How to submit a Continuing Review and Study Closure

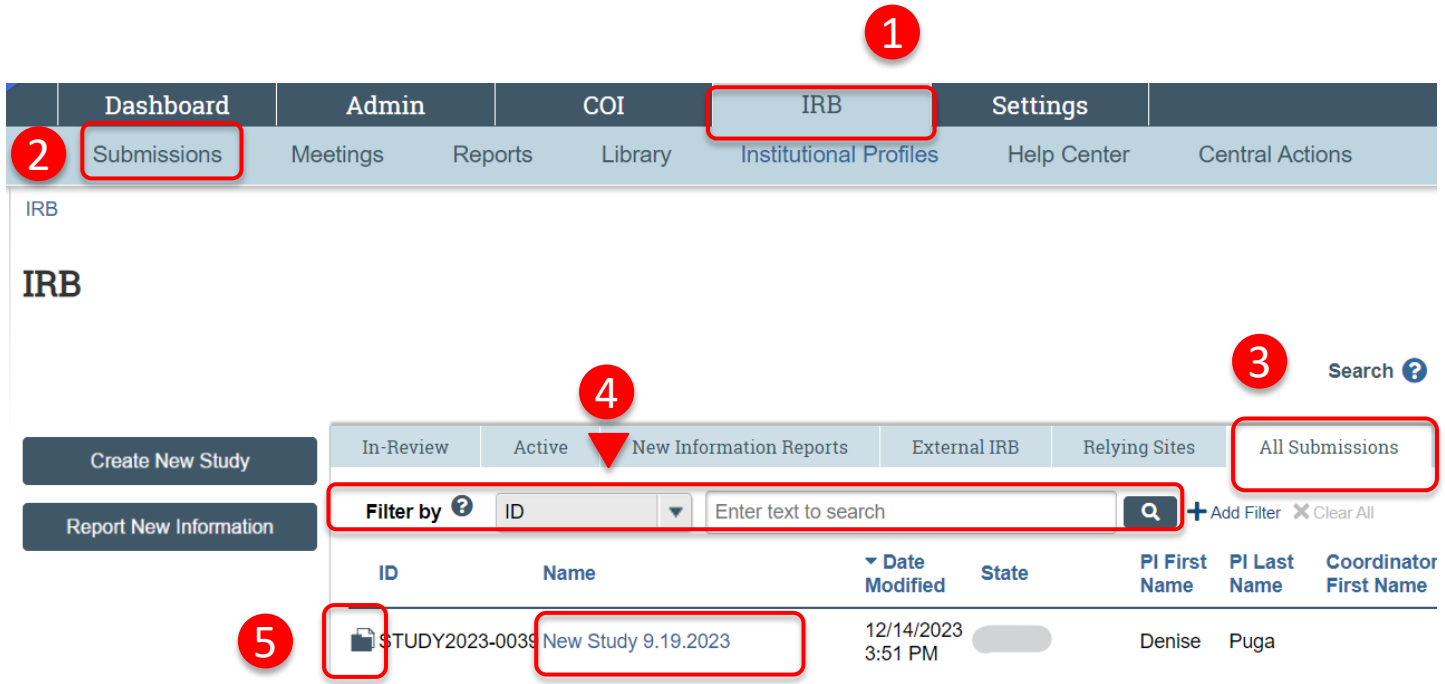
Human Research Protection Program

(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

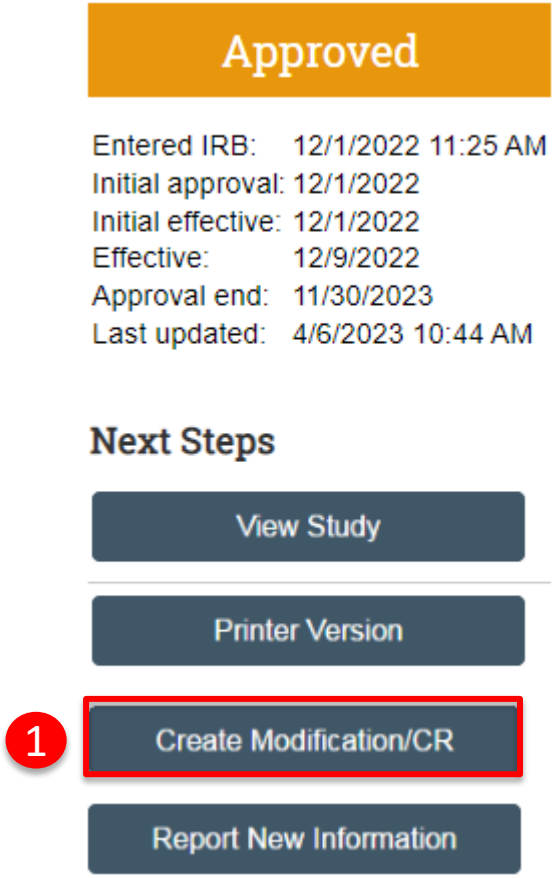
1. Navigate to the **IRB workspace**
2. Select **Submissions** tab
3. Select **All Submissions** tab
4. Note: **Filter by** allows you to sort through your studies by name, PI first and last name, and submission type.
5. Open your study by selecting the **folder symbol** or the **name** of the study.



