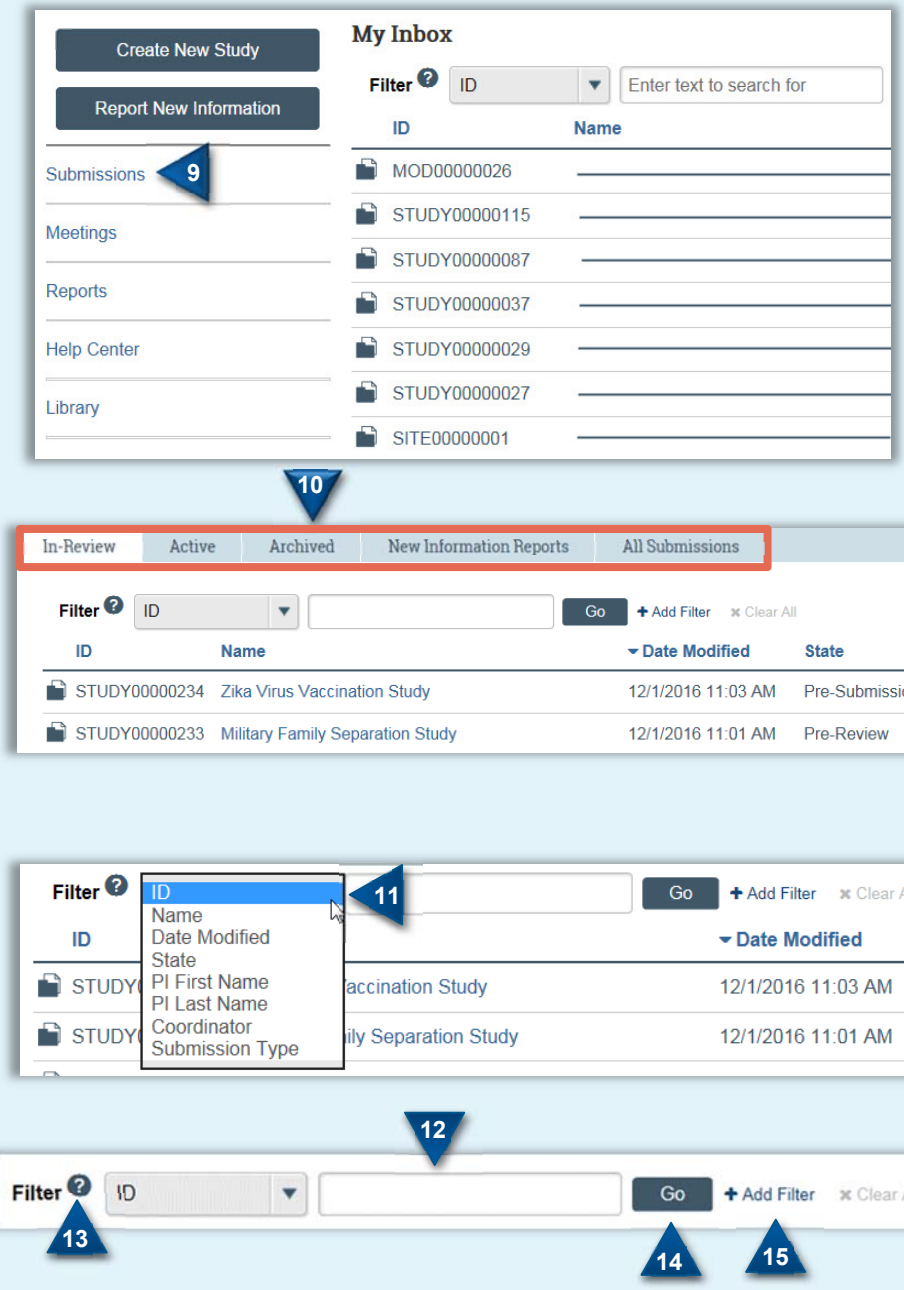
4. Review the state of submissions in your inbox. The state gives a clue as to what to do next. For example, "Pre-Submission" means you haven't submitted the study. You can finish and submit it for review.

Open a Submission

5. From your Inbox, or from the Submissions page, 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.

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

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

15. To combine multiple filter criteria, click **Add Filter**.

Checklist of Information to Attach

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 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)

- Sponsor/Multicenter protocol
- Investigator-initiated protocol
- Emergency Use protocol
- Exempt application forms

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

- Grant applications

Drug details: (**Drugs** page)

- Package inserts
- 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)

- Product labeling/device instructions
- Investigator brochure
- Verification of IDE:
    - Sponsor protocol with the IDE number
    - Communication from the FDA or sponsor with the IDE number

Research Site details: (Research Sites page**)**

- Permission letters

Recruitment details: (**Recruitment Methods** page)

- All material to be seen or heard by subjects, such as:
    - Evaluation instruments and surveys
    - Advertisements, including printed, audio, and video
    - Recruitment materials and scripts
- Foreign-language versions of materials for subjects

Non-English Speakers details: (Non-English Speakers page**)**

- Translator certification forms

Nursing Home Patients in PA details: (Nursing Home Patients in PA page**)**

- Pennsylvania Department of Health approval letter

Research Activities details: (Research Activities page**)**

- All materials used to collect data about subjects

- Surveys, scripts, data collection form (excludes case report forms, SCID, KSADS)

Consent Form details: (Consent Forms page)

- Consent documents:
  - Consent forms
  - For non-written consent, a script of the information provided orally to the subjects

Use of Deception details: (Deception page)

- Debriefing script

Honest Broker details: (Honest Broker page)

- Honest Broker Agreements

All other relevant documents: (Local Supporting Documents page)

- Conflict of Interest Management Plan
- Templates shared with other sites
  - Consent document templates for use by participating sites
  - Recruitment materials templates for use by participating sites
  - Other supporting documents needed by participating sites

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20270 NW AmberGlen Ct

Suite 100

Hillsboro, OR 97006