Submitting a new study in Huron

Human Research Protection Program

(Last Updated: 01/29/2024)

This PowerPoint will guide you through how to submit a *new* initial application in Huron.

Before getting started:

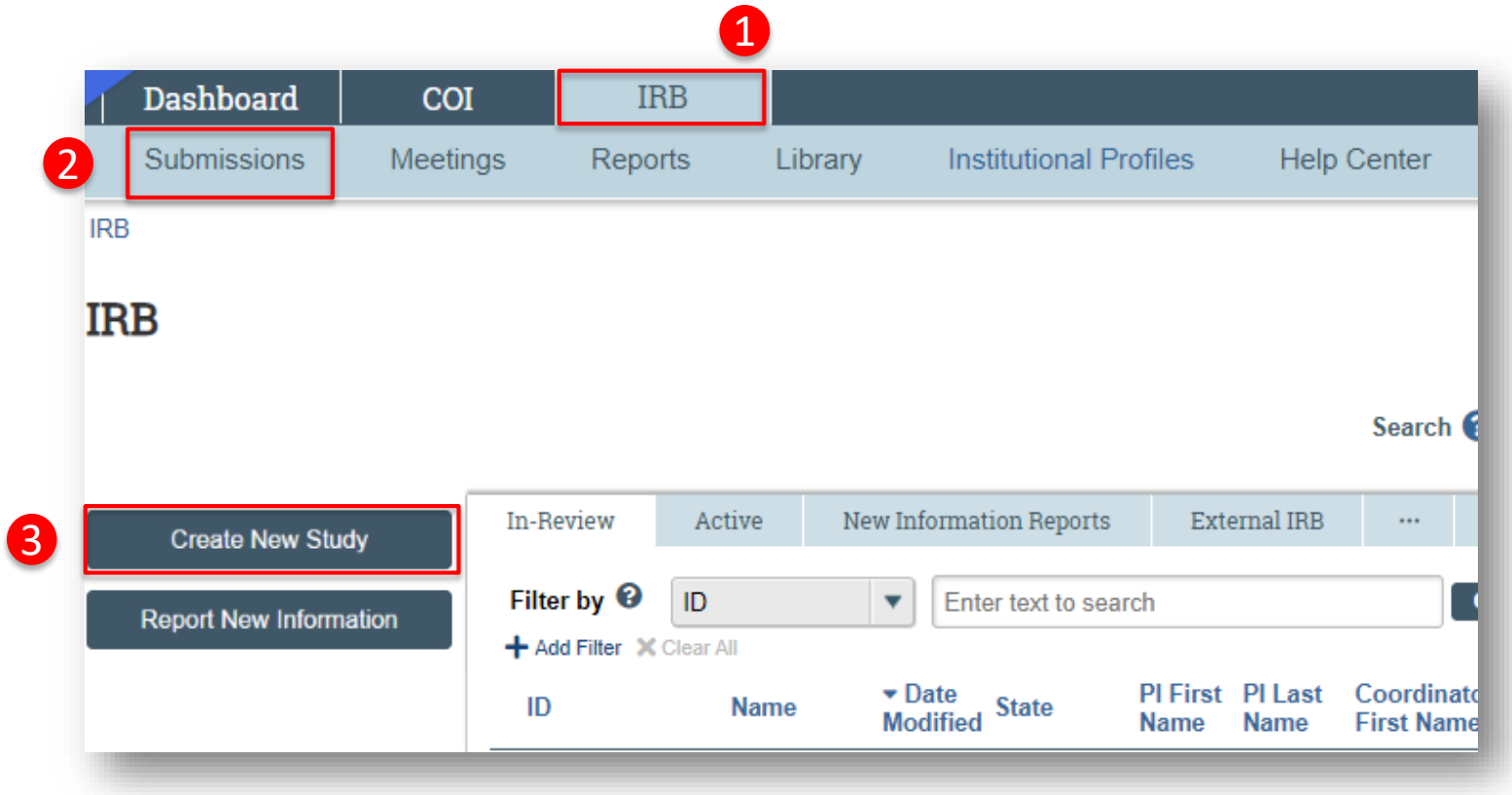
1. **You must complete your study protocol!** Study protocol templates are located on the **HRPP website**.
   IMPORTANT! Grant proposals, sponsor proposals, dissertation and thesis proposals may ***not*** be used to fulfill this requirement. You must attach your Word protocol document in the first page of your IRB application in Huron.

2. **Gather all your study documents.** You will need to submit ***all your study documents*** at the time of initial review. This includes, but is not limited to, your consent document, recruitment materials, data gathering instruments, site authorization letters, and grant proposal. Click **here** for a comprehensive list of supporting documents.

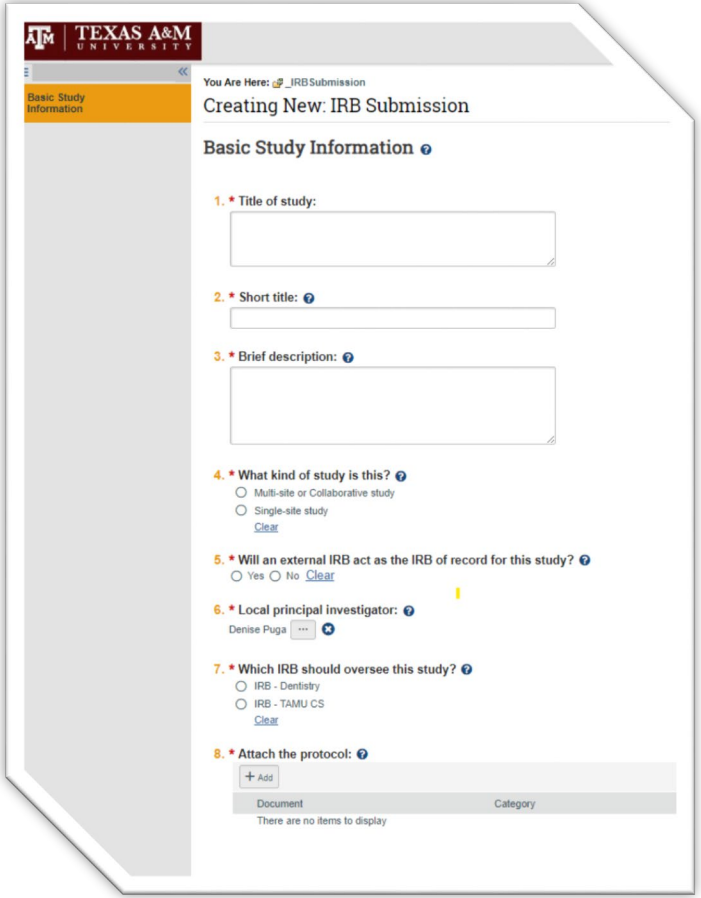
3. **Learn the basics of how to navigate Huron**. A brief PowerPoint presentation can be found **here**. It will walk you through some basic steps for navigating the Huron Dashboard, IRB Workspace, and Study Workspace.

Getting Started

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



Basic Study Information Page



All questions marked with a red asterisk (*) require a response.

Note: This page has branching logic that may cause additional questions and pages to appear based on your responses.

Question guidance:

- **Title of study**. Enter the complete study title.
- **Short title**. The short title identifies the study throughout the system, such as in the Dashboard and in an IRB reviewer's list of submissions to review.
- **Brief description or abstract**. Enter a brief description of the study or the study abstract.
- **What kind of study is this?** Most studies conducted at TAMU are considered ***single-site studies***. This is true even when external personnel or institutions assist with data collection on behalf of TAMU. If you believe your study is a ***multi-site or collaborative study***, please contact your **IRB coordinator** before proceeding. Your IRB coordinator will assist you in determining if your study is truly a multi-site/collaborative study.

Basic Study Information Page continued

Question guidance:

- **Will an external IRB act as the IRB of record for this study?**
  - For a ***multi-site study or collaborative study***, select **Yes** if an IRB outside TAMU will review and approve this study. Selecting **Yes** will:
    - Generate additional pages on the IRB Application that need to be completed prior to submitting your study to the IRB.
    - Change Question 6 – Question 6 will now ask for the name of the **Lead Investigator**. If the lead investigator is not a member of TAMU, leave blank.

IMPORTANT! Contact your **IRB coordinator** to identify if TAMU is willing to rely on another institution for IRB review for this study before proceeding with your application.