Creating a Continuing Review

1. Select **Create Modification/CR**

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



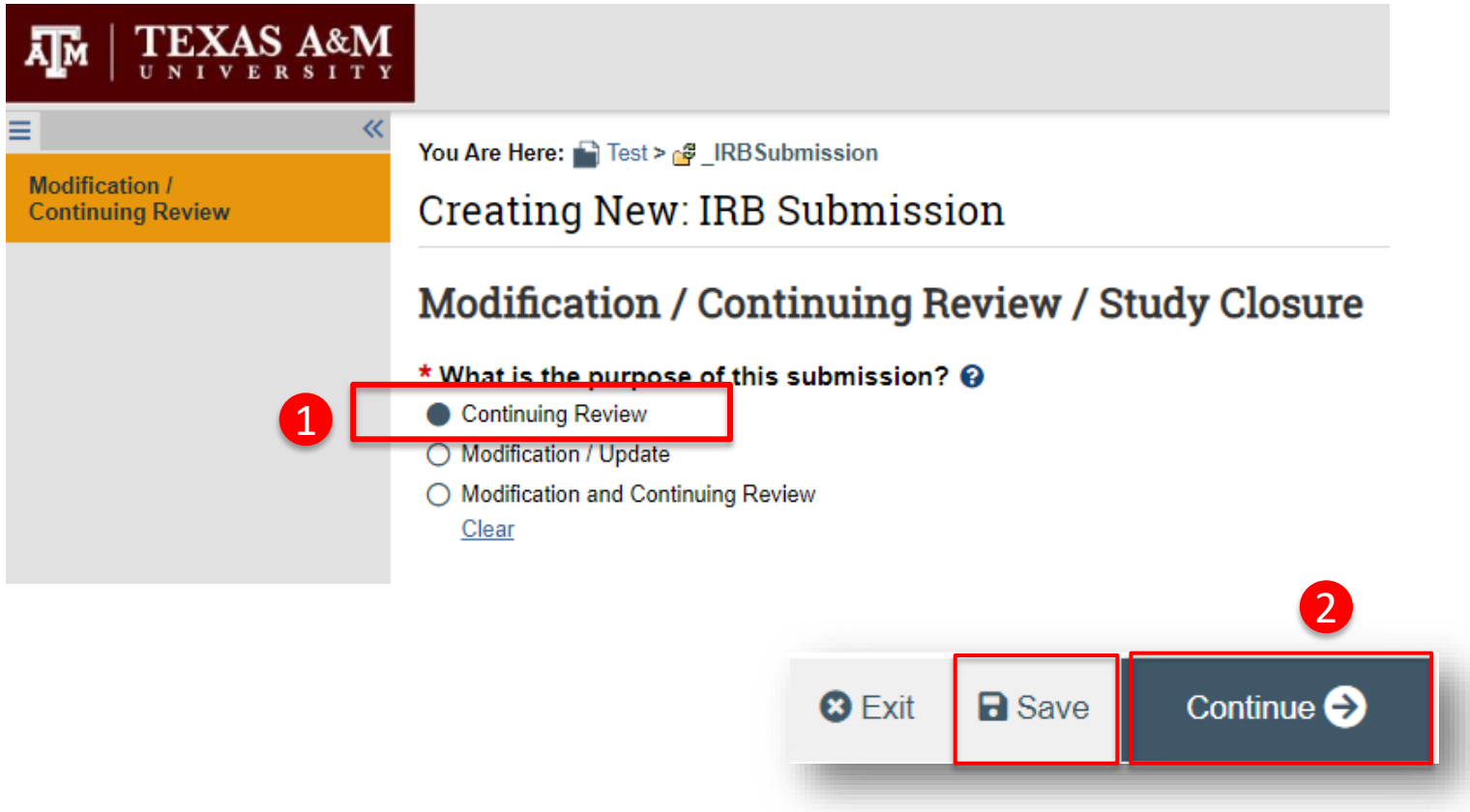
Initiating a Continuing Review Form

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**



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:

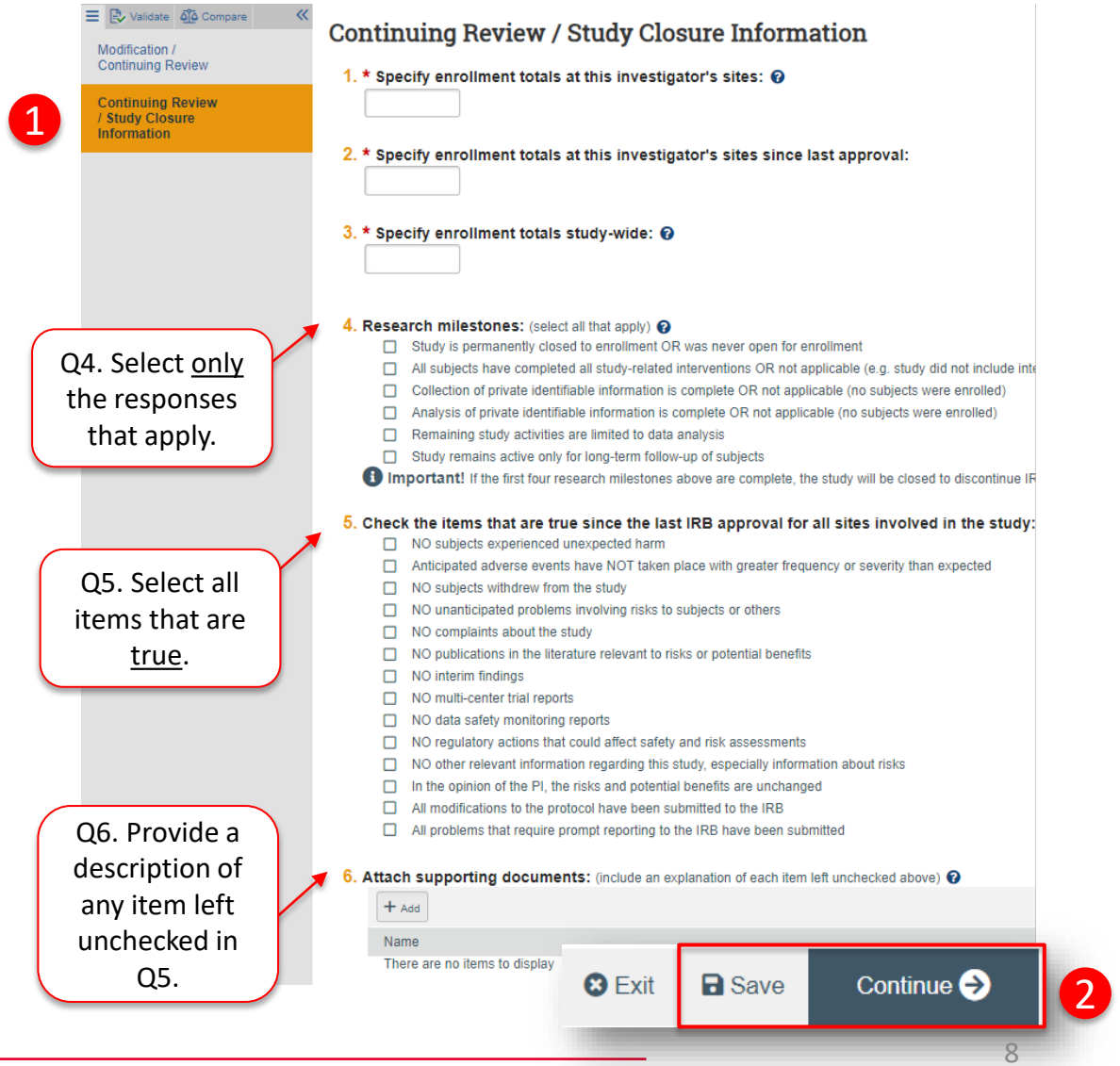
> At the convened meeting on 01/06/2021 the IRB approved this research from 01/12/2021 to 01/05/2022 inclusive.
>
> It is recommended that you submit your next continuing review by 12/05/2021 to avoid a lapse in approval. Your study approval will end on 01/05/2022.

