



How to submit a Continuing Review and Study Closure

Human Research Protection Program

(Last Updated: 07/01/2025)



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 tabs: 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'. On the left, there are two buttons: 'Create New Study' and 'Report New Information'. On the right, there is a search bar with a magnifying glass icon and a question mark, labeled 'Search ?' (callout 3). Below the search bar, there is a row of tabs: In-Review, Active, New Information Reports (highlighted with a red box and callout 4), External IRB, and Relying Sites. To the right of these tabs is a button labeled 'All Submissions' (highlighted with a red box and callout 3). Below the tabs, there is a 'Filter by' section with a dropdown menu set to 'ID' and a search input field with the placeholder text 'Enter text to search' and a magnifying glass icon. To the right of the search input are links for '+ Add Filter' and 'X Clear All'. Below the filter section is a table with the following columns: ID, Name, Date Modified, State, PI First Name, PI Last Name, and Coordinator First Name. The first row of the table shows a folder icon (highlighted with a red box and callout 5) next to the ID 'STUDY2023-0038', the name 'New Study 9.19.2023' (highlighted with a red box), the date '12/14/2023 3:51 PM', a toggle switch, and the names 'Denise' and 'Puga'.

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name
STUDY2023-0038	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

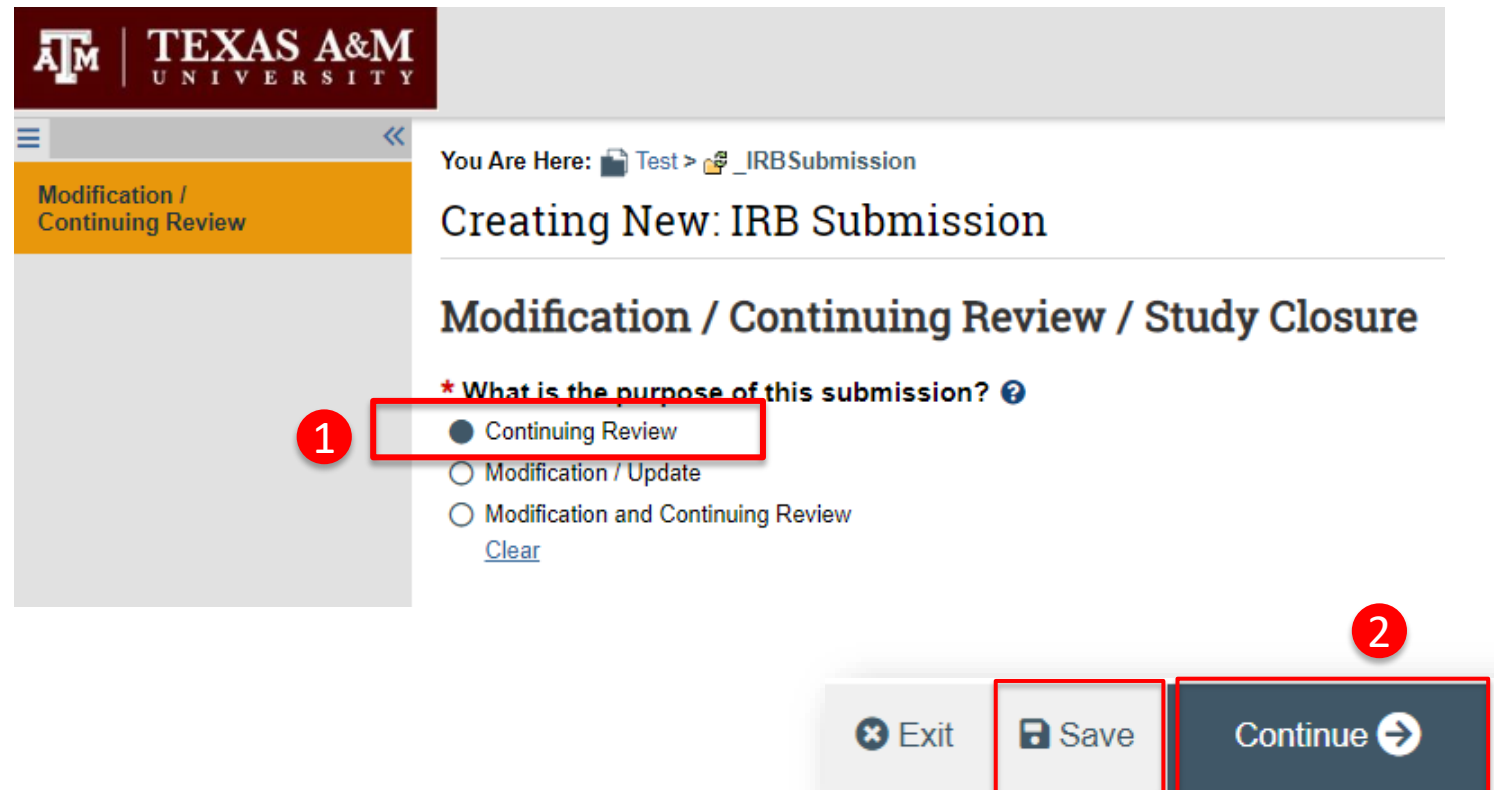
Initiating a Continuing Review Form

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**



ATM | TEXAS A&M UNIVERSITY

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

☐ Modification and Continuing Review

[Clear](#)

Exit Save Continue →



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.
 - You will also need to complete the [Studies that require 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 vertical sidebar on the left contains navigation links: 'Modification / Continuing Review' and 'Continuing Review / Study Closure Information' (highlighted in orange). A red circle with the number '1' is next to the sidebar. The main form area contains six numbered questions. Red callout boxes with arrows point to specific parts 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; 'Q6. Provide a description of any item left unchecked in Q5 and attach the completed Studies that require Continuing Review form' points to Question 6. At the bottom right, there are three buttons: 'Exit', 'Save', and 'Continue' (highlighted with a red box and a red circle with the number '2').

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 discontinue IRB review.

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) ?

+ Add

Name

There are no items to display

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**

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**

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, 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.

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

4. **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**

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
☒ **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

[Exit](#) [Save](#) [Continue](#)

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 the 'Modification / Continuing Review' page for submission CR00000007. The page title is 'Modification / Continuing Review / Study Closure'. The main question is '* What is the purpose of this submission?' with three radio button options: 'Continuing Review' (selected), 'Modification / Update', and 'Modification and Continuing Review'. At the bottom, there are three buttons: 'Exit' (highlighted with a red box and a red circle with the number 1), 'Save', and 'Continue'. 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' (highlighted with a red box and a red circle with the number 2), and '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.
 - You will also need to complete the [Studies that require 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 vertical sidebar on the left contains a navigation menu with 'Modification / Continuing Review' and 'Continuing Review / Study Closure Information' (highlighted in orange). A red circle with the number '1' is next to the sidebar. The main form area contains six numbered questions. Red callout boxes with arrows point to specific parts 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; 'Q6. Provide a description of any item left unchecked in Q5 and attach the completed [Studies that require Continuing Review form](#)' points to question 6. At the bottom right, there are three buttons: 'Exit', 'Save', and 'Continue' (with a right arrow). A red circle with the number '2' is next to the 'Continue' button. The form content includes:

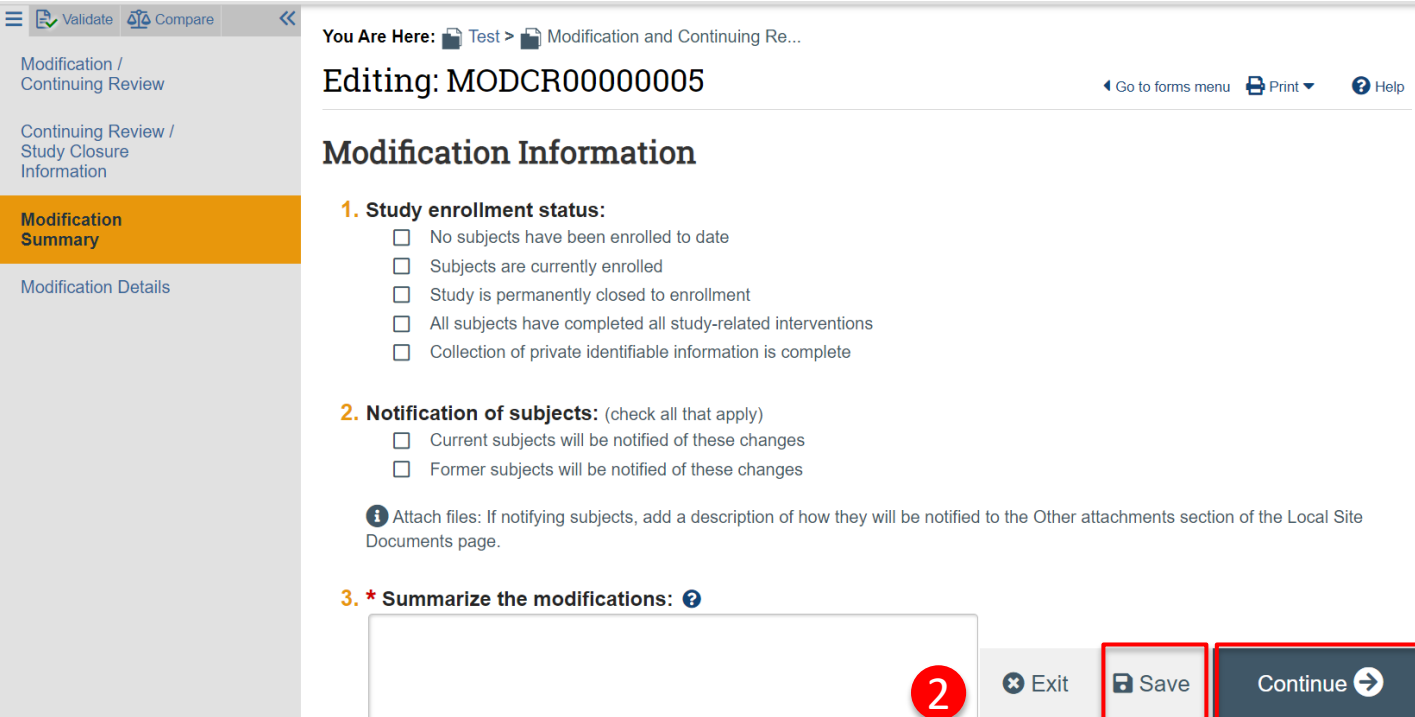
- 1. * Specify enrollment totals at this investigator's sites: [text input]
- 2. * Specify enrollment totals at this investigator's sites since last approval: [text input]
- 3. * Specify enrollment totals study-wide: [text input]
- 4. Research milestones: (select all that apply)
 - ☐ Study is permanently 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
- 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)
 - + Add
 - Name
 - There are no items to display

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

[Go to forms menu](#) [Print](#) [Help](#)

Modification Information

- 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:** [?](#)

