



How to submit a Continuing Review and Study Closure

*Human Research Protection Program
(Last Updated: 12/14/2023)*



This PowerPoint will assist you in submitting a continuing review. Please be aware that the continuing review form is the same form used to close out a study.

Getting started

1. Navigate to the **IRB workspace**
2. Select **Submissions** tab
3. Select **All Submissions** tab
4. Note: **Filter by** allows you to sort through your studies by name, PI first and last name, and submission type.
5. Open your study by selecting the **folder symbol** or the **name** of the study.

The screenshot shows the IRB workspace interface. At the top, there is a navigation bar with tabs: Dashboard, Admin, COI, IRB (highlighted with a red box and callout 1), and Settings. Below this is a sub-navigation bar with: Submissions (highlighted with a red box and callout 2), Meetings, Reports, Library, Institutional Profiles, Help Center, and Central Actions. The main content area is titled 'IRB' and contains a search bar (callout 3) and a filter bar (callout 4). The filter bar has a dropdown menu with 'All Submissions' selected. Below the filter bar is a table of studies. The first row is highlighted with a red box and callout 5. The table has columns: ID, Name, Date Modified, State, PI First Name, PI Last Name, and Coordinator First Name.

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name
STUDY2023-0039	New Study 9.19.2023	12/14/2023 3:51 PM	<input type="checkbox"/>	Denise	Puga	



Creating a Continuing Review

1. Select **Create Modification/CR**

IMPORTANT! Select this option even if you are needing to close out a study.

Approved

Entered IRB: 12/1/2022 11:25 AM
Initial approval: 12/1/2022
Initial effective: 12/1/2022
Effective: 12/9/2022
Approval end: 11/30/2023
Last updated: 4/6/2023 10:44 AM

Next Steps

View Study

Printer Version

1

Create Modification/CR

Report New Information

Initiating a Continuing Review Form

1. Select **Continuing Review*****

***If you would like to submit a *Modification and Continuing Review*, please jump to [Slide 13](#).

Important notice: Once you select *Save or Continue*, you will not be able to edit your response on this page. If an incorrect response was chosen, you will need to discard the submission and start again (instructions on how to discard a submission can be found on [Slide 15](#)).

2. Click **Save** and then **Continue**

The screenshot shows the Texas A&M University IRB submission interface. The breadcrumb trail is 'You Are Here: Test > _IRBSubmission'. The page title is 'Creating New: IRB Submission'. The main heading is 'Modification / Continuing Review / Study Closure'. A question asks 'What is the purpose of this submission?' with three radio button options: 'Continuing Review' (selected), 'Modification / Update', and 'Modification and Continuing Review'. A 'Clear' link is below the options. At the bottom, there are three buttons: 'Exit', 'Save', and 'Continue'. Red circles with numbers 1 and 2 highlight the 'Continuing Review' radio button and the 'Continue' button, respectively.



How would you like to proceed?

- 1) **Submit a continuing review.** Please continue to the next slide.
- 2) **Close out my study.** Please click [here](#) to be directed to Slide 10.

IMPORTANT NOTICE!

Before proceeding, determine if your study requires an Administrative Check In or a Continuing Review:

Most minimal risk studies approved after January 20, 2019 do not require a continuing review, *but still must* undergo an Administrative Check In.

To identify if your study requires a continuing review or an administrative check in, please reference your initial approval letter. If your study requires an Administrative Check In, exit this guidance document and navigate to the Administrative Check In guidance tool found [here](#).

Example of a study that requires a continuing review:

At the convened meeting on 01/06/2021 the IRB approved this research from 01/12/2021 to 01/05/2022 inclusive.

▶ It is recommended that you submit your next continuing review by 12/05/2021 to avoid a lapse in approval. Your study approval will end on 01/05/2022.

Example of a study that requires a an administrative check in:

The IRB approved this research on 08/29/2022.

▶ Before 06/28/2023, you are to submit an Administrative Check-In Form to the HRPP/IRB. If the HRPP/IRB does not receive the form, there will be no approval of new research after 08/28/2023.

Continuing Review ONLY

- Complete the **Continuing Review/Study Closure Information** page:
 - All questions marked with a red asterisk (*) require a response.
 - Read carefully over **Question 4**. Select only the response(s) that apply. If none apply, do not check any boxes. *Note: If you select the first four items, you will be prompted to close out your study.*
 - Read through each item in **Question 5** and select all items that are true. For example, if no participants withdrew from the study since the last IRB approval, select “No subjects withdrew from the study.”
 - If an item was left unchecked in Question 5, a description of the event must be uploaded in **Question 6**. Please use a Word document.
- Click **Save** and then **Continue**

The screenshot shows the 'Continuing Review / Study Closure Information' form. A red circle with the number '1' is placed over the left-hand navigation menu. Three red callout boxes with arrows point to specific sections of the form: 'Q4. Select only the responses that apply.' points to question 4; 'Q5. Select all items that are true.' points to question 5; and 'Q6. Provide a description of any item left unchecked in Q5.' points to question 6. At the bottom right, a red box highlights the 'Exit', 'Save', and 'Continue' buttons, with a red circle containing the number '2' next to it.

