



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

History	Funding	Contacts	Documents	Follow-on Submissions	Reviews	Snapshots
Study Related Documents						
Draft		Category		Final		
IRB2021-0701 - Outcome Letter Notification (Approved)		Correspondence		IRB2021-0701 - Outcome Letter Notification (Approved)		
Site Related Documents						
Draft	Category	Final	Last Finalized	Document History		



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.

The screenshot shows the IRB workspace interface. At the top, there is a navigation bar with tabs: Dashboard, Admin, COI, IRB (highlighted with a red box and callout 1), and Settings. Below this is a secondary navigation bar with tabs: Submissions (highlighted with a red box and callout 2), Meetings, Reports, Library, Institutional Profiles, Help Center, and Central Actions. The main content area is titled 'IRB' and contains a 'Create New Study' button, a 'Report New Information' button, and a search bar. The search bar has a dropdown menu with 'All Submissions' selected (highlighted with a red box and callout 3). Below the search bar is a table with columns: ID, Name, Date Modified, State, PI First Name, PI Last Name, and Coordinator First Name. The first row of the table is highlighted with a red box and callout 4, showing a folder icon, ID 'STUDY2023-0039', Name 'New Study 9.19.2023', Date Modified '12/14/2023 3:51 PM', State 'Off', PI First Name 'Denise', PI Last Name 'Puga', and Coordinator First Name. A 'Filter by' dropdown menu is also visible, with 'ID' selected (highlighted with a red box and callout 5).



Creating a modification

1. Select **Create Modification/CR**

Approved

Entered IRB: 12/1/2022 11:25 AM
Initial approval: 12/1/2022
Initial effective: 12/1/2022
Effective: 12/9/2022
Approval end: 11/30/2023
Last updated: 4/6/2023 10:44 AM

Next Steps

View Study

Printer Version

1

Create Modification/CR

Report New Information

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**

ATM | TEXAS A&M UNIVERSITY

You Are Here: Test > _IRBSubmission

Creating New: IRB Submission

Modification / Continuing Review / Study Closure

1 * What is the purpose of this submission? ?

Continuing Review

Modification / Update

Modification and Continuing Review

[Clear](#)

2 ⓘ To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

Study team member information

Other parts of the study

3 Save

4 Continue →

Exit

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.

The screenshot displays the 'Modification / Continuing Review' interface for submission MOD00000018. The page title is 'Modification / Continuing Review / Study Closure'. A red circle with the number '1' highlights the 'Save' button in the bottom right corner of the form. The form contains a section titled '* What is the purpose of this submission?' with three radio button options: 'Continuing Review', 'Modification / Update' (selected), and 'Modification and Continuing Review'. Below this is a 'Modification scope' section with two checked checkboxes: 'Study team member information' and 'Other parts of the study'. At the bottom of the form, there are three buttons: 'Exit', 'Save', and 'Continue'. A red circle with the number '2' highlights the 'Discard' option in the 'Next Steps' sidebar menu on the right. The 'Next Steps' menu includes options like 'Edit Modification/CR', 'Printer Version', 'Submit', 'Manage Ancillary Reviews', 'Create Ad Hoc Certifications', 'Add Comment', 'Add Private Comment', 'Discard', and 'Manage Tags'.

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.

1

You Are Here: IRB sample application (not re... > Modification / Update #1 for S...

Editing: MOD00000001

Modification Information

1. **Study enrollment status:**
 - No subjects have been enrolled to date
 - Subjects are currently enrolled
 - Study is permanently closed to enrollment
 - All subjects have completed all study-related interventions
 - Collection of private identifiable information is complete
2. **Notification of subjects:** (check all that apply)
 - Current subjects will be notified of these changes
 - Former subjects will be notified of these changes

i Attach files: If notifying subjects, add a description of how they will be notified to the Oth
3. *** Summarize the modifications:** **?**

This modification is (1) to finish populating the Huron Application and (2) to add a new recruitment flyer

