

Modification Submissions

1) Click on the **IRB** tab

The screenshot shows a navigation bar with four tabs: 'My Inbox', 'COI', and 'IRB'. The 'IRB' tab is circled in red. Below the navigation bar is a sidebar with three options: 'IRB', 'COI', and 'Grants'. The main content area is titled 'My Inbox' and features a search filter set to 'ID' with a search input field containing 'Enter text to search for'. Below the search bar is a table header with columns for 'ID' and 'Name'.

2) Use one of the various filters to search for your study using the IRBNet ID number (no hyphen, no package number). Search under the **All Submissions** tab. Notice that you can also filter by ID as well as the study name listed in IRBNet or the PI first/last name.

The screenshot shows the 'All Submissions' tab selected in the navigation bar. Below the navigation bar is a search filter set to 'ID' with a search input field containing 'Enter text to search for'. A 'Go' button and '+ Add Filter' and 'x Clear All' options are visible. Below the search bar is a table header with columns for 'ID', 'Name', 'Date Modified', 'State', 'PI First Name', and 'PI Last Name'.

3) Select the study title. This will route you to the study's main workspace with several actions available to you on the left side of the screen. Select **Create Modification/CR**.

The screenshot shows the study workspace for 'IRB2019-00031: Brand New Study'. The status is 'Approved'. The principal investigator is 'PI One' and the submission type is 'Initial Study'. The primary contact is 'PI One'. The workspace includes a flowchart showing the process from 'Pre-Submission' to 'Pre-Review', 'IRB Review', and 'Post-Review', with 'Clarification Requested' steps in between. On the left side, there are several action buttons: 'View Study', 'Printer Version', 'View Differences', 'Create Modification/CR', and 'Report New Information'. A red arrow points to the 'Create Modification/CR' button. Below the flowchart is a navigation bar with tabs for 'History', 'Funding', 'Contacts', 'Documents', and 'Follow-on Submissions'. The 'Activity' tab is selected, showing a search filter set to 'Activity' and a search input field containing 'Enter text to search for'. Below the search bar is a table header with columns for 'Activity'.

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4) Select **Modification** as the purpose of the submission.

Important Note: If you select any option other than Modification and then select Continue, **the system will not allow you to update this selection.** You will need to select Discard (on the left navigation area of the main workspace) and start again.

You Are Here: Brand New > IRBSubmission

<< Back Save Print

Modification / Continuing Review (* Refer to the latest approval letter to confirm that a c required this year) / Study Closure (If requesting a subject-specific protocol exception, s

* What is the purpose of this submission? 

Continuing Review

Modification

Modification and Continuing Review

[Clear](#)


<< Back Save Print

5) Choose the **Study Team Member Information** scope if you must make a change to the **Study Team Members page list ONLY**. If you choose this scope alone, you will not be able to modify any previously approved documents or update any other sections of the most recently approved application SmartForm. If your modification is associated with changes to previously approved study documents (e.g. removing a study team member that is also listed in the protocol/data collection sheet/consent form) or other sections of the SmartForm, you must choose **BOTH** scopes (**Study Team Member Information and Other Parts of the Study**). **Recommendation: Review your approved documents and the application SmartForm prior to making this selection.**

Modification / Continuing Review (* Refer to the latest appro required this year) / Study Closure (If requesting a subject-s

* What is the purpose of this submission? (NOTE: For continuing reviews, select Modification

- Continuing Review
- Modification
- Modification and Continuing Review
- [Clear](#)

 To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

- Study team member information
- Other parts of the study

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6) Complete the **Modification Information** page. Confirm that the selections for study enrollment status are appropriate. In the Summarize the Modifications section, summarize each proposed modification and **provide a clear rationale for each modification in the text box.**


Modification Information

1. Study enrollment status:

- No subjects have been enrolled to date
- Subjects are currently enrolled
- Study is permanently closed to enrollment
- All subjects have completed all study-related interventions
- Collection of private identifiable information is complete

2. Notification of subjects: (check all that apply; N/A if requesting a subject-specific protocol exception)

- Current subjects will be notified of these changes
- Former subjects will be notified of these changes

 Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.

3. * Summarize the modifications: 

7) Once the page is complete, select **Continue** to review each page of the application for accuracy and upload/delete documents as needed.