Basic Study Information Page continued

Question guidance:

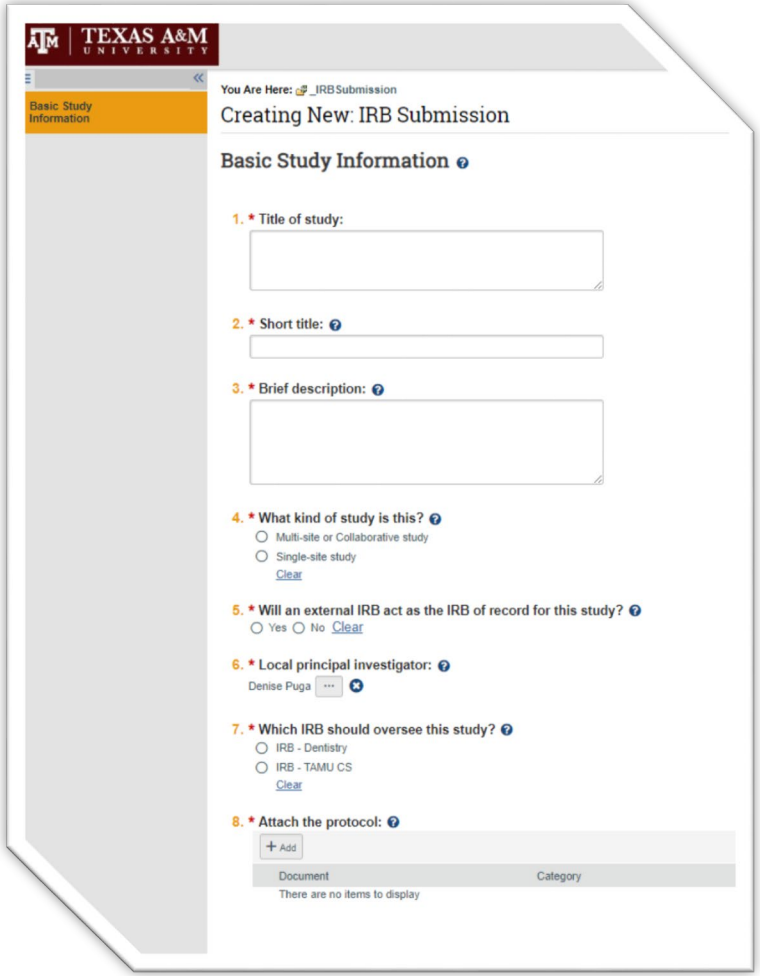
- **Will your IRB act as the single IRB of record for any other participating sites?** (*Only displays if question 4 is marked "Multi-site or Collaborative" AND question 5 is marked "no")*:

  - Select **Yes** if you are submitting an application requesting that TAMU IRB review on behalf of another institution or IRB.
  - Select **No** if you are sure that additional sites will complete their own review of the study.

- **Local Principal Investigator**. For details on who may be listed as Principal Investigator, please visit the Investigator Manual.

- **"Which IRB should oversee this study?"** (*This questions is most likely to be Question 7, but not always.*)
  - Select which IRB should oversee the study, Texas A&M University IRB (**IRB – TAMU CS**) or the Texas A&M College of Dentistry IRB (**IRB – Dentistry**).

- **Attach the protocol**: Always add a WORD version of the protocol document. Click here to access the TAMU protocol templates.

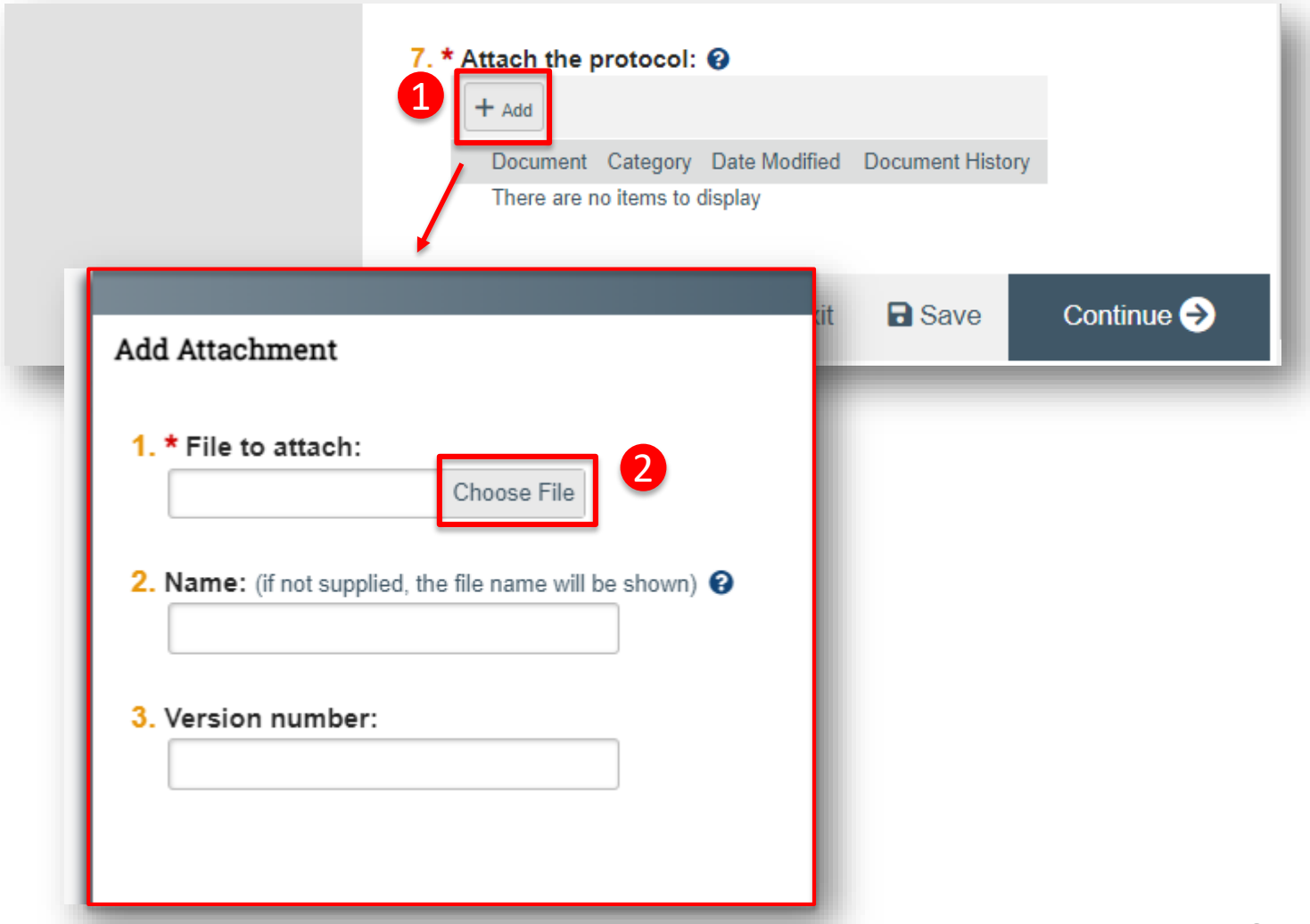


Go to the next slide to learn how to attach your study protocol.

How to attach the Study Protocol

1. Click **Add+** under **Attach the protocol**
2. Click **Choose File** to select your desired document from your desktop

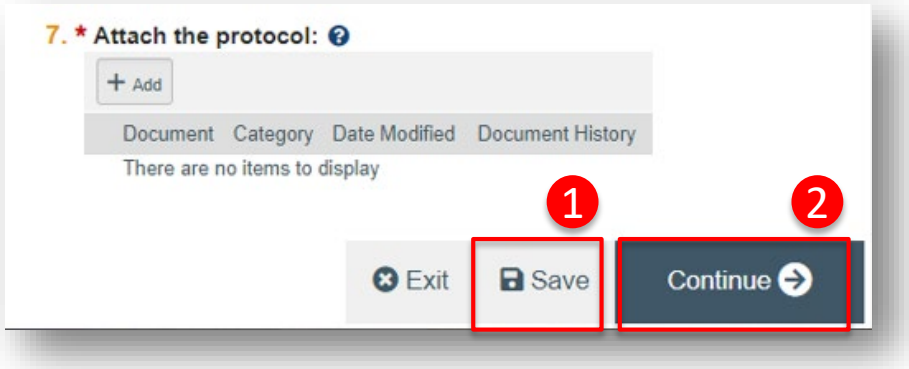
   Note: You will be given the opportunity to create a version number for your file; if one is not given, Huron will autogenerate one.
3. Click **OK**