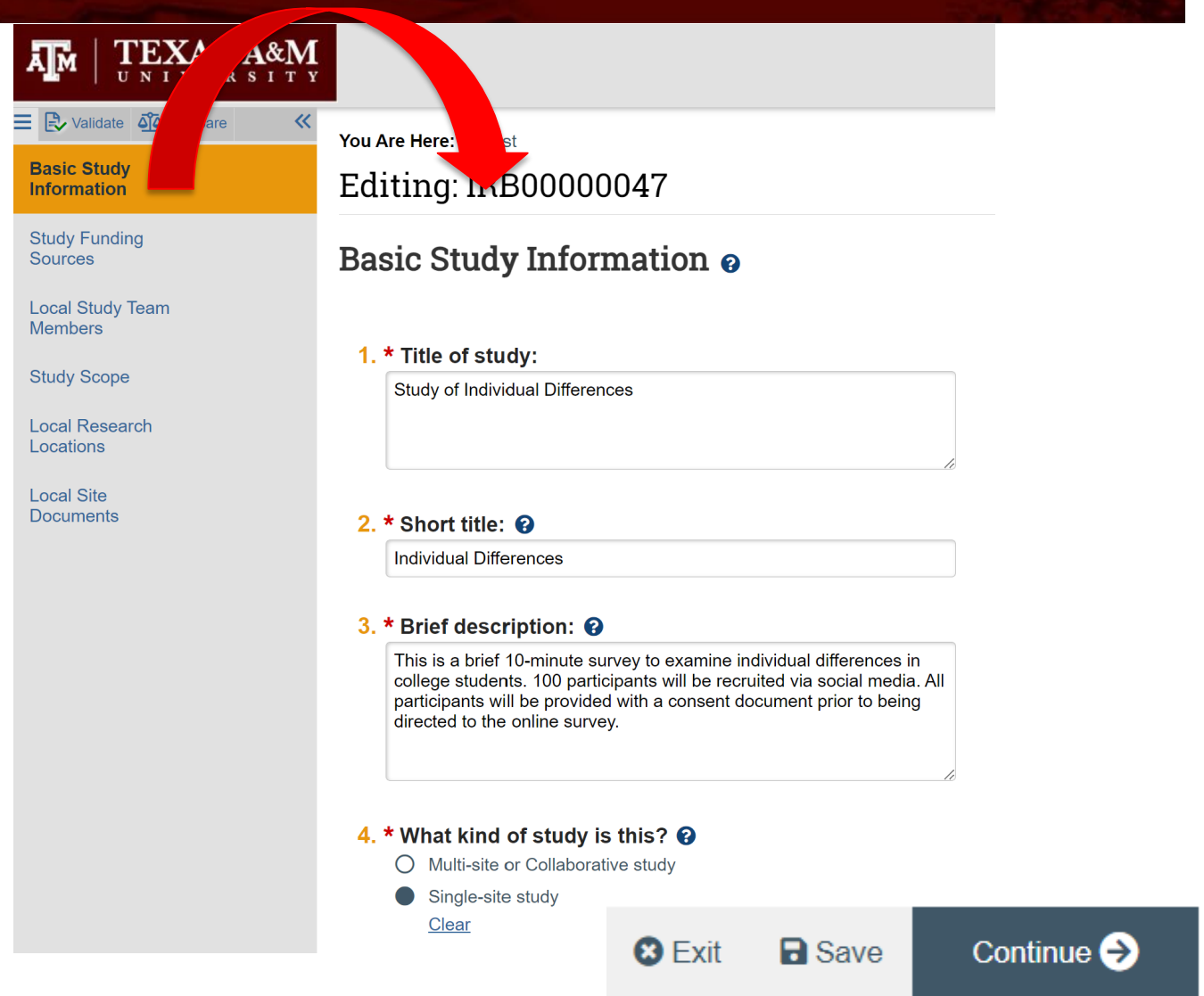
✕ Exit **💾** Save **Continue** **➔**

2

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.



The screenshot displays the IRB application interface. On the left is the **Page Navigator**, a vertical list of menu items: **Basic Study Information** (highlighted in orange), Study Funding Sources, Local Study Team Members, Study Scope, Local Research Locations, and Local Site Documents. On the right is the **Basic Study Information** form. At the top of the form, it says "You Are Here: [unclear] st" and "Editing: IRB00000047". The form contains four required fields:

- * Title of study:** A text box containing "Study of Individual Differences".
- * Short title:** A text box containing "Individual Differences".
- * Brief description:** A text box containing "This is a brief 10-minute survey to examine individual differences in college students. 100 participants will be recruited via social media. All participants will be provided with a consent document prior to being directed to the online survey."
- * What kind of study is this?** Radio button options: Multi-site or Collaborative study, Single-site study. A [Clear](#) link is below.

At the bottom of the form are three buttons: **Exit** (with a close icon), **Save** (with a save icon), and **Continue** (with a right arrow icon).

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.

6. * Local principal investigator: ?
Denise Puga ... ✕

7. * Attach the protocol: ?

+ Add

Document	Category	Date Modified	Document History
There are no items to display			

✕ Exit Save Continue →

Clarification Requested Clarification Requested Modifications Required

History	Contacts	COI	Documents	IRB Assignment Details	Reviews	Related RNIs	Snapshots	...
Study Related Documents								
Draft	Updated in Modification	Category	Final	Last Finalized	Document History			
IRB2023-0001 Application PDF	No	Correspondence	IRB2023-0001 Application PDF	8/10/2023 9:05 AM	History			
IRB2023-0001 Initial Review	No	Correspondence	IRB2023-0001 Initial Review	8/10/2023 9:05 AM	History			

Next Steps

Edit Modification/CR

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](#).

