Creating and submitting a modification

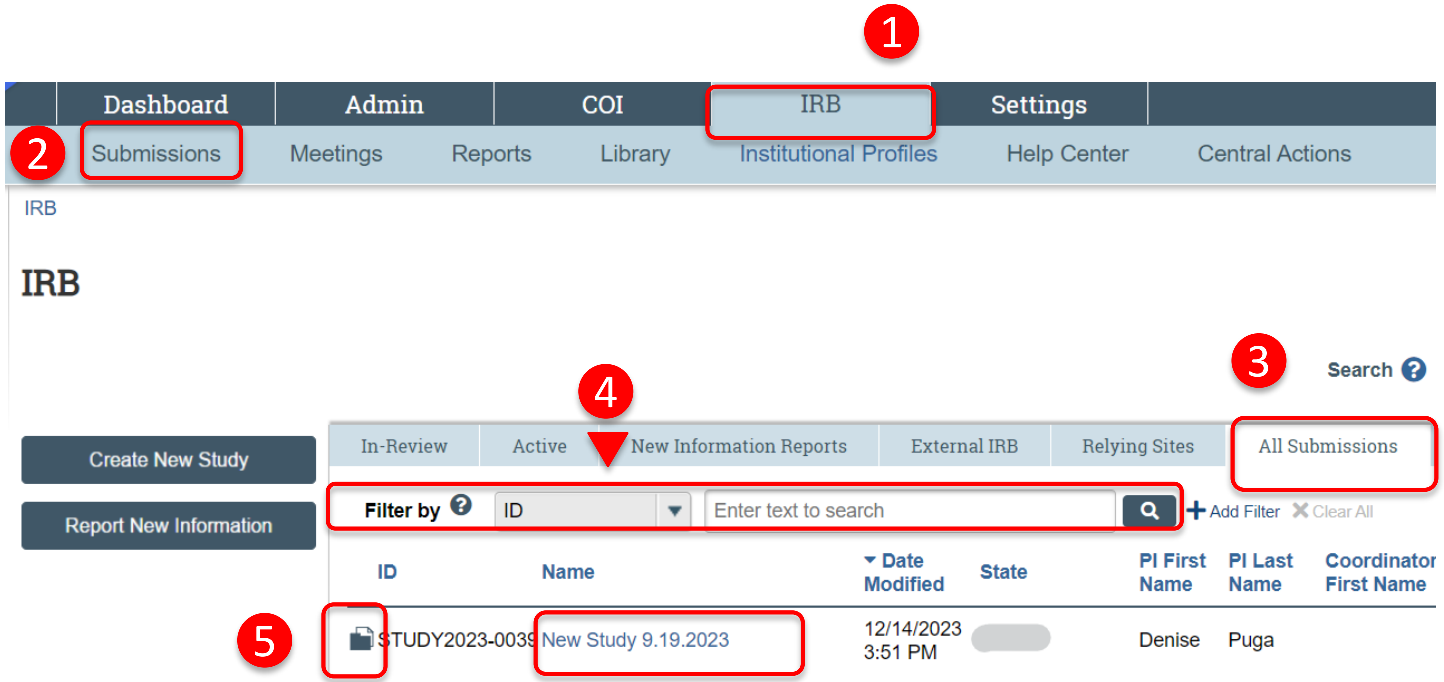
Human Research Protection Program

(Last Updated: 01/29/2024)

This PowerPoint will guide you through how to create and submit a modification to an approved IRB protocol.

