



How to submit a Continuing Review and Study Closure

Human Research Protection Program

(Last Updated: 10/16/2023)



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. The top navigation bar includes 'Dashboard', 'Admin', 'COI', 'IRB', and 'Settings'. The 'IRB' tab is selected and highlighted with a red box and a red circle containing the number 1. Below this, the 'Submissions' tab is also highlighted with a red box and a red circle containing the number 2. The main content area shows the 'IRB' workspace with a search bar (highlighted with a red circle containing the number 3) and a filter dropdown menu (highlighted with a red circle containing the number 4) set to 'All Submissions'. Below the filter, there are buttons for 'Create New Study' and 'Report New Information'. A table of studies is displayed with columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, and Coordinator First Name. The first row of the table is highlighted with a red box and a red circle containing the number 5, showing a study with ID 'STUDY2023-0039', Name 'New Study 9.19.2023', Date Modified '12/14/2023 3:51 PM', State 'Off', PI First Name 'Denise', PI Last Name 'Puga', and Coordinator First Name 'Puga'.

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	Off	Denise	Puga	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 red circle with the number '1' points to the 'Continuing Review' radio button, which is selected. Below it are 'Modification / Update' and 'Modification and Continuing Review' options, along with a 'Clear' link. At the bottom, a red circle with the number '2' points to the 'Continue' button, which is highlighted in a dark blue box. Other buttons include 'Exit' and 'Save'.



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.
 - For Full Board studies**, you will also need to complete the [Full Board Continuing Review](#) form and attach it to Question 6.
- 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 'Continuing Review / Study Closure Information' menu item. Three red callout boxes provide instructions: '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

Important! If the first four research milestones above are complete, the study will be closed to discontinuation if the study is not renewed.
- 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)
 -
 - Name: There are no items to display

Buttons:



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

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

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**

The screenshot shows a web interface for creating a new IRB submission. 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 required question asks 'What is the purpose of this submission?' with three radio button options: 'Continuing Review', 'Modification / Update', and 'Modification and Continuing Review'. The third option is selected and highlighted with a red box and the number 1. Below this is a 'Clear' link and an information icon with the text 'To change the PI, choose 'Other parts of the study/site' scope'. A section titled 'Modification scope:' contains two checkboxes: 'Study team member information' and 'Other parts of the study', both of which are highlighted with a red box and the number 2. At the bottom right, there are three buttons: 'Exit', 'Save', and 'Continue'. The 'Save' and 'Continue' buttons are highlighted with a red box and the number 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.

Validate Compare

You Are Here: Test > Continuing Review for St

Editing: CR00000007

Go to forms menu Print

Modification / Continuing Review

Continuing Review / Study Closure Information

Modification / Continuing Review / Study Closure

* What is the purpose of this submission?

Continuing Review

Modification / Update

Modification and Continuing Review

1 Exit Save Continue

2 Discard

Next Steps

Edit Modification/CR

Printer Version

Submit

Manage Ancillary Reviews

Create Ad Hoc Certifications

Add Comment

Add Private Comment

Discard

Manage Tags

Modification and Continuing Review

1. 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.
 - **For Full Board studies**, you will also need to complete the [Full Board Continuing Review](#) form and attach it to Question 6.

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

The screenshot shows the 'Continuing Review / Study Closure Information' form. A red circle with the number '1' is next to the form title. Three callout boxes with red arrows point to specific sections: 'Q4. Select only the responses that apply.' points to the 'Research milestones' section; 'Q5. Select all items that are true.' points to the 'Check the items that are true since the last IRB approval' section; and 'Q6. Provide a description of any item left unchecked in Q5.' points to the 'Attach supporting documents' section. 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

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:
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)
 - 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

Important! If the first four research milestones above are complete, the study will be closed to discontinuation if the study is not active.
5. **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
6. **Attach supporting documents:** (include an explanation of each item left unchecked above)
 -
 - Name: There are no items to display

Buttons:

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**

The screenshot displays the 'Modification and Continuing Review' web application. The breadcrumb trail shows 'You Are Here: Test > Modification and Continuing Re...'. The page title is 'Editing: MODCR00000005'. The sidebar on the left contains the following menu items: 'Modification / Continuing Review', 'Continuing Review / Study Closure Information', 'Modification Summary' (highlighted in orange), and 'Modification Details'. The main content area is titled 'Modification Information' and contains three sections:

- 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
- 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.
- * Summarize the modifications:** **?**

 At the bottom right, there are three buttons: 'Exit', 'Save', and 'Continue'. The 'Save' and 'Continue' buttons are highlighted with red boxes. A red circle with the number '1' is positioned over the 'Modification Summary' menu item, and a red circle with the number '2' is positioned over the 'Save' and 'Continue' buttons.

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 'Basic Study Information' menu item in the sidebar is highlighted with a red box and the number 1. The 'Update' button at the bottom of the page is highlighted with a red box and the number 2. The 'Add Attachment' dialog box is open, and the 'Choose File' button is highlighted with a red box and the number 3. The dialog box contains the following fields:

- 1. * File to attach: Choose File
- 2. Name: (if not supplied, the file name will be shown)
- 3. Version number:

The main page content includes the following questions:

- * Title of study: Pilot Study to Test the effectiveness of Factor A
- * Short title: Factor A
- * Brief description: This study examines how Factor A improves students. Students will be asked to complete how exposure to Factor A improves overall te will be recruited via posted notice.
- * What kind of study is this?
 - Multi-site or Collaborative study
 - Single-site study[Clear](#)
- * Will an external IRB act as the IRB
 - Yes
 - No[Clear](#)
- * Local principal investigator: Denise Puga [...](#) [✕](#)
- * Attach the protocol:
 - [+ Add](#)
 - Document
 - [Update](#)
 - TEMPLATE - Exempt p

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 shows the 'Local Site Documents' page for 'Factor A' in the 'Editing: STUDY2023-0027' workspace. The sidebar on the left contains navigation options: Basic Study Information, Study Funding Sources, Local Study Team Members, Study Scope, Local Research Locations, and **Local Site Documents** (highlighted with a red circle 1). The main content area is titled 'Local Site Documents' and features three sections:

- 1. Consent forms:** (include an HHS-approved s...)
 - + Add (highlighted with a red box and circle 2)
 - Document
 - Update (highlighted with a red box and circle 3) | Study Consent (1)
- 2. Recruitment materials:** (add all material to...)
 - + Add
 - Document
 - Update | Flyer(1)
- 3. Other attachments:**
 - + Add
 - Document
 - Update | Survey (1)

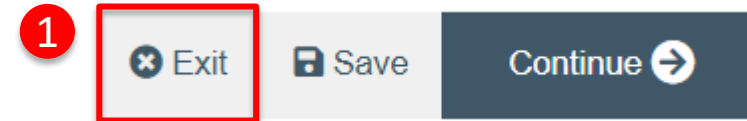
Submitting your submission to the IRB

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**



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Next Steps