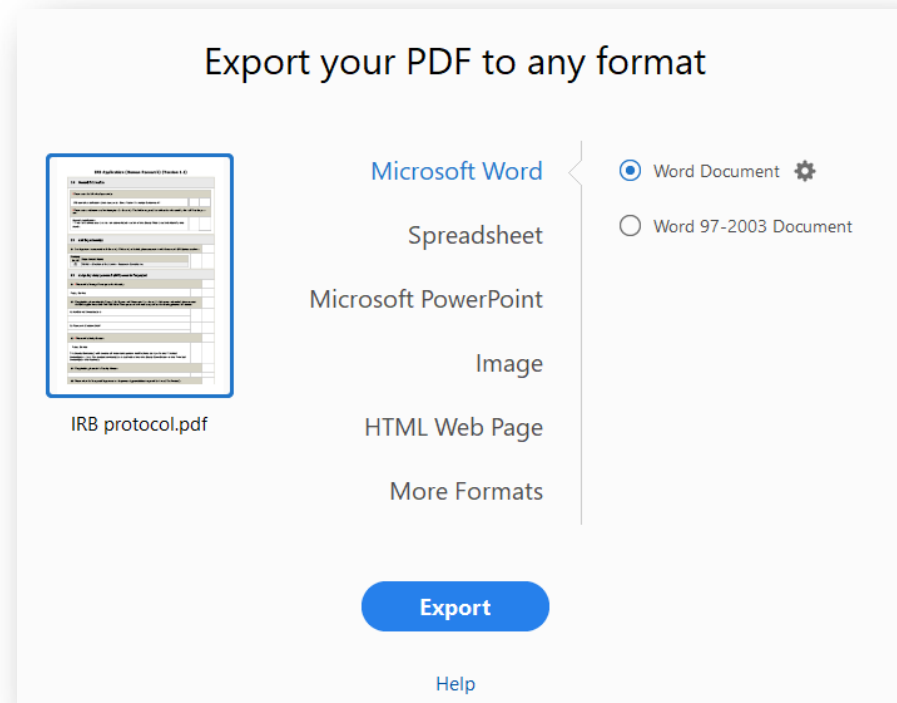
Important! *All requested modifications to an approved study must be reflected in the Word document that you upload by choosing either Option A or B.* For example, if you are increasing maximum study enrollment, you must update your study protocol and your consent document to reflect the increase in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

1



Instructions continued

Option A (continued)

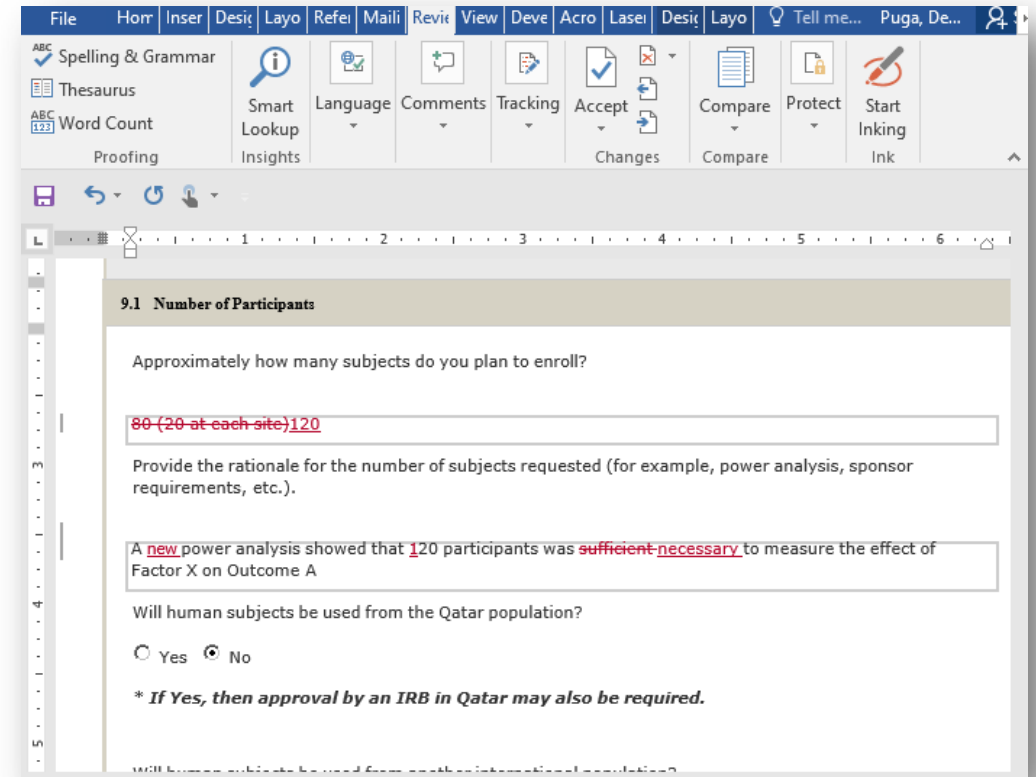
2. Edit the Word document to reflect the proposed changes and save your work.
Important! Use Track Changes to capture all changes made to the approved protocol. Instructions on how to use Track Changes in Word can be found [here](#).

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.

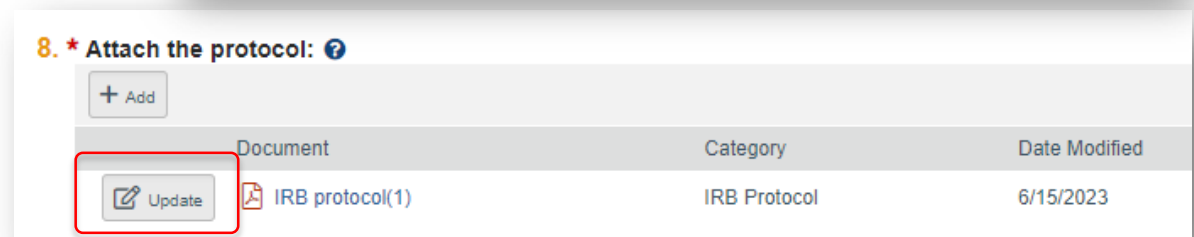


Go to the next slide to learn how to add and update documents in Huron.