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

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**



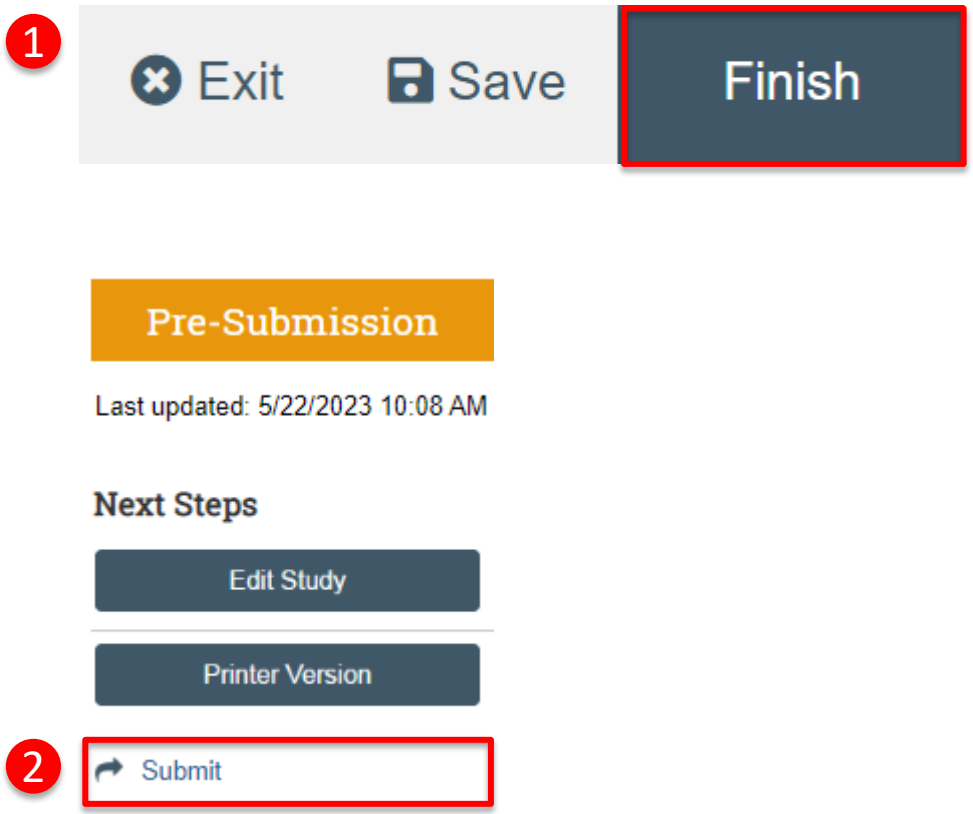
Submitting your form to the IRB

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**

