Legacy studies:
First Submission in Huron

Human Research Protection Program

(Last Updated: 04/10/2024)

This PowerPoint will guide you through how to submit a modification to finish populating your legacy study in Huron. Legacy studies are studies that were transferred from iRIS to Huron.

This guidance is intended solely for studies that migrated from iRIS to Huron.

- "Shells" of all active expedited and full board studies were imported from iRIS to Huron. These legacy studies contain some information previously housed in iRIS, but not all.

- During your first submission in Huron, you will need to finish populating your legacy study in Huron by filling in any missing fields or information on your online application that did not transfer from iRIS to Huron.

- You will also need to upload all currently approved study materials to your legacy study. Please be aware that ***the only way to add or edit information in Huron is via a modification***.

Before getting started, determine which option is needed for your first submission:

Option A : Submit a modification only.

- This option is appropriate if you are submitting a modification to finish populating your legacy study.
- During this process, you will also have the opportunity to update previously approved study procedures and/or study documents.

Option B : Submit a modification and continuing review

- This option is appropriate if you are submitting a modification to finish populating your legacy study, AND your protocol requires a continuing review.
- During this process, you will also have the opportunity to update previously approved study procedures and/or study documents.

Option C: Close your study

- This option is appropriate if you are ready to close your study.
- If you are ready to close your legacy study, navigate out of this tutorially and click **here** for instructions on how to close your study.

Before getting started, determine if your study requires an Administrative Check In or a Continuing Review:

- Most minimal risk studies approved under the Revised Common Rule do not require a continuing review. However, you are still required to submit an annual Administrative Check In for your study.

- On the next slide, you will learn how to identify if your study requires a continuing review or an administrative check in.

How can I tell if my study requires a continuing review or an administrative check in?

1. Your initial approval letter states whether your study requires a continuing review or an administrative check in.

2. You can locate your initial approval letter under the **Documents** tab of your study's workspace. *Instructions on how to navigate the Study Workspace can be found **here**.*

1

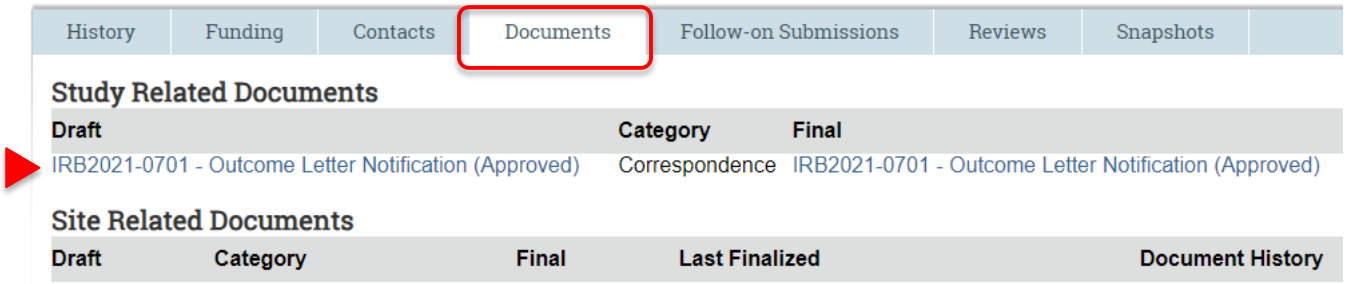
At the convened meeting on 01/06/2021 the IRB approved this research from 01/12/2021 to 01/05/2022 inclusive.

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.

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.

2



If your study requires an ***administrative check in***, you will first need to submit a modification to finish populating your application, **AND** then you will need to submit an administrative check in Huron.

*Instructions on how to complete an administrative check in Huron can be located **here**.*

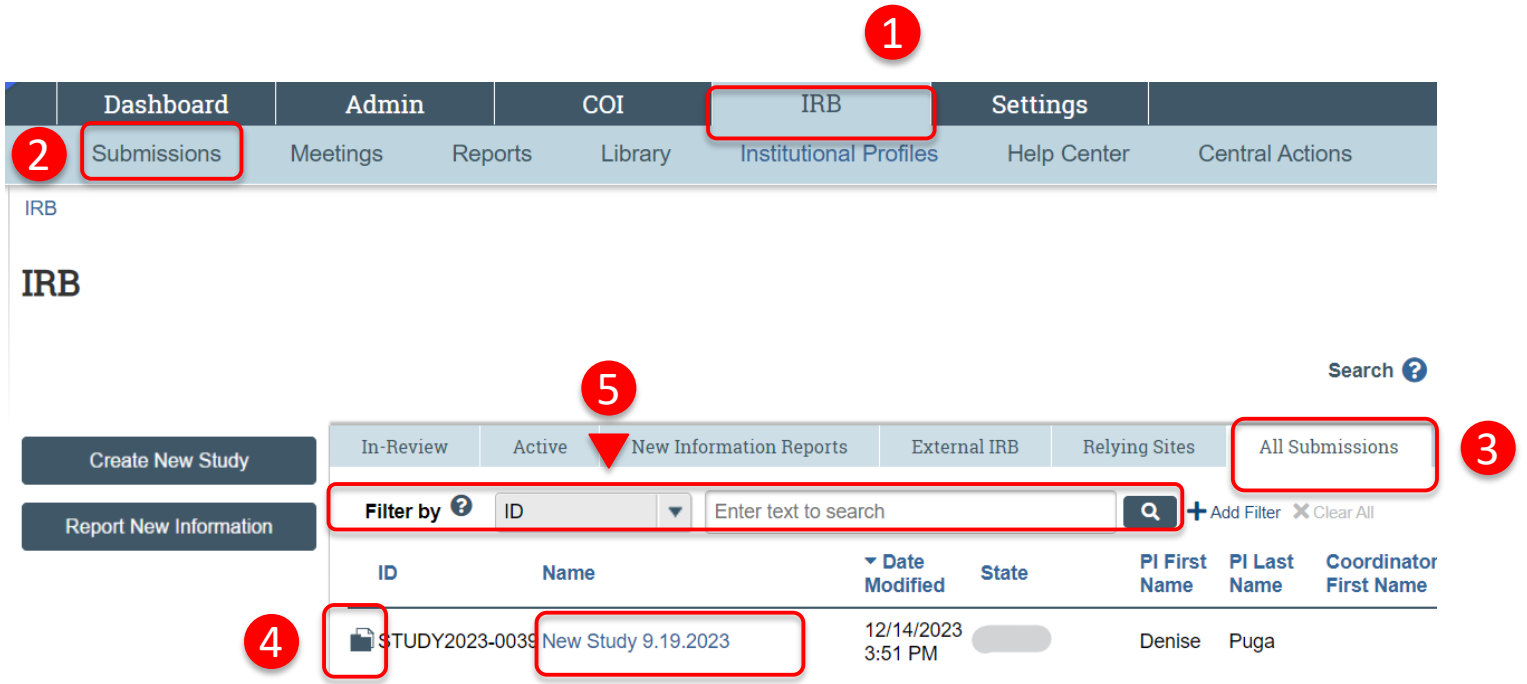
How would you like to proceed?

1) If you are only submitting a Modification, please continue to the next slide.
2) If you are submitting a Modification and a Continuing Review, select here to be directed to Slide 41.

