

Submitting a Modification/Amendment

In order to begin the process of submitting a modification/amendment to the Institutional Review Board (IRB) click on the **IRB** tab.

The screenshot shows the top navigation bar with tabs for 'My Inbox', 'COI', and 'IRB'. The 'IRB' tab is highlighted with a red circle. Below the navigation bar, there is a sidebar on the left with a dropdown menu containing 'IRB', 'COI', and 'Grants'. The main content area is titled 'My Inbox' and features a search filter set to 'ID' and a search input field with the placeholder text 'Enter text to search for'. Below the search bar, there are columns for 'ID' and 'Name'.

Use one of the various filters to search for your study using the IRB number. Click on the “All Submissions” tab. **NOTE:** You can also filter by ID as well as the study title or the PI first/last name.

The screenshot shows the top navigation bar with tabs for 'In-Review', 'Active', 'Archived', 'New Information Reports', 'External IRB Studies', 'Sites', and 'All Submissions'. The 'All Submissions' tab is highlighted with a red circle. Below the navigation bar, there is a search filter set to 'ID' and a search input field with the placeholder text 'Enter text to search for'. To the right of the search bar are buttons for 'Go', '+ Add Filter', and 'x Clear All'. Below the search bar, there is a table with columns for 'ID', 'Name', 'Date Modified', 'State', 'PI First Name', and 'PI Last Name'. The 'Date Modified' column shows the value '7/31/2016'.

Once you are in the study’s “main workspace” there will be several actions available to you on the left side of the screen. Select “Create Modification/CR”.

The screenshot shows the main workspace for study IRB2019-00031: Brand New Study. On the left side, there is a sidebar with a red header 'Approved' and a list of 'Next Steps' including 'View Study', 'Printer Version', 'View Differences', 'Create Modification/CR', and 'Report New Information'. A red arrow points to the 'Create Modification/CR' button. The main content area shows a flowchart of the study process with steps: Pre-Submission, Pre-Review, IRB Review, and Post-Review. Below the flowchart, there is a search filter set to 'Activity' and a search input field with the placeholder text 'Enter text to search for'. Below the search bar, there is a table with columns for 'History', 'Funding', 'Contacts', 'Documents', and 'Follow-on Submissions'. The 'Activity' column shows the value 'Continuing Review IRB2019-00031_CR001 review complete: Approved'.

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Select “Modification” as the purpose of the submission.

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](#)

Choose “Study Team Member Information” if you must make a change to the “Study Team Members” page list only. If you choose this only, you will not be able to modify any previously approved documents or update any other sections of the most recently approved application. 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 application, you must choose both “Study Team Member Information” and “Other Parts of the Study”. Review your approved documents and the application 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](#)

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

Modification scope:

Study team member information

Other parts of the study

Submitting a Modification/Amendment

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

i 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: 

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:

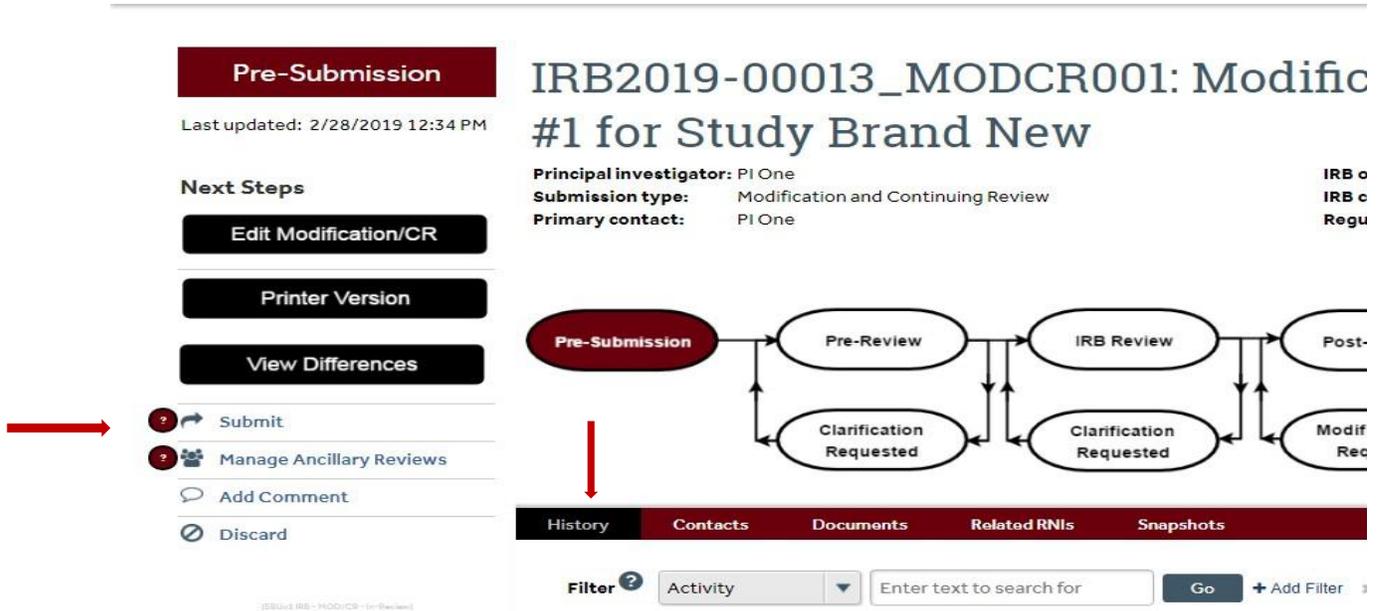
- In cases where the “Other Parts of the Study” scope is selected you must upload a completed Amendment Cover Sheet. The latest version is available in the myResearch library (click Library > click For Investigators > select the correct template). Navigate to the “Local Site Documents” page in your submission 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. 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.

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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.

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: The 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 populations). Any major amendment submission missing documentation will result in a clarification request or submission withdrawal. Minor amendments do not require departmental approval.

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: Modification #1 for Study Brand New

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

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Flowchart: Pre-Submission → Pre-Review → IRB Review → Post-Review
Clarification Requested (between Pre-Review and IRB Review, and between IRB Review and Post-Review)

Navigation: History, Contacts, Documents, Related RNIs, Snapshots

Filter: Activity [Enter text to search for] Go + Add Filter