Protocol templates 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

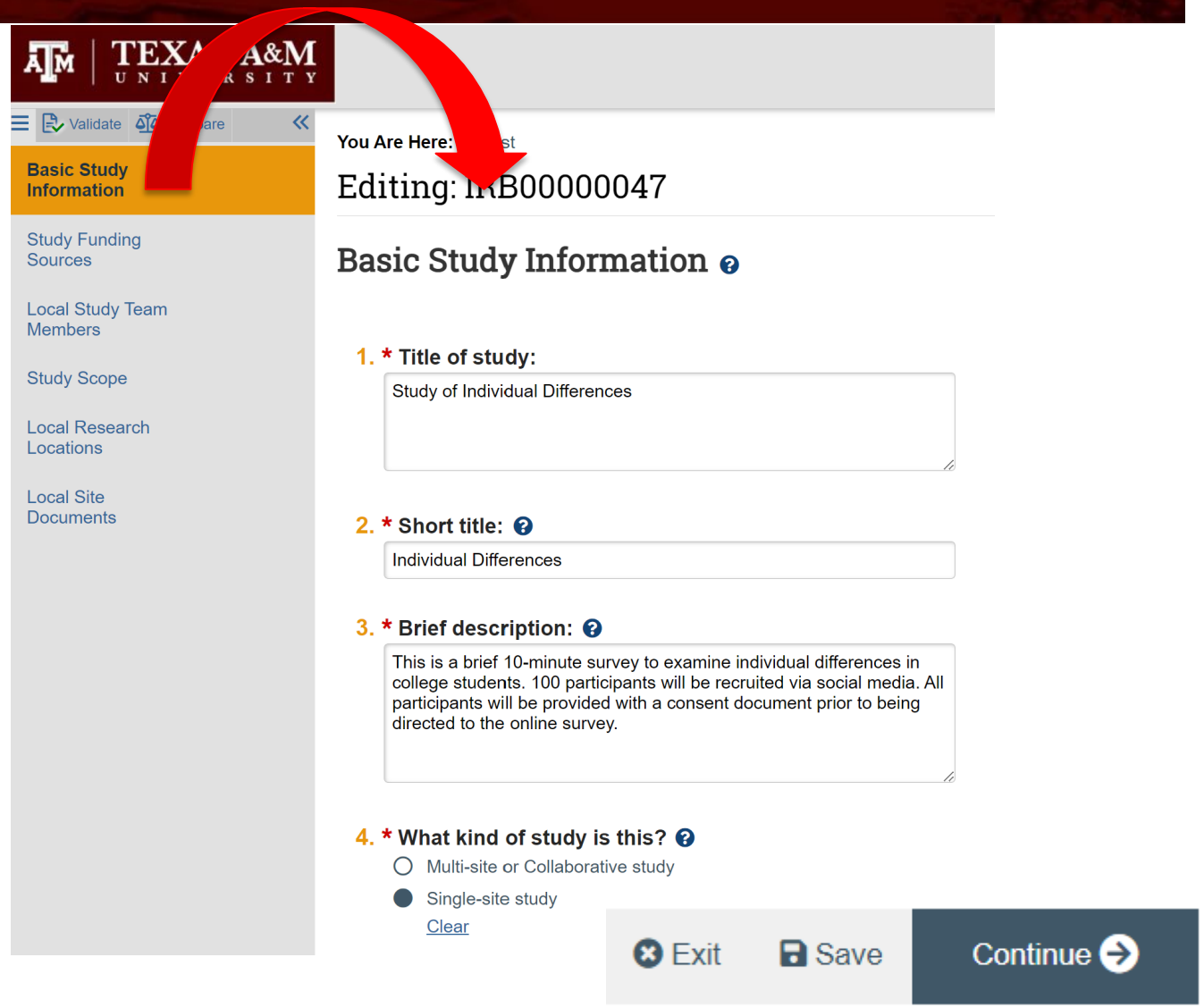


Navigate the IRB Application

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.

The simplest approach to completing your submission is to follow the pages in order, answering the questions and clicking **Continue** to save your information and move to the next form. When you reach the end of the series of forms, click the **Save** & **Exit** button.

Note: To save or exit a page at any time, click on Save and Exit button in the lower right of the page. Exit will take you to that submission's workspace.



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.

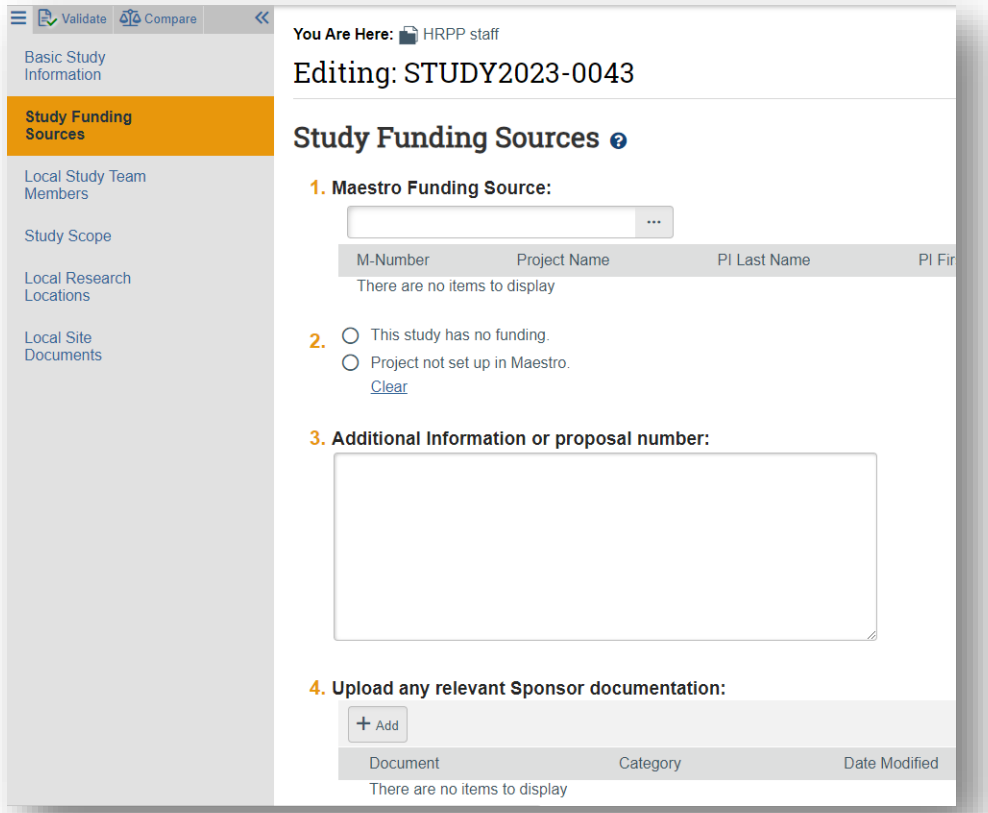
- **If your study is funded:**

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**.**



Local Study Team Members

In this section include the name of individuals that (a) have contact with human subjects, (b) have access to data that is identifiable, and/or (c) are responsible for the design, conduct, or reporting of the research.

You and all your study team members must log into the new Texas A&M SSO CITI URL.

- Complete this step even if your CITI training is up to date. This step permits your training information to feed into Huron.
- *IMPORTANT! Your submission will **not be delayed** if your CITI completion information is not feeding into Huron*. Your IRB coordinator will confirm you have completed the required CITI training by logging into the CITI website, and they will continue processing your application as normal.

If you have not yet complete your CITI training, click **here** for instructions on how to sign up for the required training.

Go to the next slide, to learn how to add and remove study personnel

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?

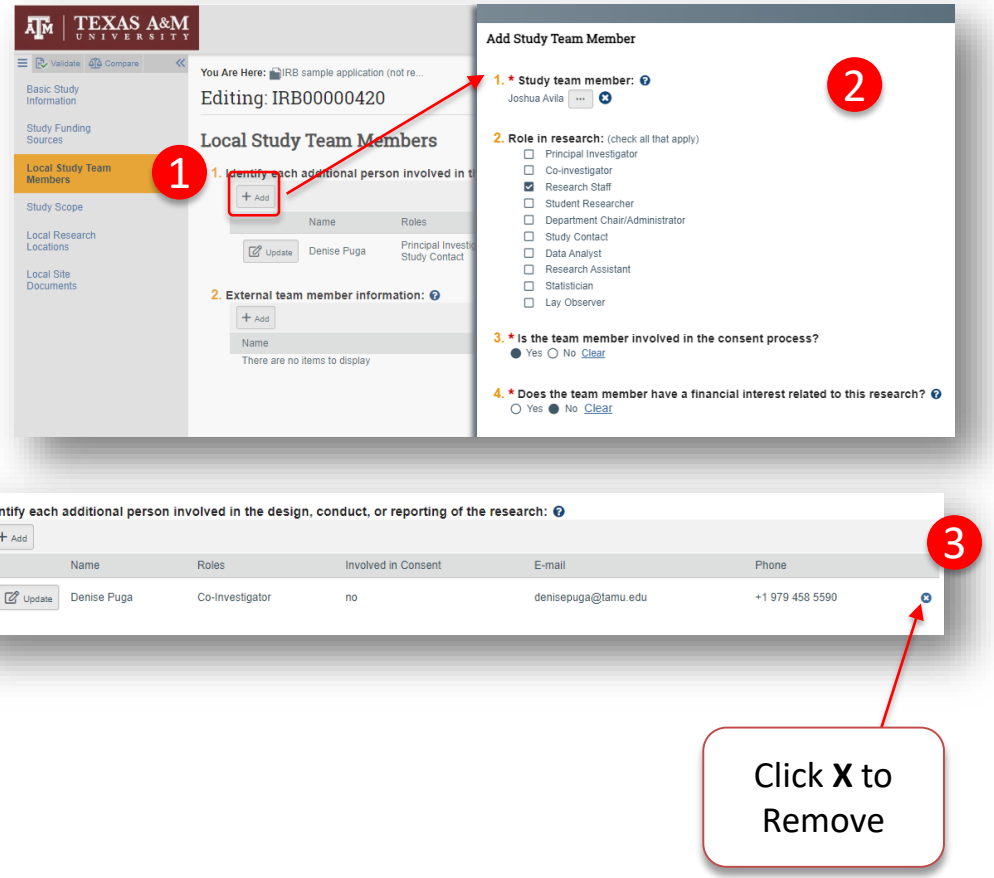
   Some TAMU members (such as undergraduates, visiting scholars, and adjunct/affiliate professors) need to opt into their information being fed into Huron before they are active in the system. If you are not able to locate a member of your research team, have that individual visit the following website: **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.



