



# Not Human Subjects Research

---

*Human Research Protection Program*



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

## Getting Started

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

The screenshot shows the IRB workspace interface. The top navigation bar includes tabs for Dashboard, COI, and IRB. The IRB tab is selected and highlighted with a red box and a red circle containing the number 1. Below the navigation bar, the Submissions tab is selected and highlighted with a red box and a red circle containing the number 2. On the left side, the 'Create New Study' button is highlighted with a red box and a red circle containing the number 3. The main content area displays the IRB workspace with a search bar and a table of IRB submissions. The table has columns for ID, Name, Date Modified, State, PI First Name, PI Last Name, and Coordinator First Name. The table is currently empty.

ID	Name	Date Modified	State	PI First Name	PI Last Name	Coordinator First Name
----	------	---------------	-------	---------------	--------------	------------------------

## Complete the Basic Study Information page

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

The screenshot shows a web interface for creating a new IRB submission. The page title is 'Creating New: IRB Submission'. The main heading is 'Basic Study Information'. There are four required questions:

- 1. \* Title of study:** A text input field containing 'Teaching for student success'.
- 2. \* Short title:** A text input field containing 'Student Success'.
- 3. \* Brief description:** A text area containing 'I am submitting this application to obtain a not human subject research determination.'
- 4. \* What kind of study is this?:** Radio button options for 'Multi-site or Collaborative study' (unselected) and 'Single-site study' (selected). A 'Clear' link is below the options.

## Complete the Basic Study Information page continued

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

5. \* Will an external IRB act as the IRB of record for this study? ⓘ  
 Yes  No [Clear](#)

6. \* Local principal investigator: ⓘ  
Heather Cline

7. \* Attach the protocol: ⓘ

Document	Category	Date Modified	Document History
<input type="button" value="Update"/> <input type="button" value="Not Human Subjects Research Template(1)"/>	IRB Protocol	6/14/2023	History <input type="button" value="✕"/>

## How to attach the Not Human Subjects Research Template

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

The Not Human Subjects Research template can be located on the HRPP website:

<https://vpr.tamu.edu/human-research-protection-program/toolkit/templates/>

7. \* Attach the protocol: ?

1. + Add

Document Category Date Modified Document History

There are no items to display

Save Continue →

### Add Attachment

2

1. \* File to attach:

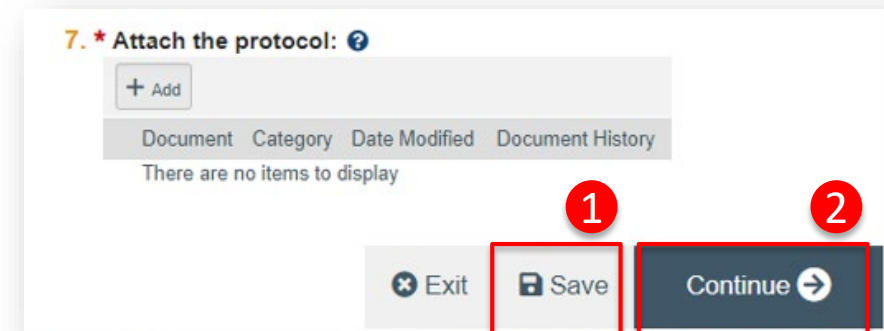
Choose File

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

3. Version number:

## 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 screenshot displays the IRB application interface. On the left is the **Page Navigator** with the following items: **Basic Study Information** (highlighted in orange), Study Funding Sources, Local Study Team Members, Study Scope, Local Research Locations, and Local Site Documents. The main content area shows 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 sections:

- \* 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 buttons for "Multi-site or Collaborative study" (unselected) and "Single-site study" (selected). A [Clear](#) link is below.

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



## 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 part of a larger system with a sidebar on the left containing navigation options like 'Basic Study Information', 'Study Funding Sources', 'Local Study Team Members', 'Study Scope', 'Local Research Locations', and 'Local Site Documents'. The main content area is titled 'Study Funding Sources' and includes a breadcrumb 'You Are Here: HRPP staff'. It features four numbered sections: 1. 'Maestro Funding Source' with a search input field and a table with columns 'M-Number', 'Project Name', 'PI Last Name', and 'PI Fir'. Below the table, it states 'There are no items to display'. 2. Two radio button options: 'This study has no funding.' and 'Project not set up in Maestro.', with a 'Clear' link below. 3. 'Additional Information or proposal number:' with a large empty text area. 4. 'Upload any relevant Sponsor documentation:' with an '+ Add' button and a table with columns 'Document', 'Category', and 'Date Modified'. Below this table, it also states 'There are no items to display'.