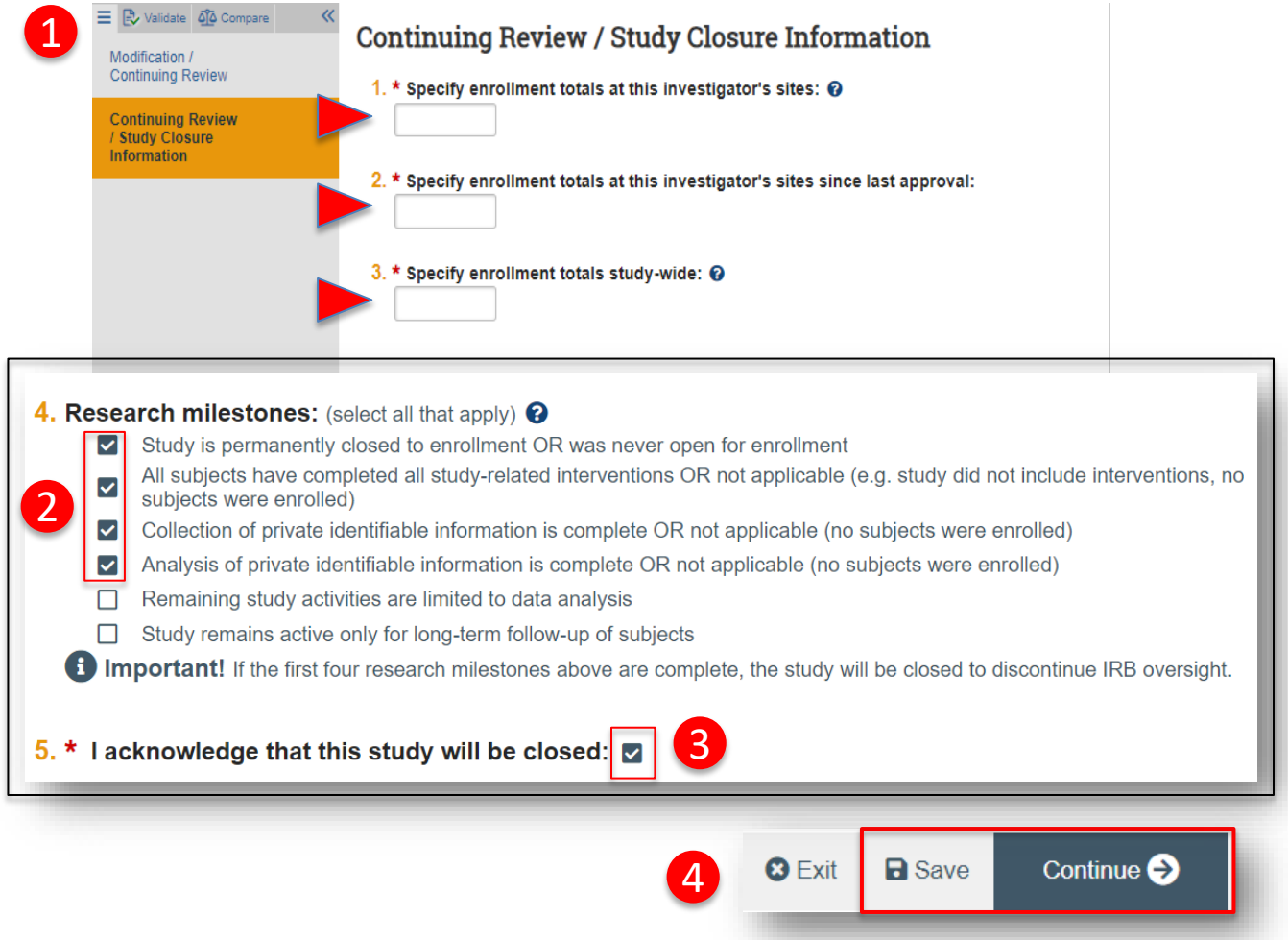


HOW TO CLOSE OUT A STUDY

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**



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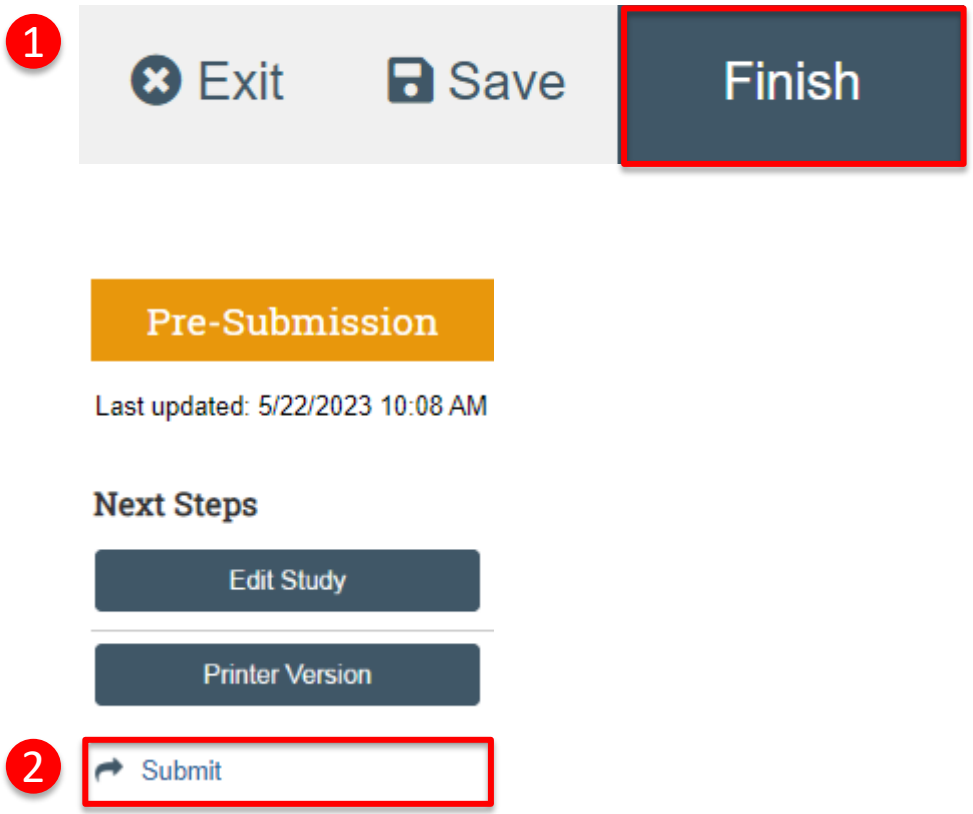


