

This guide describes how to submit a request for a Study Closure using a Continuing Review (CR) on an IRB-approved, active study.

Study Closure Request

Follow the steps below to submit a **Continuing Review (CR) ONLY** request:

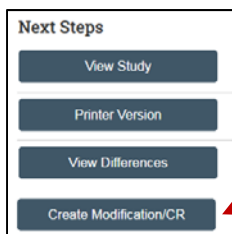
1. Navigate to the Study Workspace. This can be done by selecting the *IRB* tab, selecting the *Active* or *All Submissions* tab, and then selecting or searching for your study. Click the study name to display the Study Workspace.



Note: Click the **Filter by Help** button for quick search tips, including the wild card search using the “%” sign.



2. On the Study Workspace, select the **Create Modification/CR** activity.

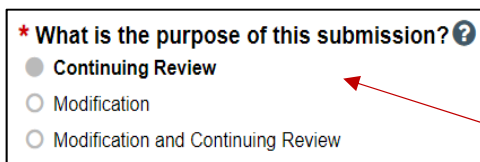


3. The first page that appears is **Modification/Continuing Review/Study Closure**.



Note: After submitting to the IRB, this page is final and you will NOT be able to edit it during Pre-Review or IRB Review. If you have made a mistake on this page **and** have submitted the study, the IRB will ask you to DISCARD the submission.

- a. For **What is the purpose of this submission?** Select Continuing Review.



4. The next page that will appear is **Continuing Review / Study Closure Information**.

On this page you will include your total number of participants enrolled in the study under the **Total** Column as well as the total number of participants enrolled since the last Continuing review under the **Since Last Approval** column. **NOTE:** If your study does not require continuing review, than the number listed in both columns should be the same.

1. * Specify enrollment totals:

	Subjects Enrolled	Total	Since Last Approval
At this investigator's sites:	?	0	0
Study-wide:	?	0	

For Study Closures:

If the first four research milestones are selected:

- 1) Study is permanently closed to enrollment OR was never open for enrollment,
- 2) All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled),
- 3) Collection of private identifiable information is complete OR not applicable (no subjects were enrolled), &
- 4) Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)


This indicates that the study is ready to be closed. A question will populate the PI to answer “**I acknowledge that this study will be closed.**”

- If the study is *NOT* being closed, revise the responses to the first four milestones.
- If the study is being closed, be sure to check YES to acknowledge that this study will be closed. Once complete, click through to **Finish** and submit. *You will NOT need to attach study documents (protocol, consent form, etc.) if submitting a study closure.*

2. Research milestones: (select all that apply) ?

- ☒ Study is permanently closed to enrollment OR was never open for enrollment
- ☒ All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
- ☒ Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ☒ Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
- ☐ Remaining study activities are limited to data analysis
- ☐ Study remains active only for long-term follow-up of subjects

i Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.


* I acknowledge that this study will be closed: ☒ 

- Complete the series of questions (also known as the “SmartForm”).
- After completing the **Continuing Review / Study Closure Information** page, the **Final Page** page will appear where you will click the **Finish** button.
- After clicking the **Finish** button, you are returned to the applicable Workspace for Continuing Reviews.
- For the **Continuing Review** request, select the **Submit** activity in the Workspace. In the *Submit* dialog box, click **OK** to complete the submission.

Next Steps

Edit Modification/CR

Printer Version

 **Submit** 

 Manage Ancillary Reviews

! **Important:** The study will remain in pre-submission and will **NOT** be received by the IRB for review until **Submit** has been selected. Once submitted the study status will change to **pre-review**:

