How to respond to requests for clarifications from the IRB

Human Research Protection Program

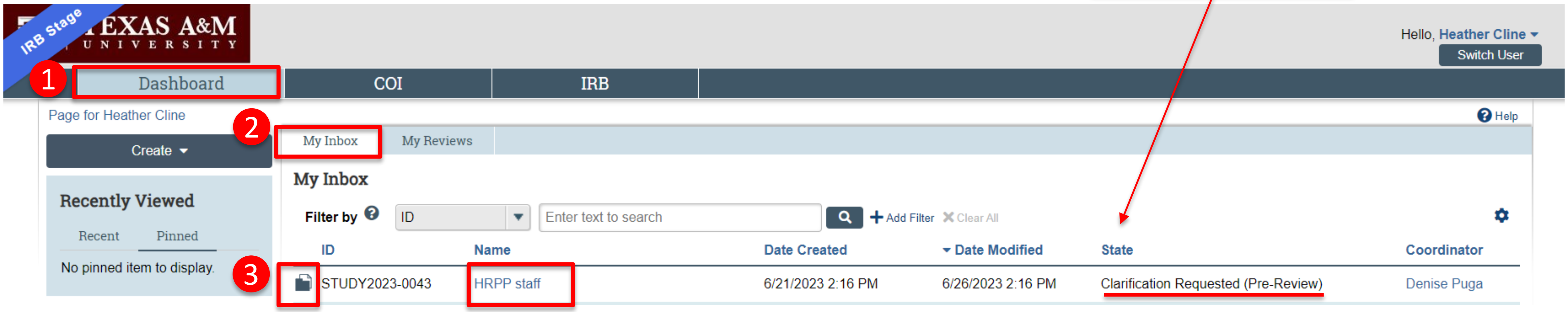
This PowerPoint will guide you through how to respond to requests for clarification from the IRB.

Responding to clarification requested

Log into Huron:

1. From the **Dashboard**
2. Click on **My Inbox**
3. Select the **folder symbol** or the **Name** of the submission to open and review the request for clarifications.

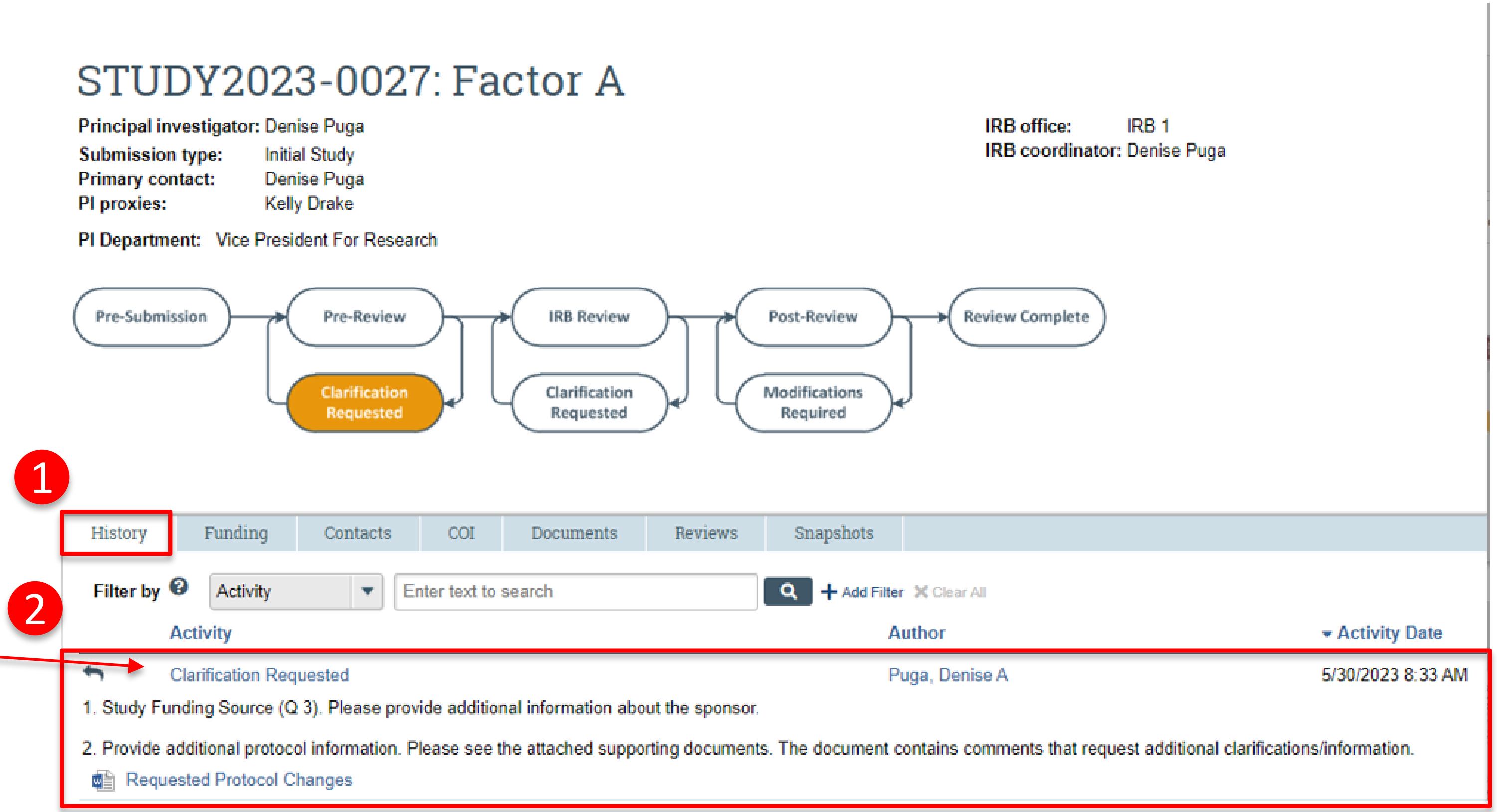
State informs what actions are pending for the submission.



Review the Clarification Requested

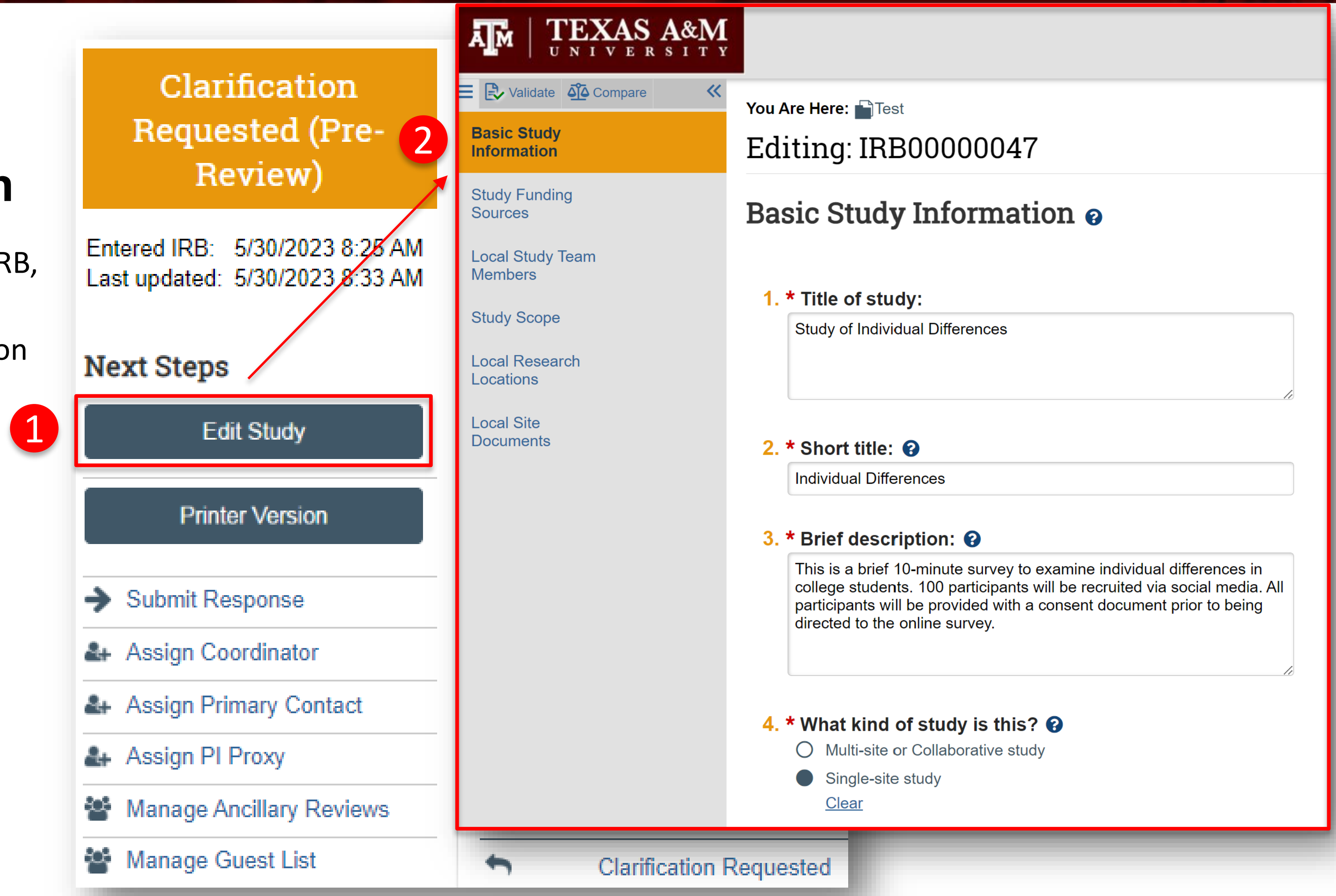
1. The **History** tab lists the activities taken on a submission including clarifications requested from the IRB reviewer or coordinator.
2. Under the History tab, review the **Clarification Requested**.

   Note: the clarification will be directly embedded in this location, but you can also click on the blue link labeled with *Clarification Requested* to open the requests in a separate window.



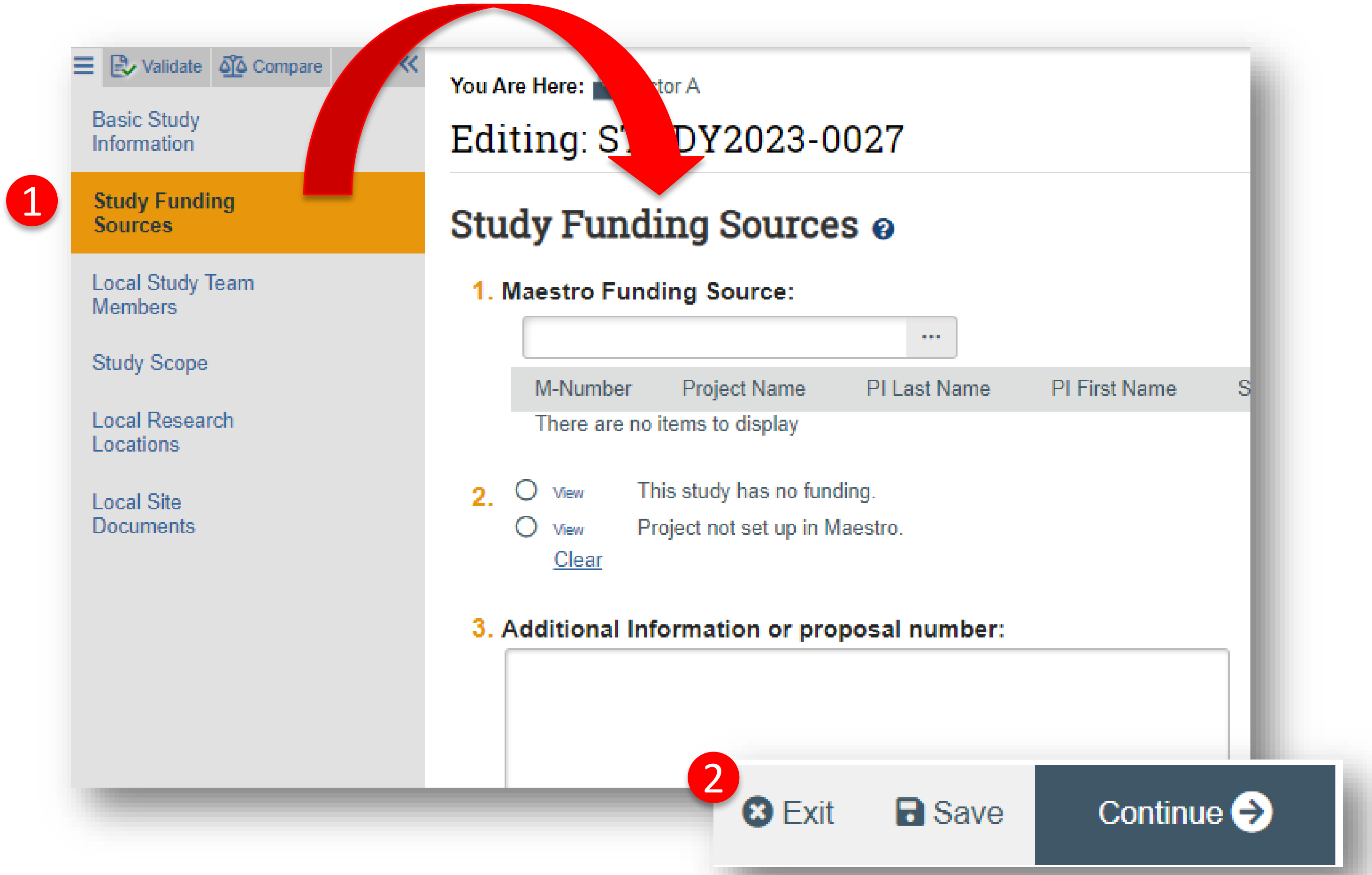
How to Edit the application

1. If changes are needed or requested by the IRB, click the **Edit Study**.
2. This will give you access to the IRB application and allow for any edits to be made.



How to navigate the application

1. The page navigator will appear on the left side of the screen. The page currently being viewed will be shown highlighted in orange.
   - Click on the page that requires edits to be made.
   - Make your edits on the page selected
2. Once the edits have been made, click **Save** and:
   - **Continue** to navigate to other pages in the application; or
   - **Exit** to return to the IRB workspace



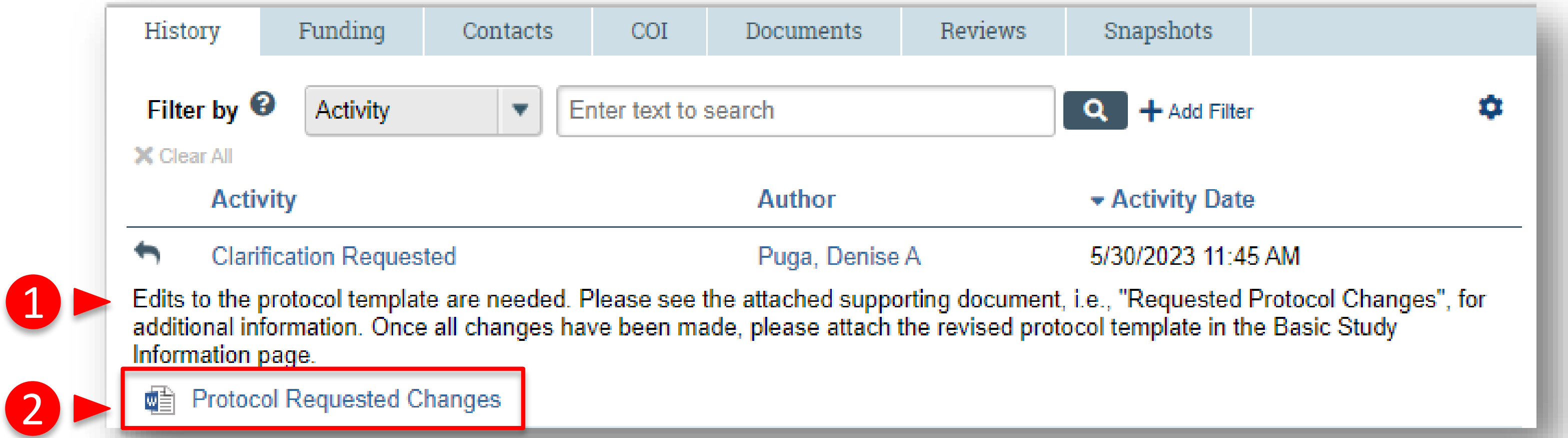
How to revise your protocol

During the review process, you may be asked to edit your protocol document. To do this:

1. Read the **clarification requested**: the request contains important information about what steps need to be completed.

2. Click the attached supporting document. This will automatically download a copy of the revised protocol to your computer.

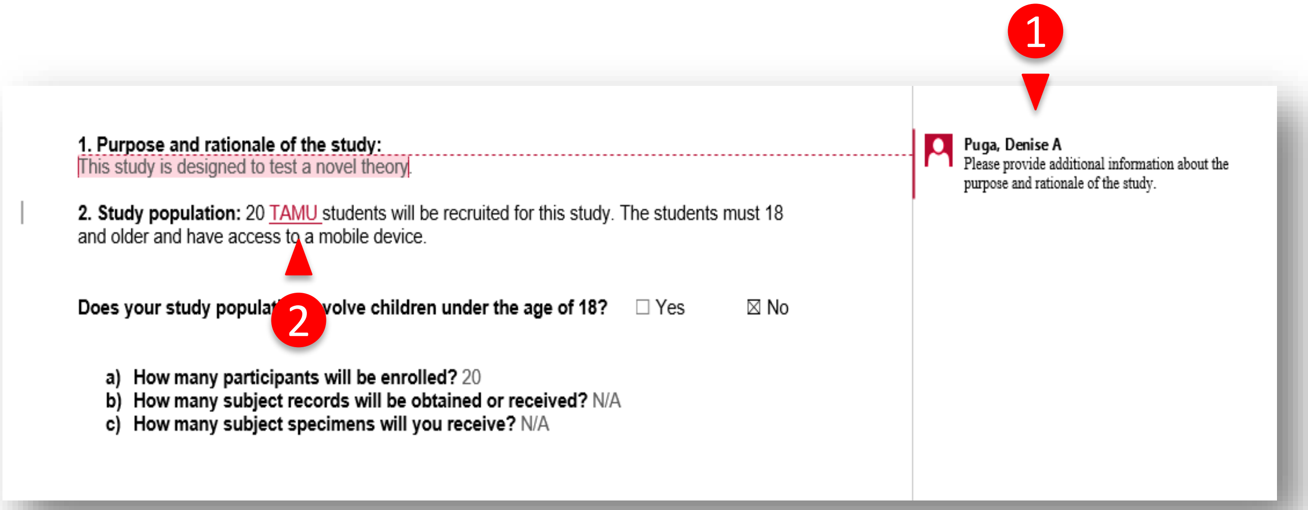
3. Open the downloaded document from your computer.



How to revise your protocol

The document provided by the IRB may include one or both of the following:

1. **Comments in the margin** requesting clarifications.
    - The comments will appear in the exact location on the Word document where the clarifications are being requested. Please provide the information being requested in the location indicated.
    - Use Track Changes to capture all edits to the protocol document. Instructions on how to use Track Changes in Word can be found **here**.
2. **Track Changes** suggesting edits.
    - Suggested track changes are intended to help clarify or enhance information presented in the protocol document. Please be aware that you have the option to either accept or decline the suggested edits.
    - Instructions on how to accept/decline tracked changes can be found **here**.



1. Purpose and rationale of the study:
This study is designed to test a novel theory

2. Study population: 20 TAMU students will be recruited for this study. The students must 18 and older and have access to a mobile device.

Does your study populat... volve children under the age of 18? ☐ Yes ☒ No

a) How many participants will be enrolled? 20
b) How many subject records will be obtained or received? N/A
c) How many subject specimens will you receive? N/A

