Not Human Subjects Research

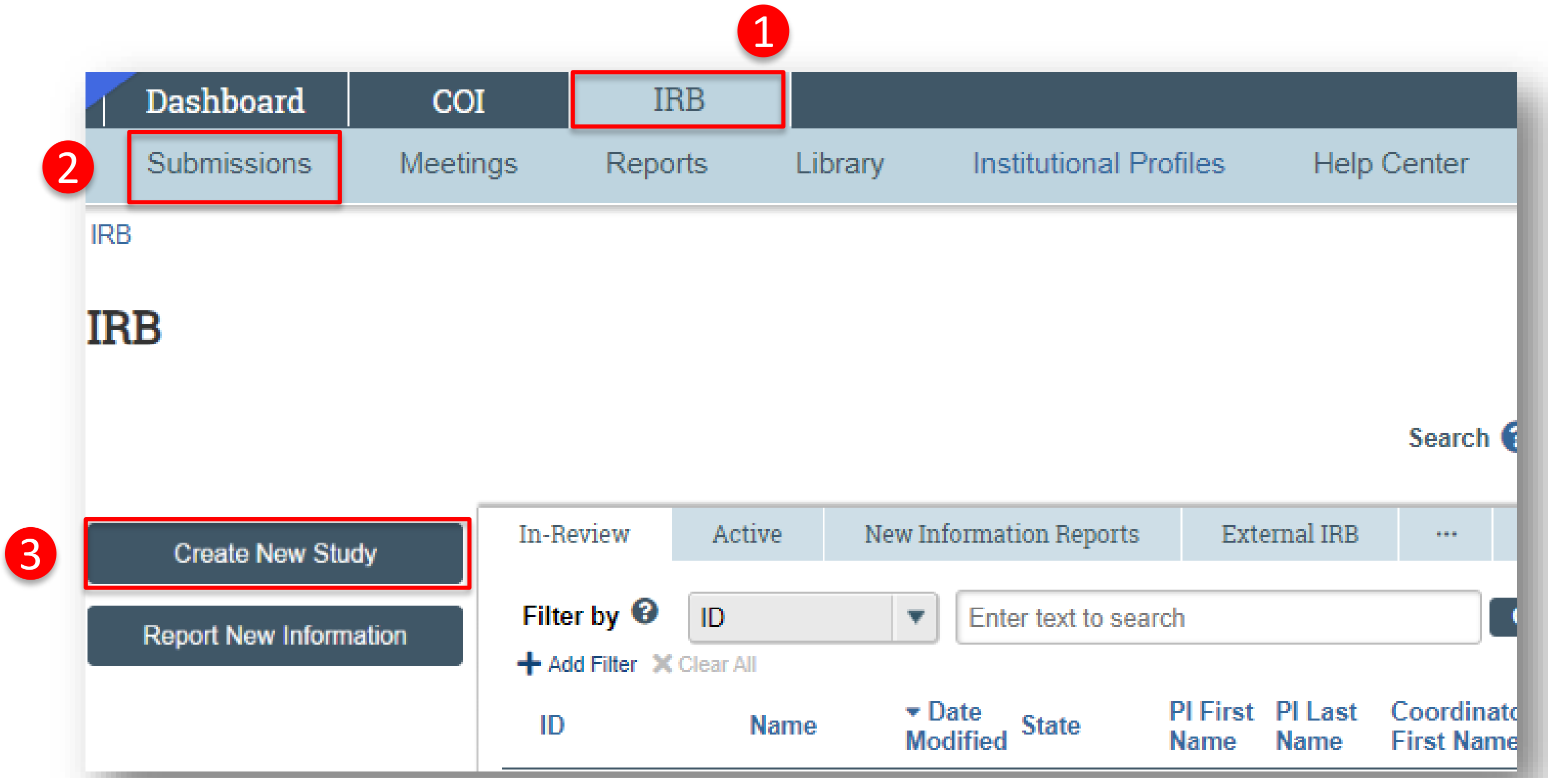
Human Research Protection Program

TEXAS A&M UNIVERSITY

This PowerPoint will guide you through how to submit a Not Human Subjects Research determination.