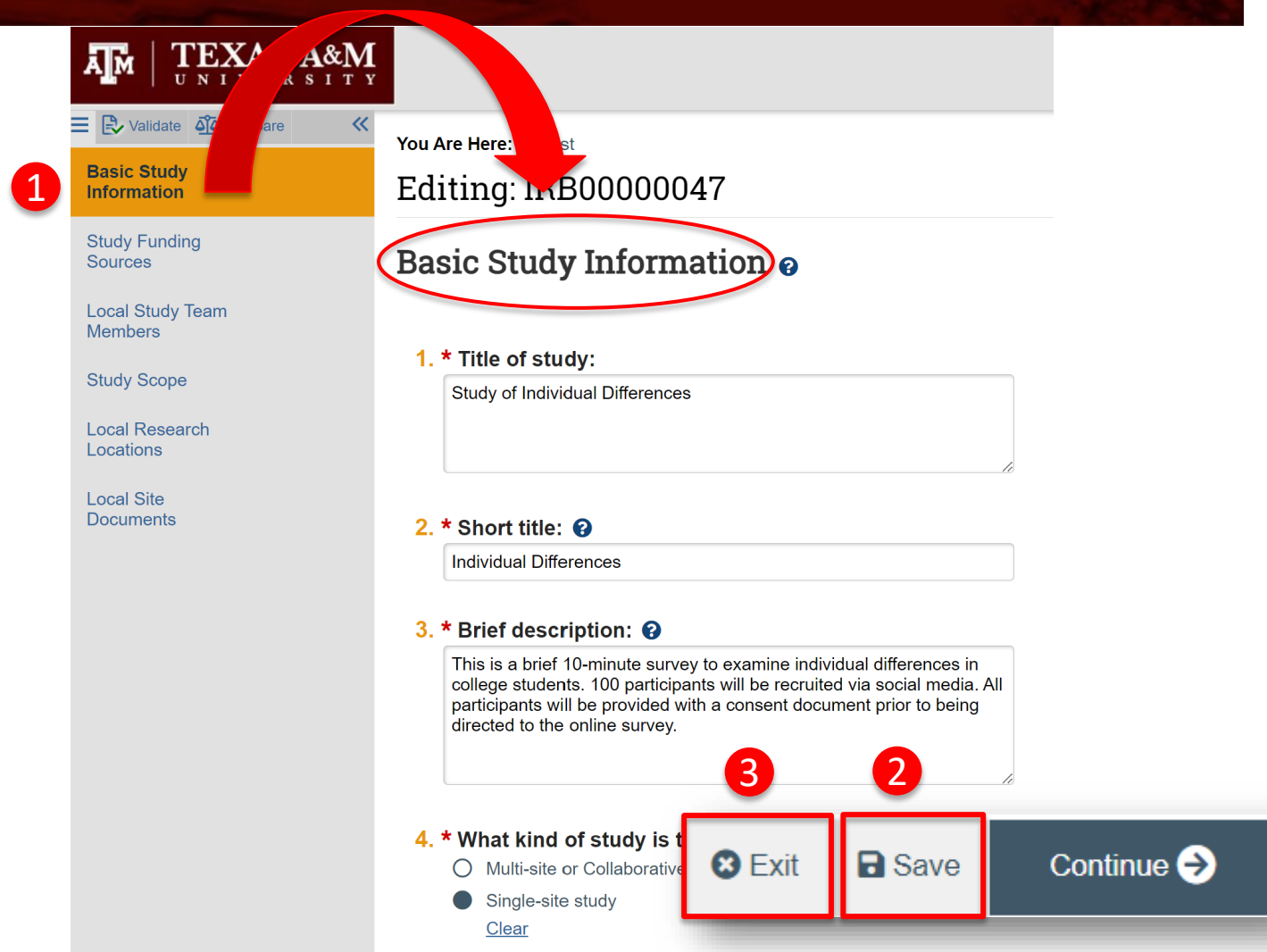
2

[Exit](#) [Save](#) [Continue](#)

Navigate the IRB Application to make edits

Once **Continue** is selected on the **Modification Summary** page, you will be brought to the application to make edits.

1. Use the navigator on the left side of the screen to locate any pages that need to be edited. The page currently being viewed will be shown highlighted in orange. To view a specific page, select the desired page on the navigator.
2. Click **Save** after making any edits to ensure your work is saved.
3. Once all edits have been made and saved, click **Exit**.