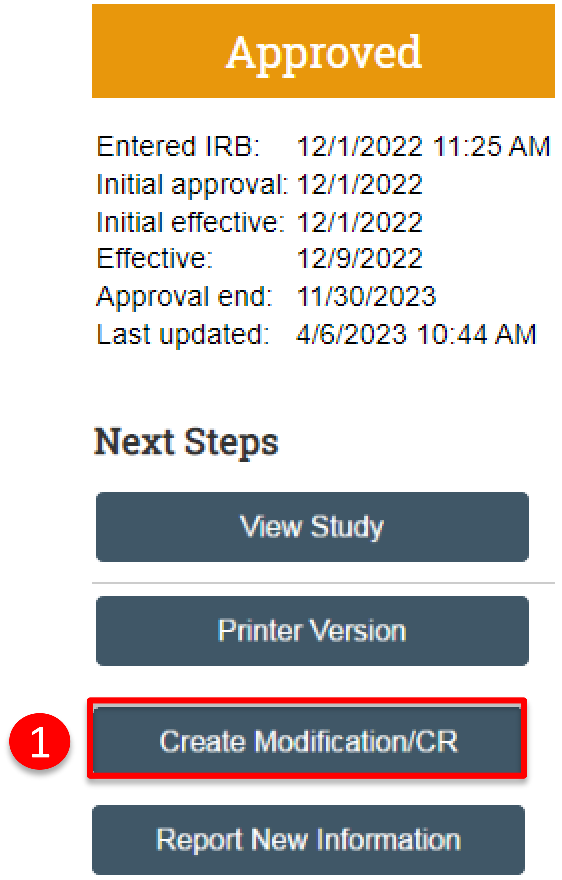
Getting started

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 modification

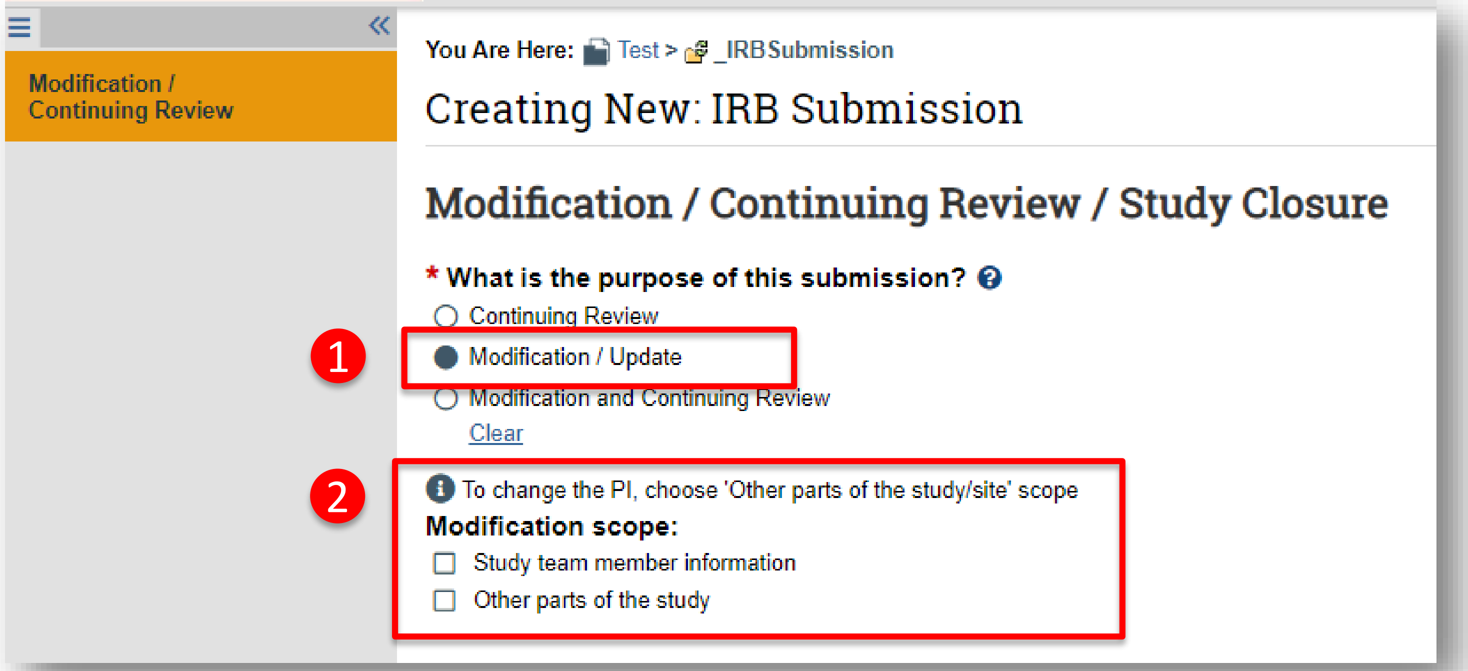
1. Select **Create Modification/CR**



Modification/Update

1. Select **Modification/Update*****

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



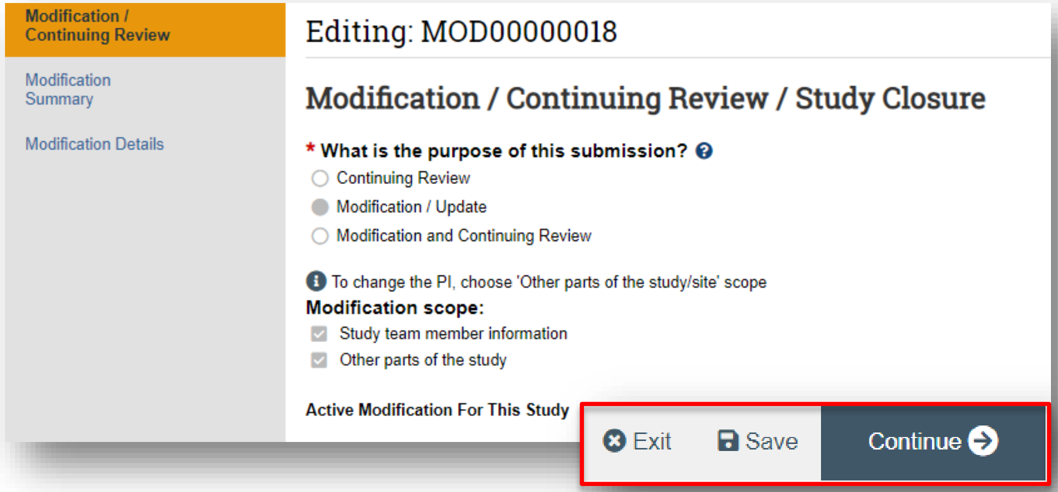
*** Do not select *Modification and Continuing Review* unless you are confident that your study requires a continuing review. Most minimal risk studies approved after January 20, 2019 do not require a continuing review, but still must undergo an Administrative Check In (instructions on how to create and submit an Administrative Check In can be found here). To identify if your study requires a continuing review or an administrative check in, please reference your initial approval letter.

How to discard a modification

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

2. If an incorrect response was chosen for either “*What is the purpose of this submission?*” or “*Modification scope*” and the form has been saved, then click **Exit** to leave the submission and select **Discard** from the study record workspace. A new Modification/CR request will need to be created to continue with the modification request.