4



5



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.

The screenshot shows a web interface for managing documents. At the top, there is a header "8. * Attach the protocol: ?". Below this is a table with columns: Document, Category, Date Modified, and Document History. A red circle with the number "1" points to a "+ Add" button. A red box labeled "Click to Add" points to this button. The table contains one row with the following data: Document: IRB protocol.docx(1.01), Category: IRB Protocol, Date Modified: 6/15/2023, Document History: History. A red circle with the number "2" points to an "Update" button on the left side of the row. A red box labeled "Click to Update" points to this button. A red box labeled "Click to Remove" points to a small "X" icon on the right side of the row.

Document	Category	Date Modified	Document History
IRB protocol.docx(1.01)	IRB Protocol	6/15/2023	History

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.

9.4 Inclusion/Exclusion Criteria

What are the inclusion and exclusion criteria for study participation?

Inclusion criteria: 18 and older
Exclusion criteria: No known history of ever taking Factor X prior to this study

Do the exclusion criteria exclude specific populations or individuals based on gender, culture, language, economics, race, or ethnicity?

Yes No

TEMPLATE-Protocol_Social-Behavioral_WITHOUT_instructions.docx - Word

File Home Insert Design Layout References Mailings Review View Developer Acrobat Laserfiche Tell me... Puga, De... Share

Clipboard Font Paragraph Styles Editing Create and Share Adobe PDF Request Signatures Adobe Acrobat

3.0 Inclusion and exclusion criteria:

Inclusion criteria: 18 and older
Exclusion criteria: No known history of ever taking Factor X prior to this study

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.

The screenshot shows the 'Study Funding Sources' page for a study identified as 'STUDY2023-0043'. The page is divided into several sections:

- Navigation:** A sidebar on the left contains links for 'Basic Study Information', 'Study Funding Sources' (highlighted), 'Local Study Team Members', 'Study Scope', 'Local Research Locations', and 'Local Site Documents'.
- User Information:** At the top right, it says 'You Are Here: HRPP staff' and 'Editing: STUDY2023-0043'.
- Section 1: Maestro Funding Source:** Includes a search input field with a dropdown arrow and a table header with columns: 'M-Number', 'Project Name', 'PI Last Name', and 'PI Fir'. Below the header, it states 'There are no items to display'.
- Section 2:** Contains two radio button options: 'This study has no funding.' and 'Project not set up in Maestro.' A 'Clear' link is positioned below the second option.
- Section 3: Additional Information or proposal number:** Features a large, empty text input area.
- Section 4: Upload any relevant Sponsor documentation:** Includes a '+ Add' button and a table header with columns: 'Document', 'Category', and 'Date Modified'. Below the header, it states 'There are no items to display'.

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?

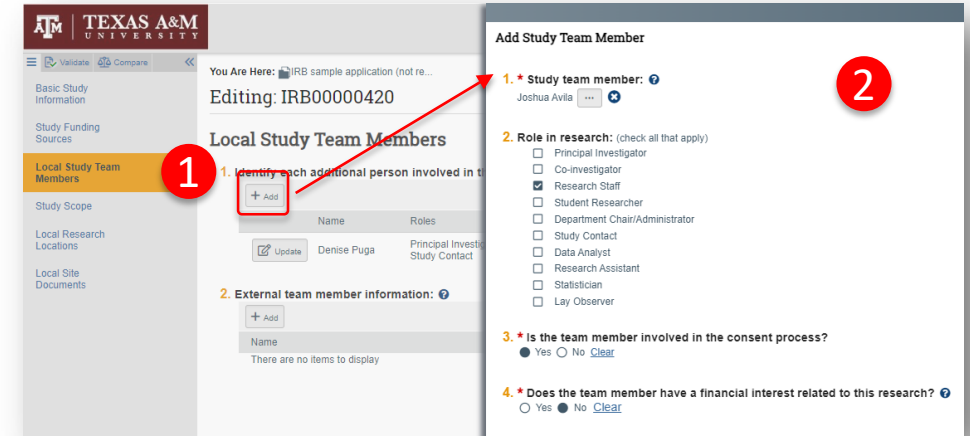
Some TAMU members (such as undergraduates, visiting scholars, and adjunct/affiliate professors) need to opt into their information being fed into Huron before they are active in the system. If you are not able to locate a member of your research team, have that individual visit the following website: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



Click **X** to Remove

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.