HOW TO SUBMIT A MODIFICATION

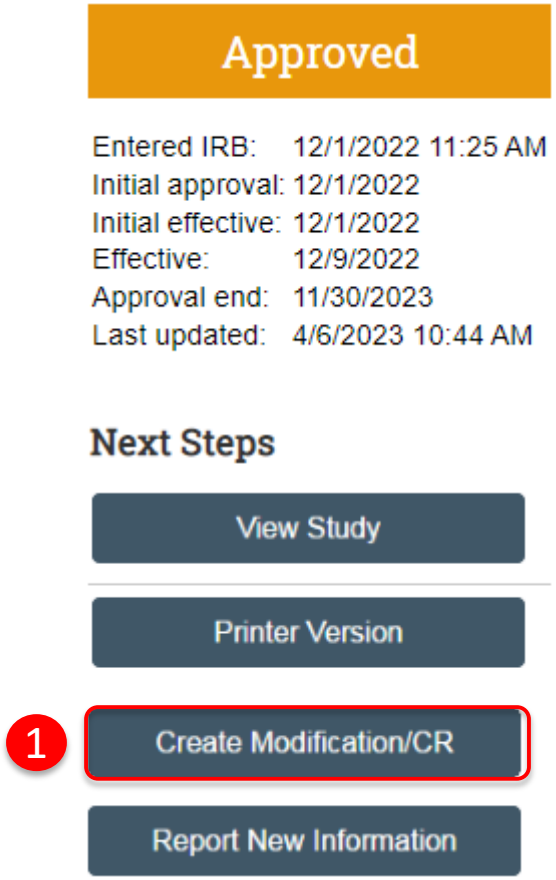
Getting started

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



Creating a modification

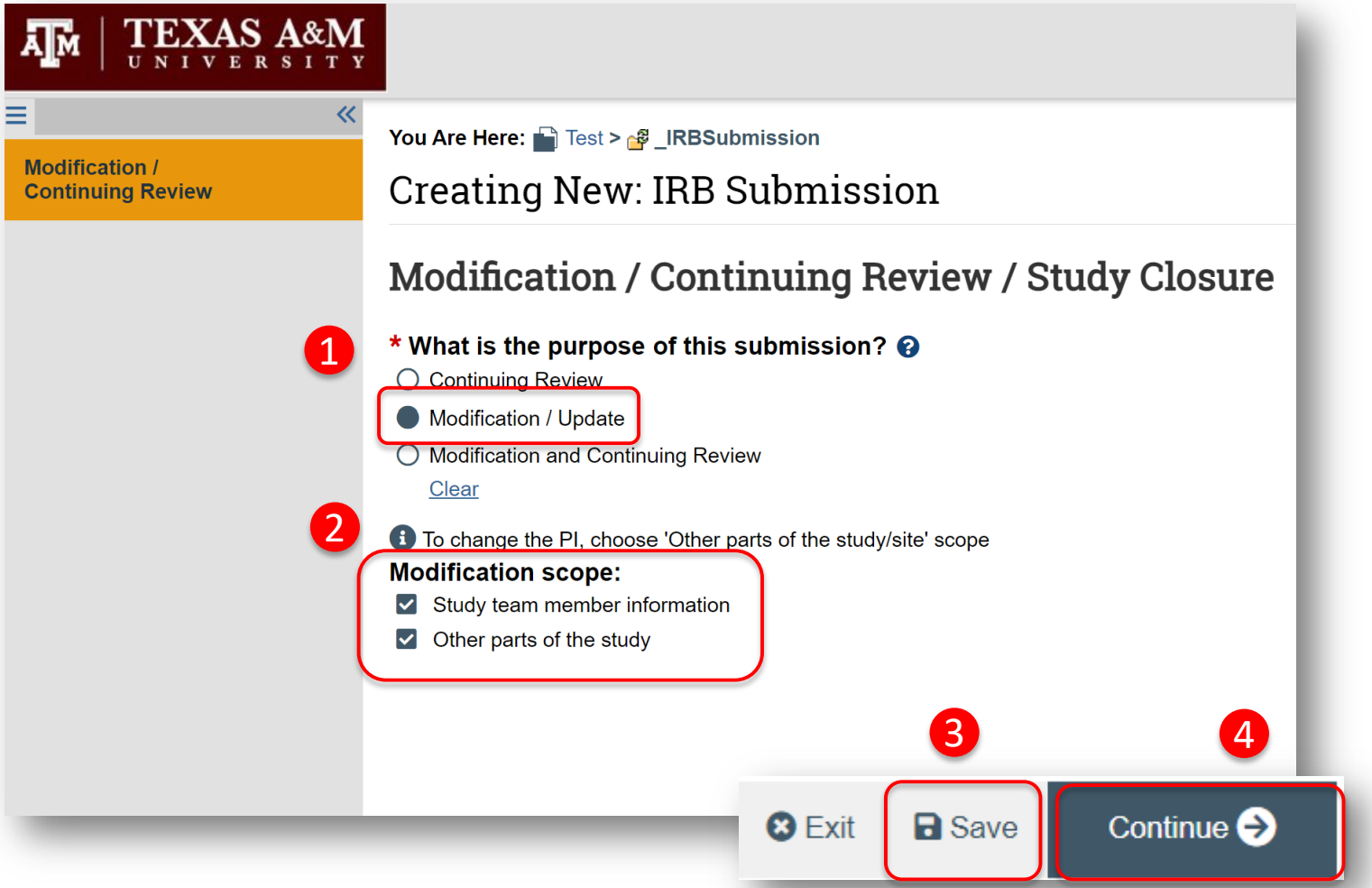
1. Select **Create Modification/CR**



Modification/Update

1. Select **Modification/Update**

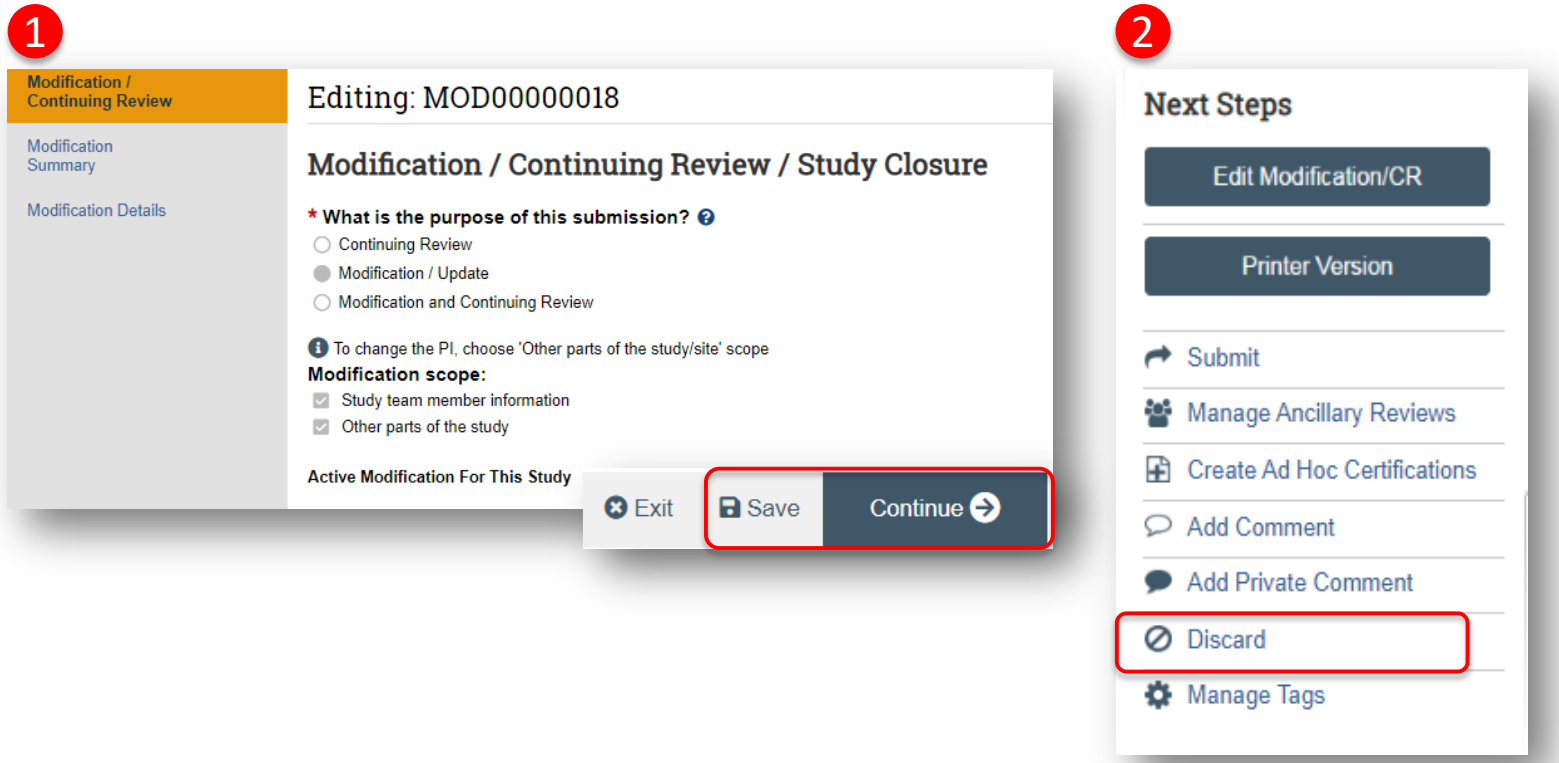
2. Identify the **modification scope** *(you **must** select both)*:
   - Select **Study team member information** to add new study personnel
   - Select **Other parts of the study** for all other modifications to the protocol
3. Click **Save**
4. Click **Continue**



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.

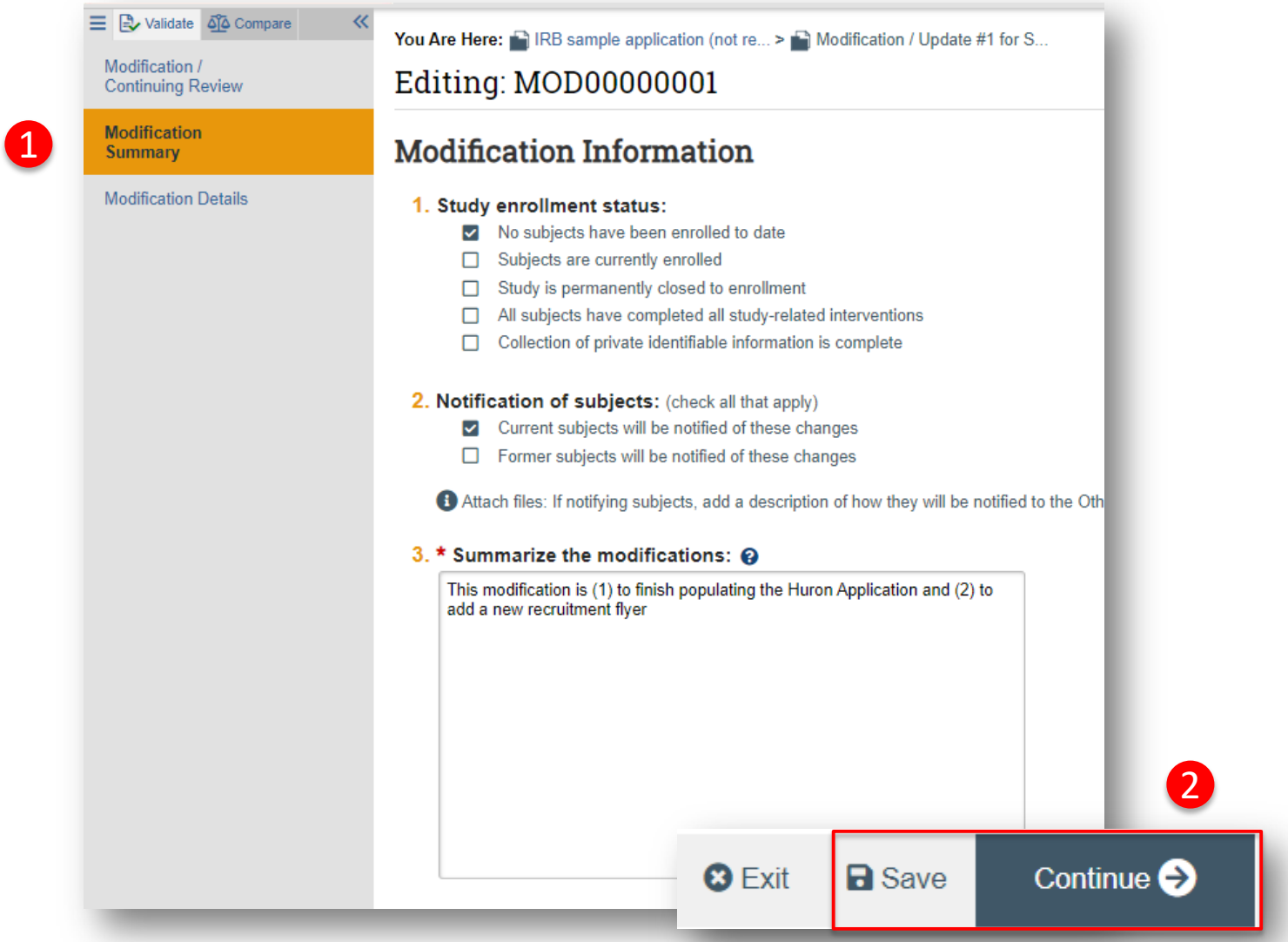
2. If an incorrect response was chosen for either "*What is the purpose of this submission?*" or "*Modification scope*" and the form has been saved, then click **Exit** to leave the submission and select **Discard** from the study record workspace. A new Modification/CR request will need to be created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



Complete the Modification Summary

1. Complete the **Modification Summary** page:
   - Provide answers to **Q1** and **Q2**
   - In addition to completing the migration of your legacy study, you may also take this opportunity to make planned modifications to your protocol; just ensure that you identify what changes are being made to the protocol in **Q3.**

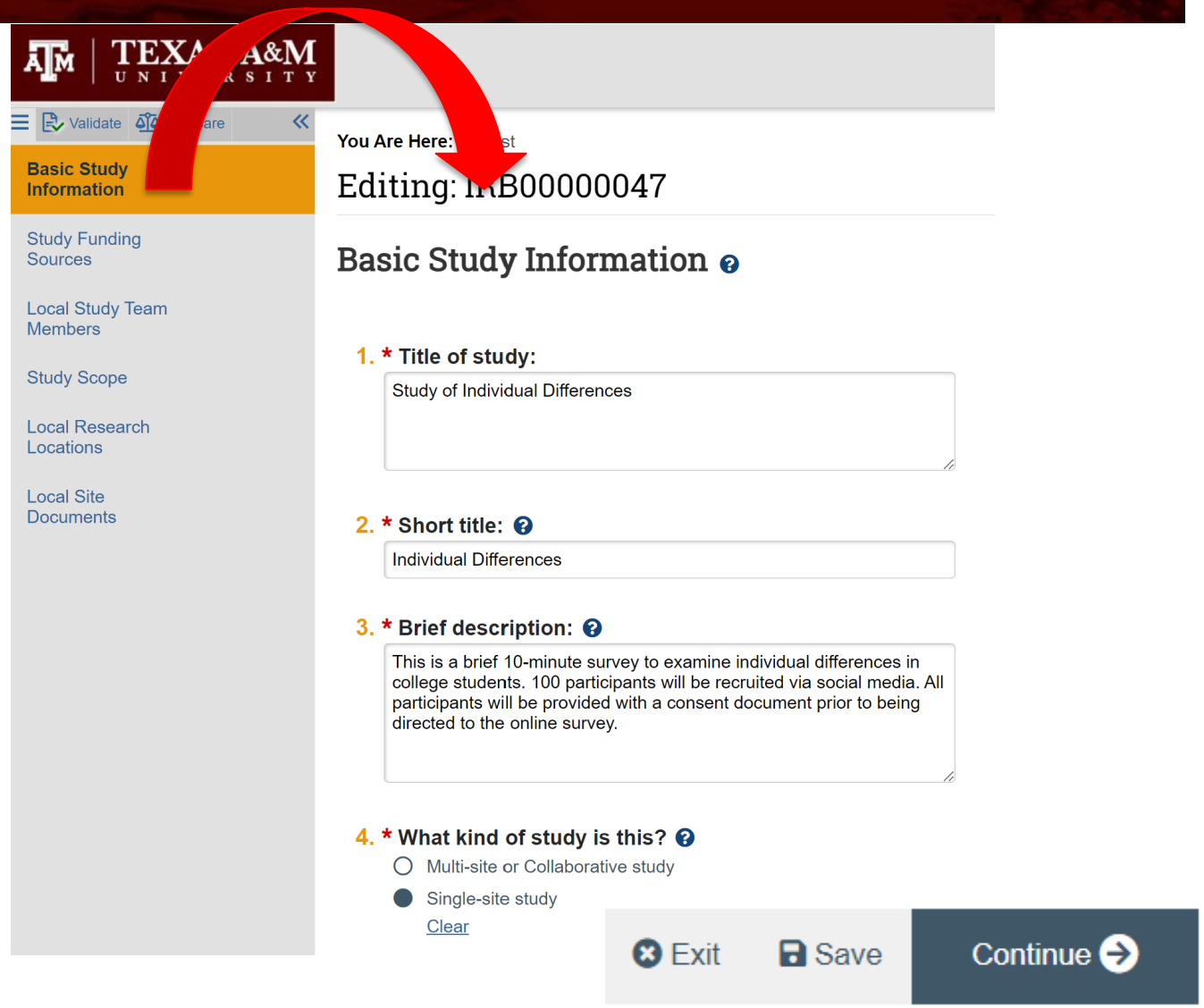
2. Select **Save** and then **Continue**
   - Once you click **Continue**, you will be re-directed to the application to make edits.



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.

Important! During your first submission, you will need to go through every page of the application and fill in all missing data. The best approach is to navigate the application in chronological order by clicking **Save** and then **Continue** at the bottom of each page.