1



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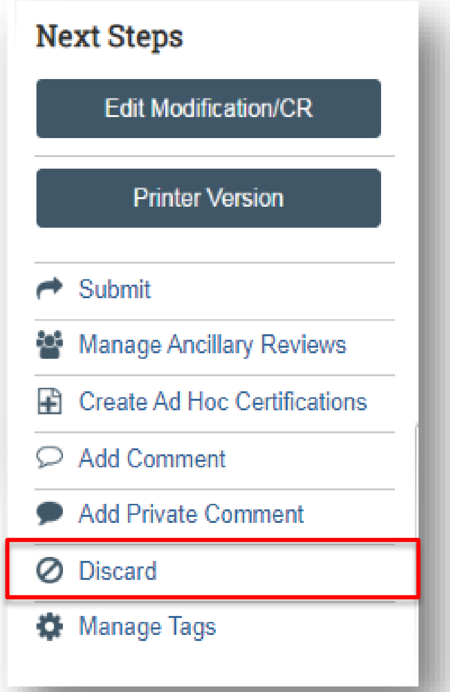
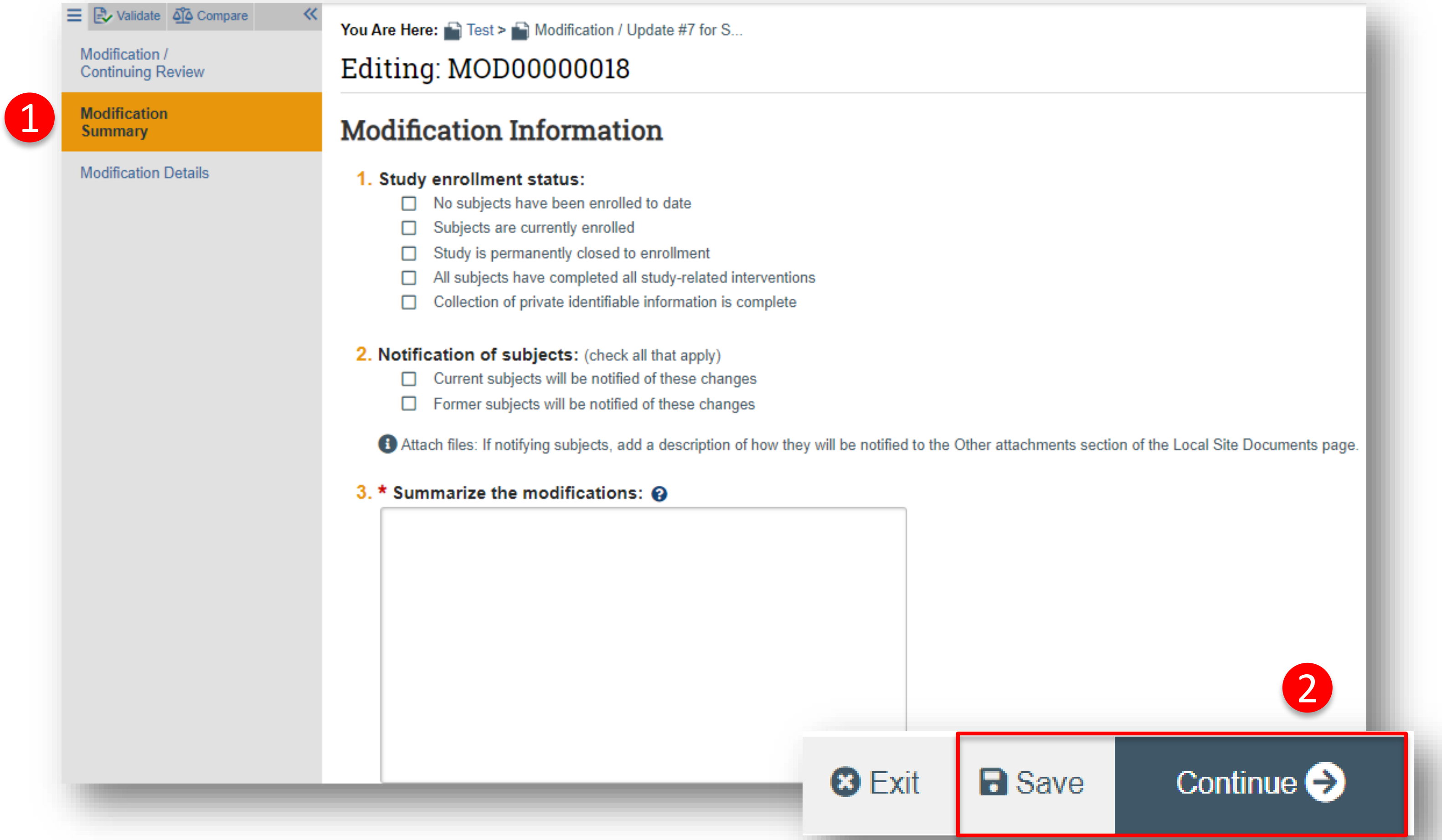


Complete the Modification Summary

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.