Getting Started

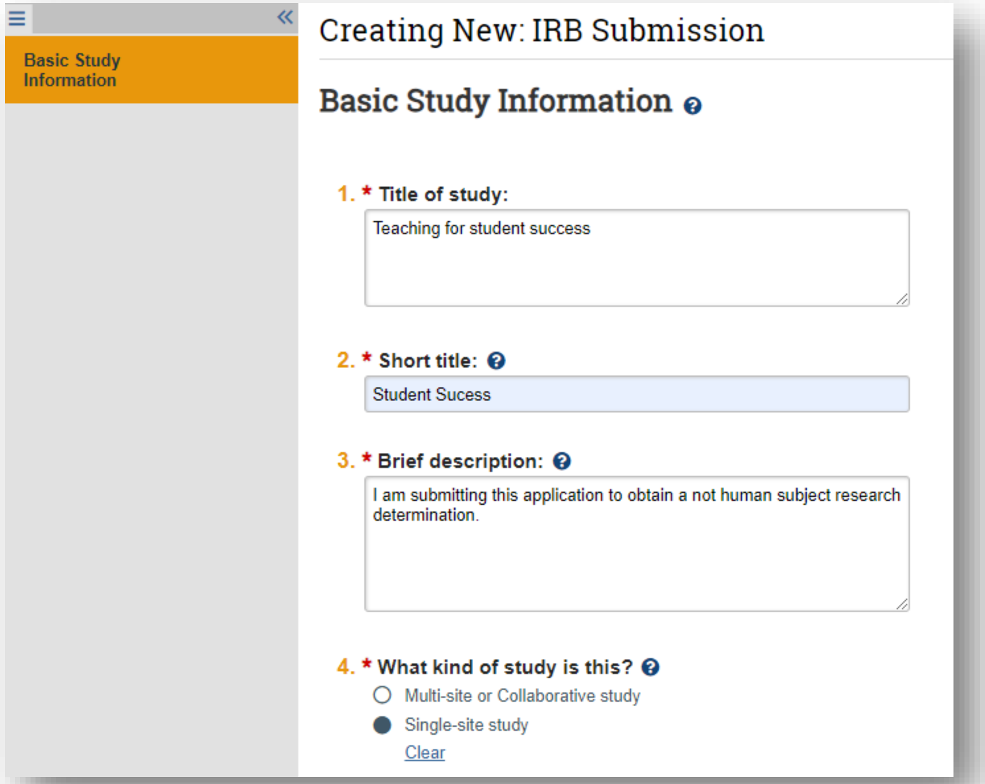
1. Navigate to the **IRB** workspace
2. Select **Submissions** tab
3. Click **Create New** Study



Complete the Basic Study Information page

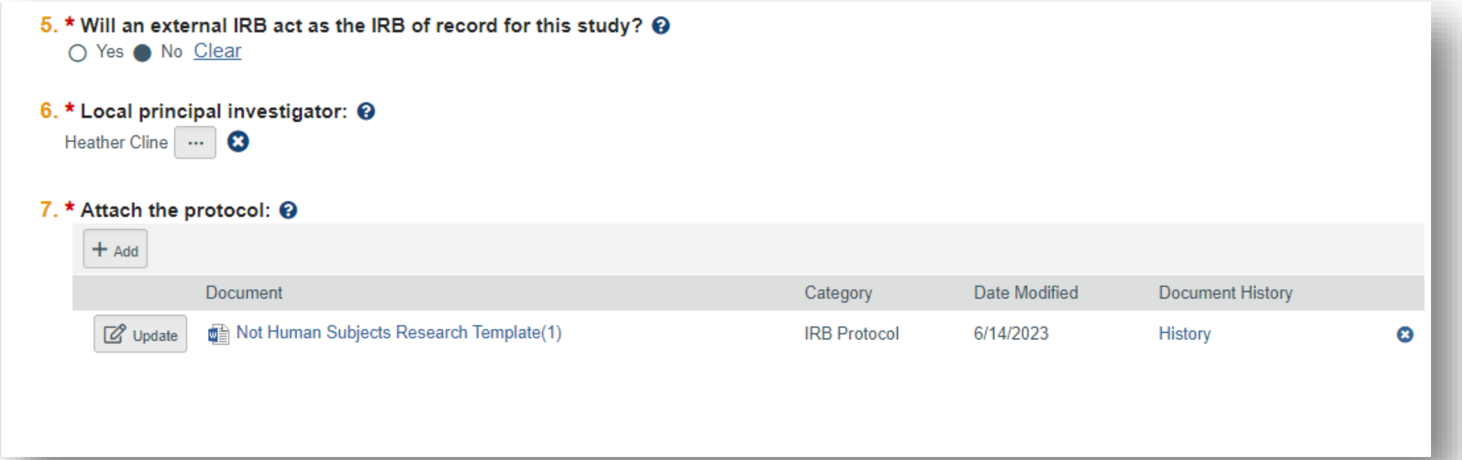
- ❑ When completing the **Basic Study Information:**
  - All questions marked with a red asterisk (*) require a response.

- ❑ **Important instructions** for completing the Basic Information page (***Note:*** *these instructions are* *only* *to be used when requesting a Not Human Subjects Research determination*):
  - **Q1** – Provide the title of the project
  - **Q2** – Provide the short title of the project
  - **Q3** – Indicate that the purpose of the submission is to obtain a not human subjects research determination
  - **Q4** – Select ***Single-site study,*** *even if the project involves multiple institutions, and/or collaborators.*



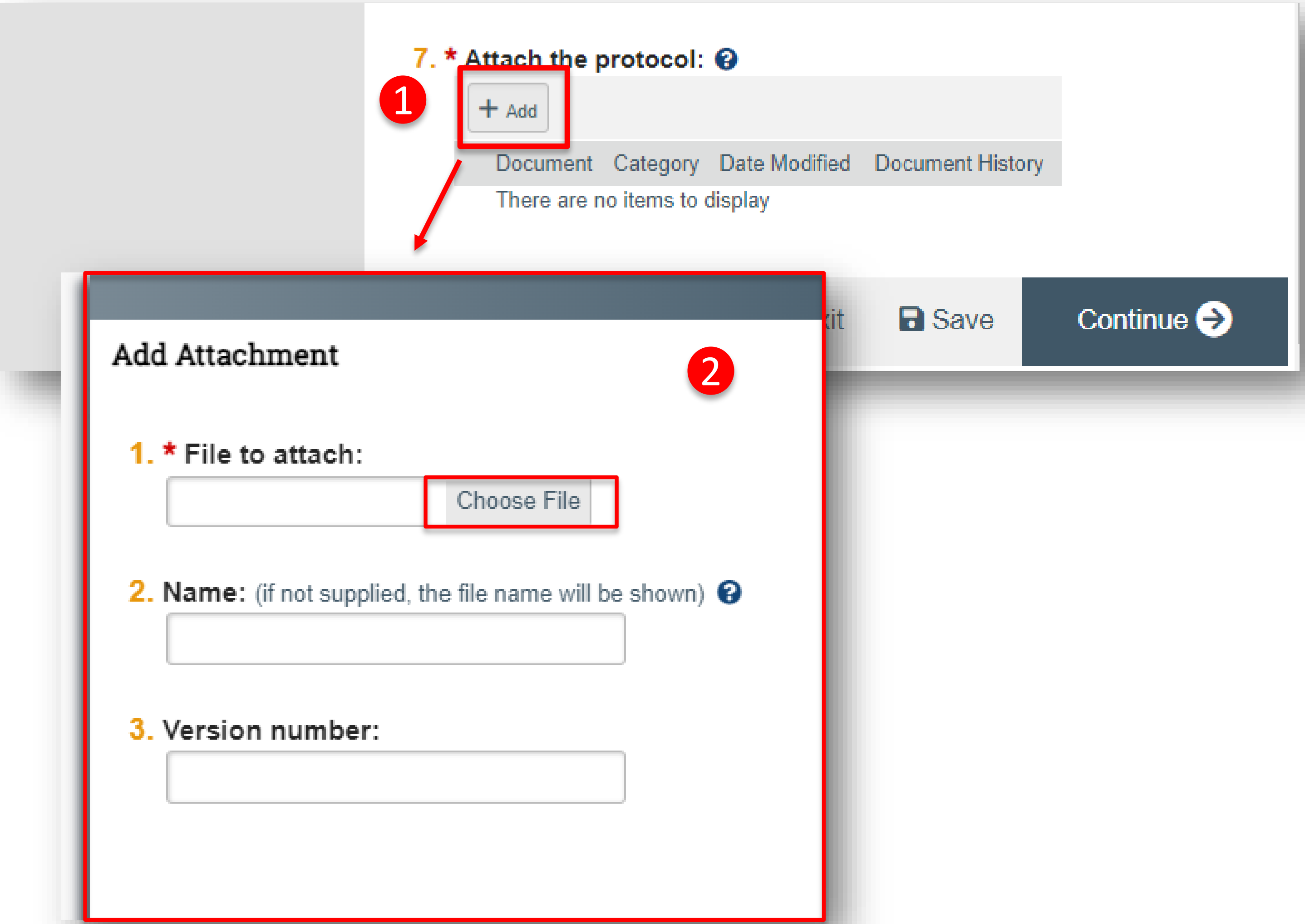
Complete the Basic Study Information page continued

- **Important instructions** for completing the Basic Information page (***Note:*** *these instructions are* <u>*only*</u> *to be used when submitting a Not Human Subject Research request*):
  - **Q5** – Select ***No***, *even if an external IRB has previously issued a determination on this project.*
  - **Q6** – Identify the TAMU principal investigator
  - **Q7** – Attach the completed Not Human Subjects Research protocol template:
    1. The Not Human Subjects Research protocol template can be found **[here](#)**.
    2. Complete the template and attach it to the Huron submission.
    3. Instructions on how to attach the Not Human Subjects Research request to the submission can be found on the next slide.



How to attach the Not Human Subjects Research Template

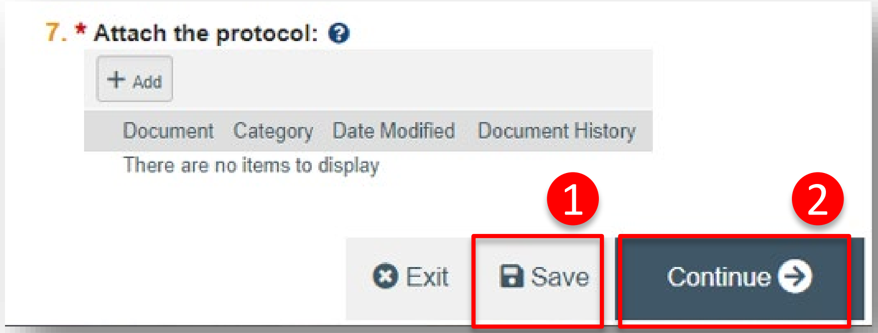
1. Click **+Add** in Question 7 of the Basic Study Information page
2. Click **Choose File** to locate the desired document from your desktop
3. Click **OK**



The Not Human Subjects Research template can be located on the HRPP website: https://vpr.tamu.edu/human-research-protection-program/toolkit/templates/

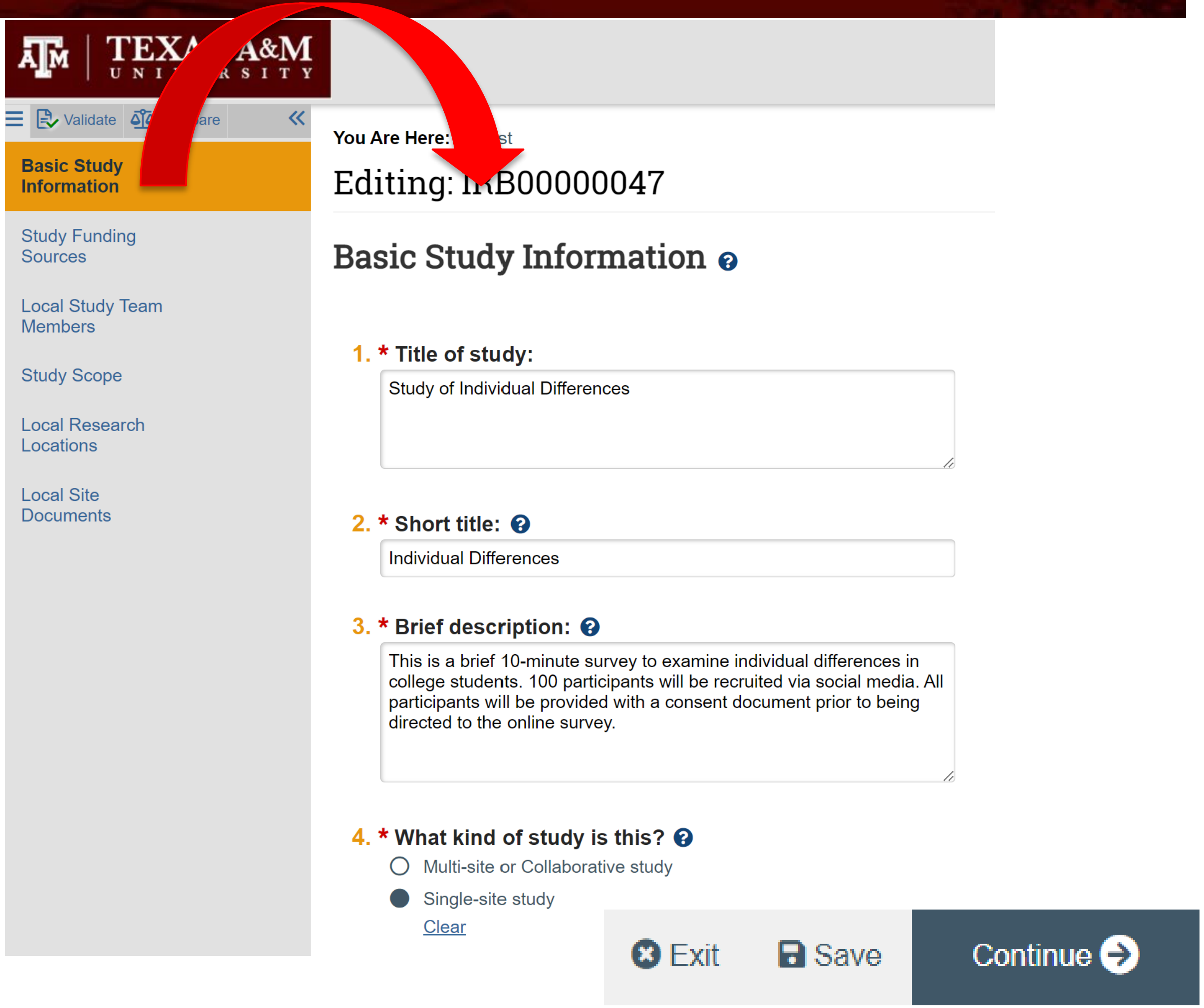
Saving your work

1. Click **Save**
2. Click **Continue** to navigate to the next page of the application



Navigate the IRB Application

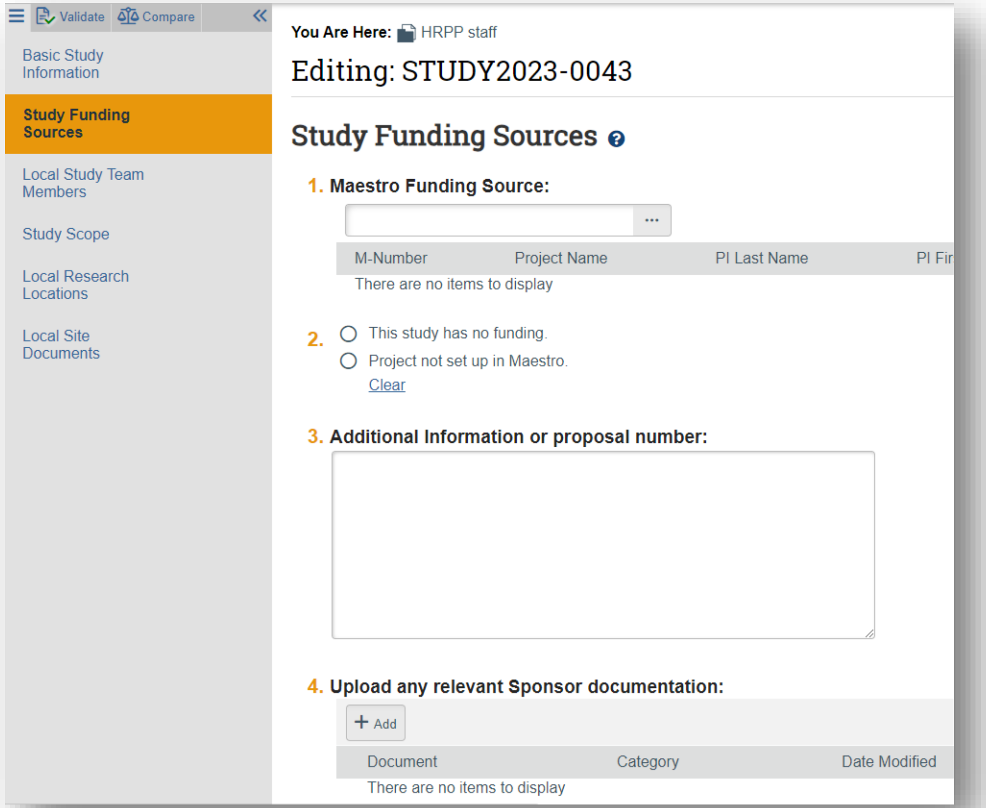
The **Page Navigator** is located on the left side of the screen, and it allows the user to switch between the main pages of the IRB application. The page currently being viewed will be shown highlighted in orange.