The screenshot displays the Texas A&M University research management system interface. The top navigation bar includes the ATM logo and the text 'TEXAS A&M UNIVERSITY'. The main content area is titled 'Editing: STUDY2023-0027' and 'Local Study Team Members'. A sidebar on the left contains navigation options: 'Basic Study Information', 'Study Funding Sources', 'Local Study Team Members' (highlighted), 'Study Scope', 'Local Research Locations', 'Drugs', 'Devices', and 'Local Site Documents'. The main content area shows a table of team members with columns for 'Name' and 'Update' buttons. A red circle '1' highlights the '+ Add' button. To the right, a 'Submit a Document' form is visible with a 'Choose File' button highlighted by a red circle '2'. A red arrow points from the 'Add' button to the 'Submit a Document' form.

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.



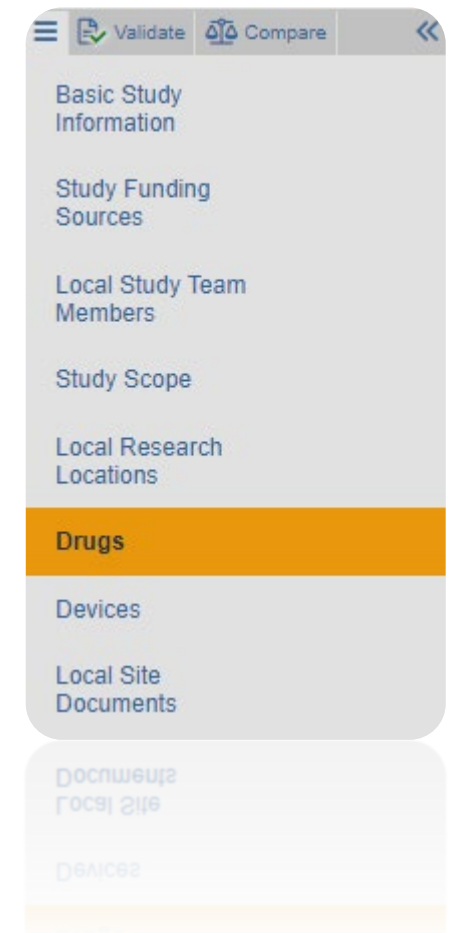
The next 4 slides will cover what information needs to be provided in the Drugs and Devices pages. You may [skip](#) these slides if they are not applicable to your study.



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):

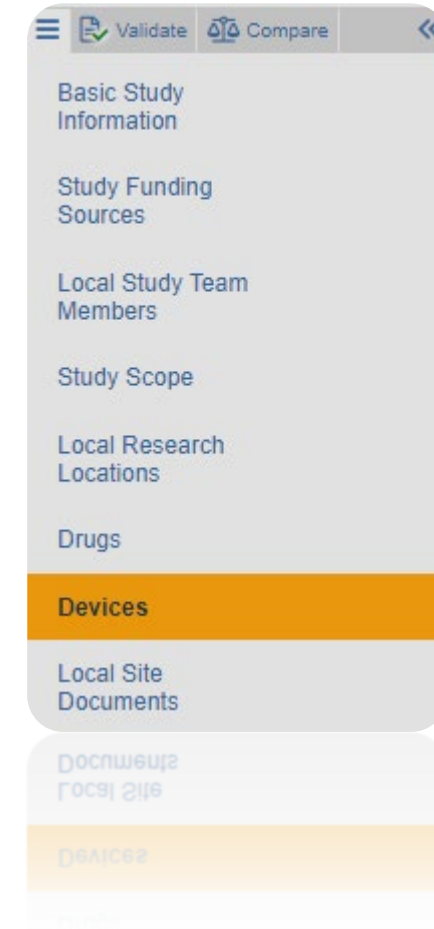
1. In the **Drugs** page, select **+Add** in Q1.
2. Type in the generic and brand name of the drug/biologic/food product/dietary supplement in Q1 of the **Add Drug Information** smart form.
IMPORTANT! The drop-down menu is not loaded and will NOT populate drug information. The name of the drug must be 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**.

The screenshot shows the Texas A&M University system interface. The left sidebar contains navigation options: Basic Study Information, External IRB, Study Funding Sources, Local Study Team Members, Study Scope, Local Research Locations, **Drugs** (highlighted), and Local Site Documents. The main content area shows 'You Are Here: Factor A' and 'Editing: STUDY2023-0027'. Under the 'Drugs' section, there are three numbered callouts: 1. A red circle around the '+ Add' button in the 'List all foods, dietary supplements, d...' section. 2. A red circle around the 'Add Drug Information' form, which includes a dropdown menu for 'Select the drug:' (with a red arrow pointing to it and a callout box stating 'Do not use this menu to identify drug(s)'), and input fields for 'Generic name:' and 'Brand name:'. 3. A red circle around the '+ Add' button in the 'Attach files related to this item:' section. The form also includes a question about FDA IND evaluation and radio button options for drug type (Drug, Biologic, Food Product, Dietary Supplement, Other).