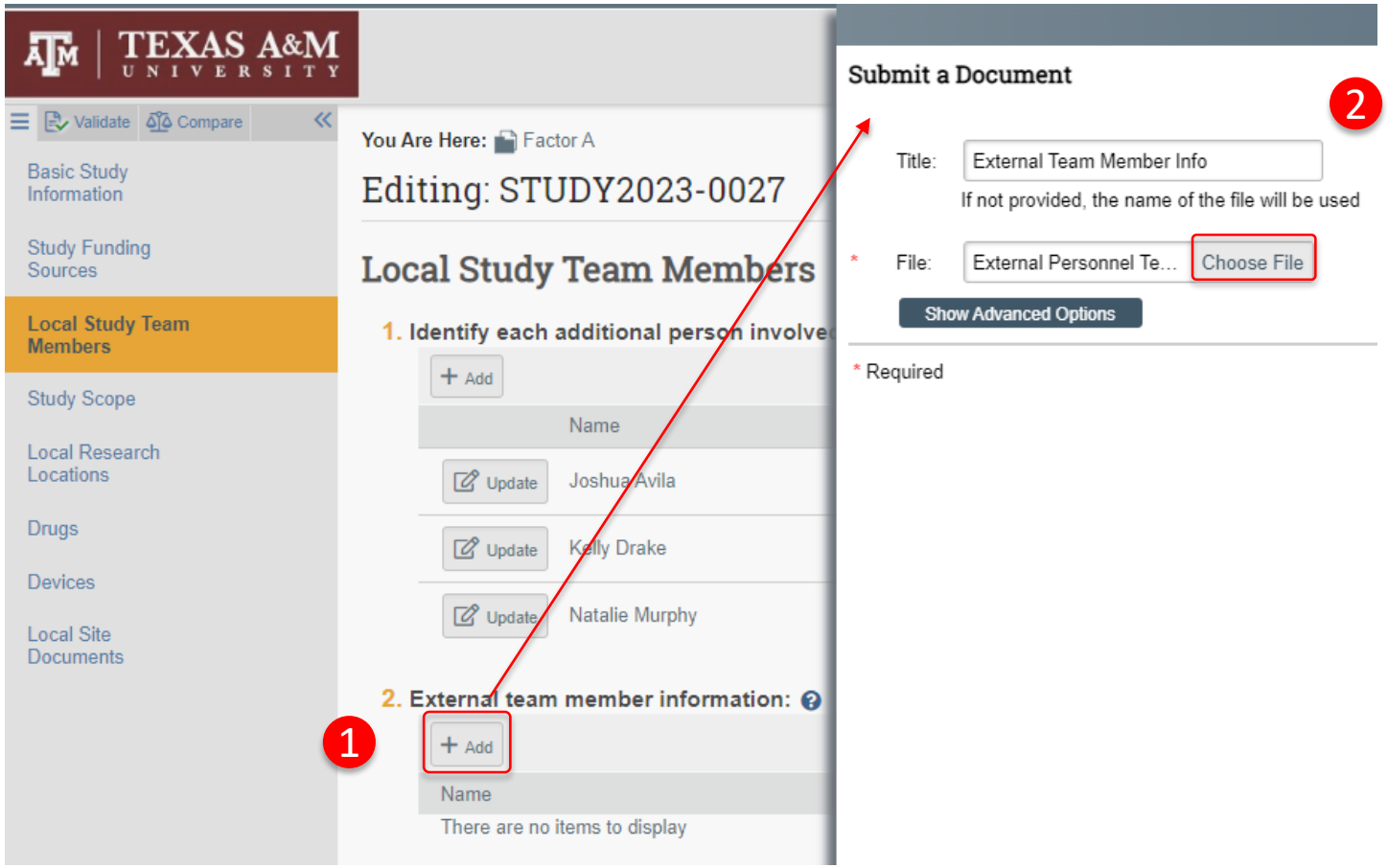
Slide added: 1/29/2024

Adding External Team Members (Single-Site)

Q2 – To add external personnel on **Single-site studies:**

Important! This option is only intended for single-site studies where data is being collected on behalf of TAMU. For multi-site studies, skip this option.

1. Click **Add+** under **External team member information**
2. Attach the completed External Personnel Template (found **here**; instructions on how to complete the template are provided in the READ ME-Instructions tab). The template should list every non-TAMU individual engaged in the research.



Study Scope

1. Select the correct answer(s) that apply to your protocol procedures.

   Note: If you select *yes* to Q1 and/or Q2, additional page(s) will appear on the left navigator. You will need to complete these pages.

The next 4 slides will cover what information needs to be provided in the Drugs and Devices pages. You may skip to Slide 20 these slides if they are not applicable to your study.

Drugs

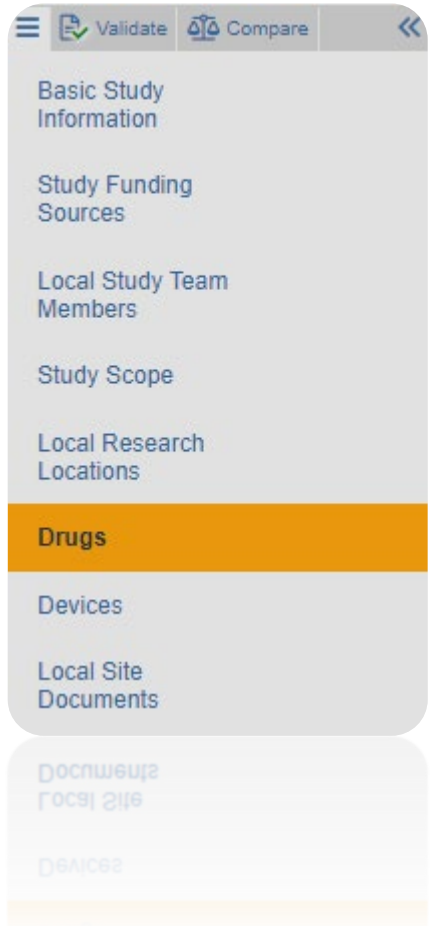
If your study includes the use of food, dietary supplements, an approved drug or biologic, or an unapproved drug or biologic, you will be asked to:

1. Identify all drugs, biologics, foods and dietary supplements (approved and unapproved) being used in the study, AND attach the current package insert (e.g., drug label, nutritional label) for each item listed.

2. Identify if the study evaluates the use of food, dietary supplements, an approved drug or biologic, or an unapproved drug or biologic to diagnose, cure, treat, or mitigate a disease or condition under an Investigational New Drug (IND). HRP 306 Worksheet Drugs and Biologics

3. If you have an IND number, you will be asked to attach one of the following documents:

    - Sponsor protocol with the IND number
    - Communication from the sponsor with the IND number; or
    - Communication from the FDA with the IND number.



Instructions for entering study drug information can be found on the next slide.

Entering Drug Information

To add study drug(s):

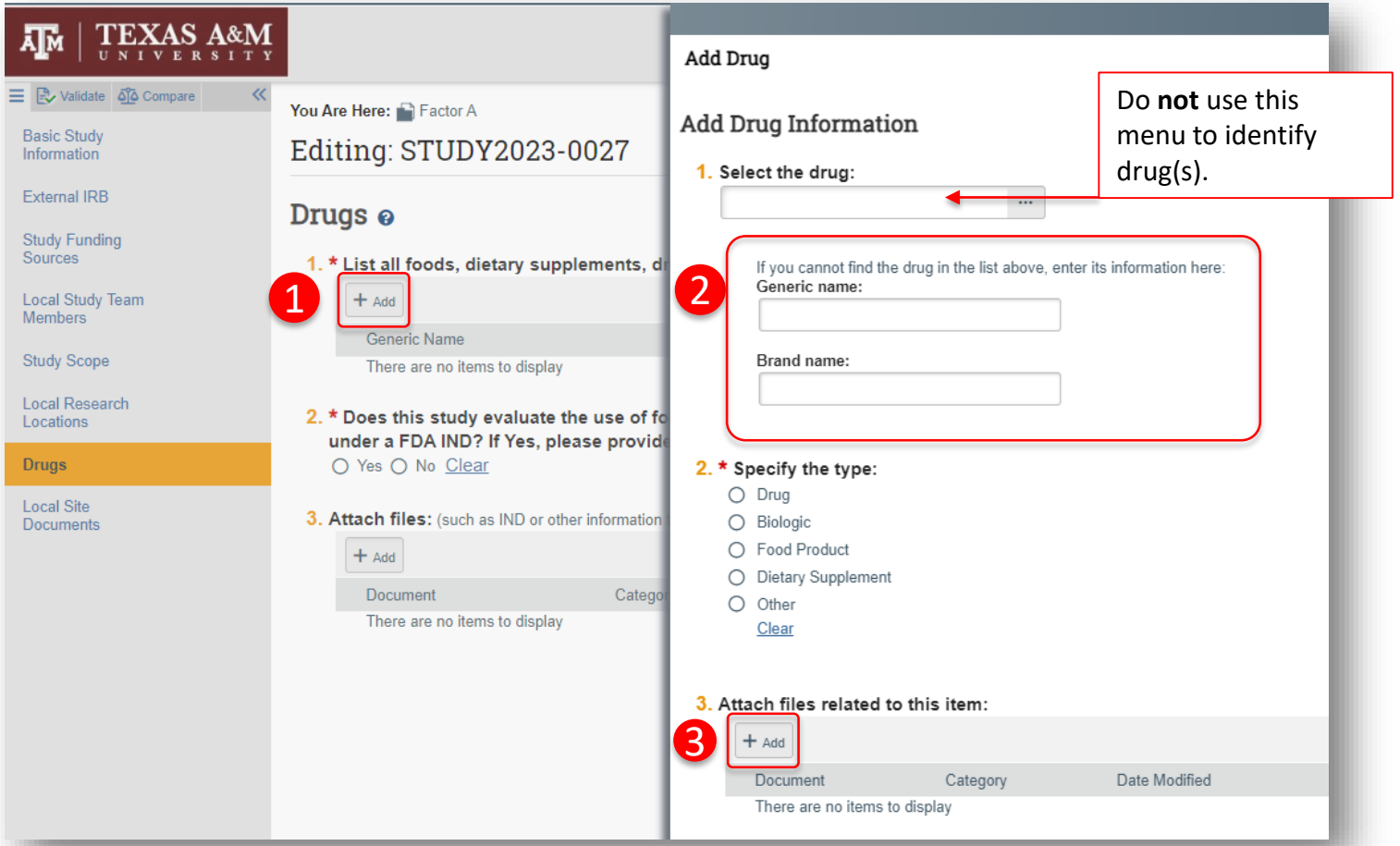
1. In the **Drugs** page, select **+Add** in Q1**.**

2. Type in the generic and brand name of the drug/biologic/food product/dietary supplement in Q1 of the **Add Drug Information** smart form.

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

3. Attach any related files (e.g., drug label, nutrition label) by selecting **+Add** in Q3 of the **Add Drug Information** smart form.

4. Ensure all questions in the Add Drug Information smart form are completed before selecting **OK.**



Devices

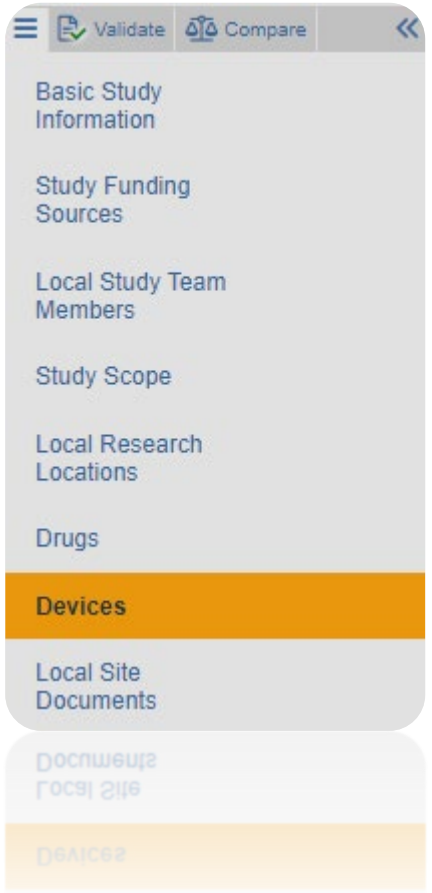
If your study includes devices, you will be asked to:

1. Identify all devices being used in your study and attach the device manual/brochure for each device listed.

2. Identify if an Investigational Device Exemption (IDE) is required for your study.
   - You may use the HRP 307 Worksheet Devices to identify if an IDE is required.

3. If an IDE is required, you will be asked to attach one of the following:
   a. sponsor protocol with the IDE number;
   b. communication from the sponsor with the IDE number; or
   c. communication from the FDA with the IDE number. Indicate whether the device is being submitted under the "Abbreviated IDE requirements" in 21 CFR 812.2(b)

4. Identify if the study evaluates the safety or effectiveness of a device.



Instructions for entering device information can be found on the next slide.

Entering Device Information

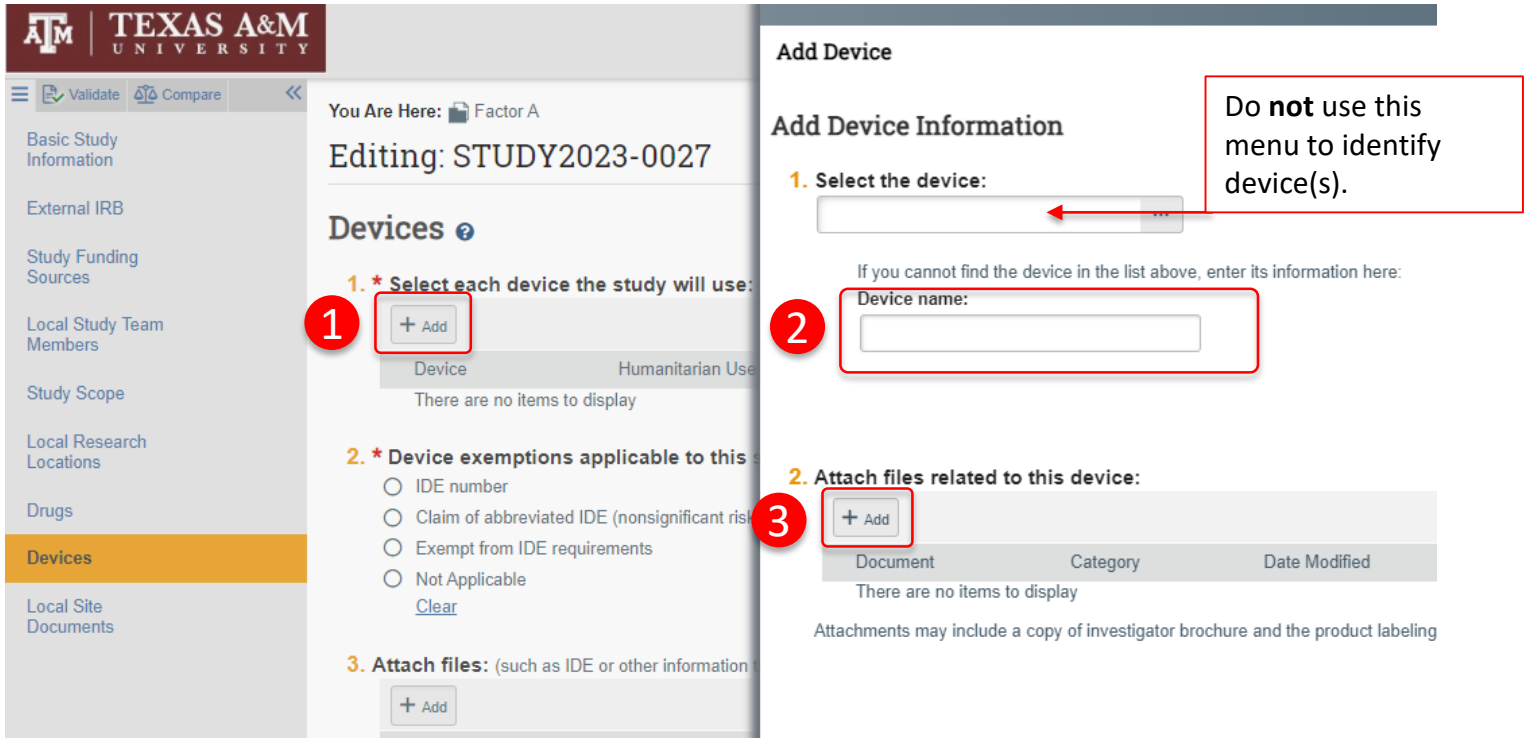
To add study device(s):

1. In the **Devices** page, select **+Add** in Q1

2. Type in the name of the device (avoid using acronyms when possible) in Q1 of **Add Device Information** smart form.

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

3. Attach the device manual by selecting **+Add** in Q2 **Add Device Information** smart form.



Adding Study Location

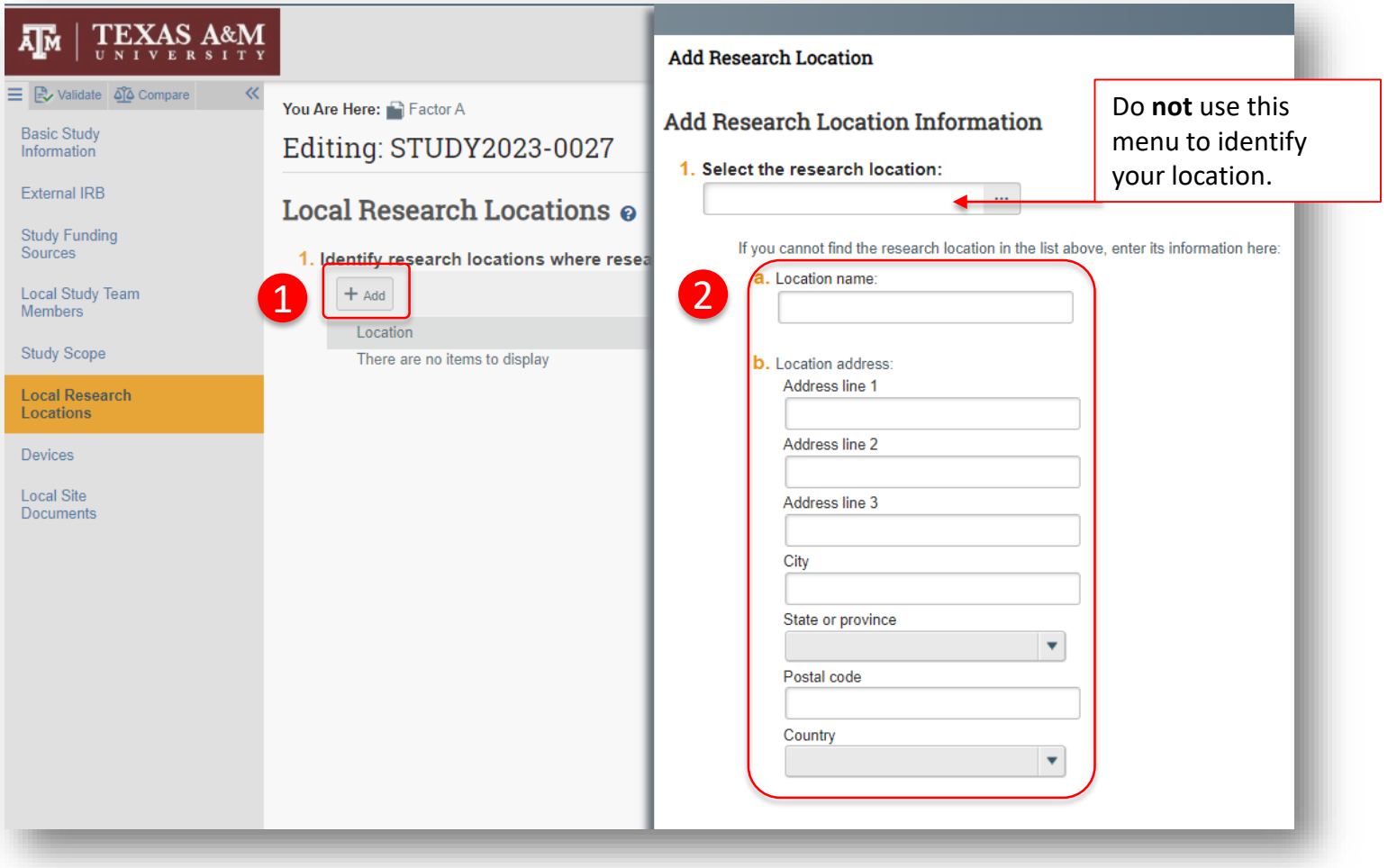
Identify research locations where the investigator will conduct or oversee the research. If a Site Authorization letter is required, attach the document in the Local Sites Document page (under Q3 – Other Attachments) .