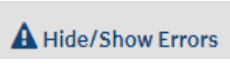
Reminders related to the various pages:

- **In cases where the Other Parts of the Study scope is selected:** You must upload a completed **Amendment Cover Sheet**. The latest version is available in the myResearch library (click **Library** > click **For Investigators** > select the correct template). Navigate to the **Local Site Documents** page in your submission and upload the completed form in the **Other Attachments** section.
- Confirm that you have replaced/removed documents that no longer require approval. For example, if you are making changes to a previously approved consent form, you should update the version in the system rather than simply adding the additional document. There should be only one version of a given document to reduce clutter in

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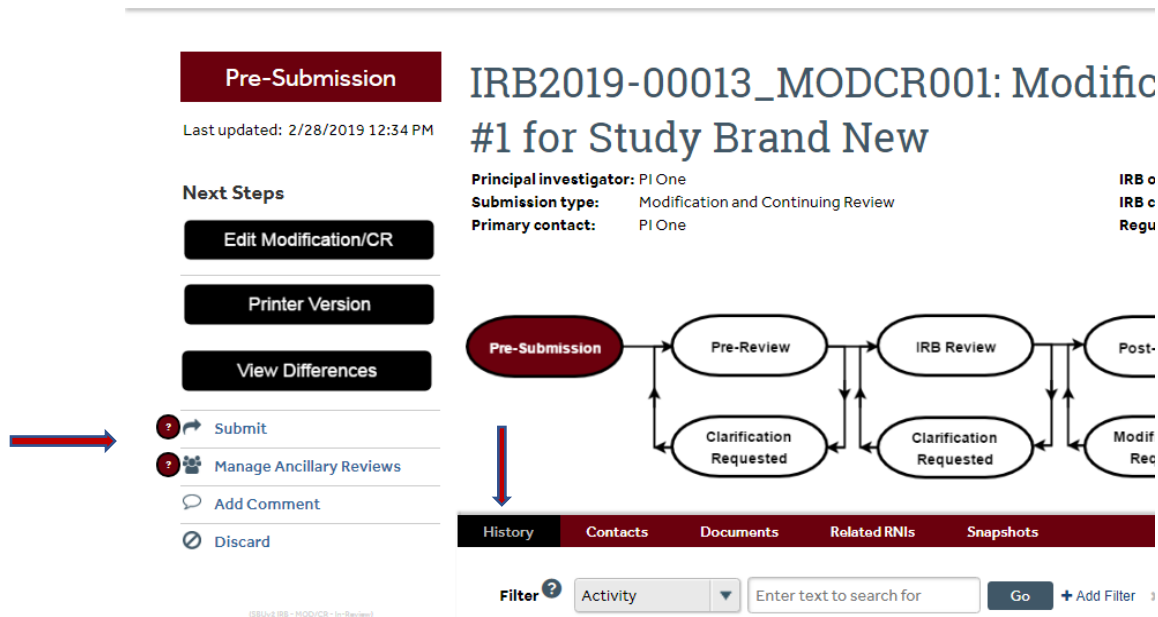
the system. Revisions should be indicated with Tracked Changes. Please do not use highlighting to indicate changes in documents that need to be stamped for use (e.g. advertisements, consent forms, recruitment scripts).

- Be sure to click **Save** on the top/bottom of the page once you complete each page to ensure that you do not lose your work.

8) Select  at the top/bottom of the page to see a list of required sections that have not been completed. This will check for completeness, not verify accuracy of responses.

9) Review each page of the application SmartForm until you reach the **Final Page**. This page provides you with reminders related to managing ancillary reviews before submission. **NOTE: Department Chair approval via ancillary review must be obtained before submission of a MAJOR amendment (see Amendment Cover Sheet for full explanation – e.g. modification associated with increased risk to subjects, inclusion of a vulnerable population). Any major amendment submissions missing documentation of this review will result in a clarification request or submission withdrawal. Minor amendments do not require departmental approval.**

10) Click **Finish** to exit the page and select **Manage Ancillary Reviews** to request necessary reviews (if applicable). The PI and study team will receive an email notification when the Department Chair/Designated Signatory has submitted a review and accepted/approved the submission. This notification will also appear in the **History** section (see previous image). Once Department Chair/Designated Signatory approval is confirmed (if applicable), the Principal Investigator can click **Submit** (see previous image) and agree to the Principal Investigator certification by clicking **OK**.



Pre-Submission
Last updated: 2/28/2019 12:34 PM

Next Steps

- Edit Modification/CR
- Printer Version
- View Differences
- Submit
- Manage Ancillary Reviews
- Add Comment
- Discard

IRB2019-00013_MODCR001: Modific #1 for Study Brand New

Principal investigator: PI One
Submission type: Modification and Continuing Review
Primary contact: PI One

IRB o
IRB c
Regu

Pre-Submission → Pre-Review → IRB Review → Post-Review
Pre-Review ↔ Clarification Requested ↔ IRB Review
IRB Review ↔ Clarification Requested
Post-Review → Modif Rec

History | Contacts | Documents | Related RNIs | Snapshots

Filter **Activity** | Enter text to search for | Go | + Add Filter