Study Funding Source Page

- If your study is not *externally* funded, simply select **This Study has no funding** on question 2 and click **Continue** to navigate to the next page.
- **If your study is funded:**

1. **Q1** – List any grant proposal or contract routed via Sponsored Research for this study. To search for funding in the space provided, begin typing the Maestro number, grant sponsor, or the grant PI full name (first and last name), a list will appear with options from which to select.
2. **Q2** – If the project has not yet been set up in Maestro, or the project is not pulling in Maestro Funding Source, select **Project not set up in Maestro** and provide additional funding information in Q3.
3. **Q3** – If funding information is not available in Maestro Funding Source, provide sponsor and grant information (e.g., grant title, m number, sponsor number).
4. **Q4** – Attach a copy of the funding application, contract, agreement, or sponsor correspondence (e.g., just in time notice) for the listed funded sources.

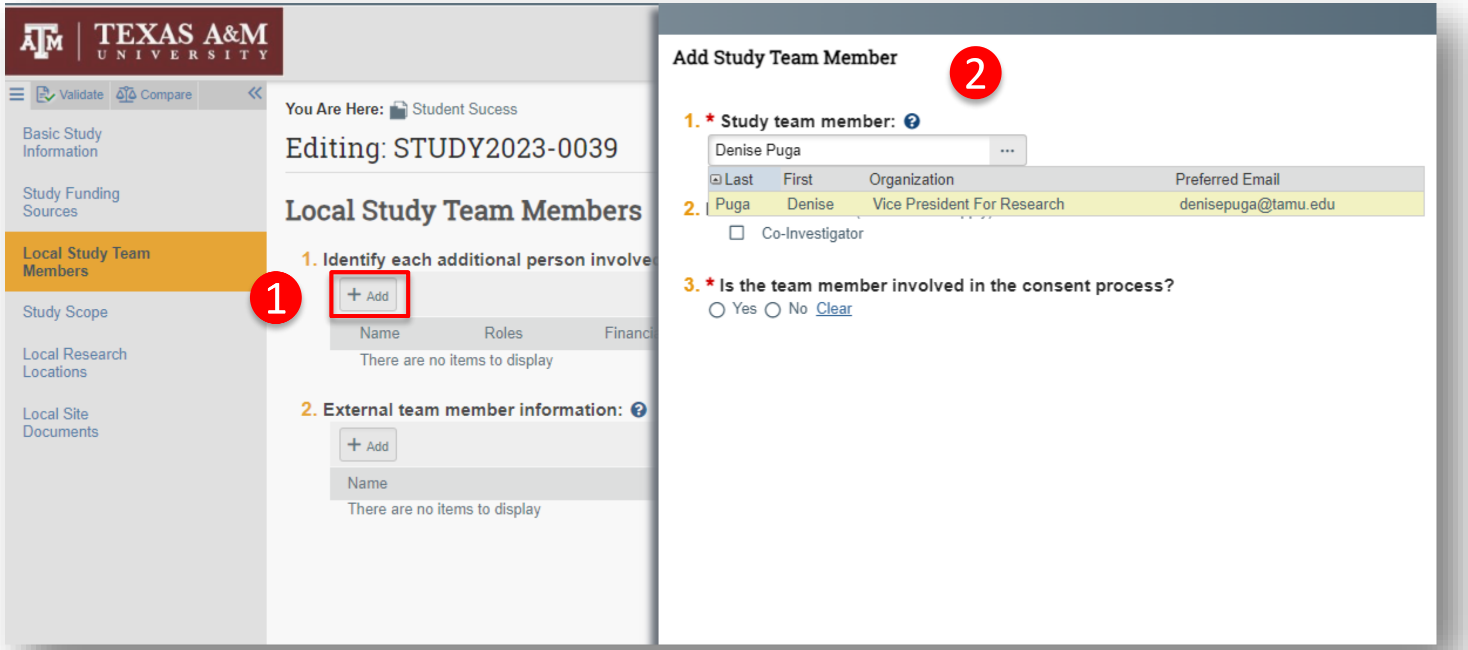


Adding Local Study Team

NOTE: Completing this page is optional when requesting a not human subjects research determination

Identify all the individuals involved in this project:

1. Click **+Add** (Q1 for TAMU personnel)
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.
3. Click **OK**
4. Click **Save** and then **Continue**