To add the location(s) where your 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.



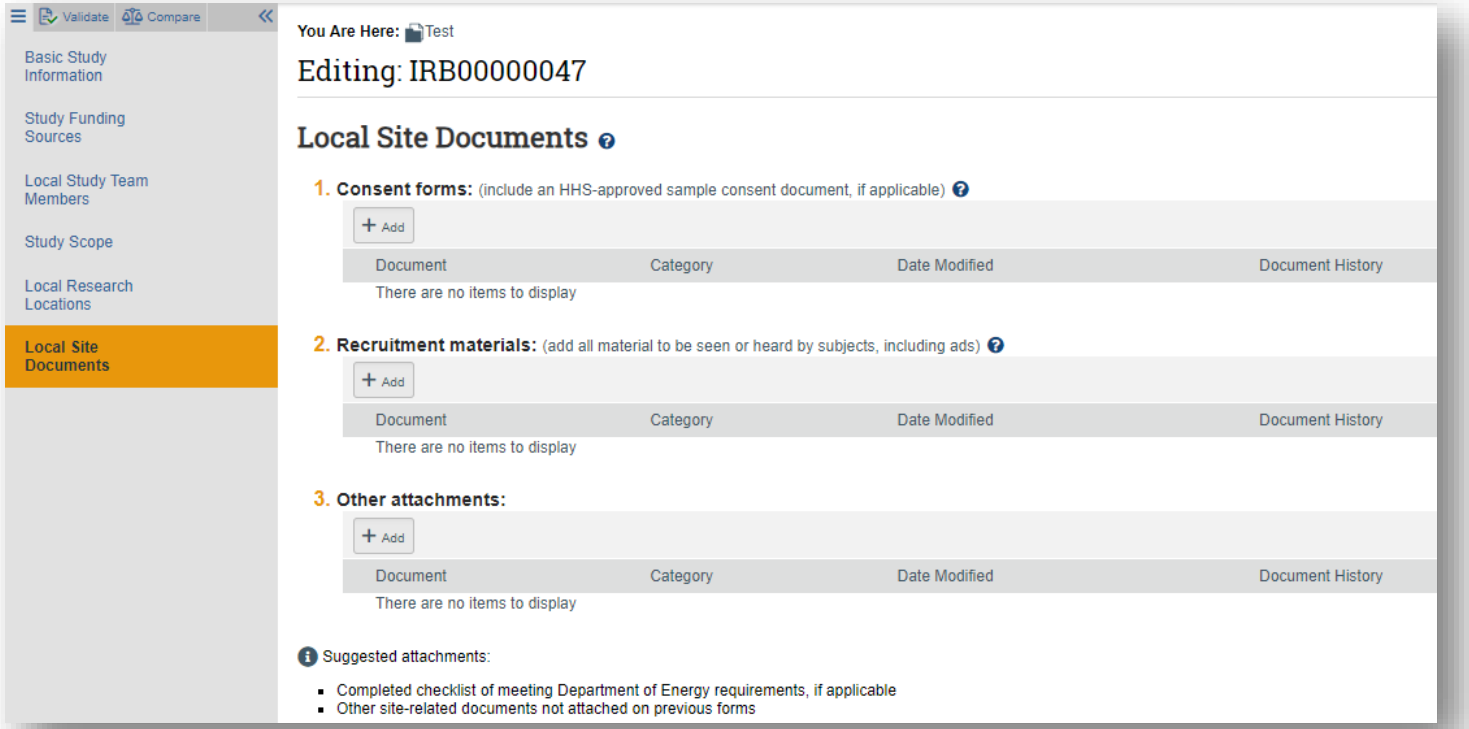
Uploading your documents

When uploading your documents, be aware that there are three separate locations for you to upload your documents:

Q1 – Consent Forms: Only your consent documents should be uploaded (e.g., informed consent document, parent consent document, child assent form, information sheet).

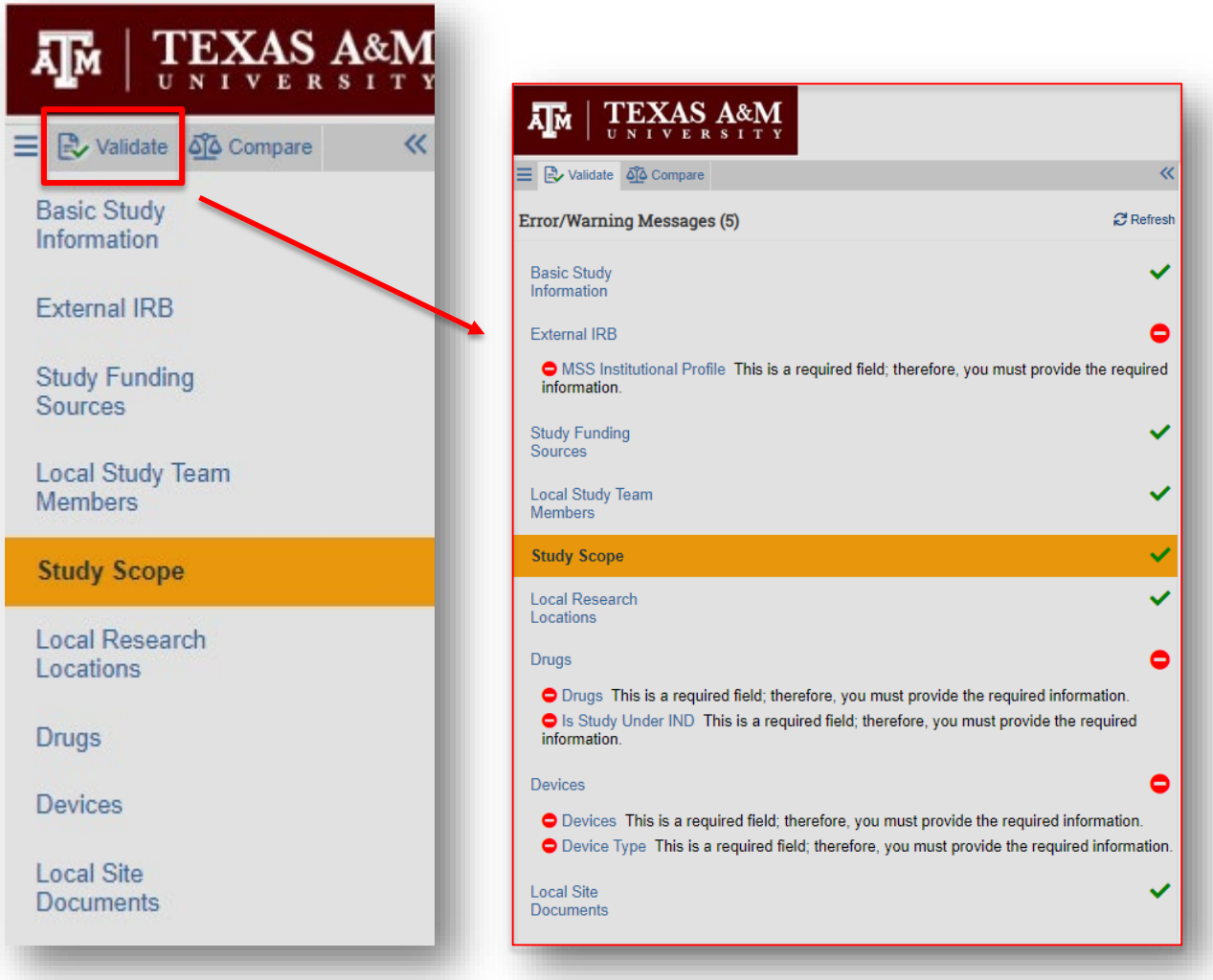
Q2– Recruitment Materials: Only your recruitment materials should be uploaded (e.g., flyers, recruitment email, verbal recruitment script).

Q3 – Other attachments: is designated for you to attach your data collecting instruments (e.g., survey/questionnaires, data collecting forms, screening forms) and other important documents (e.g., translation certificates, site authorization).



Optional: Validating Study Responses

You can validate the submission prior to submitting it to the IRB by clicking **Validate.** A list of all incomplete items will be revealed.