## Adding Local Study Team

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

Identify all the individuals involved in this project:

1. Click **+Add** (Q1 for TAMU personnel)
2. Complete the **Add Study Team Member** smart Form
  - Q1 – Type the name of the team member being added or click the ellipsis
  - Q2 – Identify the role of the team member
  - Q3 – Identify if the team member will be involved in collecting consent.
3. Click **OK**
4. Click **Save** and then **Continue**

The screenshot shows the Texas A&M University interface for editing a study (STUDY2023-0039). The left sidebar contains navigation options: Basic Study Information, Study Funding Sources, Local Study Team Members (highlighted), Study Scope, Local Research Locations, and Local Site Documents. The main content area is titled 'Local Study Team Members' and includes a '+ Add' button (circled with a red '1'). Below this is a table with columns for Name, Roles, and Financial. A second section, 'External team member information', also has a '+ Add' button. A modal window titled 'Add Study Team Member' (circled with a red '2') is open, showing a search for 'Denise Puga' and a table of results with columns for Last, First, Organization, and Preferred Email. The table shows 'Puga, Denise' as 'Vice President For Research' with email 'denisepuga@tamu.edu'. Below the table are checkboxes for 'Co-Investigator' and a question: 'Is the team member involved in the consent process?' with 'Yes' and 'No' radio buttons and a 'Clear' link.

## Study Scope

1. Complete the **Study Scope** (Note: these instructions are only to be used when requesting a Not Human Subjects Research Determination):
  1. **Q1** – Select **No**, even if your project involves the use of food, a dietary supplement, an approved drug or biologic, or an unapproved drug or biologic.
  2. **Q2** –Select **No**, even if your project includes the use of a device
2. Click **Save**
3. Click **Continue**

The screenshot shows the Texas A&M University research system interface. The sidebar menu on the left has 'Study Scope' highlighted with a red circle labeled '1'. The main content area shows the 'Study Scope' section with two questions:

1. \* Does this study use food, a dietary supplement, an approved drug or biologic, or an unapproved drug or biologic?  Yes  No [Clear](#)
2. \* Does the study include the use of a device?  Yes  No [Clear](#)