HOW TO SUBMIT A MODIFICATION AND CONTINUING REVIEW

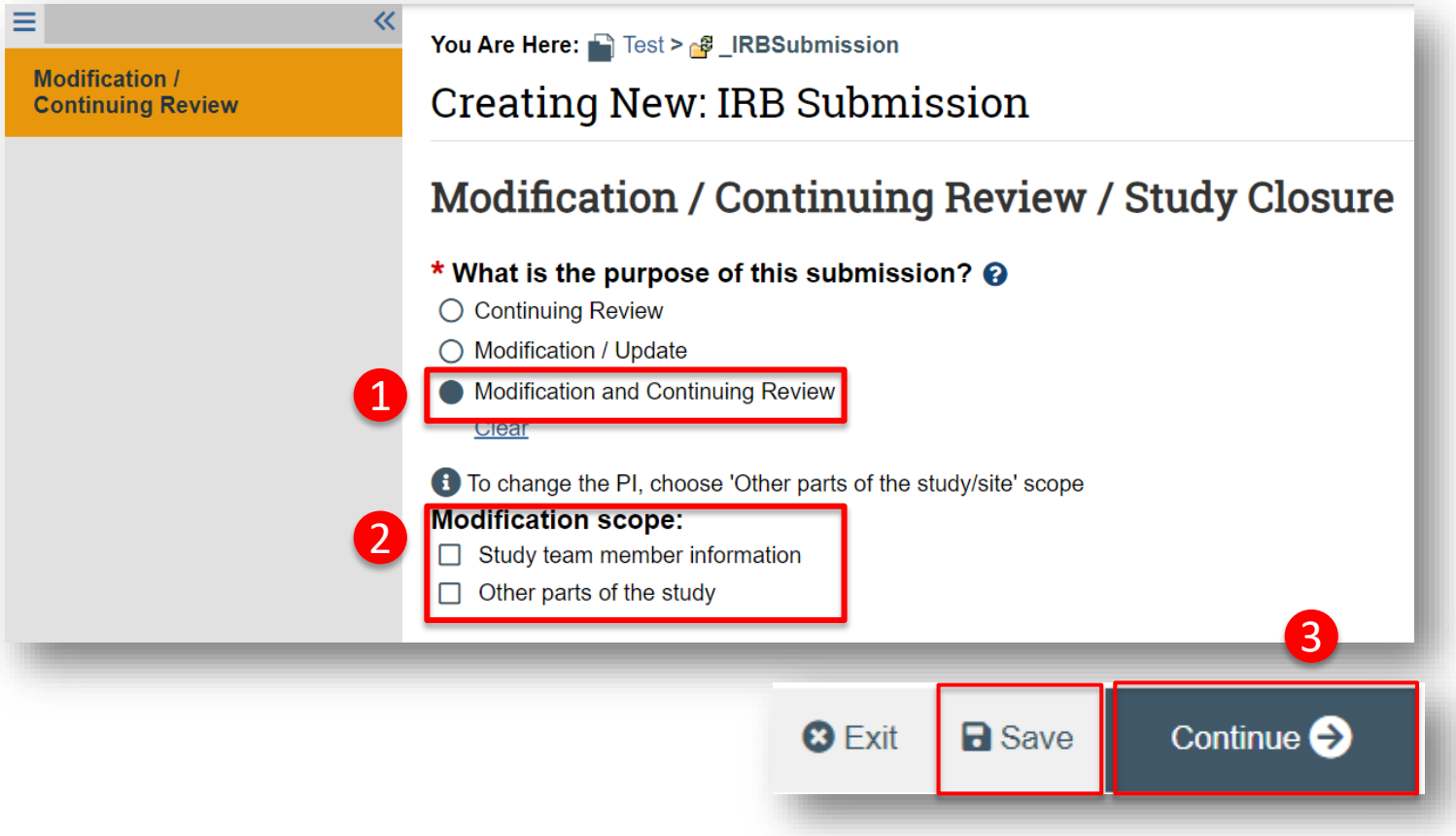
Modification and Continuing Review

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**

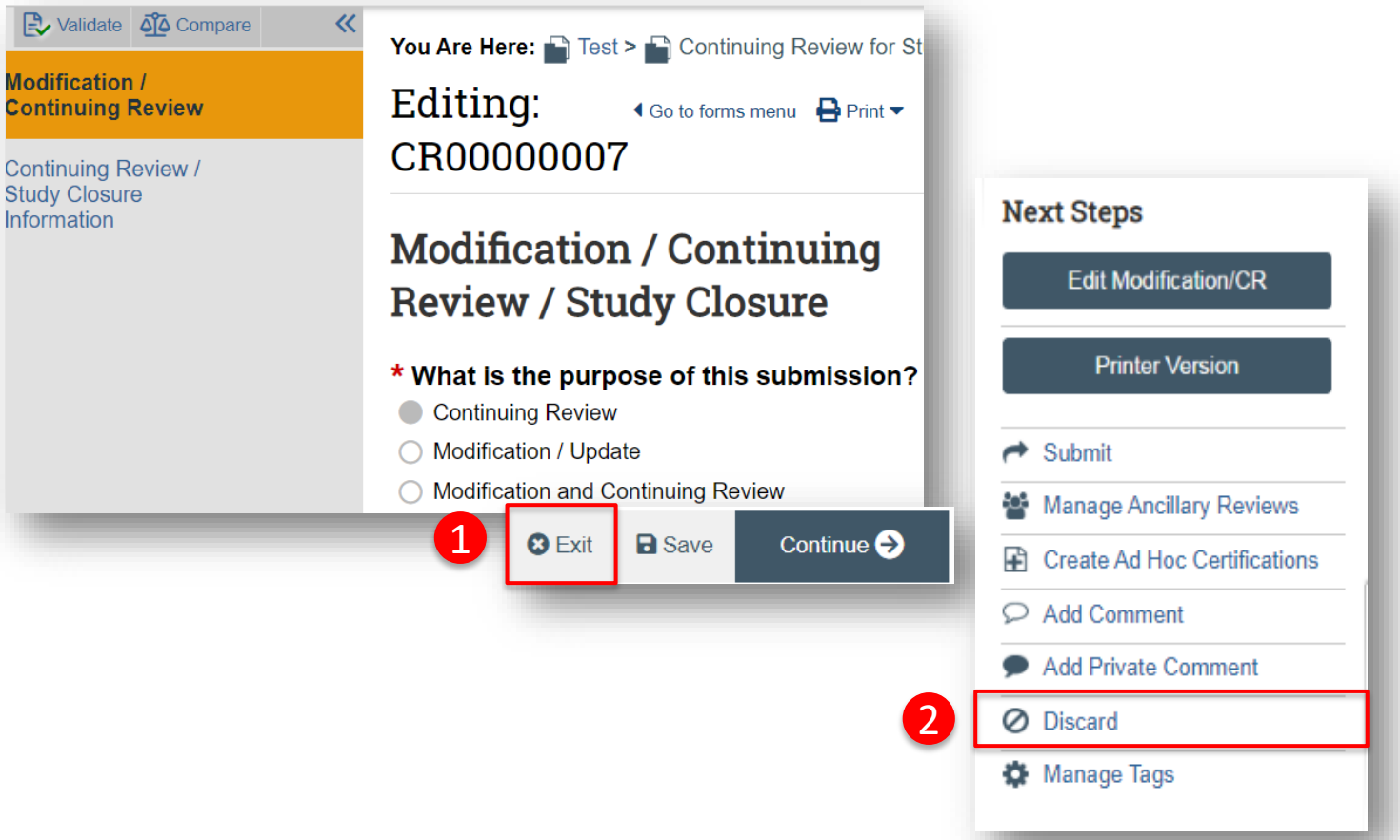


How to discard a submission

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

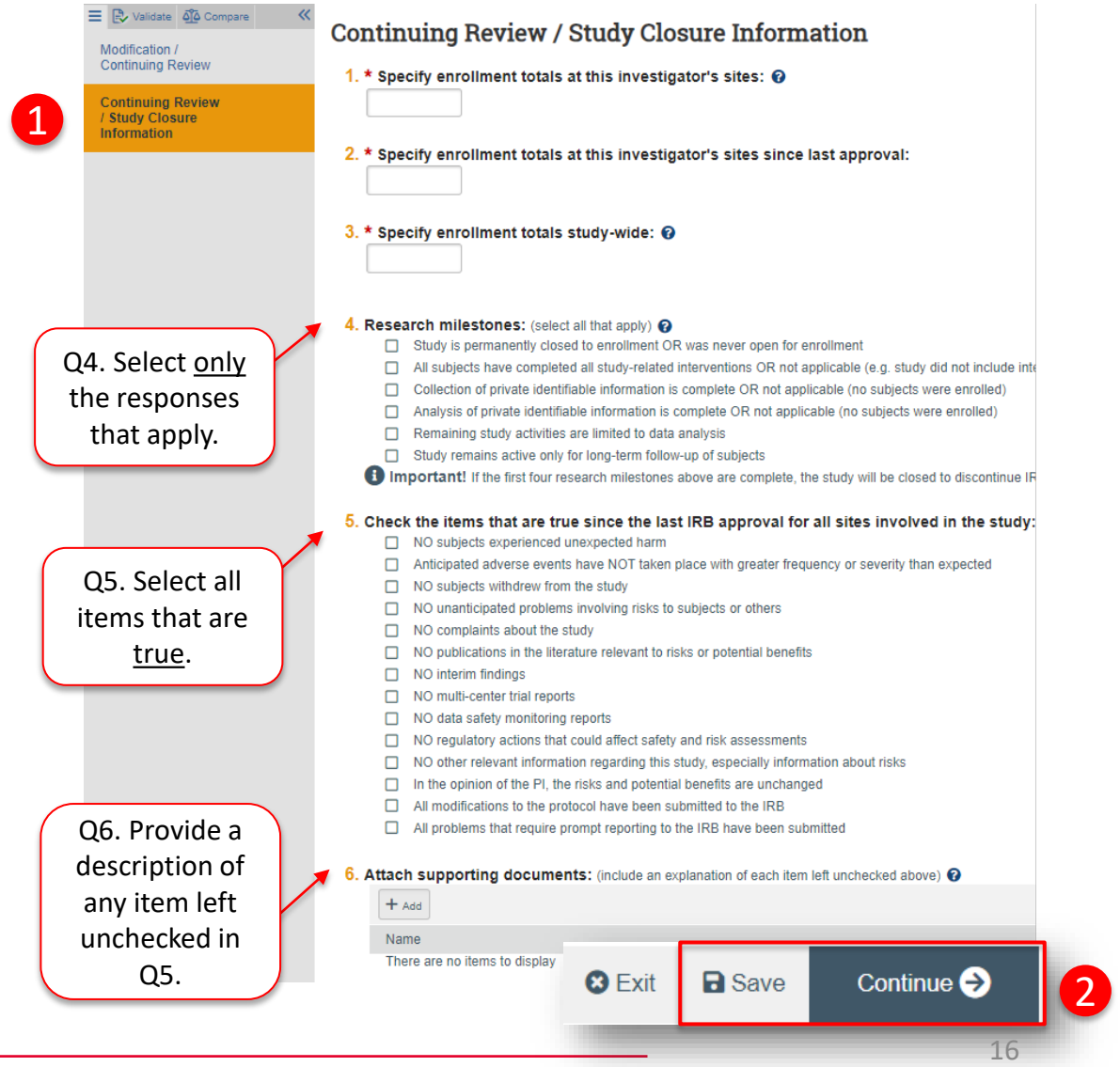