Basic Study Information Page

- All questions marked with a red asterisk (*) require a response.
- Basic study information was migrated from iRIS into Huron, including:
  - The title of the study
  - The short title of the study
  - A brief description of the study
  - Reviewing IRB information
  - The name of the local principal investigator

Action items:

1. Ensure all information is accurate
2. Update any information that is incorrect or missing
3. Attach your protocol to the Basic Study Information Page

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

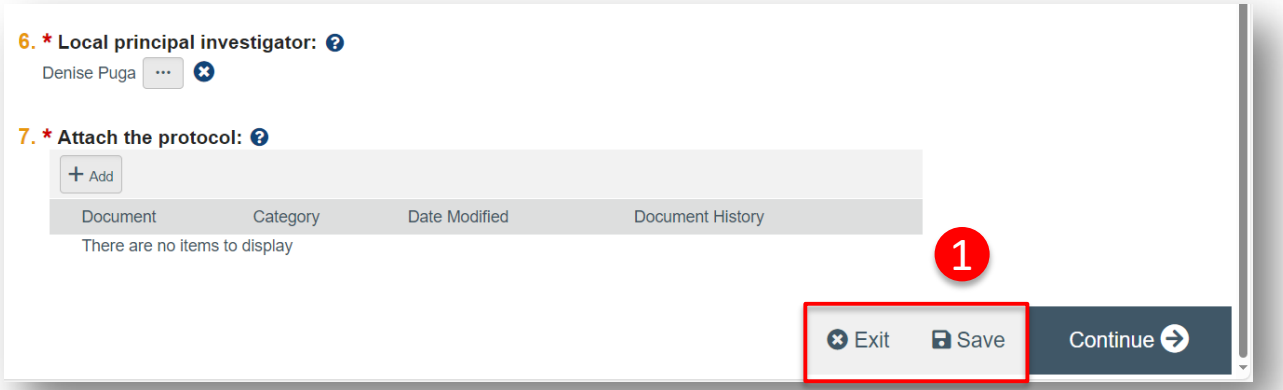
How to locate your iRIS IRB application in Huron

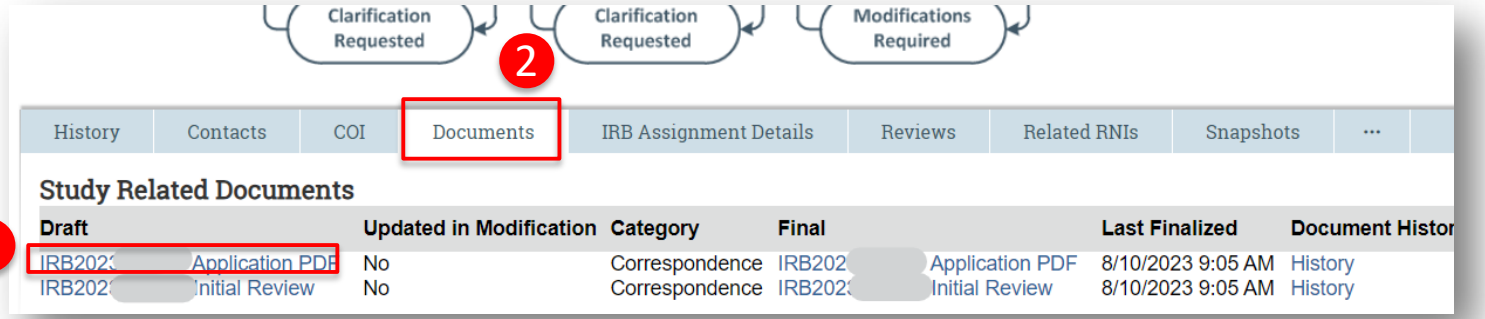
A PDF version of your IRB application was migrated from iRIS to Huron.

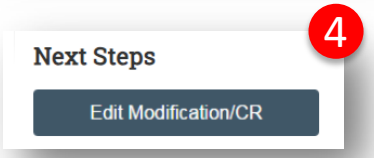
To locate the PDF version of the IRB application:

1. Exit out of the application by clicking **Save** and then **Exit**.
2. From the Study Workspace, click on to the **Documents** tab. You will be able to locate a PDF version of your IRB application under **Study Related Documents.**
3. Click on the name of the document. A separate window will open with the PDF of the application. Save the application to your desktop. (*If you are NOT able to locate a PDF of your IRB application under the Documents tab, you will need to log into **iRIS** and convert your most recently approved IRB application into a PDF.*)

4. To continue editing the IRB Application, click **Edit Modification/CR** from the Study Workspace.







Slide added: 1/29/2024

How to update your approved protocol during your first submission

During your initial submission, you may update your approved protocol or add new/revised study documents.

To update your protocol. You can either:

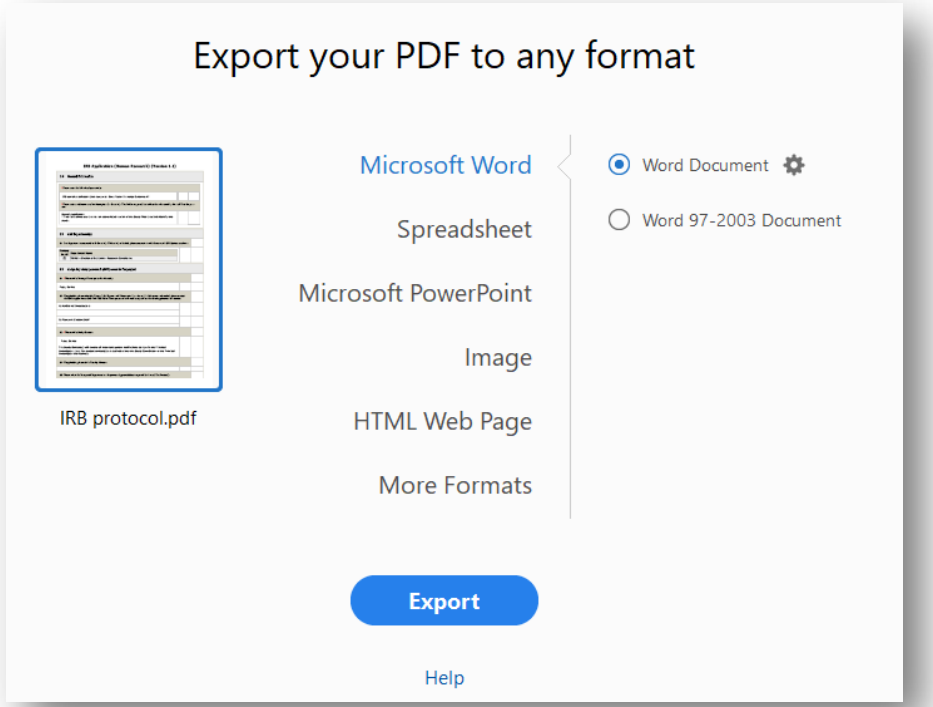
- **Option A:** Download the PDF version of your application (see **Slide 17** for a quick tutorial) and convert it to a Word document, which will allow you to update the application to reflect the proposed changes; *OR*

- **Option B**: You can feed your study information into one of our protocol templates, found **here**.

Important! ***All requested modifications to an approved study must be reflected in the Word document that you upload by choosing either Option A or B***. For example, if you are increasing maximum study enrollment, you must update your study protocol and your consent document to reflect the increase in participant enrollment.

Option A: Convert PDF application to Word document

1. Convert your downloaded iRIS application from a PDF to a Word file. Instructions on how to export a PDF into Microsoft Word can be found **here**.



Instructions continued

Option A (continued)

2. Edit the Word document to reflect the proposed changes and save your work.

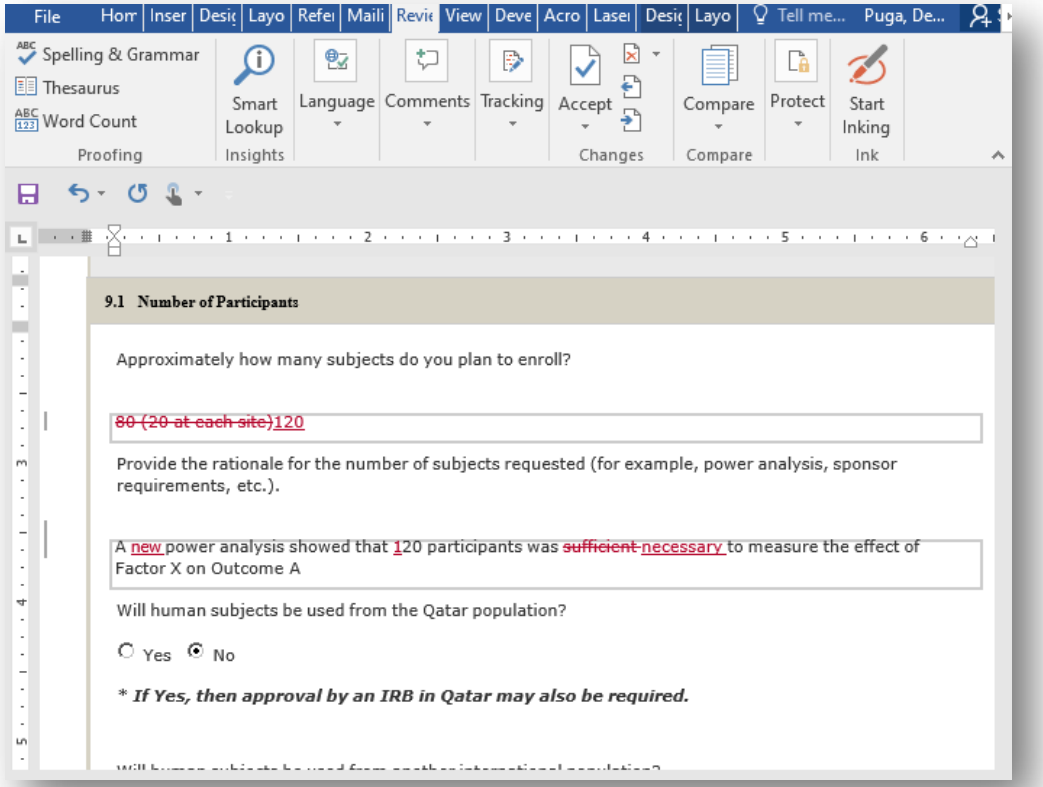
   Important! Use Track Changes to capture all changes made to the approved protocol. Instructions on how to use Track Changes in Word can be found **here**.

3. Once you are done with your edits, save your document and go back to the Basic Study Information Page. Click **Update** (under **Attach the** Protocol) to upload your revised Word protocol.

   Important! Your updated protocol must be uploaded as a Word Document.

Go to the next slide to learn how to add and update documents in Huron.

4



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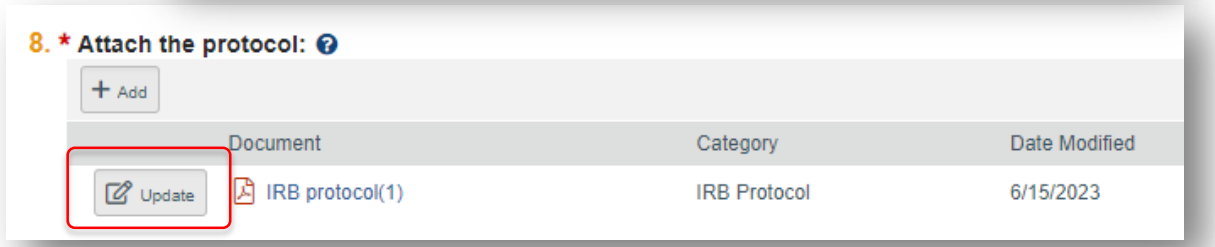
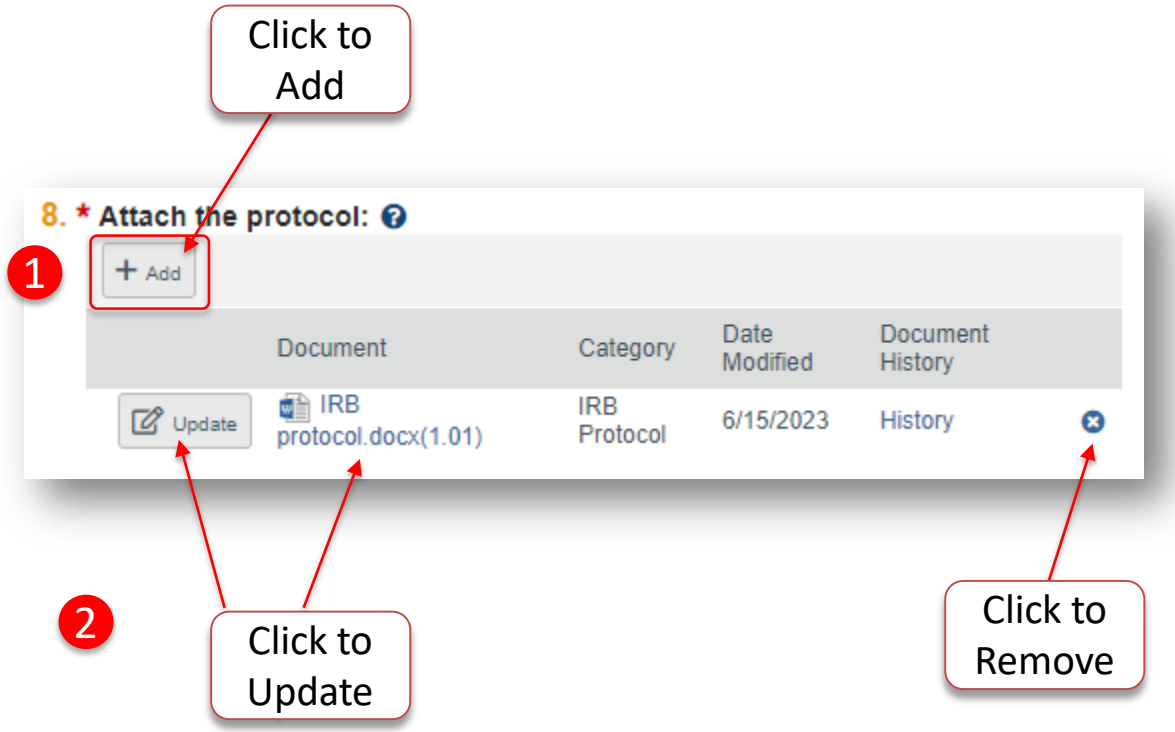


How to update and remove study documents

1. Documents can be added to pages by selecting **+Add**:
   - A SmartForm will pop up allowing for supporting documentation to be uploaded to Huron.