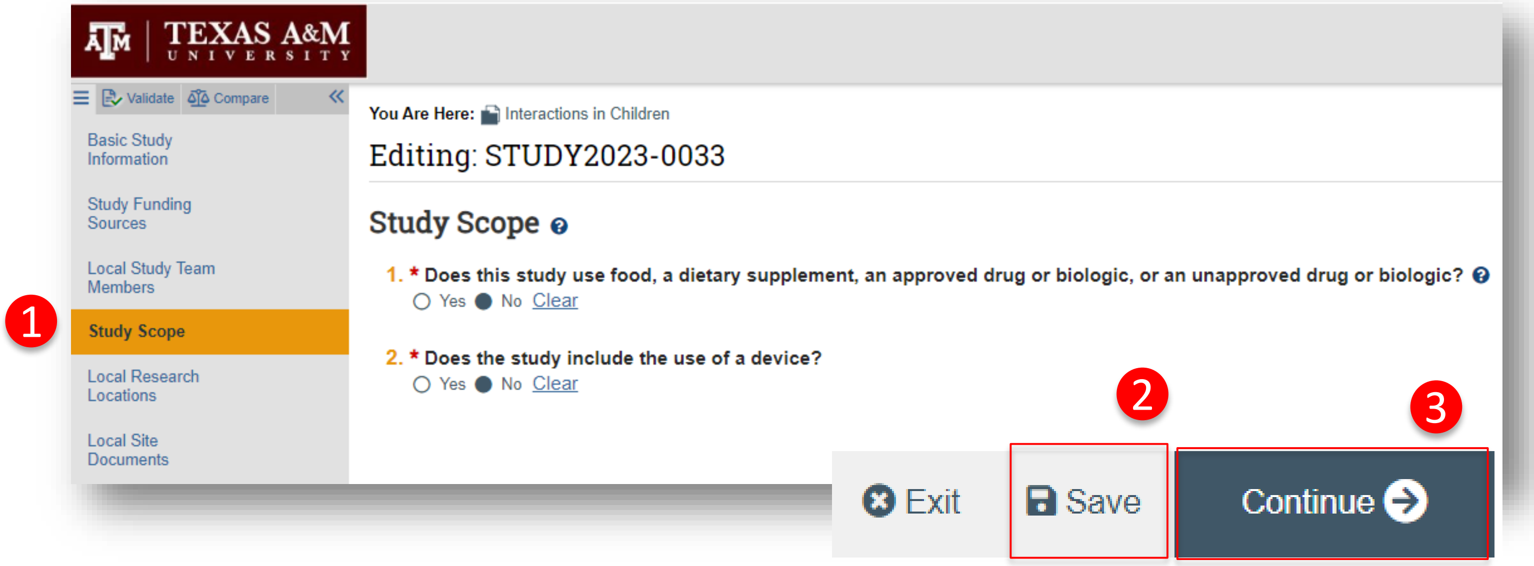
Study Scope

1. Complete the **Study Scope** (*Note: these instructions are <u>only</u> to be used when requesting a Not Human Subjects Research Determination*):

    1. **Q1** – Select ***No***, even if your project involves the use of food, a dietary supplement, an approved drug or biologic, or an unapproved drug or biologic.

    2. **Q2** –Select ***No*,** even if your project includes the use of a device

2. Click **Save**
3. Click **Continue**



Adding Study Location

To add the location(s) where the research will take place:

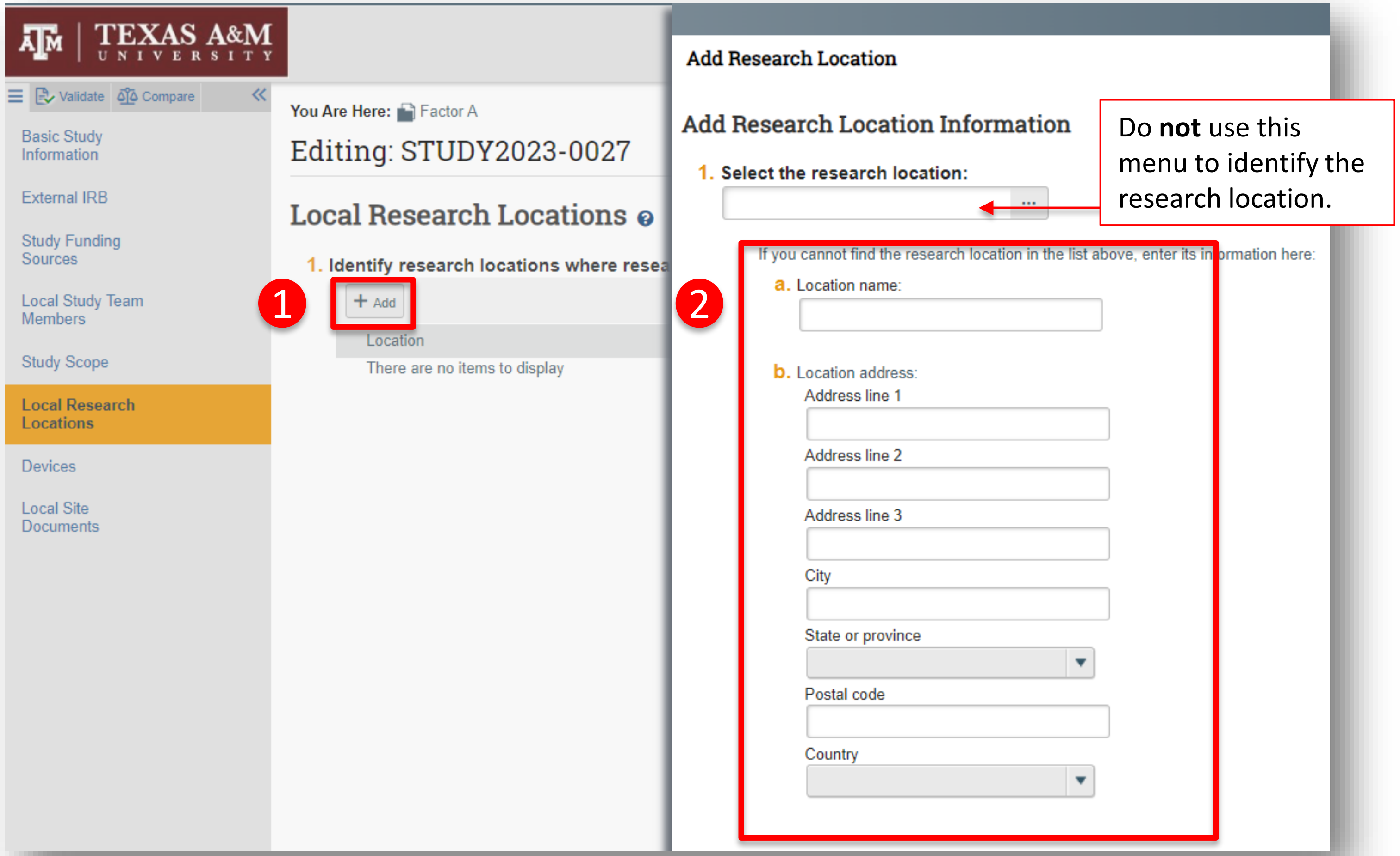
1. In the **Local Research Locations** page, select **+Add**