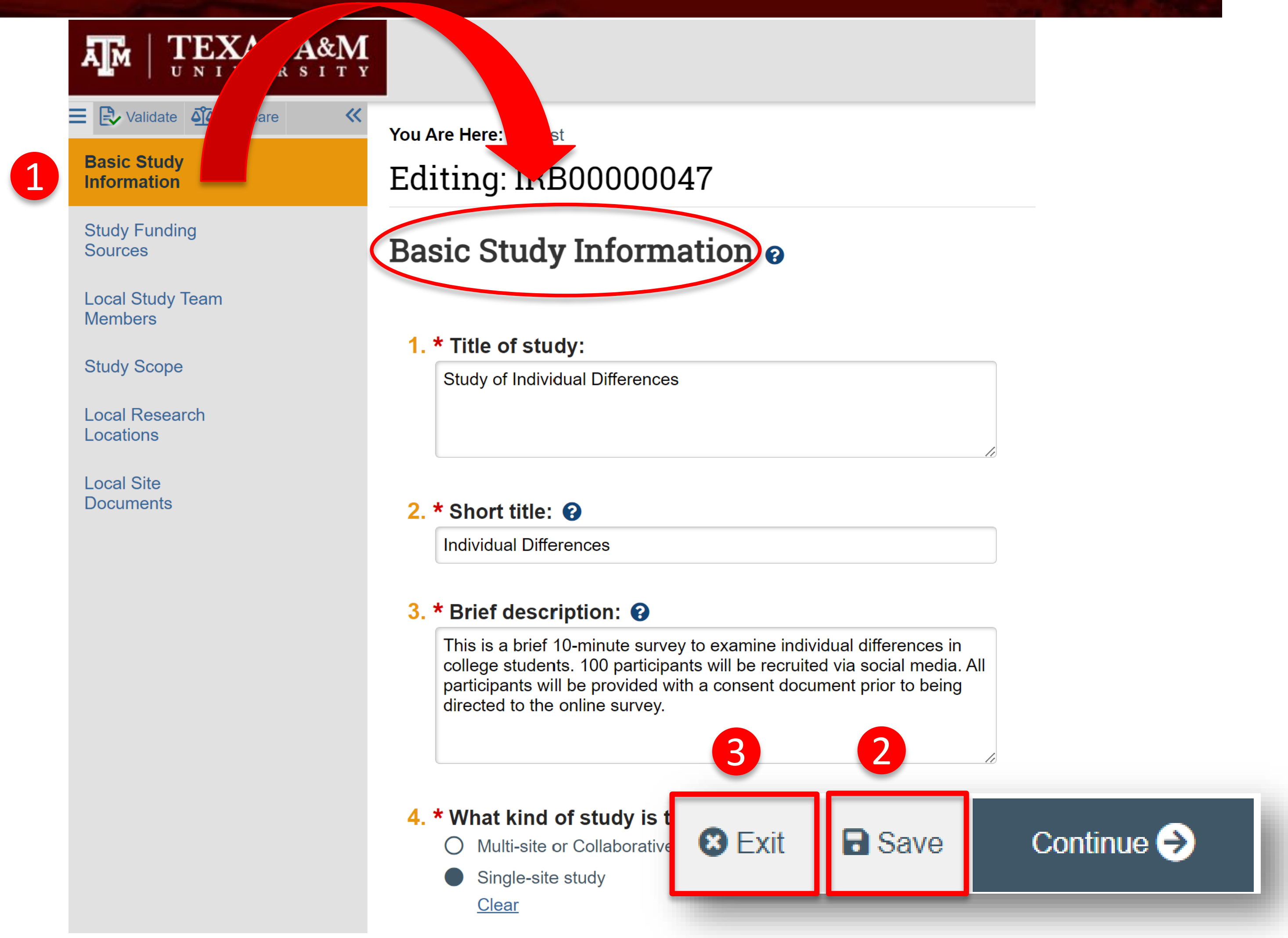
2. Select **Save** and then **Continue**



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.