Continuing Review / Study Closure Information

- * Specify enrollment totals at this investigator's sites: ?
- * Specify enrollment totals at this investigator's sites since last approval:
- * Specify enrollment totals study-wide: ?
- 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)
 - 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
- Check the items that are true since the last IRB approval for all sites involved in the study:**
 - NO subjects experienced unexpected harm
 - Anticipated adverse events have NOT taken place with greater frequency or severity than expected
 - NO subjects withdrew from the study
 - NO unanticipated problems involving risks to subjects or others
 - NO complaints about the study
 - NO publications in the literature relevant to risks or potential benefits
 - NO interim findings
 - NO multi-center trial reports
 - NO data safety monitoring reports
 - NO regulatory actions that could affect safety and risk assessments
 - NO other relevant information regarding this study, especially information about risks
 - In the opinion of the PI, the risks and potential benefits are unchanged
 - All modifications to the protocol have been submitted to the IRB
 - All problems that require prompt reporting to the IRB have been submitted
- Attach supporting documents:** (include an explanation of each item left unchecked above) ?
 - + Add
 - Name
 - There are no items to display

Buttons: Exit, Save, Continue

Submitting your form to the IRB

1. Select **Finish** in the **Final Page** to be directed to the Study Workspace
2. Click **Submit** from the Study Workspace
IMPORTANT! The PI or PI Proxy must click **Submit** for the submission to be received by the IRB.
3. Click **OK**

The screenshot displays a software interface with a top navigation bar containing three buttons: 'Exit' (with a close icon), 'Save' (with a floppy disk icon), and 'Finish' (highlighted with a red border and a red circle containing the number 1). Below this is a yellow 'Pre-Submission' button. Underneath, it shows 'Last updated: 5/22/2023 10:08 AM'. A section titled 'Next Steps' contains two buttons: 'Edit Study' and 'Printer Version'. At the bottom, a 'Submit' button (with a right-pointing arrow icon) is highlighted with a red border and a red circle containing the number 2.



HOW TO CLOSE OUT A STUDY

How to close out a study

Complete the **Continuing Review/Study Closure Information** page:

1. All questions marked with a red asterisk (*) require a response.
2. Select the first four research milestones in **Question 4**.
3. Select *I acknowledge that this study will be closed* in **Question 5**.
4. Click **Save** and then **Continue**

1 Continuing Review / Study Closure Information

1. * Specify enrollment totals at this investigator's sites:

2. * Specify enrollment totals at this investigator's sites since last approval:

3. * Specify enrollment totals study-wide:

2 4. **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

3 **5. * I acknowledge that this study will be closed:**

4

Submitting your form to the IRB

1. Select **Finish** in the **Final Page** to be directed to the Study Workspace
2. Click **Submit** from the Study Workspace
IMPORTANT! The PI or PI Proxy must click **Submit** for the submission to be received by the IRB.
3. Click **OK**

1

✕ Exit 📁 Save **Finish**

Pre-Submission

Last updated: 5/22/2023 10:08 AM

Next Steps

Edit Study

Printer Version

2

↩ Submit



HOW TO SUBMIT A MODIFICATION AND CONTINUING REVIEW

Modification and Continuing Review

1. Select **Modification and Continuing Review**
2. Identify the **modification scope** (*must select at least one option, or both if applicable*):
 - Select **Study team member information** to add new study personnel
 - Select **Other parts of the study** for all other modifications to the protocol

Important notice: Once you select *Save* or *Continue*, you will not be able to edit your response on this page. If an incorrect response was chosen, you will need to discard the submission and start again. Instructions on how to discard a submission can be found on the next slide.

3. Click **Save** and then **Continue**

You Are Here: Test > _IRBSubmission

Creating New: IRB Submission

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ?

Continuing Review

Modification / Update

1 Modification and Continuing Review

[Clear](#)

2 **Modification scope:**

Study team member information

Other parts of the study

3

How to discard a submission

Once you select *Save* or *Continue* on the **Modification/Continuing Review** page, you will not be able to edit your purpose or scope.

If an incorrect response was chosen *and* the form has been saved:

1. Click **Exit** to leave the submission and
2. Select **Discard** from the Study workspace.
3. A new submission will need to be initiated.

The screenshot shows a web interface for 'Modification / Continuing Review'. At the top, there are tabs for 'Validate' and 'Compare'. The main heading is 'Editing: CR00000007'. Below this, there is a question: '* What is the purpose of this submission?' with three radio button options: 'Continuing Review', 'Modification / Update', and 'Modification and Continuing Review'. At the bottom of the form, there are three buttons: 'Exit', 'Save', and 'Continue'. A red circle with the number '1' is placed over the 'Exit' button. To the right, a 'Next Steps' sidebar contains several options: 'Edit Modification/CR', 'Printer Version', 'Submit', 'Manage Ancillary Reviews', 'Create Ad Hoc Certifications', 'Add Comment', 'Add Private Comment', 'Discard', and 'Manage Tags'. A red circle with the number '2' is placed over the 'Discard' option in this sidebar.