If an incorrect response was chosen *and* the form has been saved*:*

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



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**

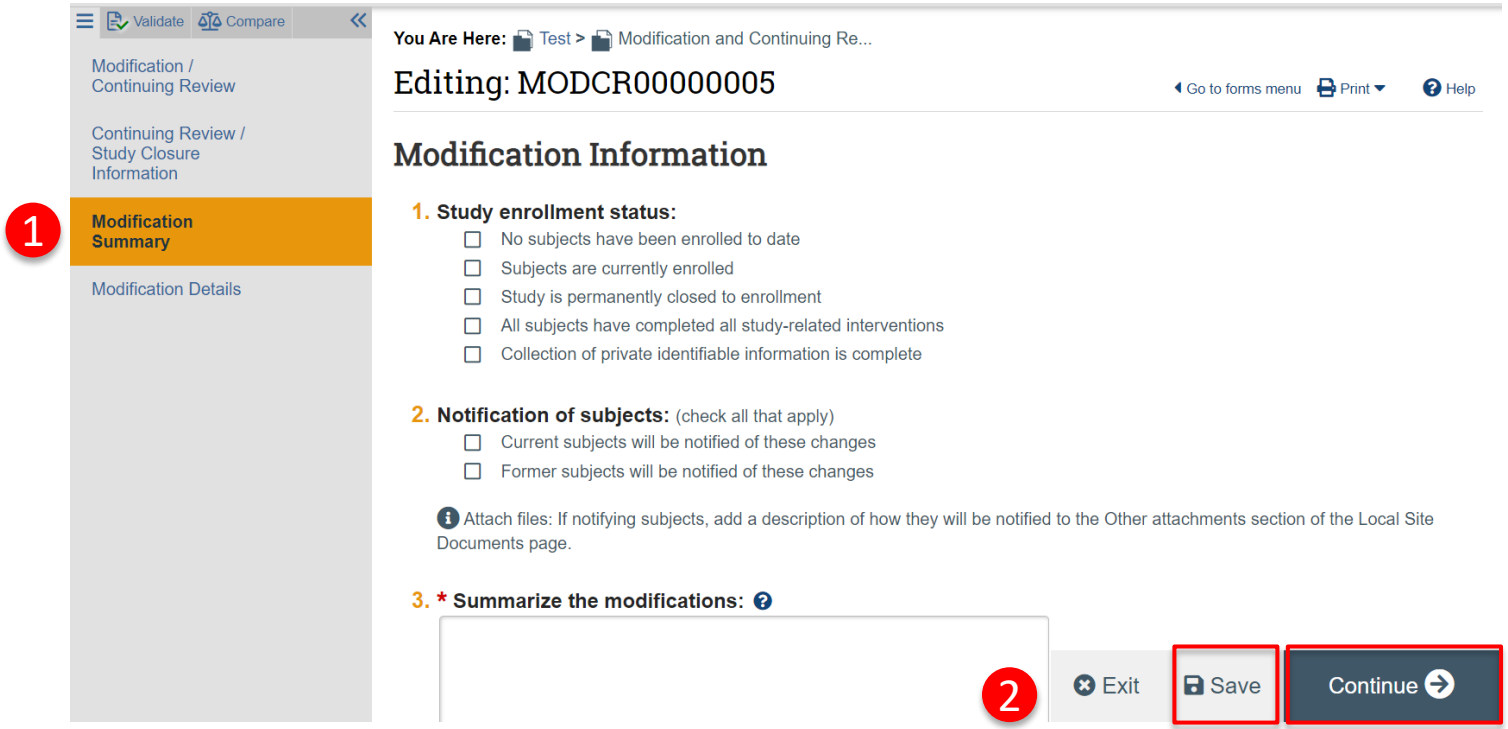


Modification and Continuing Review (continued)

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.