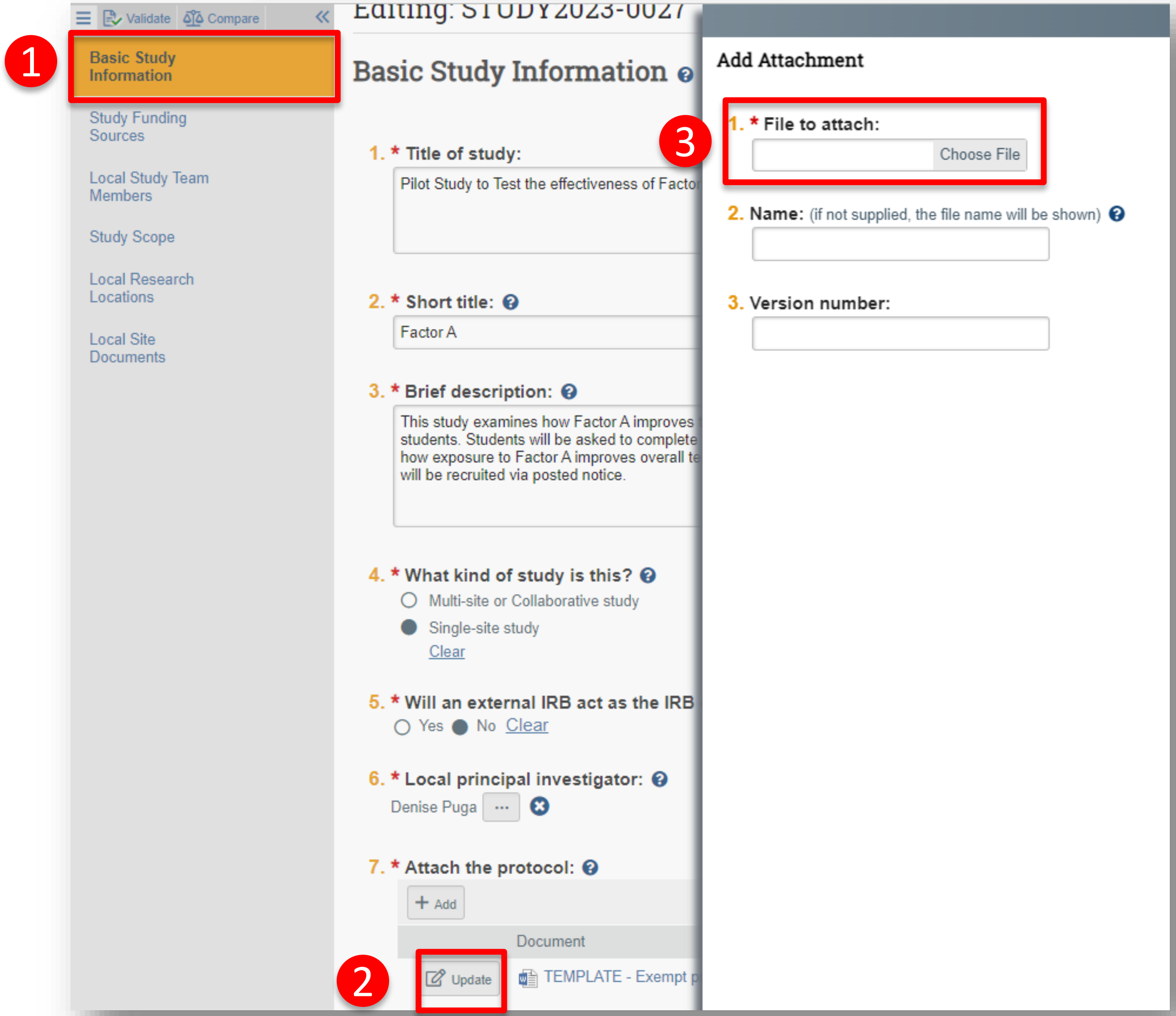
1. Use the page navigator on the left side of the screen to locate any pages that need to be edited. The page currently being viewed will be shown highlighted in orange. To view a specific page, click the desired page on the navigator.
2. Click **Save** after making any edits to ensure your work is saved.
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. Click **Update** on ***Attach the Protocol*** (this can be either Question 7 or 8)
3. Click **Choose File** and attach your revised protocol and then click **OK**