2. Items may be either added or removed:
   - **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.

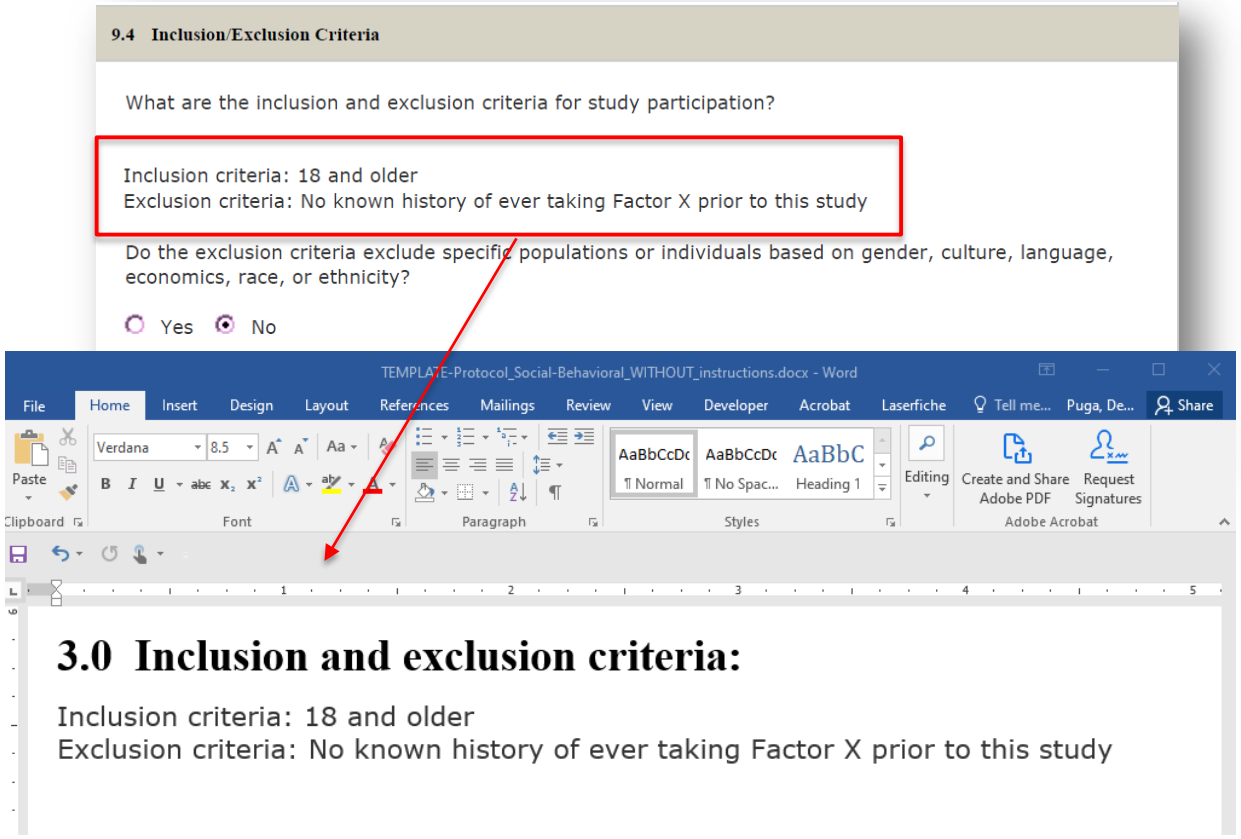


Option B: Using a Protocol Template

Moving forward, all ***new*** Initial Submissions in Huron will require that a protocol template be attached to the submission. Protocol templates can be found on the **HRPP website**.

During your first submission, you have the ***option*** to convert your existing iRIS application into a protocol template. This will require you to manually copy and paste information from your approved iRIS application into a Word protocol template. A PDF copy of your iRIS application can be located in the **Basic Study Information** page.

While this option may be initially more time consuming, it is recommended that you utilize this option if you are expecting to maintain your protocol open for a prolonged period of time. Studies that remain open for a lengthy period are more likely to undergo numerous modifications. Converting your study into a protocol template will help facilitate future modifications.



Study Funding Sources Page

- Sponsor information was migrated from Maestro to Huron.

Action Items:

1. Ensure all information is accurate
2. Update any information that is incorrect or missing
3. If the project is sponsored, attach a copy of the grant proposal, contract, and/or agreement in **Q4**.

Go to the next slide, to learn more about what information needs to be documented in the Study Funding Sources page.

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.

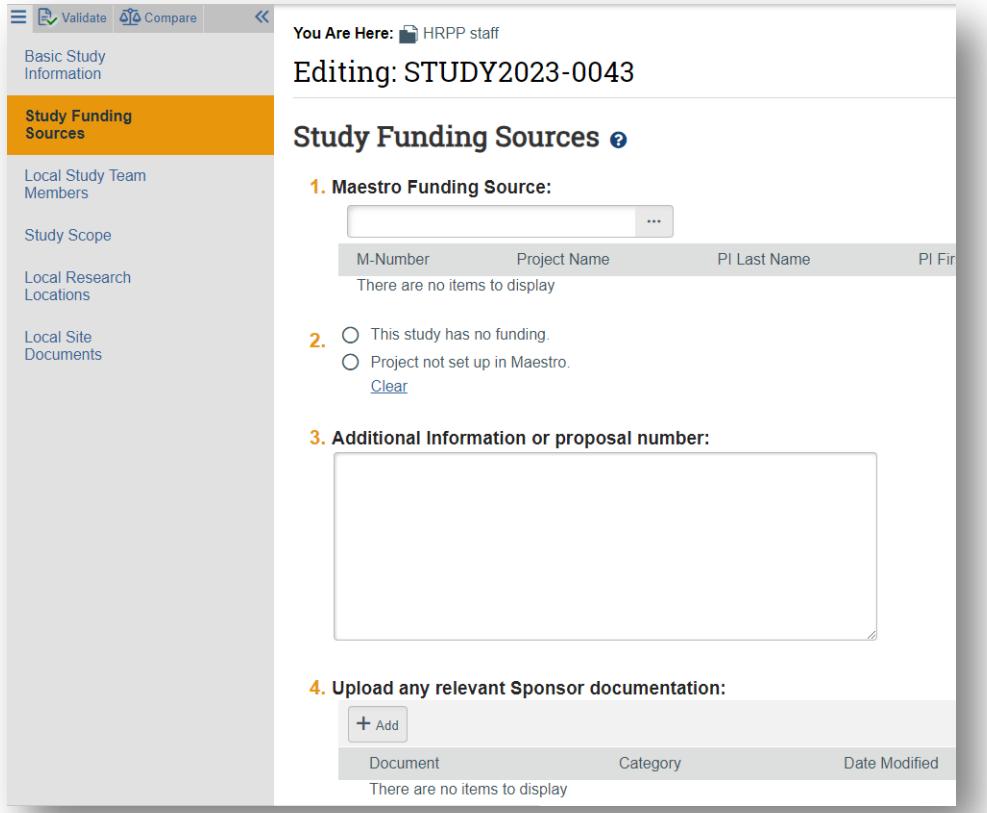
- **If your study is funded:**

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

Study Team Member Information was migrated from iRIS to Huron.

Action items:

1. Ensure study personnel is up to date
2. Add/remove personnel as needed
3. Remove Department Head from study team, ***unless*** Department Head is actually involved in the research.
4. Ask all study personnel to 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.

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**

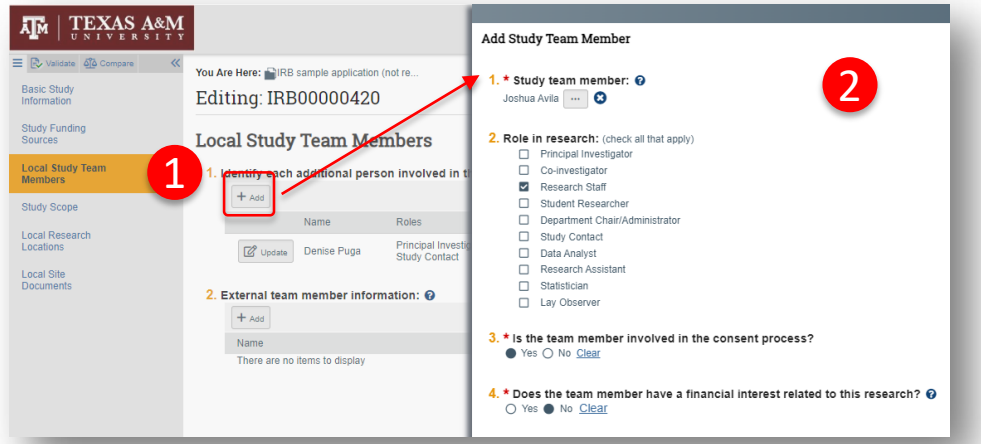
   I am trying to add study personnel to an IRB protocol, why am I not able to locate them in the system?
   Some TAMU members (such as undergraduates, visiting scholars, and adjunct/affiliate professors) need to opt into their information being fed into Huron before they are active in the system. If you 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.



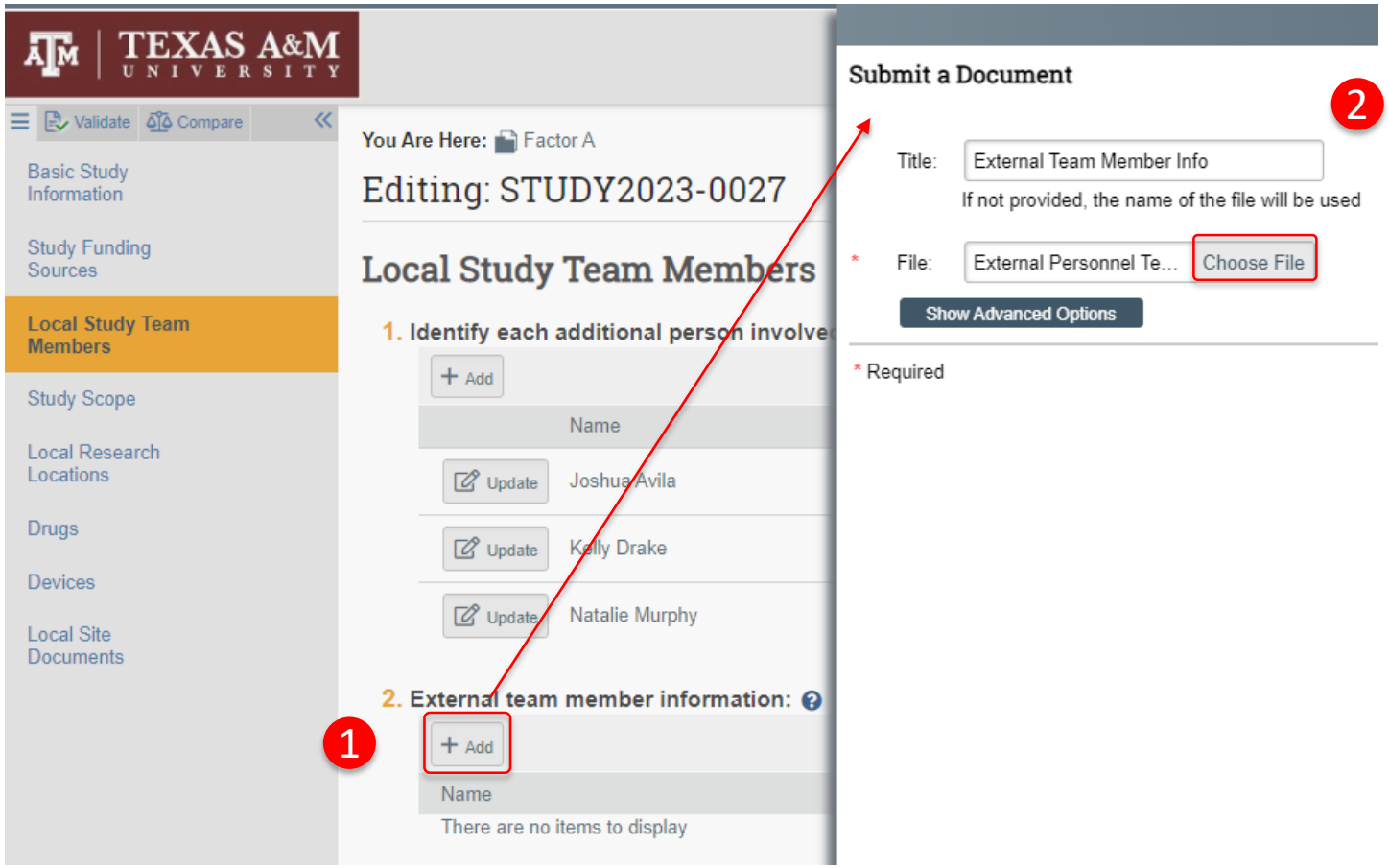
Reminder! If your Department Head is not involved in the research, remove them as Local Study Team Members.