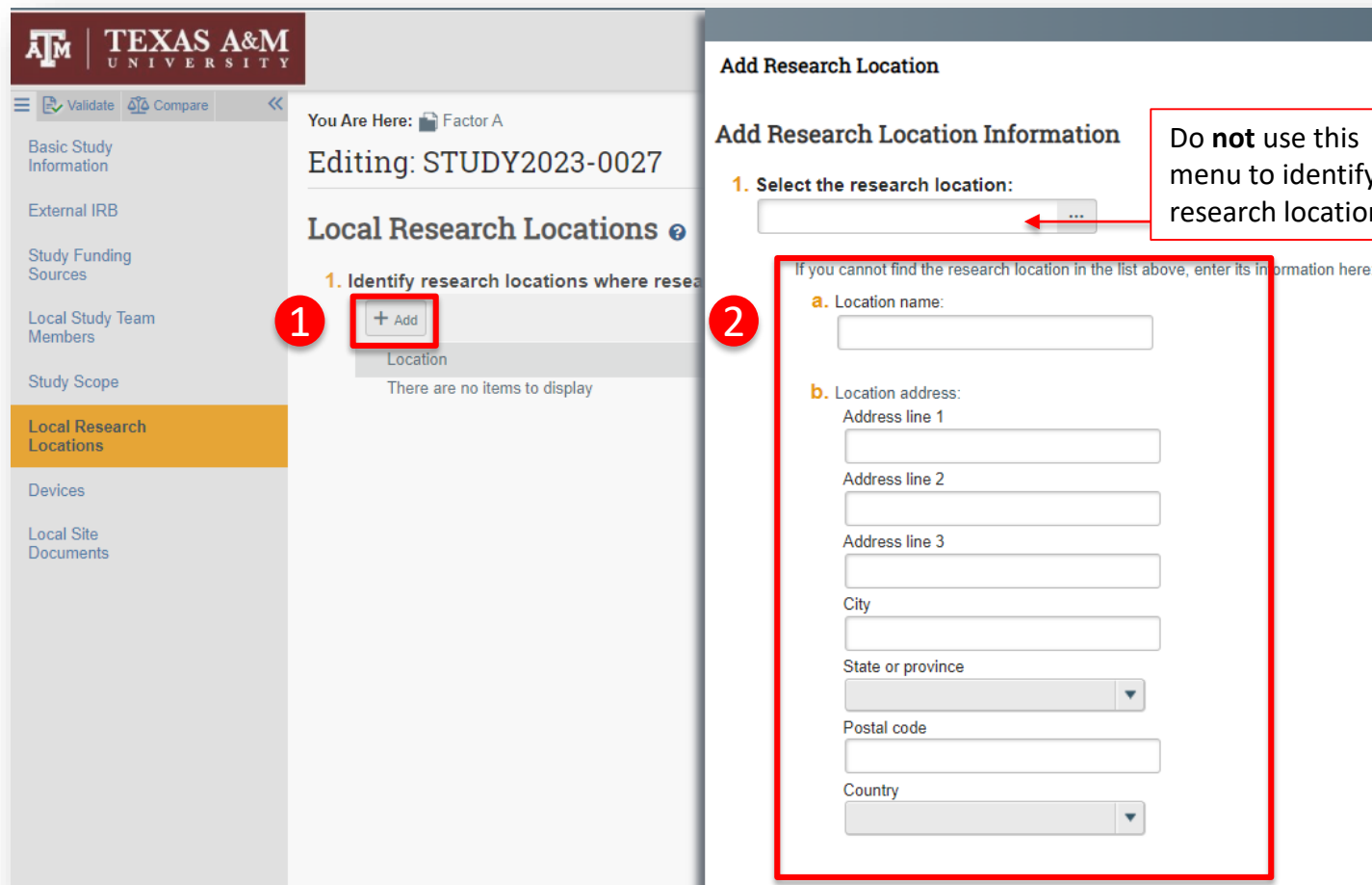
The bottom navigation bar contains three buttons: 'Exit', 'Save' (highlighted with a red box and labeled '2'), and 'Continue' (highlighted with a red box and labeled '3').

## Adding Study Location

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

1. In the **Local Research Locations** page, select **+Add**
2. Type in the name and address of the research location
3. Click **OK**
4. Click **Save** and then **Continue**

**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 '1' highlights the '+ Add' button. The right panel shows the 'Add Research Location' form. A red circle '2' highlights the form fields. A red box highlights the form fields, and a red arrow points to the dropdown menu with the text 'Do not use this menu to identify the research location.'

**Local Research Locations**

1. Identify research locations where research will take place

**+ Add**

Location

There are no items to display

**Add Research Location**

Add Research Location Information

1. Select the research location:

...

If you cannot find the research location in the list above, enter its information here:

a. Location name:

b. Location address:

Address line 1

Address line 2

Address line 3

City

State or province

Postal code

Country

## How to attach supporting documents

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

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

The screenshot shows a web application interface for managing study documents. At the top, there are 'Validate' and 'Compare' buttons. The breadcrumb trail indicates the user is in 'Factor A' and editing 'STUDY2023-0027'. The main content area is titled 'Local Site Documents' and contains three sections:

- 1. Consent forms:** (include an HHS-approved s...)
  - A red circle '2' highlights a '+ Add' button.
  - Below the button is a 'Document' header and an 'Update' button.
  - A document icon is labeled 'Study Consent (1)'.
- 2. Recruitment materials:** (add all material to...)
  - A red circle '2' highlights a '+ Add' button.
  - Below the button is a 'Document' header and an 'Update' button.
  - A document icon is labeled 'Flyer(1)'.
- 3. Other attachments:**
  - A red circle '2' highlights a '+ Add' button.
  - Below the button is a 'Document' header and an 'Update' button.
  - A document icon is labeled 'Survey (1)'.

The sidebar on the left contains the following navigation items:

- Basic Study Information
- Study Funding Sources
- Local Study Team Members
- Study Scope
- Local Research Locations
- Local Site Documents** (highlighted with a red circle '1')

## Submitting the Application to the IRB

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

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

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 the Not Human Subject Research request to the IRB

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

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

3. Click **OK**

### Pre-Submission

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

#### Next Steps

1

Edit Study

Printer Version

2

Submit

Assign PI Proxy



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