Adding/removing TAMU personnel

To add **TAMU study team members**:

1. Click **+Add**

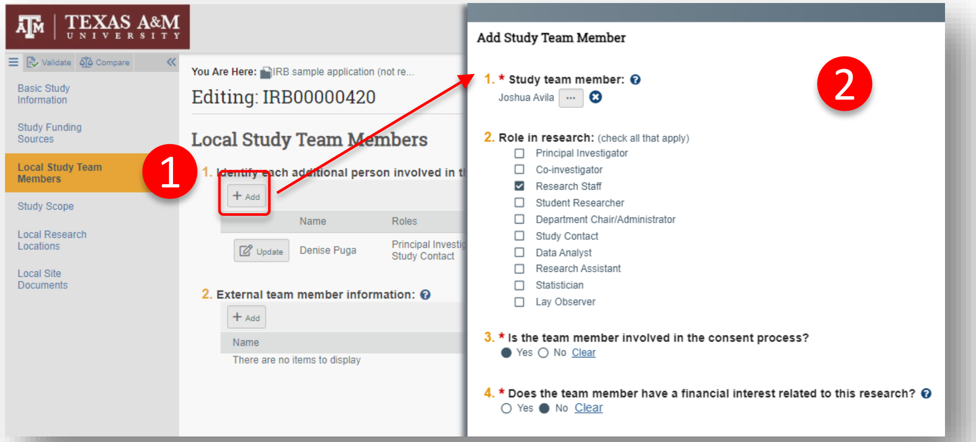
   I am trying to add study personnel to an IRB protocol, why am I not able to locate them in the system?
   Some TAMU members (such as undergraduates, visiting scholars, and adjunct/affiliate professors) need to opt into their information being fed into Huron before they are active in the system. If you are not able to locate a member of your research team, have that individual visit the following website: https://raes.dor.tamu.edu. *Note*: It will take 24 hours before their information is active in Huron.

2. Complete the **Add Study Team Member** smart Form
   - Q1 – Type the name of the team member being added or click the ellipsis […]
   - Q2 – Identify the role of the team member
   - Q3 – Identify if the team member will be involved in collecting consent.
   - Q4 – Identify if the team member has a conflict of interest.

Important! All personnel being added must have completed CITI training and log into the new **Texas A&M SSO CITI URL**

To remove study team members:

3. Click the X to the right of the team member.



Click **X** to Remove

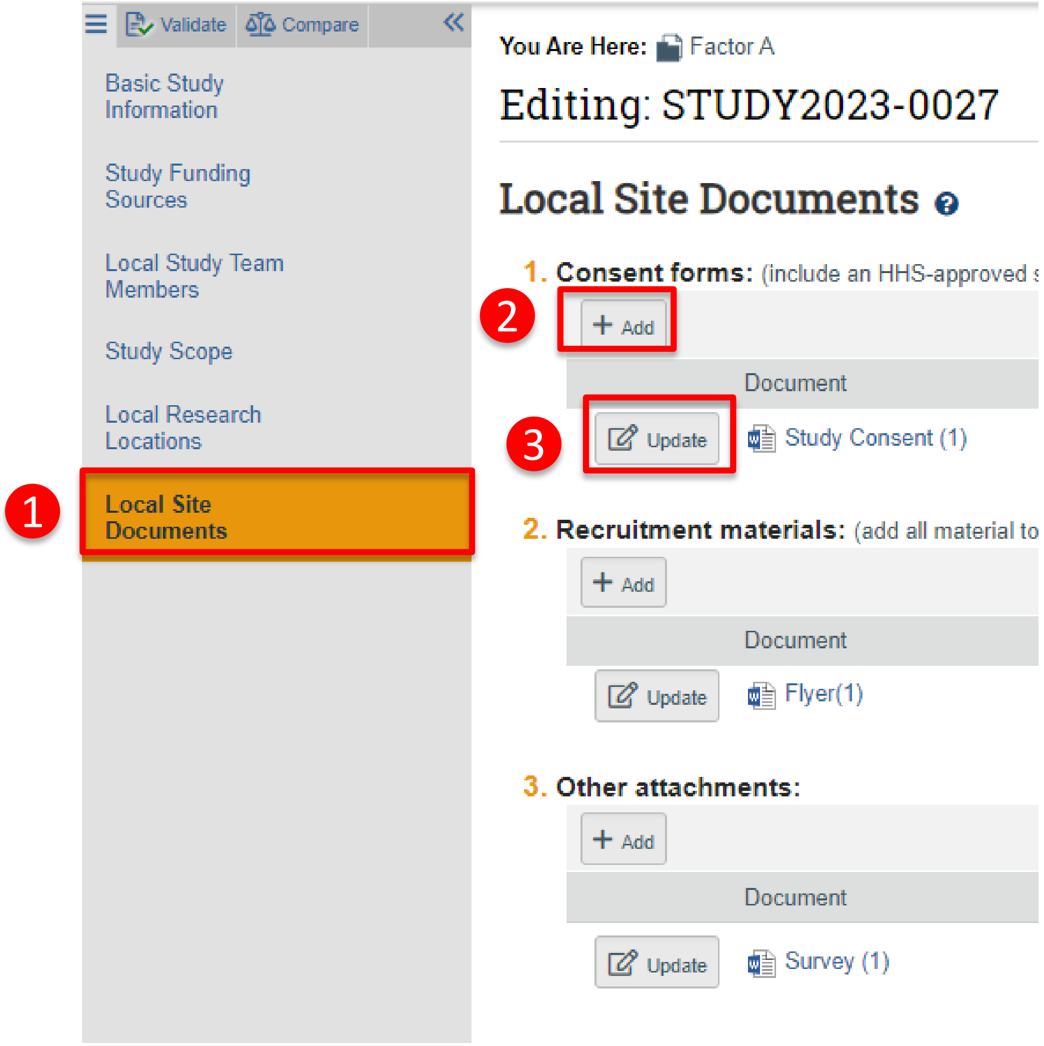
How to attach new or revised study documents

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 modification to the IRB

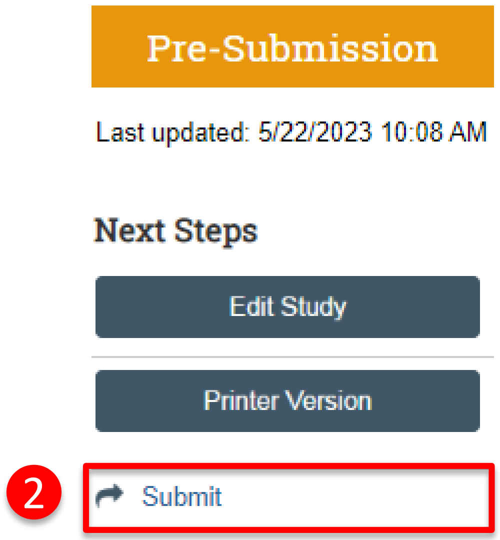
Once you have finished editing the IRB application and saved all your edits:

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**



Visit the FAQ webpage

Please take a moment to visit the frequently asked questions webpage **Huron FAQ – Division of Research (tamu.edu)** to learn more about Huron functionality.

Slide added: 1/29/2024