Adding External Team Members (Single-Site)

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). The template should list every non-TAMU individual engaged in the research.



Study Scope

The default answer for all legacy studies for Q1 and Q2 (Drug and Devices) is ***no***.

Action items:

1. If your study involve drug and/or devices, change *no* to *yes*. When 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** these slides if they are not applicable to your study.

Drugs

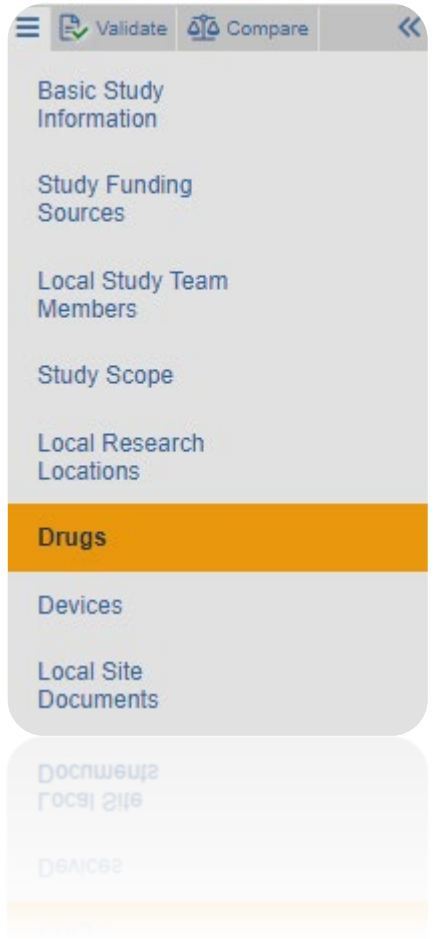
If your study includes the use of food, dietary supplements, an approved drug or biologic, or an unapproved drug or biologic, you will be asked to:

- 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 identified.

- 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).

- For those that have an IND number, you will be asked to provide 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.



Entering Drug Information

To add study drug(s):

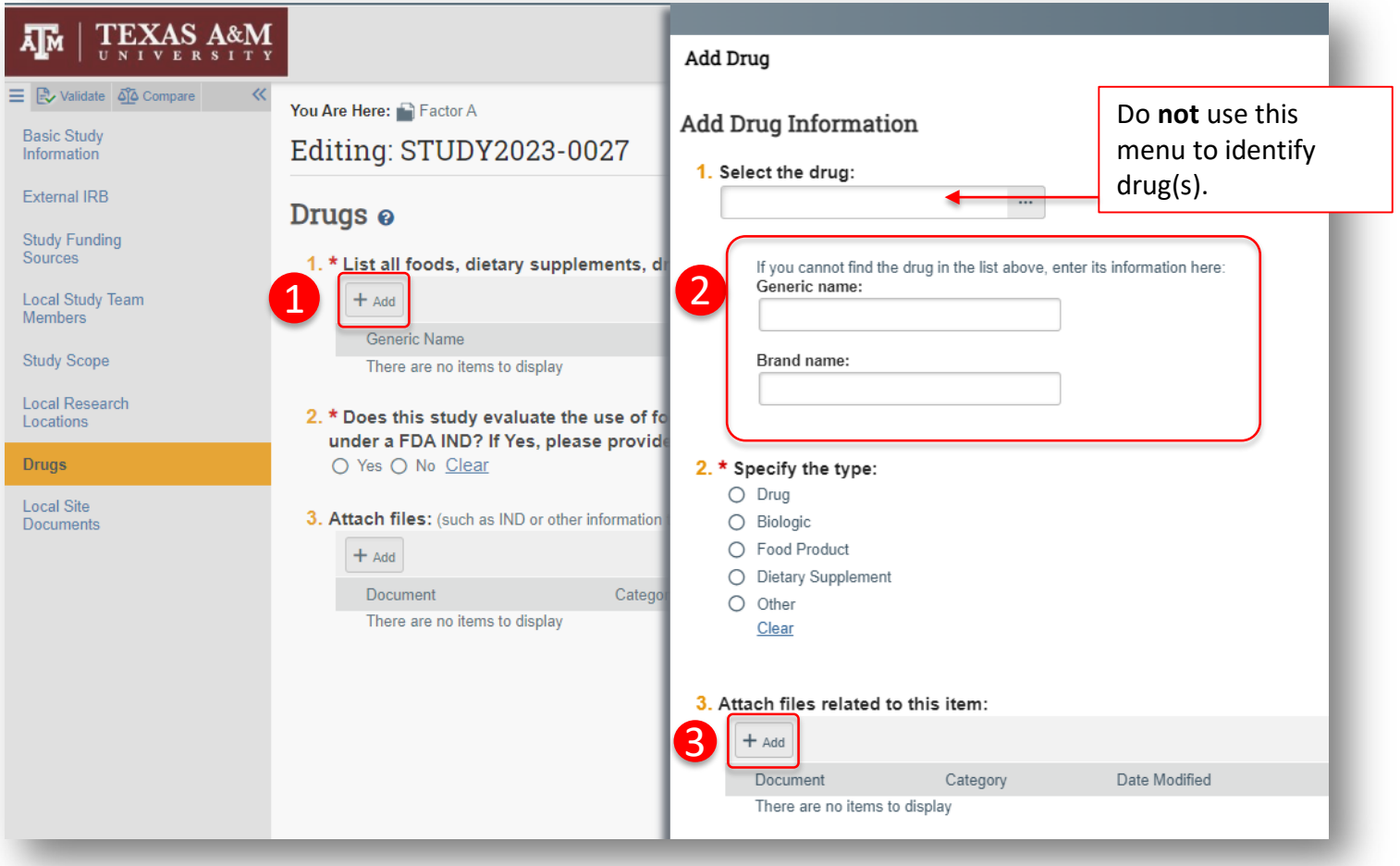
1. In the **Drugs** page, select **+Add** in Q1**.**

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

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



Devices

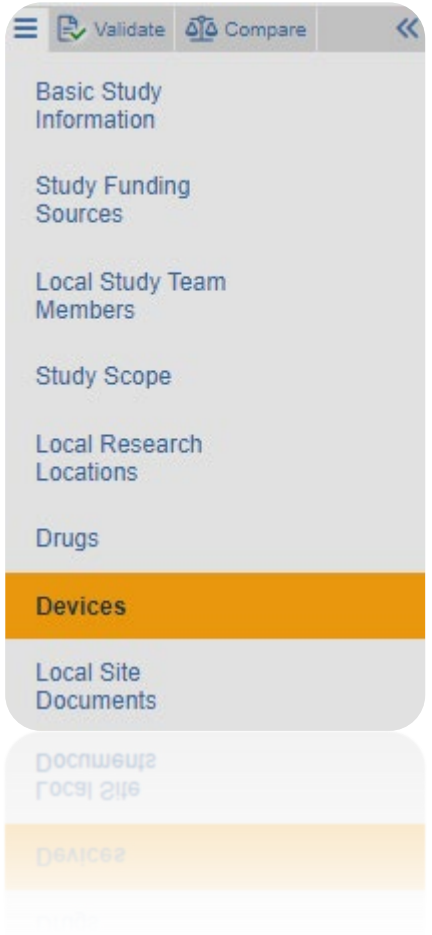
If your study includes devices, you will be asked to:

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.



Entering Device Information

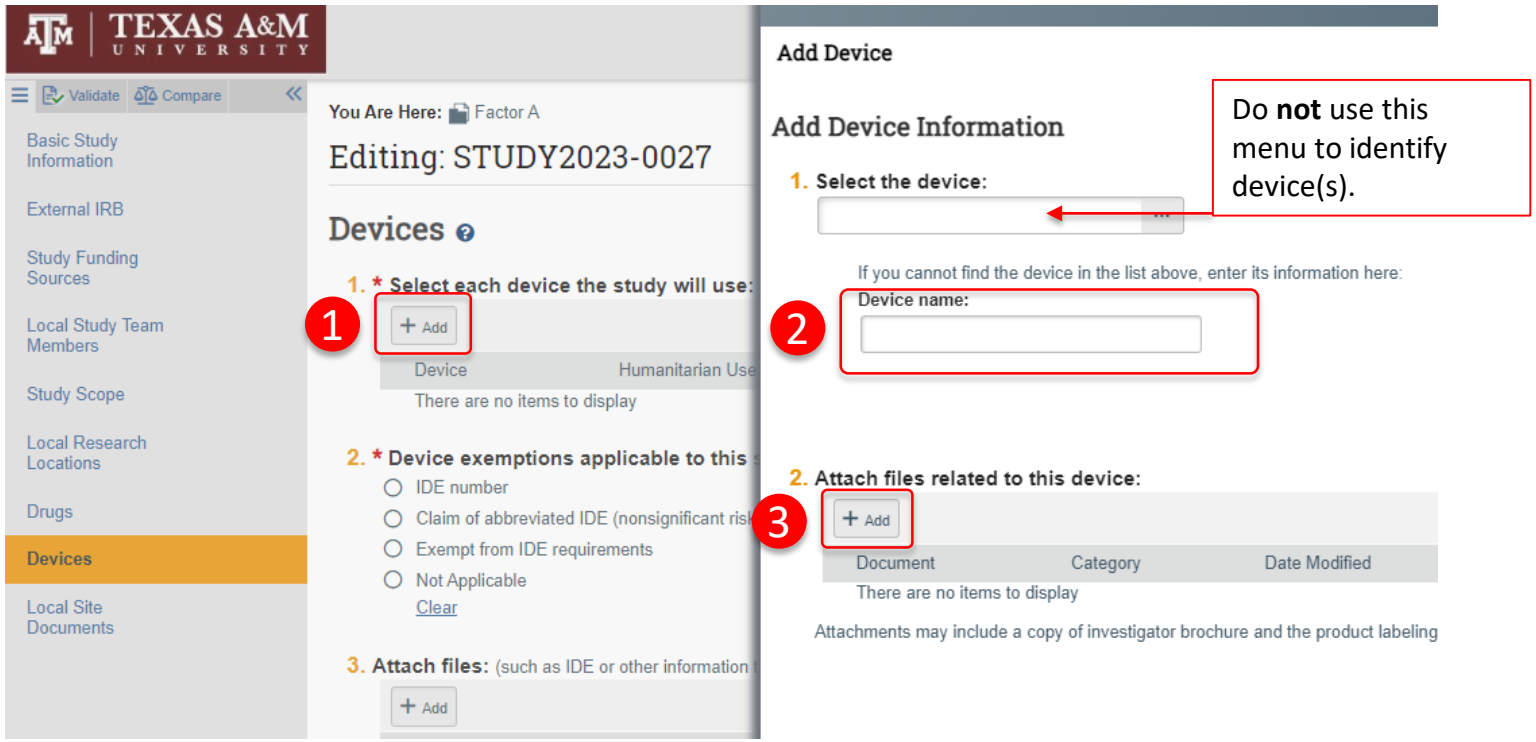
To add study device(s):

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.

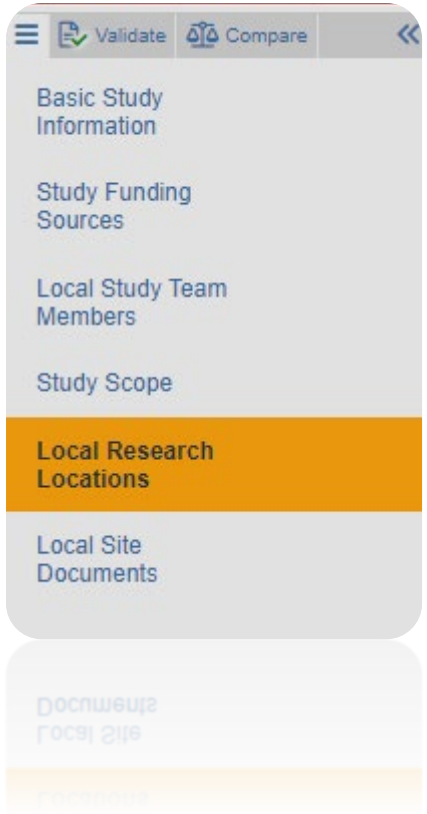
   IMPORTANT! The drop-down menu is not loaded and will NOT populate device information. The name of the device must be entered manually.

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



Local Research Locations

No location information was transferred from iRIS to Huron.