Modification and Continuing Review

- Complete the **Continuing Review/Study Closure Information** page:
 - All questions marked with a red asterisk (*) require a response.
 - Read carefully over **Question 4**. Select only the response(s) that apply. If none apply, do not check any boxes. *Note: If you select the first four items, you will be prompted to close out your study.*
 - Read through each item in **Question 5** and select all items that are true. For example, if no participants withdrew from the study since the last IRB approval, select “No subjects withdrew from the study.”
 - If an item was left unchecked in Question 5, a description of the event must be uploaded in **Question 6**. Please use a Word document.

2. Click **Save** and then **Continue**

The screenshot shows a mobile application interface for 'Continuing Review / Study Closure Information'. A red circle with the number '1' is placed over the top navigation bar. The form contains several sections:

- 1. * Specify enrollment totals at this investigator's sites:** A text input field.
- 2. * Specify enrollment totals at this investigator's sites since last approval:** A text input field.
- 3. * Specify enrollment totals study-wide:** A text input field.
- 4. Research milestones:** A list of checkboxes with instructions to select all that apply. A red callout box labeled 'Q4. Select only the responses that apply.' points to this section.
- 5. Check the items that are true since the last IRB approval for all sites involved in the study:** A list of checkboxes. A red callout box labeled 'Q5. Select all items that are true.' points to this section.
- 6. Attach supporting documents:** A section for uploading documents. A red callout box labeled 'Q6. Provide a description of any item left unchecked in Q5.' points to this section.

At the bottom of the screen, there are three buttons: 'Exit', 'Save', and 'Continue'. A red box highlights the 'Save' and 'Continue' buttons, with a red circle containing the number '2' next to it.

Modification and Continuing Review (continued)

1. Complete the **Modification Summary** page

IMPORTANT! Provide a brief summary of the modification and a revised copy of your protocol document. All modifications must be added to the written protocol. It is not sufficient to provide the modification in Question 3. The revised protocol must be attached to the Basic Study Information page. If the revised protocol is not provided, the modification will be returned.

2. Select **Save** and then **Continue**

1

You Are Here: Test > Modification and Continuing Re...
Editing: MODCR00000005

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)

- 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:** **?**

2

Exit Save Continue

How to attach your revised protocol

Modifications to approved procedures (e.g., participant enrollment, consent process, recruitment) require that you update your protocol document. Attach an updated protocol to the Basic Study Information page:

1. Navigate to the **Basic Study Information** page
2. Select **Update** on **Attach Protocol** (this can be either Question 7 or 8)
3. Click **Choose File** and attach your revised protocol and then click **OK**

The screenshot shows the 'Basic Study Information' page for 'STUDY2023-0027'. The left sidebar has 'Basic Study Information' highlighted with a red box and the number 1. The main content area has several questions, with question 7 'Attach the protocol:' highlighted with a red box and the number 2. The 'Update' button below question 7 is also highlighted with a red box and the number 2. An 'Add Attachment' modal is open on the right, with the 'File to attach:' field highlighted by a red box and the number 3. The 'Choose File' button in the modal is also highlighted with a red box and the number 3.

How to attach new or revised study documents

If you need to add a new or revised study document in response to a clarification requested:

1. Navigate to the **Local Site Document** page
2. Select **+Add** to attach a **new** study document or **Update** to attach a **revised** study document. It is important that you select the correct option to ensure good document management.
3. Click **Save**, then **Exit** to navigate back to the study Workspace.

The screenshot displays the 'Local Site Documents' page for 'Factor A' in the 'Editing: STUDY2023-0027' workspace. The interface is divided into a sidebar and a main content area. The sidebar on the left contains navigation links: 'Basic Study Information', 'Study Funding Sources', 'Local Study Team Members', 'Study Scope', 'Local Research Locations', and 'Local Site Documents' (highlighted with a red circle and box labeled '1'). The main content area shows three sections: '1. Consent forms: (include an HHS-approved s...', '2. Recruitment materials: (add all material to...', and '3. Other attachments:'. Each section has a '+ Add' button and an 'Update' button. The 'Update' button in the 'Consent forms' section is highlighted with a red circle and box labeled '3'. The '+ Add' button in the 'Consent forms' section is highlighted with a red circle and box labeled '2'. The 'Update' button in the 'Recruitment materials' section is also highlighted with a red circle and box labeled '3'.

Submitting your submission to the IRB

Once you have finished editing the IRB application and saved all your edits:

1. Select **Exit** to be directed to the IRB Workspace
2. Click **Submit**

IMPORTANT! The PI or PI Proxy must click **Submit** for the submission to be received by the IRB.

3. Click **OK**



Pre-Submission

Last updated: 5/22/2023 10:08 AM

Next Steps

Edit Study

Printer Version