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:

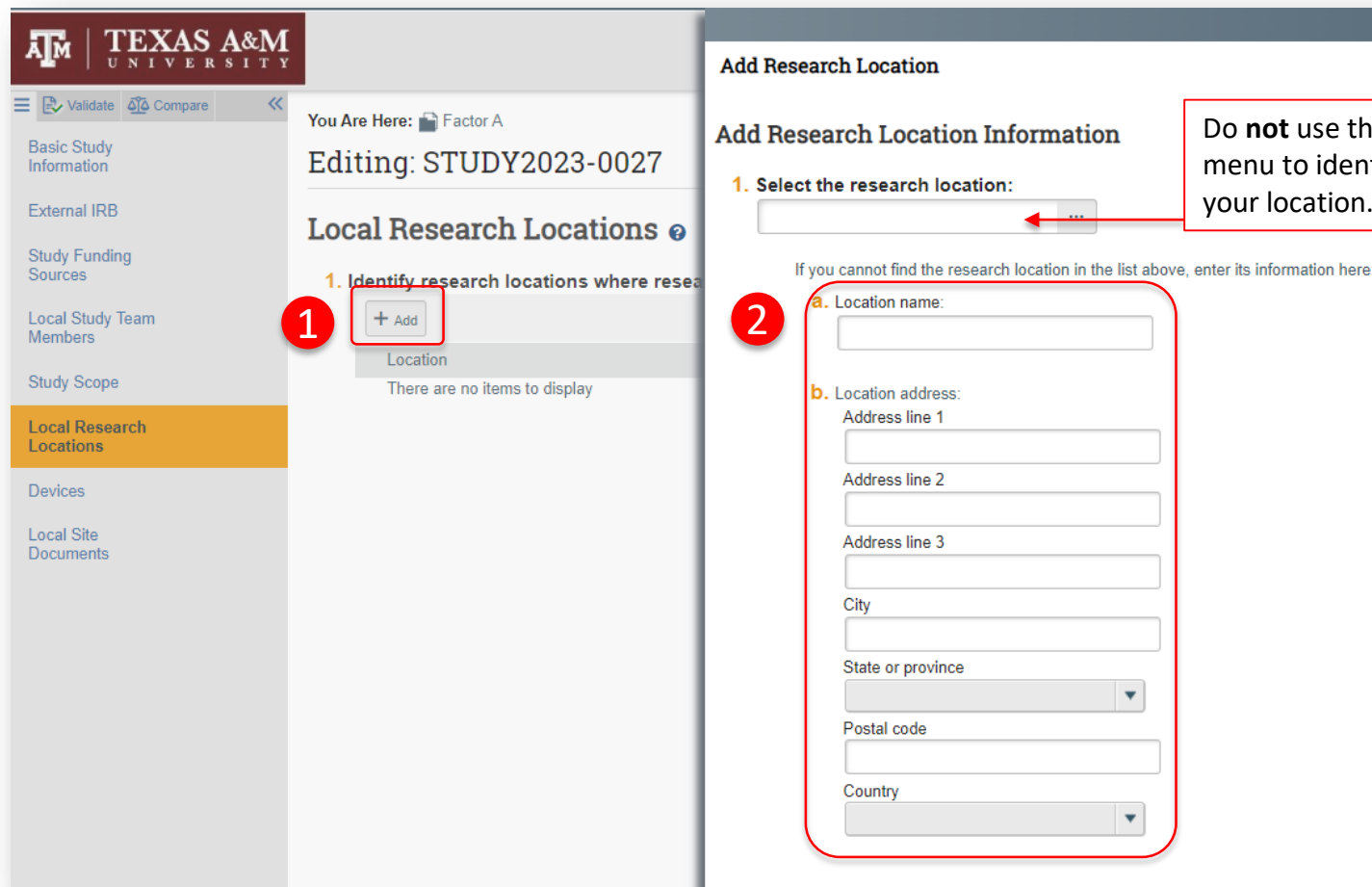
1. Provide all locations where your research will take place



Adding Study Location

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

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



The screenshot shows the 'Local Research Locations' page on the Texas A&M University system. A red circle with the number '1' highlights the '+ Add' button. Below it, a table with the header 'Local Research Locations' is shown, containing one row with the text 'Location' and 'There are no items to display'. To the right, the 'Add Research Location' form is displayed. A red circle with the number '2' highlights the form fields. A red box with an arrow points to a dropdown menu in the '1. Select the research location:' section, with the text 'Do not use this menu to identify your location.' written next to it. The form fields include: 'a. Location name:', 'b. Location address:' (with sub-fields for Address line 1, 2, and 3), 'City', 'State or province', 'Postal code', and 'Country'.

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.

Add Attachment

You Are Here:

Editing: STUDY2

Local Site Documents

1. **Consent forms:** (include)

2

Document

There are no items to

2. **Recruitment materials:**

Document

There are no items to

3. **Other attachments:**

1

Docume

1. *** File to attach:**

Consent Document.pdf

2. **Name:** (if not supplied, the file name will be shown)

3. *** Category:**

Legacy iRIS Stamped Documents

4. **Version number:**

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.