Action items:

1. Provide all locations where your research will take place

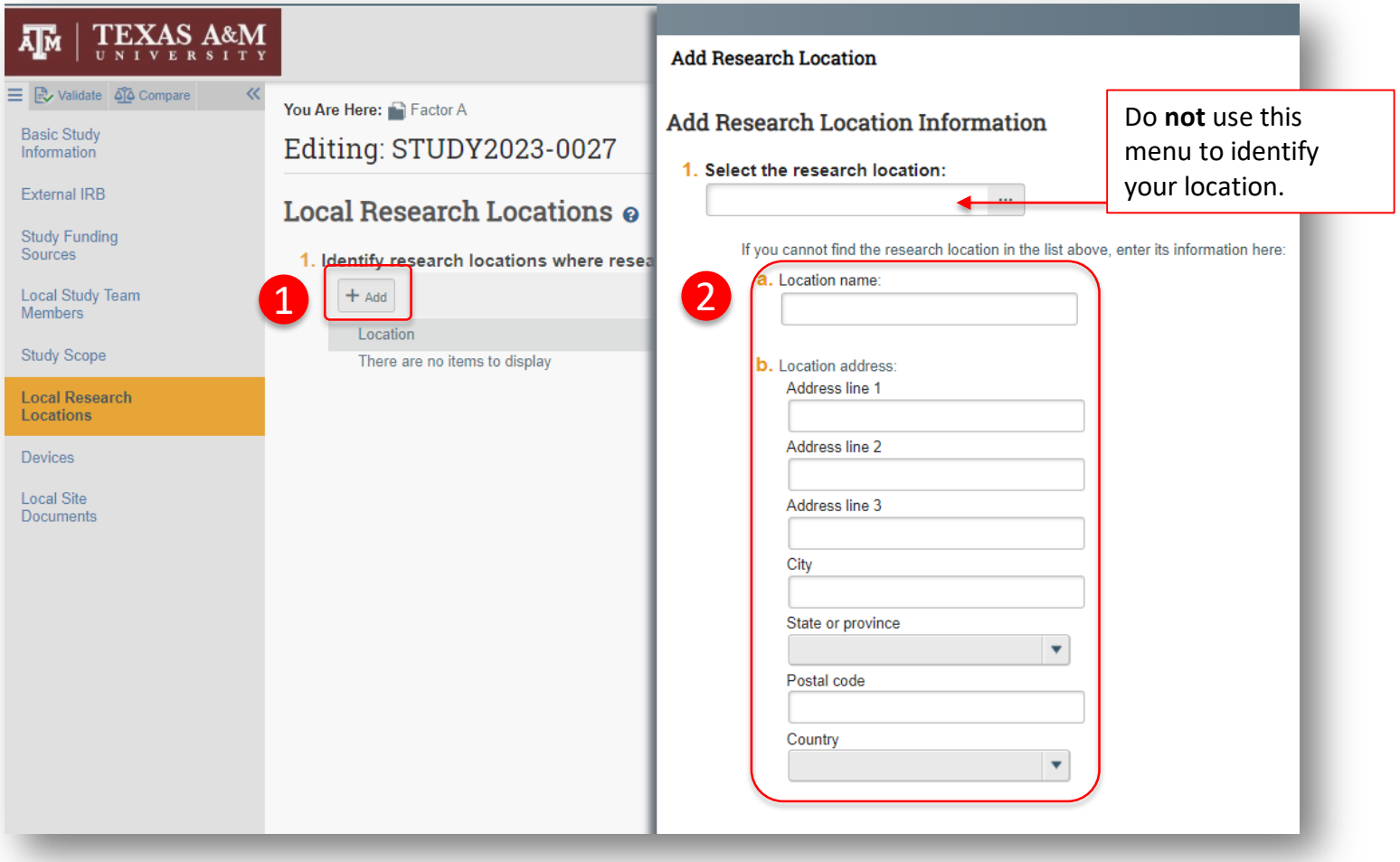
Adding Study Location

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

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

2. <u>Type in</u> the name and address of each 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.

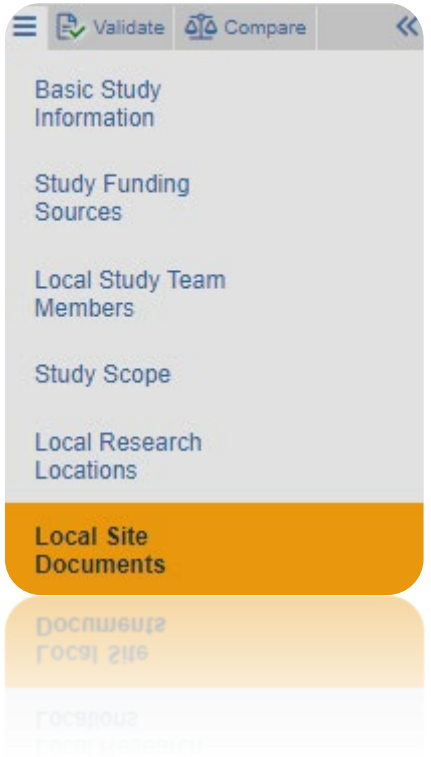


Local Site Documents

Only your study's initial approval letter, most recent approval letter, and a PDF of your protocol were transferred from iRIS to Huron.

Action items:

1. Upload only the current study documents being used.
    - You should upload your most recently approved study documents (e.g., consent documents, surveys, interview scripts, flyers, recruitment emails) and other important documents previously submitted to the IRB (e.g., site authorization letters, translation certificates, material transfer agreements).

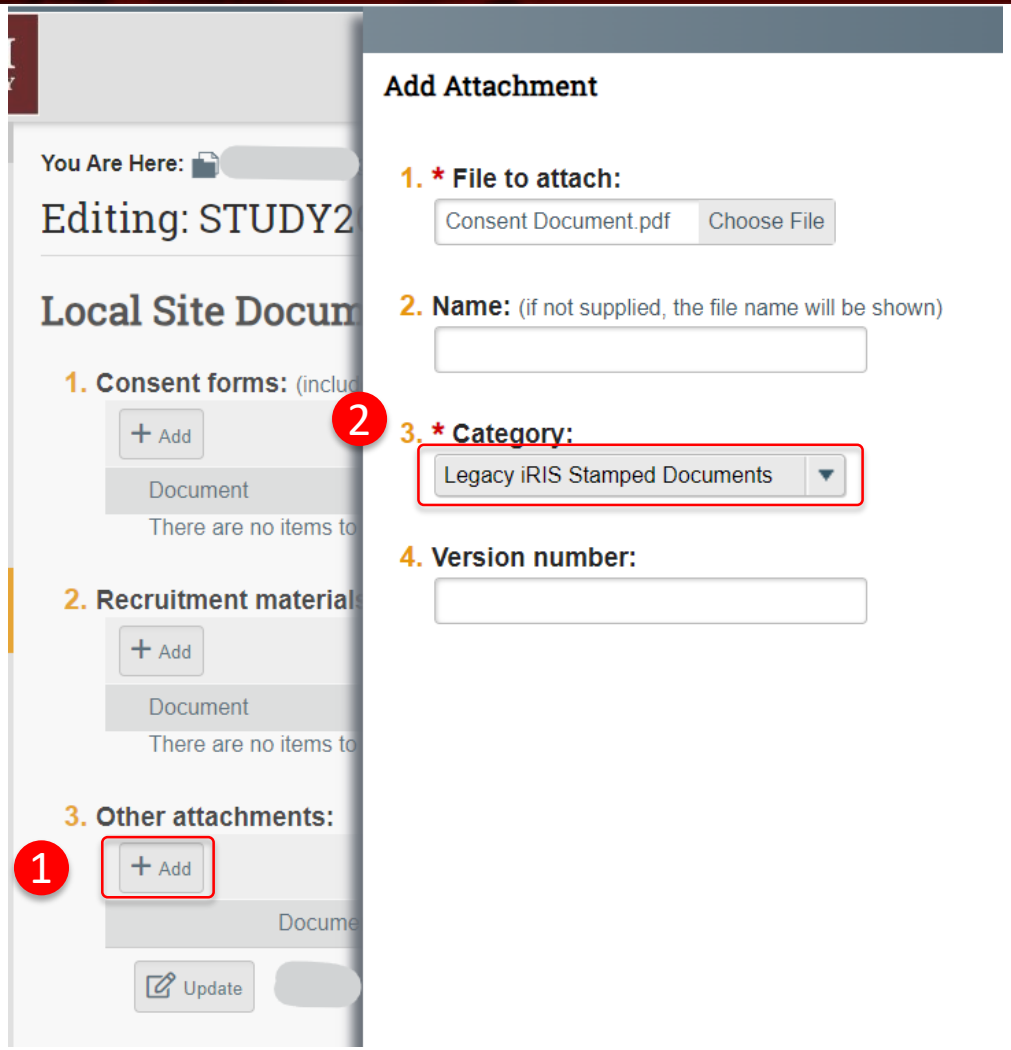


If you are uploading IRB stamped PDF documents

If you are uploading IRB stamped PDF documents, please follow these instructions carefully.

1. Attach **all your IRB stamped PDF documents** (this includes IRB stamped consent documents and recruitment materials) under **Q3 Other Attachments**.

2. Assign the Category **Legacy iRIS Stamped Documents** from the drop down menu.



Uploading documents that do not have the IRB stamp on them:

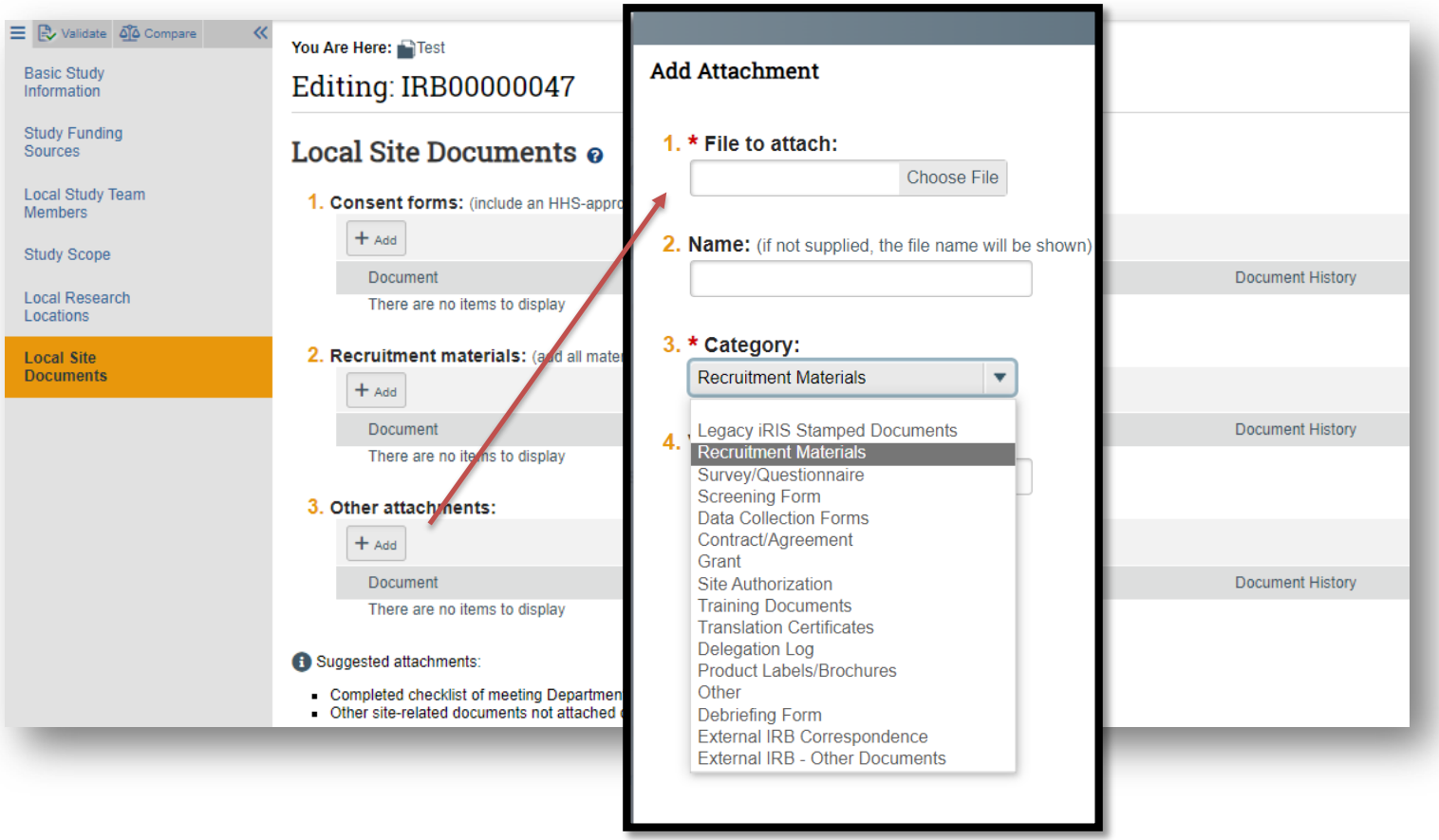
When uploading documents that do not have the IRB stamp on them, be aware that there are three separate locations for you to upload your documents:

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).