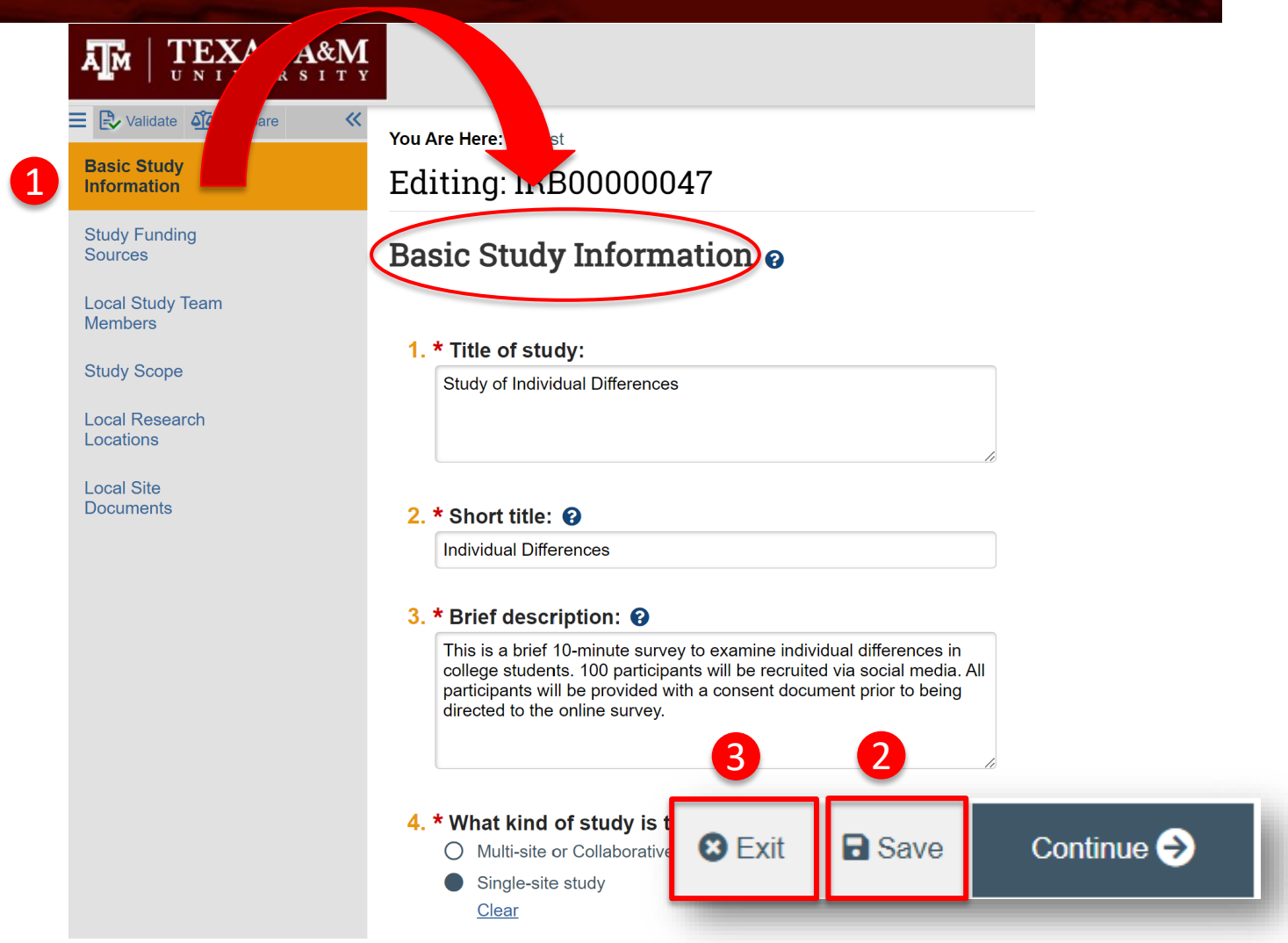
2. Select **Save** and then **Continue**



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.