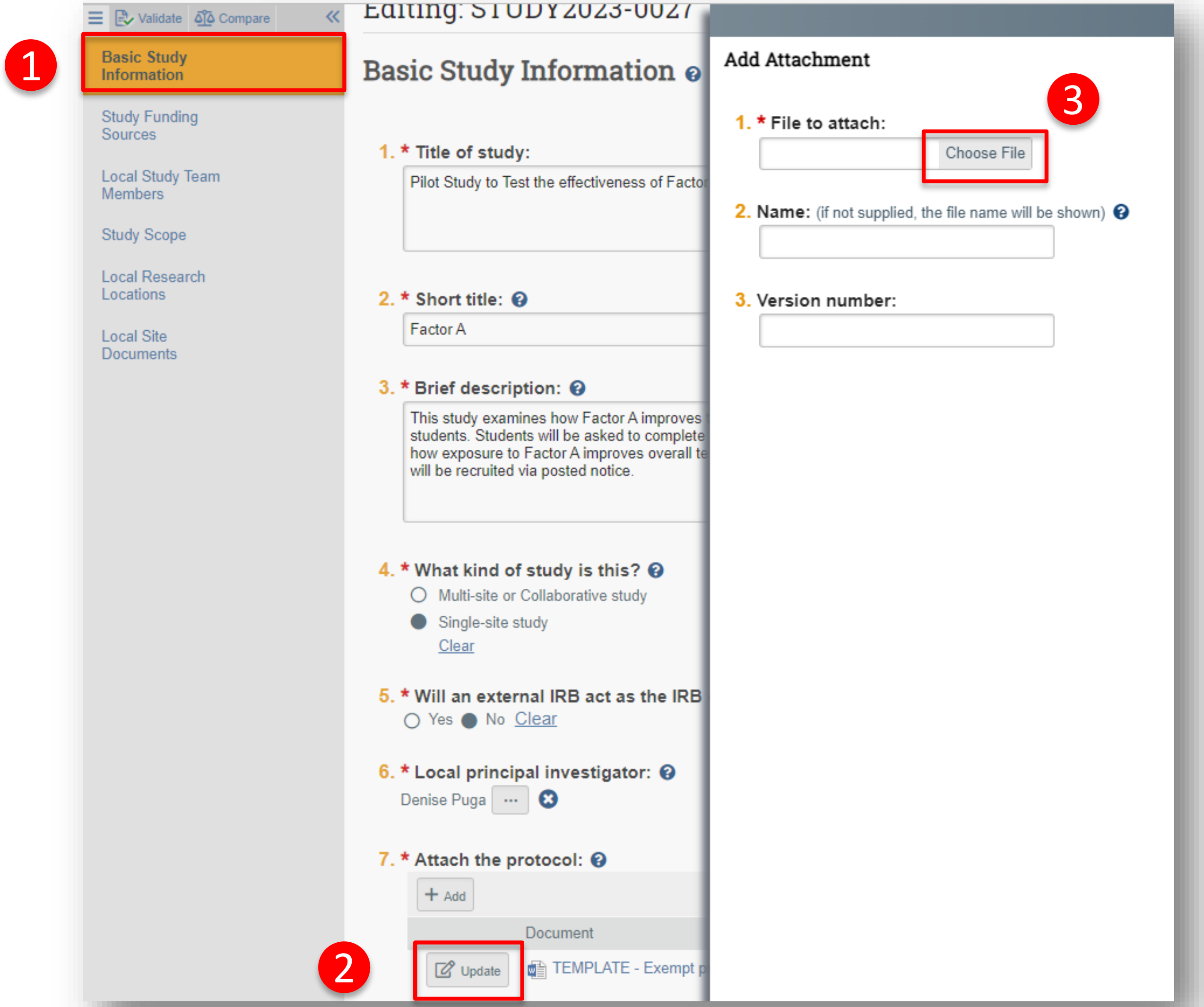
Puga, Denise A
Please provide additional information about the purpose and rationale of the study.

How to attach your revised protocol

Once you have finished editing your protocol and have addressed all the requests for clarifications, save a copy of the revised protocol document for your files and upload a copy to your initial application in Huron.