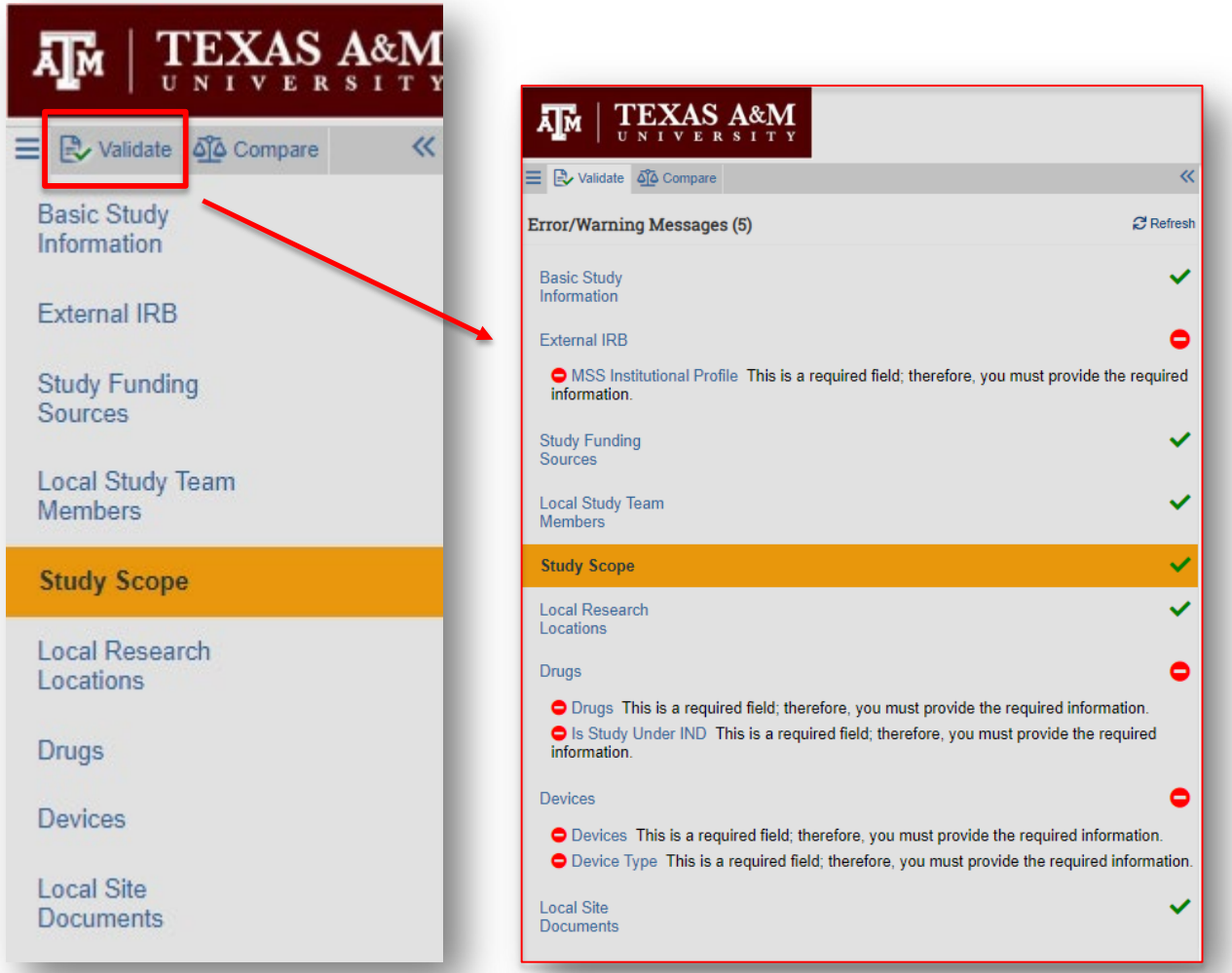
Q3 – Other attachments: is designated for you to attach your data collecting instruments (e.g., survey/questionnaires, data collecting forms, screening forms) and other important documents (e.g., translation certificates, site authorization).

IMPORTANT! Do not use the "Legacy iRIS Stamped Documents" Category for your un-stamped documents. This category is *only* intended for documents that have the IRB stamp on the bottom left hand corner.



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 shown.

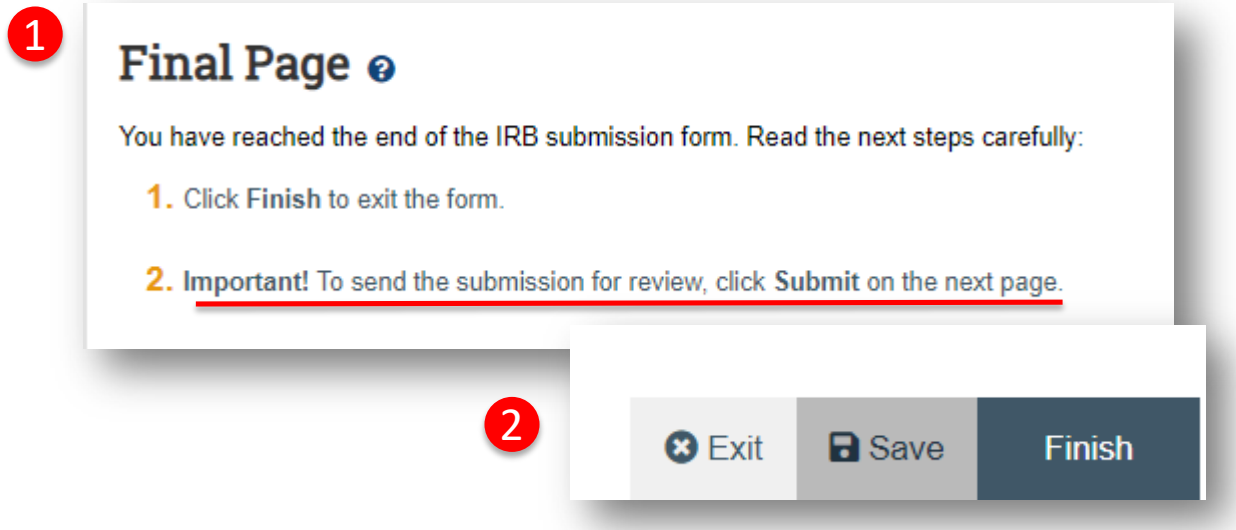


Submitting to the IRB

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.



Submitting to the IRB

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

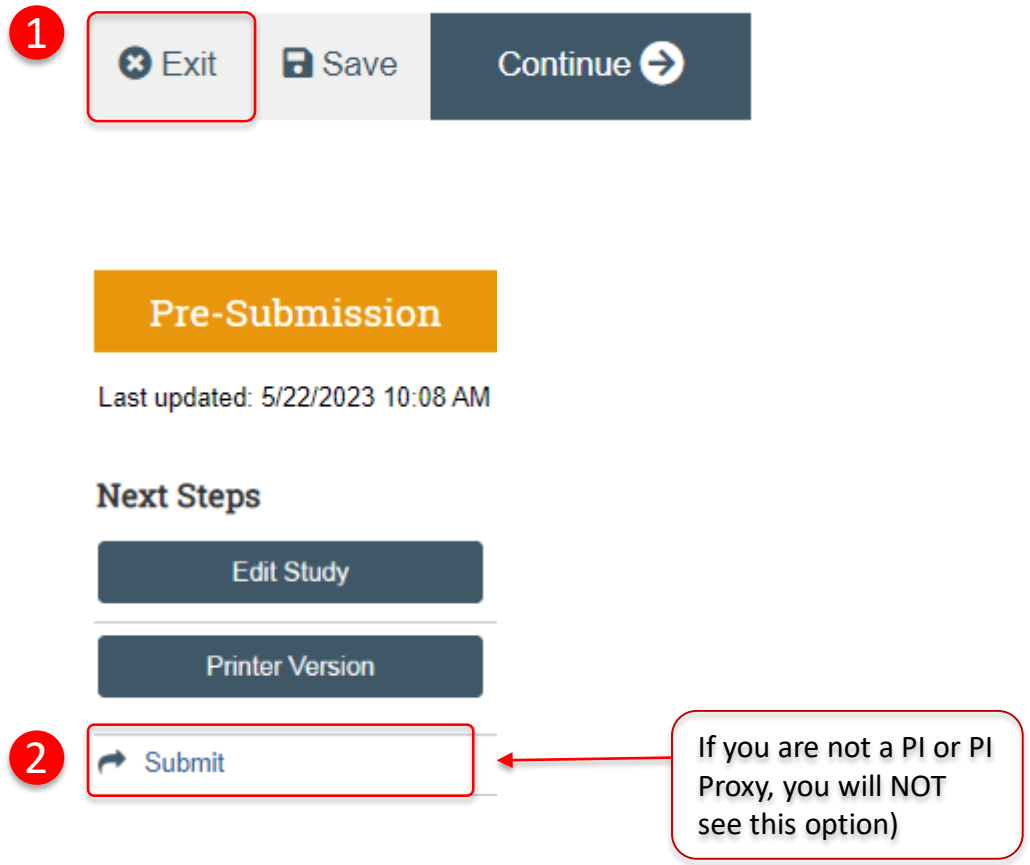
1. Select **Exit** to be directed to the IRB Workspace

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



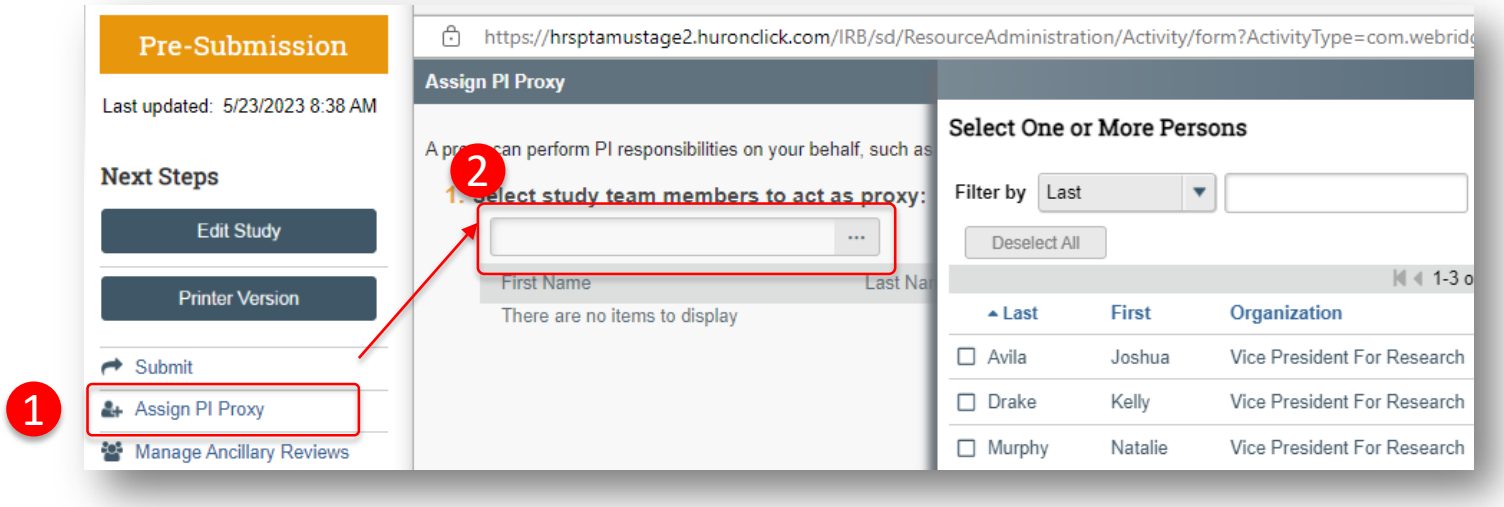
How to assign a PI Proxy

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.



IMPORTANT!

An automatic notification will **not** be generated by Huron to alert the PI that the submission is ready to be submitted.

If you are not the PI on the project, you will need to notify the PI via email or the Huron messaging system that the submission is ready to be submitted.

Learn how to use the Huron messaging system here.

Slide added: 4/10/2024

Visit the FAQ webpage

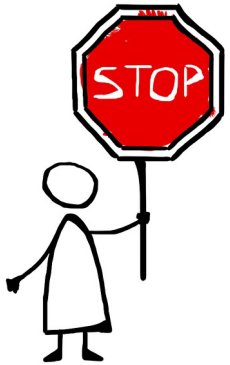
Please take a moment to visit the frequently asked questions webpage **Huron FAQ – Division of Research (tamu.edu)** to learn more about Huron functionality.

Slide added: 1/29/2024

Congratulations, you have submitted your first submission in Huron!

Once your modification 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**.