2. Type in the name and address of the research location

   IMPORTANT! The drop-down menu is not loaded and will NOT populate location information. The name and address of the research location must be entered manually.

3. Click **OK**

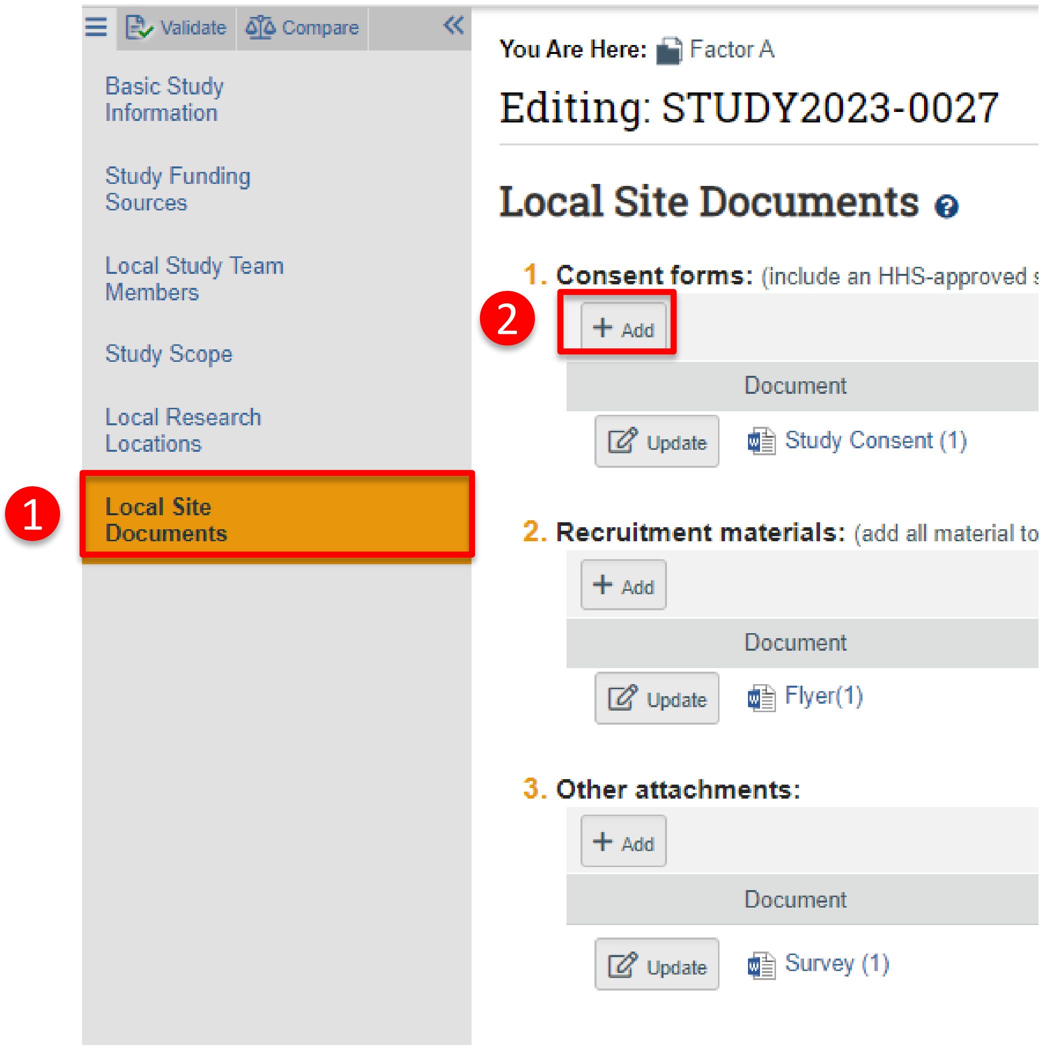
4. Click **Save** and then **Continue**



How to attach supporting documents

To add supporting documents (such as surveys, interview questions, and data lists) :