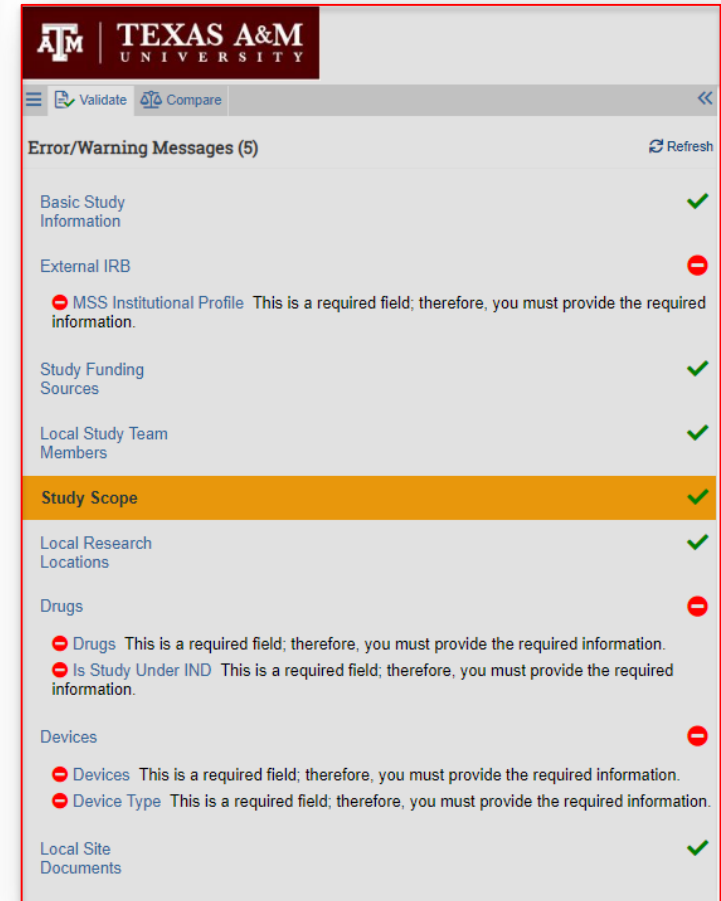
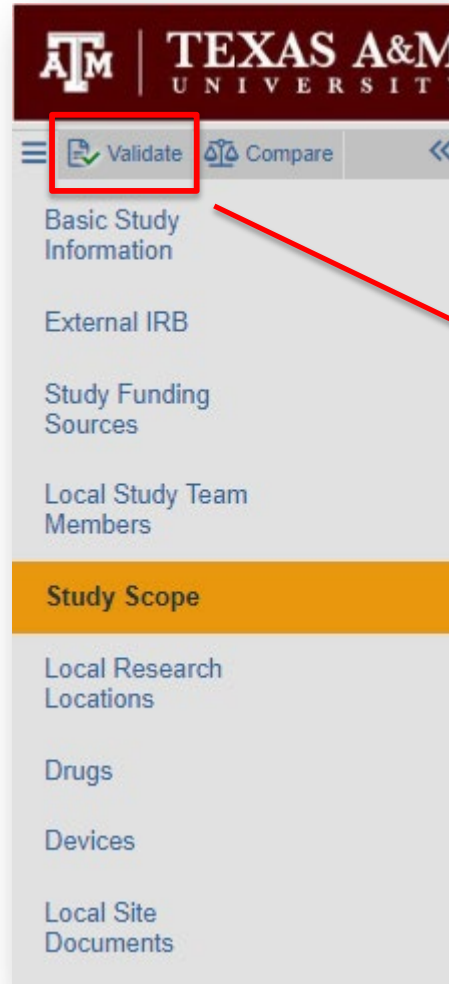
The screenshot shows the 'Add Attachment' modal in the IRB system. The modal contains the following fields:

- * File to attach:** A text input field with a 'Choose File' button.
- Name:** (if not supplied, the file name will be shown) A text input field.
- * Category:** A dropdown menu with 'Recruitment Materials' selected. The dropdown list includes: Legacy iRIS Stamped Documents, Recruitment Materials, Survey/Questionnaire, Screening Form, Data Collection Forms, Contract/Agreement, Grant, Site Authorization, Training Documents, Translation Certificates, Delegation Log, Product Labels/Brochures, Other, Debriefing Form, External IRB Correspondence, and External IRB - Other Documents.

The background shows the 'Local Site Documents' section with three categories: 1. Consent forms, 2. Recruitment materials, and 3. Other attachments. Each category has an '+ Add' button and a 'Document' label. A red arrow points from the '+ Add' button in the 'Consent forms' category to the 'File to attach' field in the modal.

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.

1

Final Page ⓘ

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, click **Submit** on the next page.

2

✕ Exit

Save

Finish

Submitting to the IRB

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

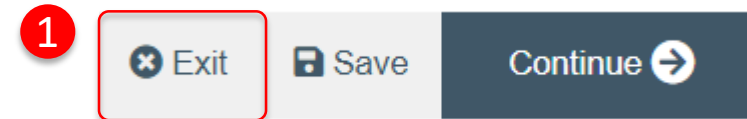
1. Select **Exit** to be directed to the IRB Workspace
2. Click **Submit** (this option is only visible to the PI and PI proxies. If you are not a PI or PI Proxy, you will NOT see this option).

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



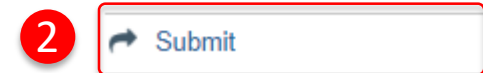
Pre-Submission

Last updated: 5/22/2023 10:08 AM

Next Steps

Edit Study

Printer Version



If you are not a PI or PI Proxy, you will NOT see this option)

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.