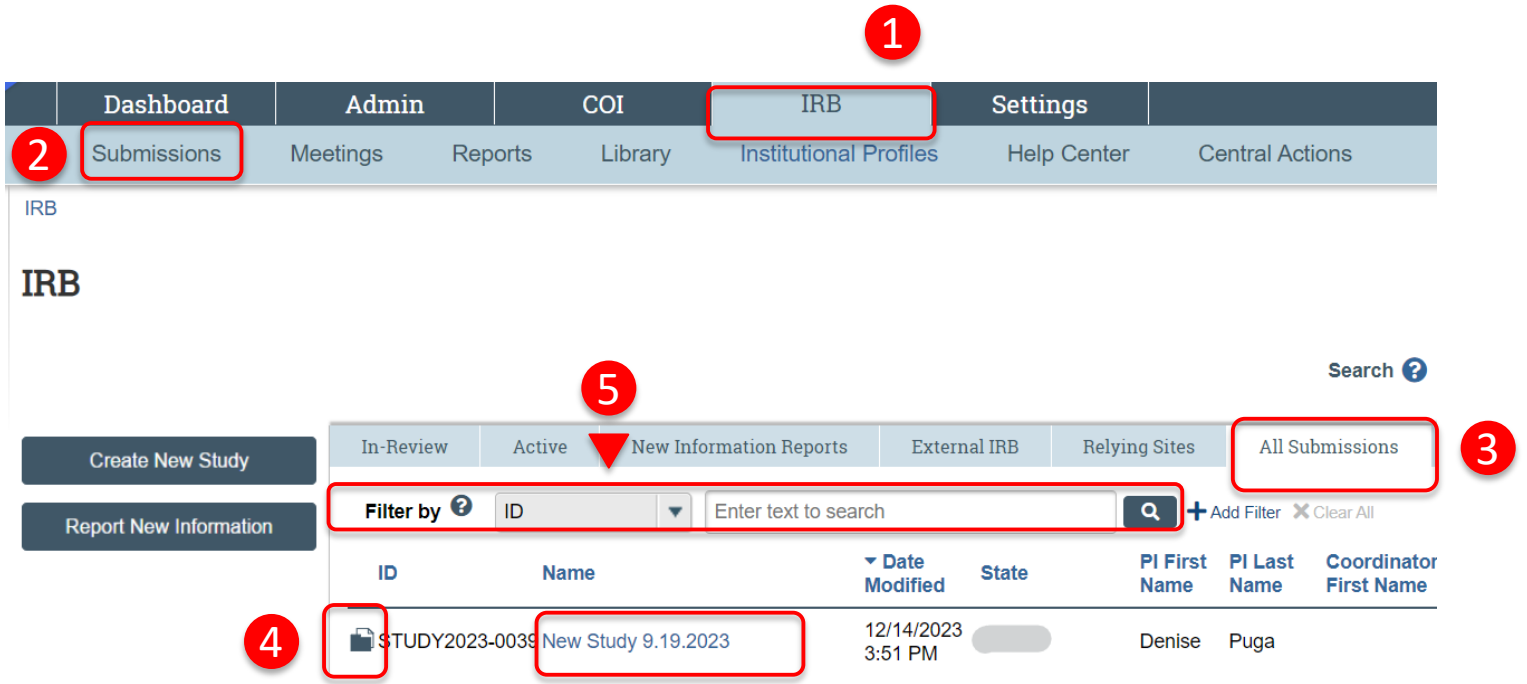
HOW TO SUBMIT A MODIFICATION AND A CONTINUING REVIEW



It is ***critical*** that you look at your initial approval letter and verify that your study requires a continuing review before proceeding. If your study requires an administrative check in *DO NOT* select ***Modification and Continuing review***. If you do, your submission will be returned and you will have to start over.

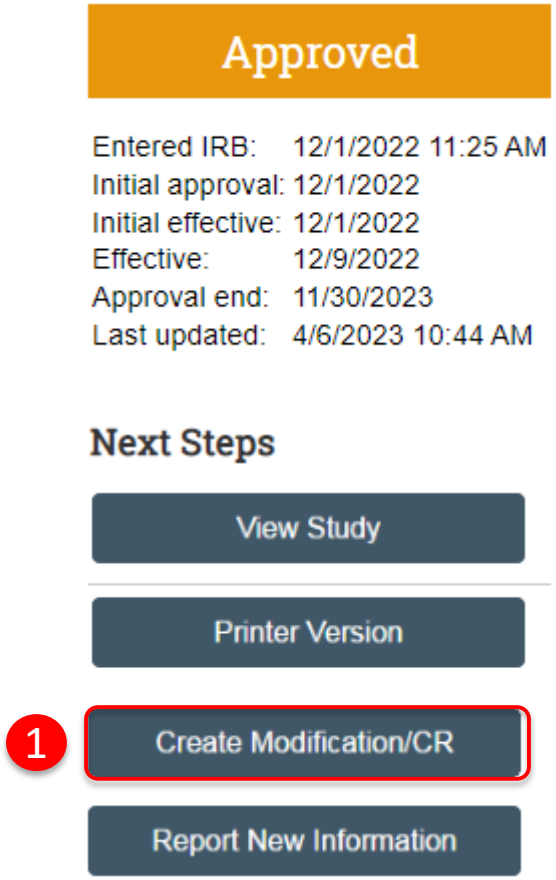
Getting started

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



Creating a modification

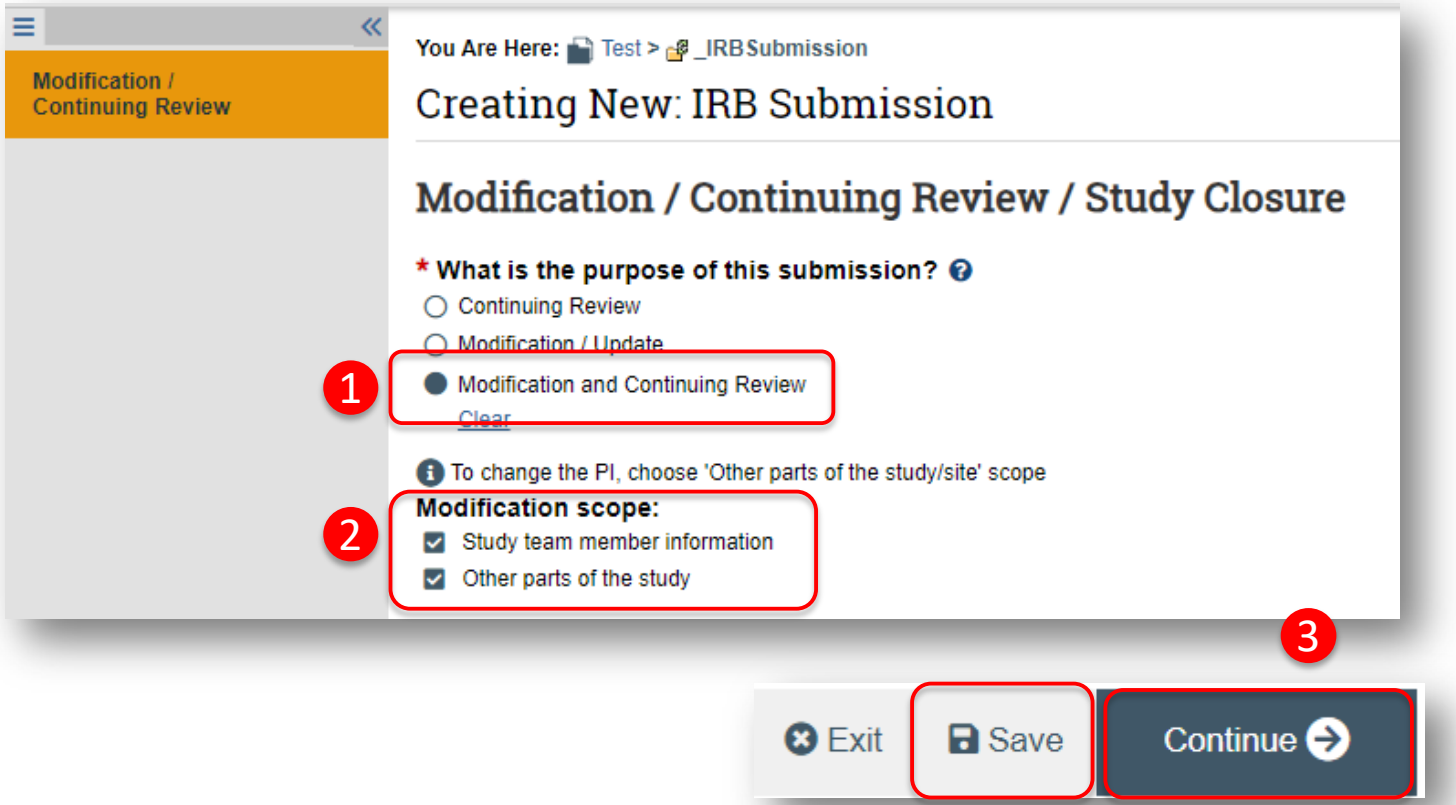
1. Select **Create Modification/CR**



Modification and Continuing Review

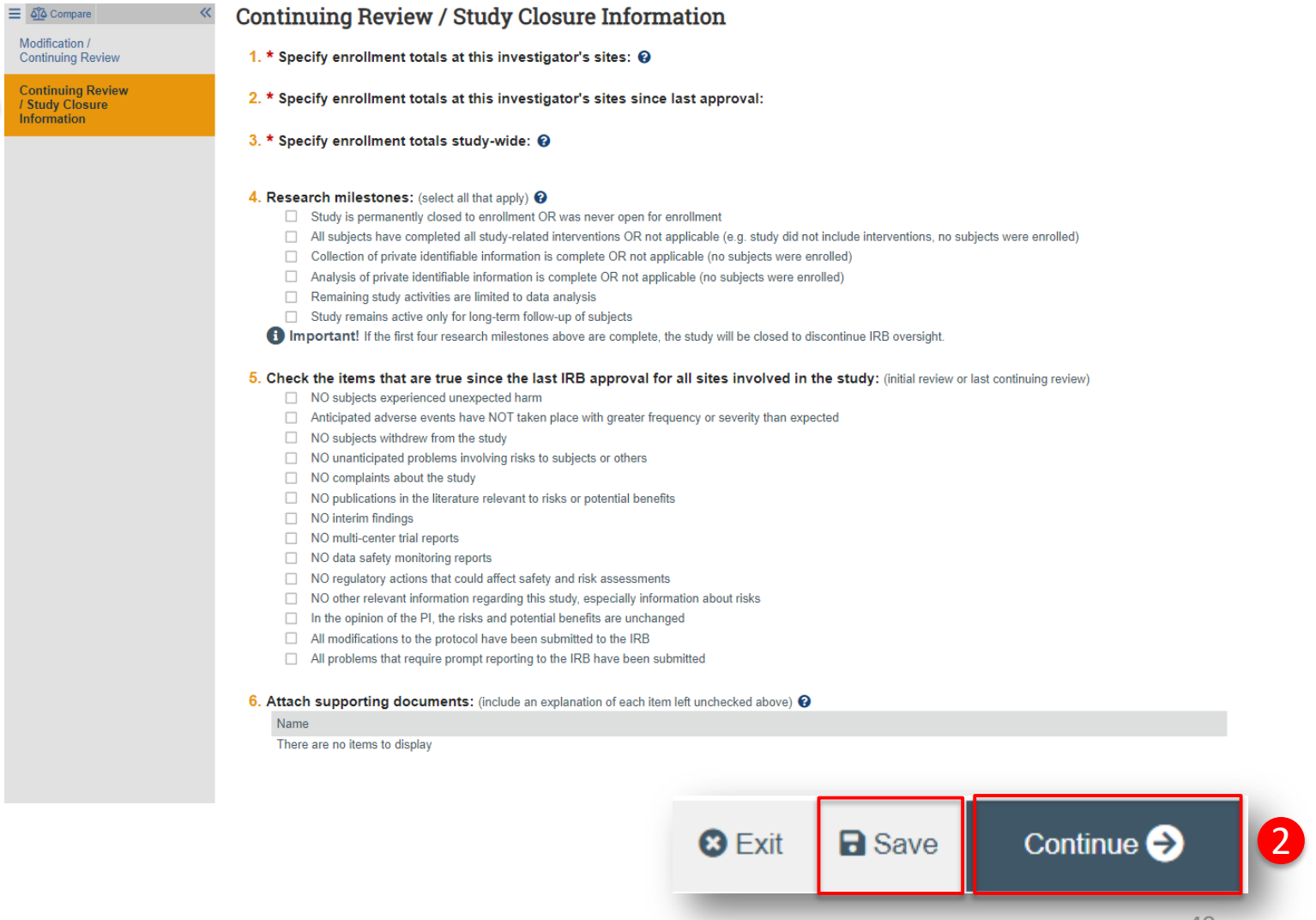
1. Select **Modification and Continuing Review**
2. Identify the **modification scope** (*must select both*):
   - Select **Study team member information** to add new study personnel
   - Select **Other parts of the study** for all other modifications to the protocol
3. Click **Save** and then **Continue**

   *Note: Once you select "Save" or "Continue", you will not be able to edit your responses 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 13**).*



Modification and Continuing Review (continued)

1. Complete the **Continuing Review/Study Closure Information** page:
   - All questions marked with a red asterisk (*) require a response.
   - Read carefully over **Questions 4**. Select only the response(s) that apply. If none apply, do not check any boxes.
   - 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.
2. Click **Save** and then **Continue**



Click **here** to be returned to **Slide 14** for instructions on how to finish your submission.