1

2

3

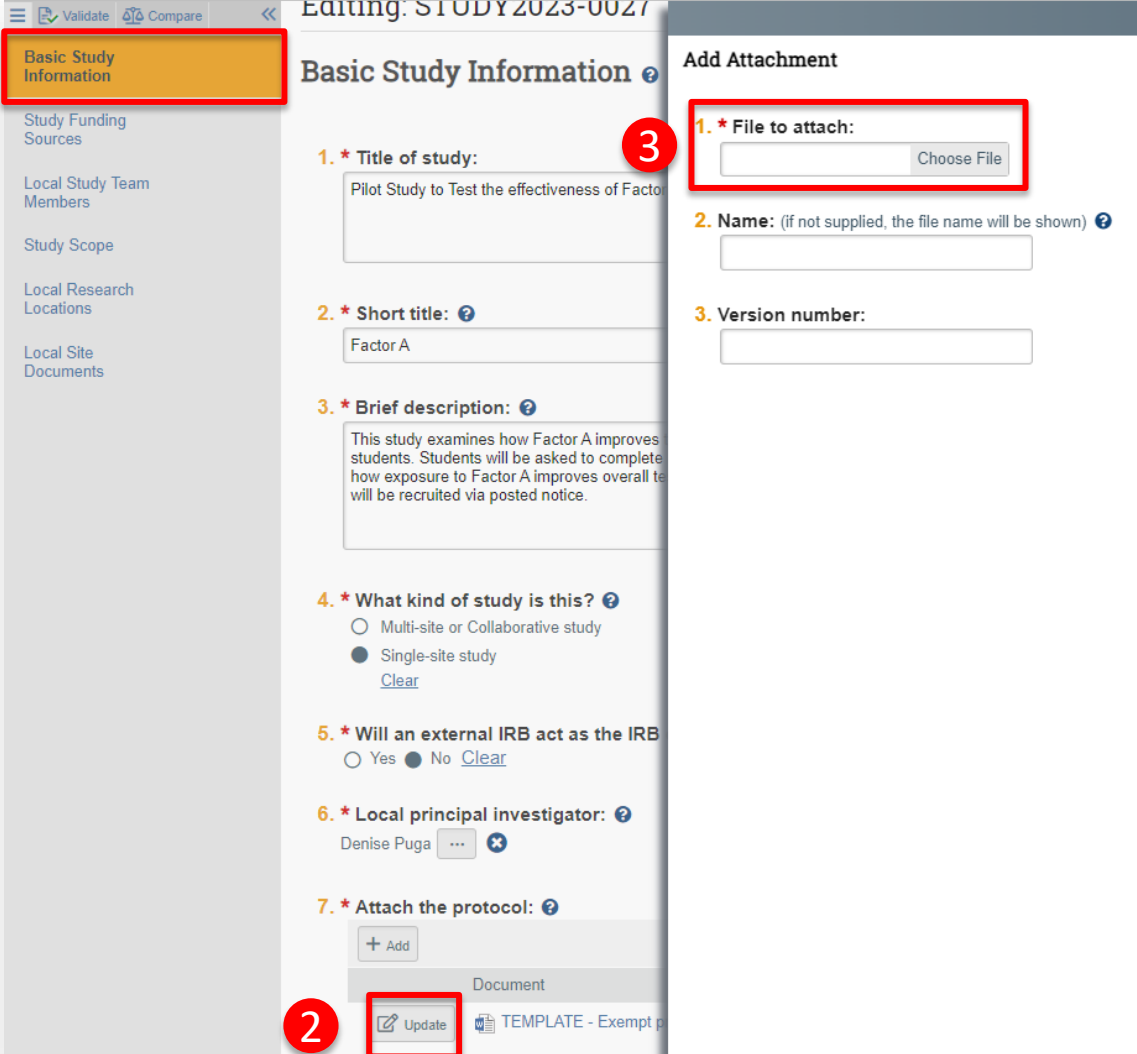
4

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 'Editing: STUDY2023-0027' interface. On the left, a sidebar contains links: 'Basic Study Information' (highlighted with a red box and a red circle with the number 1), 'Study Funding Sources', 'Local Study Team Members', 'Study Scope', 'Local Research Locations', and 'Local Site Documents'. The main area is titled 'Basic Study Information' and contains several questions. Question 7, 'Attach the protocol:', is highlighted with a red box and a red circle with the number 2. Below it, there is a '+ Add' button and an 'Update' button (highlighted with a red box and a red circle with the number 2). An 'Add Attachment' modal is open on the right, showing a red box and a red circle with the number 3 around the '1. * File to attach:' field, which includes a 'Choose File' button. The modal also shows fields for '2. Name:' and '3. Version number:'.

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 'STUDY2023-0027'. 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 1). The main content area has a breadcrumb 'You Are Here: Factor A' and the title 'Editing: STUDY2023-0027'. Below the title is the section 'Local Site Documents'. It contains 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. Red circles and boxes highlight the steps: 2. Clicking '+ Add' in the 'Consent forms' section, and 3. Clicking 'Update' in the 'Consent forms' section.

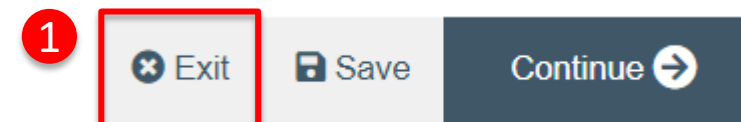
Submitting your submission to the IRB

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**



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

Next Steps