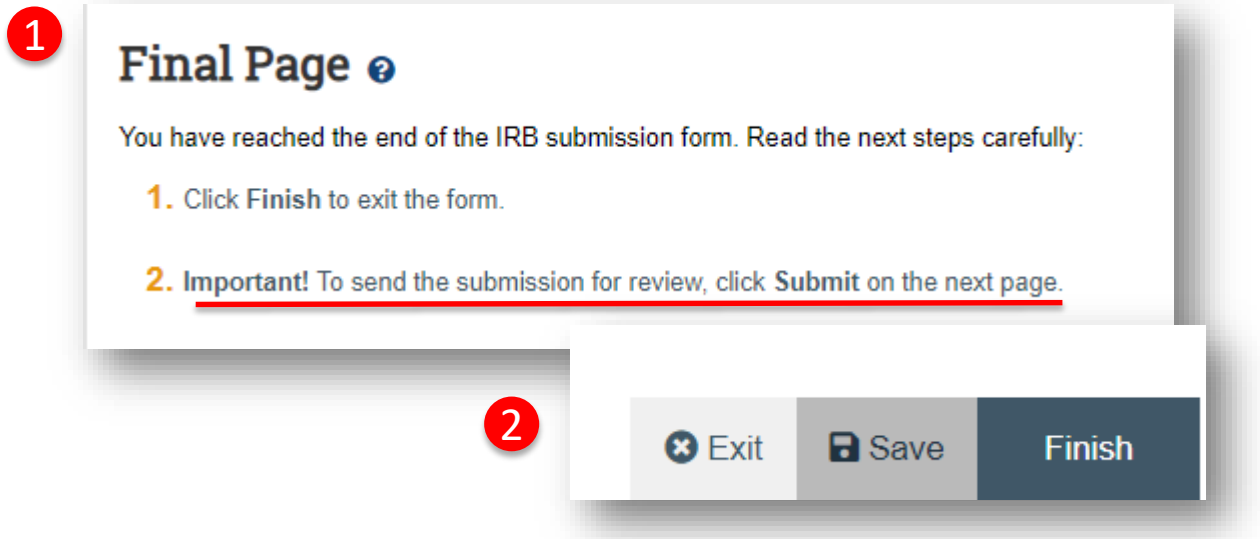


Submitting to the IRB

1. After clicking **Continue** on the **Local Site Documents** page, the user will land on the **Final Page.**

2. Follow the instructions on this page by clicking **Finish** to exit the form.

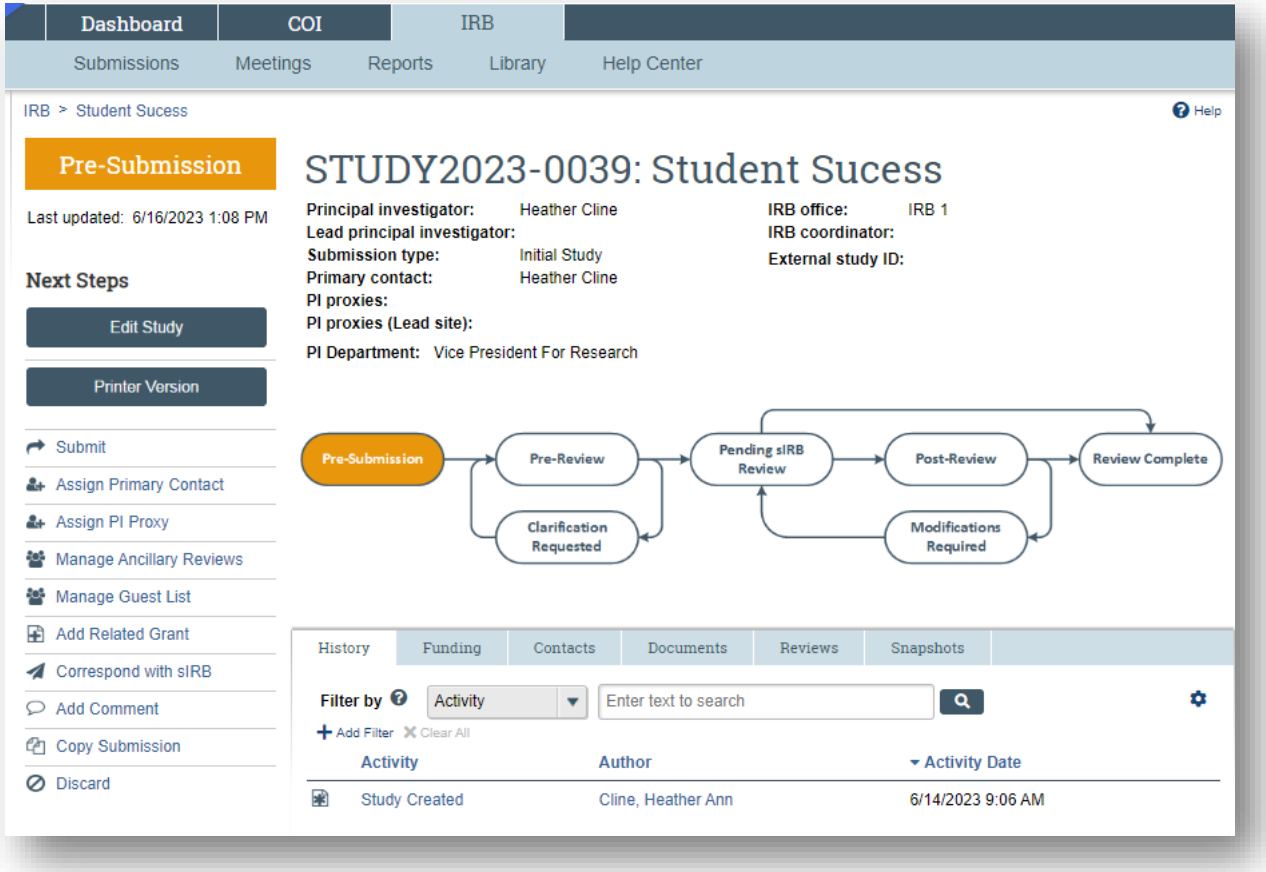
Important! Clicking Finish **does not** send the submission to the IRB. When the study is ready for IRB review, the PI or PI proxy must submit from the study record workspace (**Slide 25** provides instructions for how to designate a member of the study team as PI Proxy).



Before you submit:

After selecting Finish, you will be brought back to the **Study Workspace**. This will give you the opportunity to conduct a handful of tasks ***before*** submitting your application to the IRB:

1. Assign a PI Proxy (Slide 25)
2. Assign Department Chair Sign off (Slide 26)
3. Edit your IRB Application (Slide 27)
4. Add or update your study documents (Slide 28)



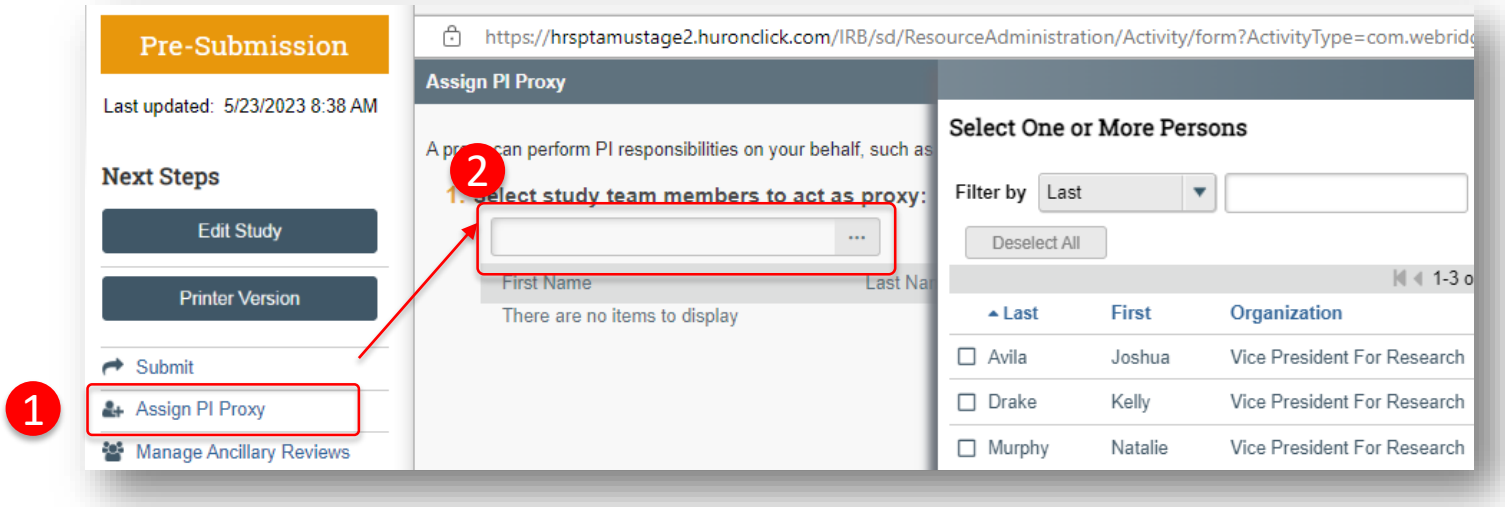
How to assign a PI Proxy

PI proxy(ies) may act on behalf of the Principal Investigator of the study. PI proxy(ies) may submit a study for initial review, modify the study, or submit for continuing review. The PI may assign more than one proxy, but all proxies must be listed as team members within the study.