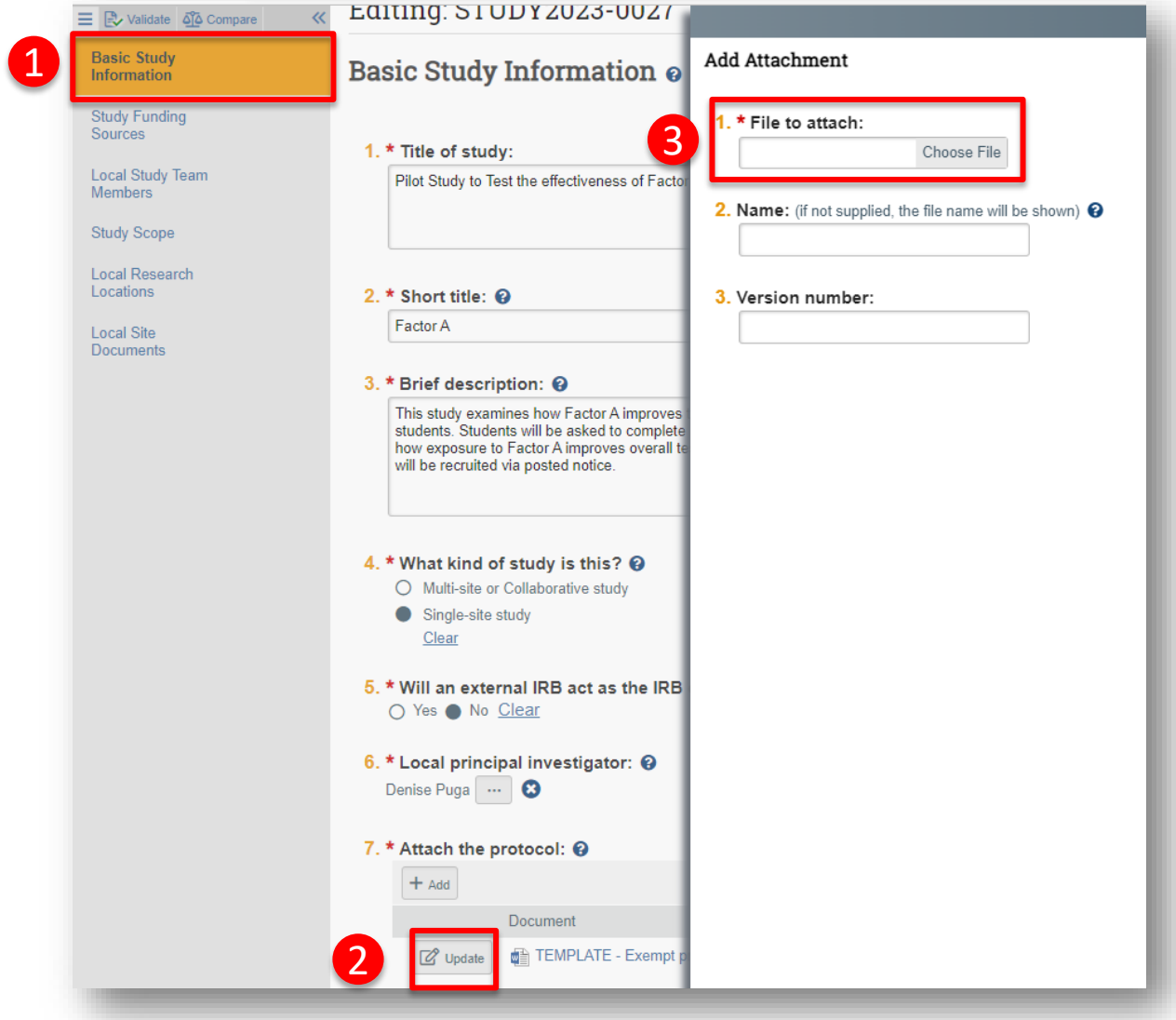
1. Use the navigator on the left side of the screen to locate any pages that need to be edited. The page currently being viewed will be shown highlighted in orange. To view a specific page, select the desired page on the navigator.
2. Click **Save** after making any edits to ensure your work is saved.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



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**



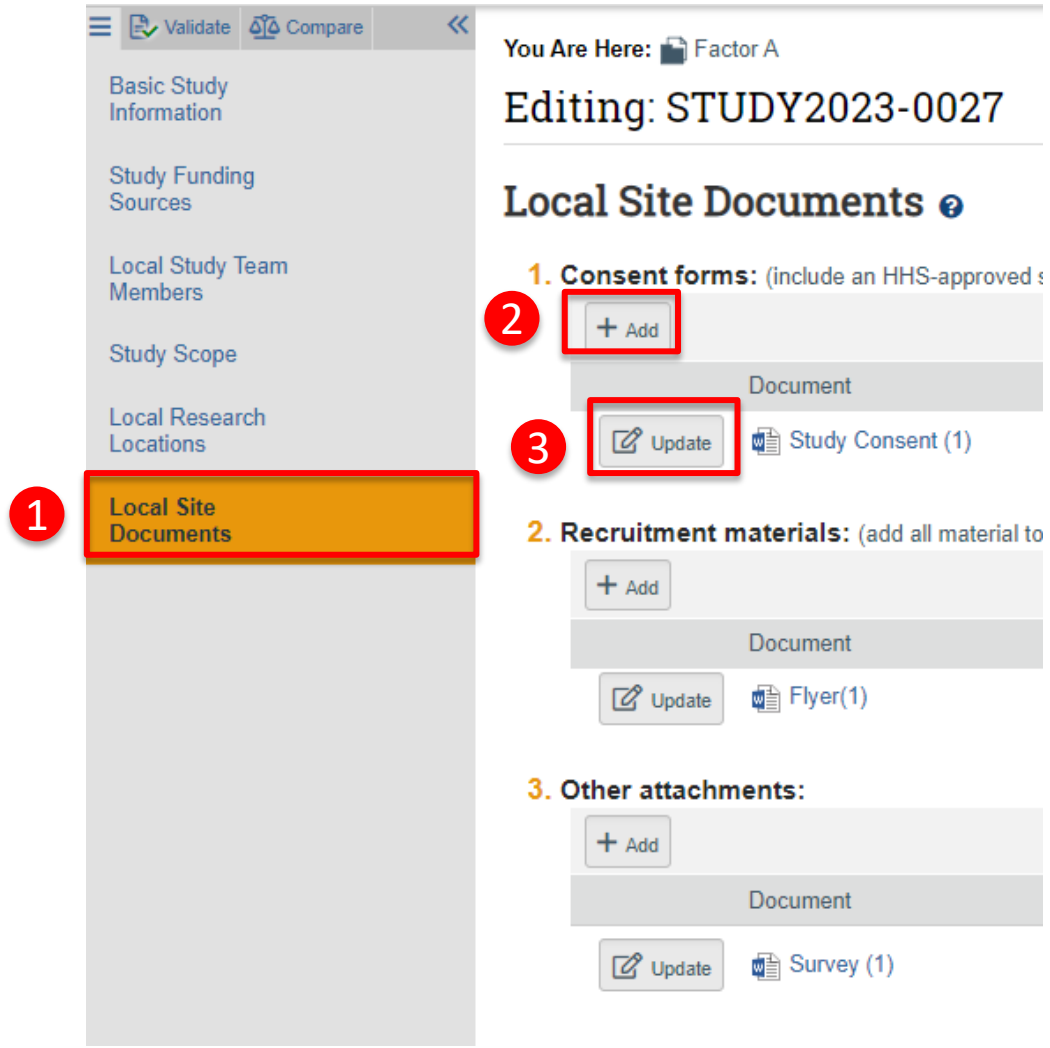
How to attach new or revised study documents

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.



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**