The screenshot shows the IRB workspace interface. On the left, a sidebar contains a 'Pre-Submission' section with a 'Last updated: 5/23/2023 8:38 AM' timestamp and a 'Next Steps' section with buttons for 'Edit Study', 'Printer Version', 'Submit', 'Assign PI Proxy', and 'Manage Ancillary Reviews'. The 'Assign PI Proxy' button is highlighted with a red box and a red circle containing the number '1'. The main content area is titled 'Assign PI Proxy' and contains a text input field for selecting study team members to act as proxy, which is highlighted with a red box and a red circle containing the number '2'. Below the input field is a table with columns for 'First Name' and 'Last Name', and a message 'There are no items to display'. On the right, a 'Select One or More Persons' modal is open, showing a search filter set to 'Last' and a table of team members with columns for 'Last', 'First', and 'Organization'. The table lists three members: Avila, Joshua, Vice President For Research; Drake, Kelly, Vice President For Research; and Murphy, Natalie, Vice President For Research.



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](#).



Visit the FAQ webpage

Please take a moment to visit the frequently asked questions webpage [Huron FAQ – Division of Research \(tamu.edu\)](https://www.tamu.edu/huron/faq) to learn more about Huron functionality.



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.

The screenshot shows the IRB workspace interface. At the top, there is a navigation bar with tabs: Dashboard, Admin, COI, IRB (highlighted with a red box and callout 1), and Settings. Below this is a sub-navigation bar with tabs: Submissions (highlighted with a red box and callout 2), Meetings, Reports, Library, Institutional Profiles, Help Center, and Central Actions. The main content area is titled 'IRB' and contains a search bar, a 'Create New Study' button, and a 'Report New Information' button. A filter bar is present with a dropdown menu showing 'In-Review', 'Active', 'New Information Reports' (highlighted with a red box and callout 5), 'External IRB', and 'Relying Sites'. A search input field contains 'All Submissions' (highlighted with a red box and callout 3). Below the filter bar is a table with columns: ID, Name, Date Modified, State, PI First Name, PI Last Name, and Coordinator First Name. The first row of the table is highlighted with a red box and callout 4, showing a folder icon, the ID 'STUDY2023-0039', the name 'New Study 9.19.2023', the date '12/14/2023 3:51 PM', the state 'On Hold', and the PI names 'Denise' and 'Puga'.



Creating a modification

1. Select **Create Modification/CR**

Approved

Entered IRB: 12/1/2022 11:25 AM
Initial approval: 12/1/2022
Initial effective: 12/1/2022
Effective: 12/9/2022
Approval end: 11/30/2023
Last updated: 4/6/2023 10:44 AM

Next Steps

View Study

Printer Version

1

Create Modification/CR

Report New Information

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](#)).

You Are Here: Test > _IRBSubmission

Creating New: IRB Submission

Modification / Continuing Review / Study Closure

* What is the purpose of this submission? ⓘ

Continuing Review

Modification / Update

Modification and Continuing Review

[Clear](#)

ⓘ To change the PI, choose 'Other parts of the study/site' scope

Modification scope:

Study team member information

Other parts of the study

⊗ Exit Save Continue →

Modification and Continuing Review (continued)

- 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.
- Click **Save** and then **Continue**



Continuing Review / Study Closure Information

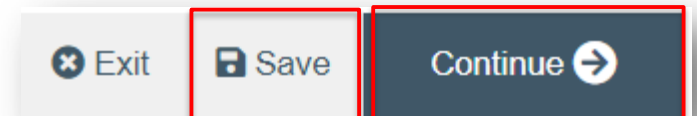
- * Specify enrollment totals at this investigator's sites: ?
- * Specify enrollment totals at this investigator's sites since last approval:
- * Specify enrollment totals study-wide: ?
- Research milestones:** (select all that apply) ?
 - Study is permanently closed to enrollment OR was never open for enrollment
 - All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
 - Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
 - Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
 - Remaining study activities are limited to data analysis
 - Study remains active only for long-term follow-up of subjects

i Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.
- Check the items that are true since the last IRB approval for all sites involved in the study:** (initial review or last continuing review)
 - NO subjects experienced unexpected harm
 - Anticipated adverse events have NOT taken place with greater frequency or severity than expected
 - NO subjects withdrew from the study
 - NO unanticipated problems involving risks to subjects or others
 - NO complaints about the study
 - NO publications in the literature relevant to risks or potential benefits
 - NO interim findings
 - NO multi-center trial reports
 - NO data safety monitoring reports
 - NO regulatory actions that could affect safety and risk assessments
 - NO other relevant information regarding this study, especially information about risks
 - In the opinion of the PI, the risks and potential benefits are unchanged
 - All modifications to the protocol have been submitted to the IRB
 - All problems that require prompt reporting to the IRB have been submitted

6. Attach supporting documents: (include an explanation of each item left unchecked above) ?

Name

There are no items to display





Click [here](#) to be returned to **Slide 14** for instructions on how to finish your submission.