From the IRB Workspace

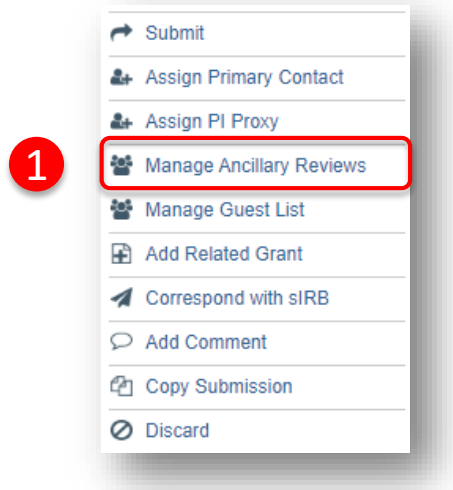
1. Click **Assign PI Proxy**
2. Select study team member to act as proxy

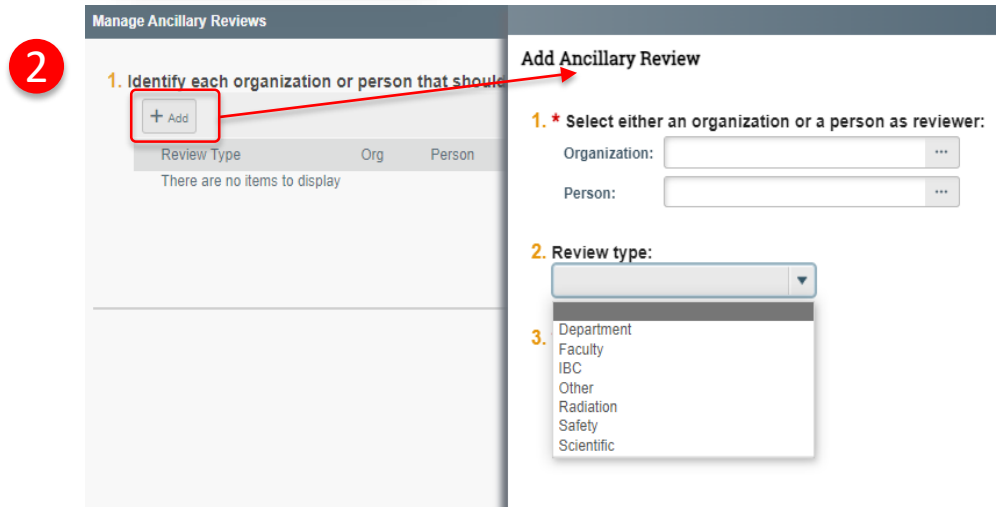
   IMPORTANT! Only individuals listed as study personnel in the IRB application, under **Local Study Team Members,** may be assigned as PI proxy.



How to assign Department Chair sign off

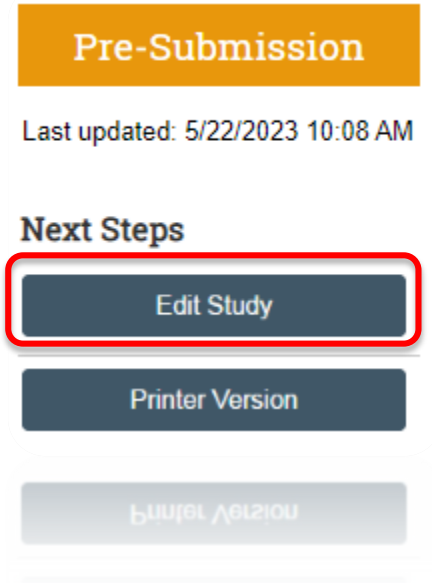
1. Click **Manage Ancillary Reviews**
2. Identify the name of your Department Chair by typing in the person's name or clicking the ellipsis […]
3. Select the Reviewer Type: **Department**
4. Select **Yes** for is the response required
5. Click **OK**





Edit your IRB Application

To edit your submission before submitting to the IRB for review, click **Edit Study**. You will be directed back to your saved IRB Application.

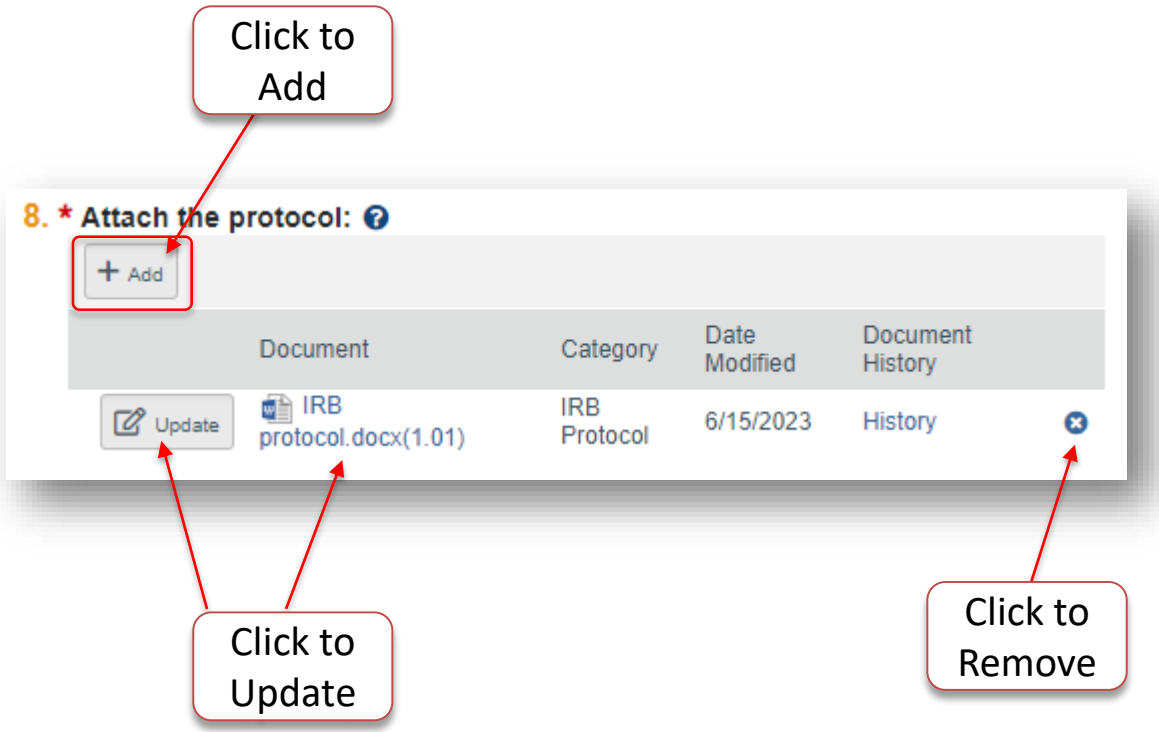


How to update and remove study documents

1. Click **Edit Study** on your study workspace

2. Use the **Page Navigator** to locate the page of interest

3. Perform the following functions to edit your study documents:
   - **Update** by clicking on the button on the left side of the item or on the item itself (if no button appears on the left)
   - **Remove** items by clicking on the X to the right of the listed entry.



Submitting to the IRB

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

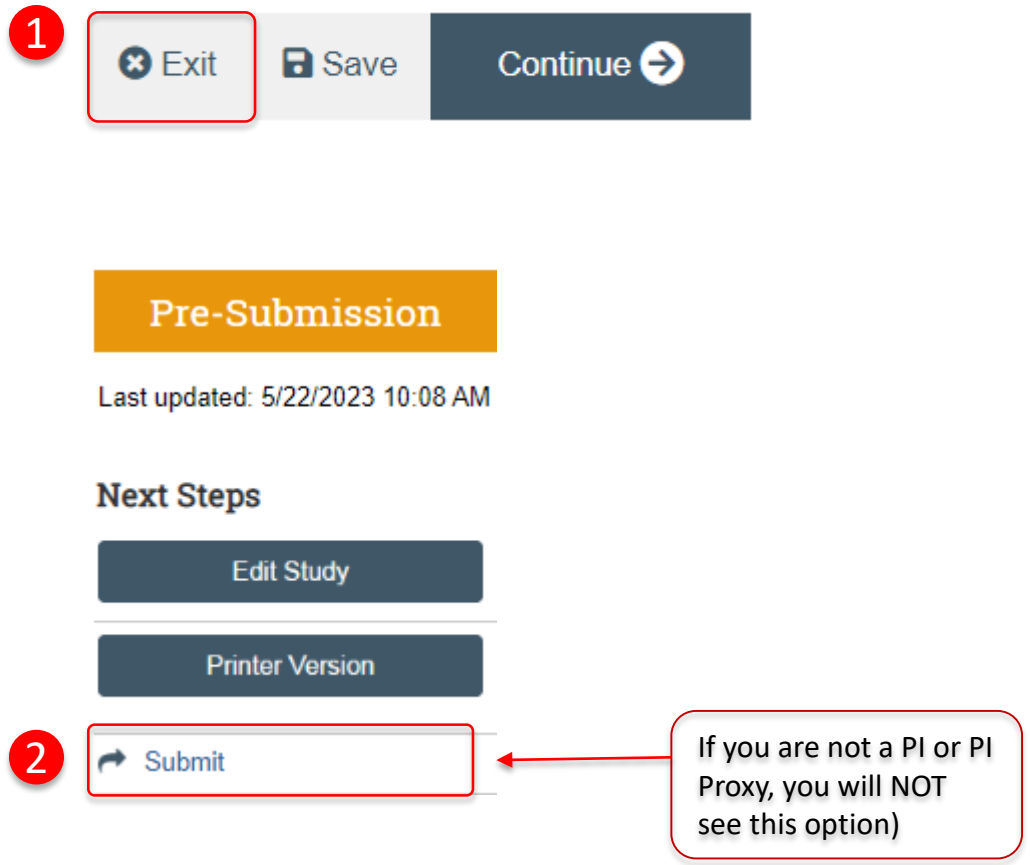
1. Select **Exit** to be directed to the IRB Workspace

2. Click **Submit** (this option is only visible to the PI and PI proxies. If you are not a PI or PI Proxy, you will NOT see this option)

IMPORTANT! The PI or PI Proxy must click ***Submit*** for the submission to be received by the IRB.

3. Click **OK**

Go to the next slide to learn how to assign a PI Proxy



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

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