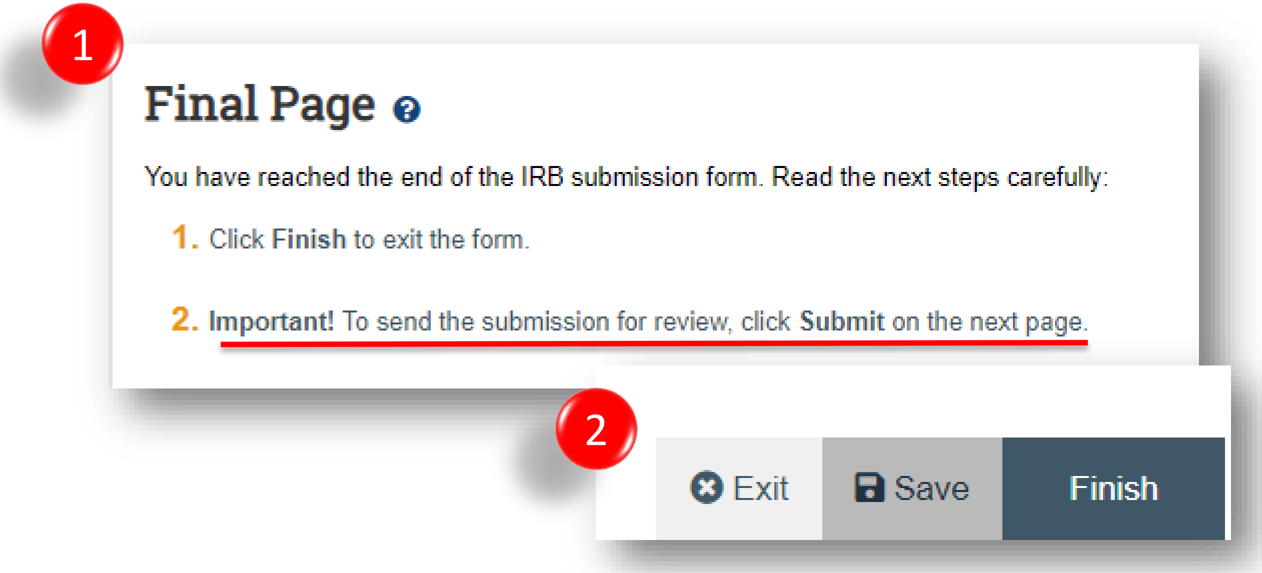
1. Navigate to the **Local Site Document** page
2. Click **+Add** to attach supporting documents.
   - Note that there is a designated area for consent forms (Q1), recruitment materials (Q2), and other attachments (Q3). Ensure that you attach your supporting documents to the correct location.
3. Click **Save** and **Continue**



Submitting the Application to the IRB

1. After clicking **Continue** on the **Local Site Documents** page, you will land on the **Final Page.**
2. Follow the instructions on this page by clicking **Finish** to exit the form.

Important! Clicking **Finish** does not send the submission to the IRB. When the study is ready for IRB review, the PI or proxy must submit from the study record workspace.



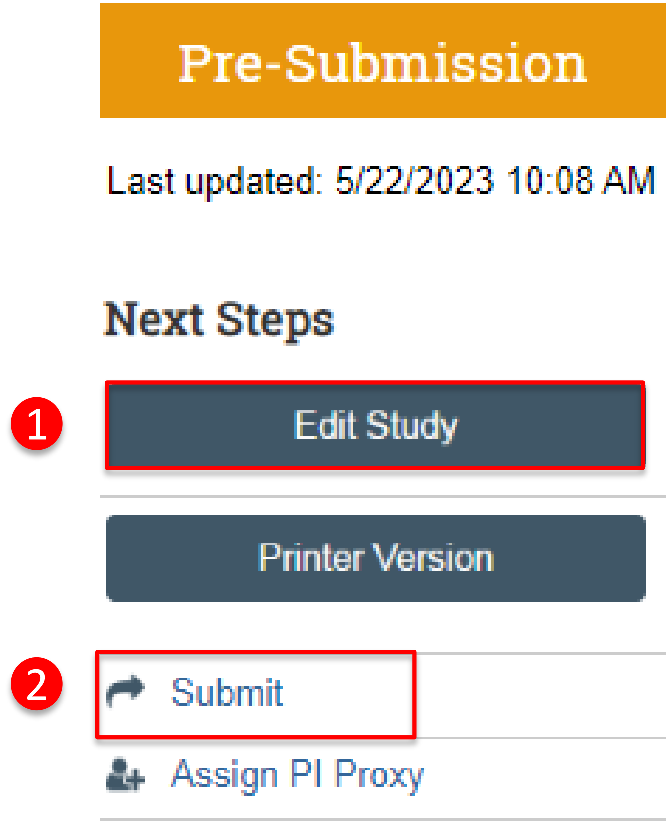
Submitting the Not Human Subject Research request to the IRB

1. The PI can continue to edit the application by clicking the **Edit Study** button, until the application is submitted to the IRB.

2. Click **Submit** to route the application to the IRB.

   IMPORTANT! Only the PI/PI Proxy can submit to the IRB. The **Submit** button will not be visible in the study workspace of any other individuals listed as study personnel.

3. Click **OK**



Once your submission is processed by the IRB, you may receive a request for clarifications. Instructions for how to respond to requests for clarification in Huron can be found **[here](#)**.