How to upload your revised protocol document:

1. Navigate to the **Basic Study Information**. To do this, click *Edit Study* from the study workspace.
    - *Note:* You may revisit **Slide 5** for instructions on how to complete this task.
2. Click **Update** under ***Attach the protocol*** (i.e., the last question on the page).
3. Click **Choose File** to attach the revised protocol document.
4. Click **OK**



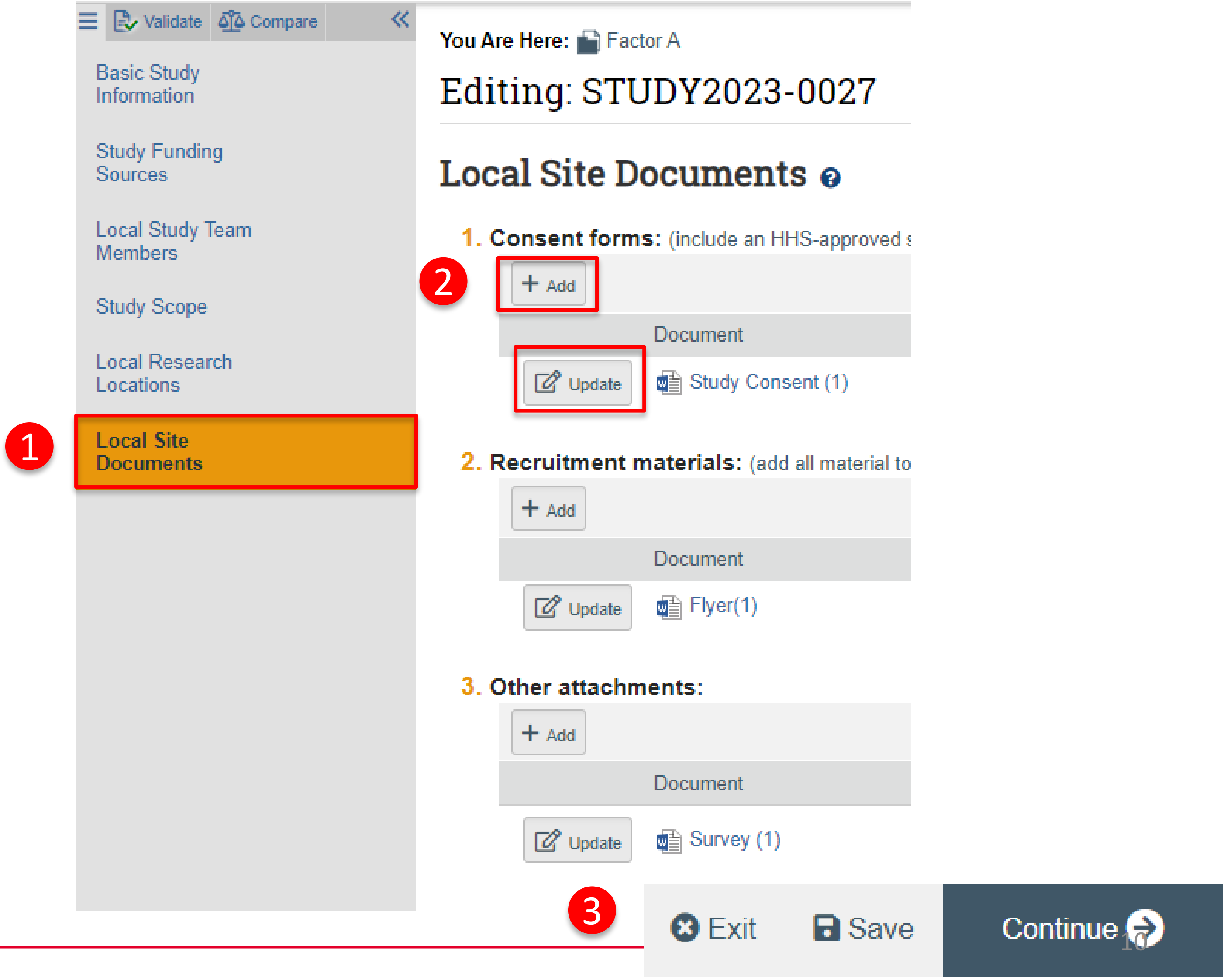
How to attach new or revised study documents

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
   - Note: You may revisit **Slides 5 and 6** for instruction on how to complete this task.

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.



Submit response to the IRB

1. Click **Submit Response** from the Study Workspace

2. The **Submit Response** smart form will appear. Use this form to provide the IRB with any additional comments or documentation.

3. Click **OK**
   - Note: Once OK is selected, your response will immediately appear in the History tab and it will be available to all with access to the submission.