



118 Determination:
Delayed Onset and Just In Time

Human Research Protection Program



This PowerPoint will guide you through how to submit a 118 Determination in Huron.

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 of the main content area, there are two buttons: 'Create New Study' and 'Report New Information'. 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 118 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 delayed onset/118 determination
 - **Q4** – Select ***Single-site study***, even if the project involves multiple institutions, and/or collaborators.

Validating... Compare

Editing: STUDY2023-0033 Go to forms menu Print Help

Basic Study Information

- Study Funding Sources
- Local Study Team Members
- Study Scope
- Local Research Locations
- Local Site Documents

1. * **Title of study:**

2. * **Short title:** ⓘ

3. * **Brief description:** ⓘ

4. * **What kind of study is this?** ⓘ
 Multi-site or Collaborative study
 Single-site study
[Clear](#)

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

6. * **Local principal investigator:** ⓘ
 Denise Puga ⓘ

7. * **Attach the protocol:** ⓘ

Document	Category	Date Modified	Document History
<input type="button" value="Update"/> 118 Determination(1)	IRB Protocol	6/5/2023	History ⓘ

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 118 determination request*):

- **Q5** – Select **No**, even if an external IRB will serve as the IRB of record for this project.
- **Q6** – Identify the TAMU principal investigator
- **Q7** – Attach the 118 determination request:
 1. The 118 Determination Request template can be found [here](#). You must use the 118 Determination Request template.
 2. Complete the template and attach it to the Huron submission.
 3. Instructions on how to attach the 118 determination request to the submission can be found on the next slide.

The screenshot shows a web form titled "Editing: STUDY2023-0033" with a sidebar menu on the left containing: Basic Study Information (highlighted), Study Funding Sources, Local Study Team Members, Study Scope, Local Research Locations, and Local Site Documents. The main form area contains the following sections:

- 1. * Title of study:** A text box containing "The Impact of Social Interactions in Young Children".
- 2. * Short title:** A text box containing "Interactions in Children".
- 3. * Brief description:** A text box containing "The purpose of this submission is to obtain a delayed onset/118 determination."
- 4. * 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.
- 5. * Will an external IRB act as the IRB of record for this study?:** Radio buttons for "Yes" (unselected) and "No" (selected). A "Clear" link is below.
- 6. * Local principal investigator:** A dropdown menu showing "Denise Puga" with a search icon.
- 7. * Attach the protocol:** A table with columns: Document, Category, Date Modified, Document History. Below the table are "Add" and "Update" buttons.

At the bottom right, there are three buttons: "Exit", "Save", and "Continue".

How to attach the 118 Determination Request

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 118 determination request 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

7. * Attach the protocol: ⓘ

+ Add

Document	Category	Date Modified	Document History
118 Determination(1)	IRB Protocol	6/5/2023	History

Update

Exit Save Continue →

Navigating the IRB Application

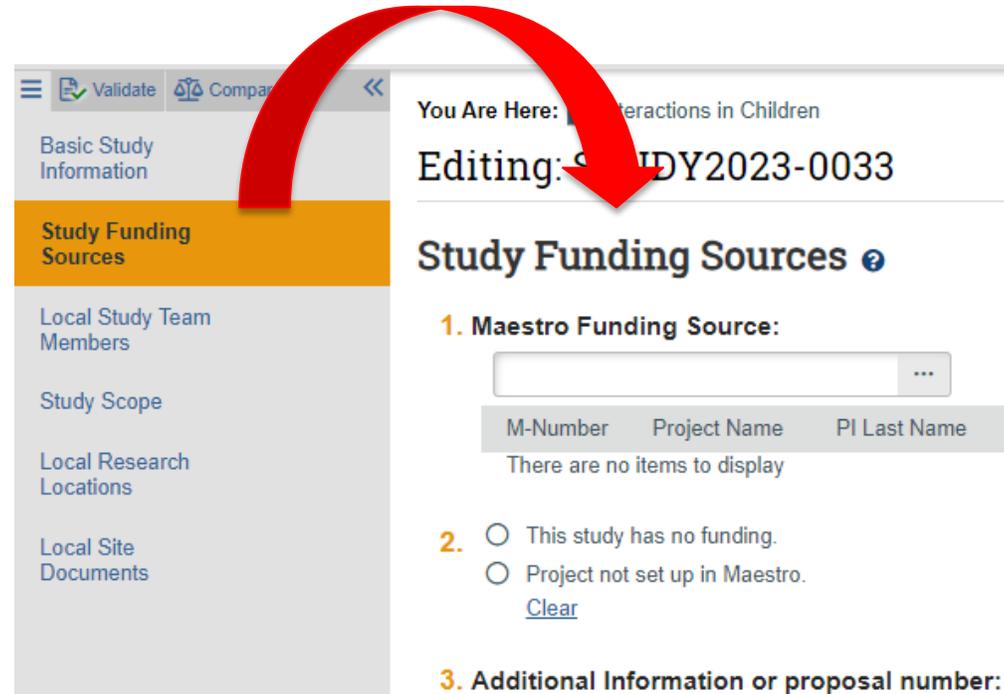
The **Page Navigator** is located on the left side of the screen, and it allows the user to switch between the main pages of the IRB application. The page currently being viewed will be shown highlighted in orange.

IMPORTANT! For a 118 Determination Request application, you only need to complete the following pages:

1. Basic Study Information
2. Study Funding Sources
3. Study Scope

You **DO NOT** need to complete the following pages:

1. Local Study Team Members
2. Local Research Locations
3. Local Site Documents.



The screenshot displays the IRB application interface. On the left is the Page Navigator with the following items: Basic Study Information, Study Funding Sources (highlighted in orange), Local Study Team Members, Study Scope, Local Research Locations, and Local Site Documents. The main content area shows the breadcrumb 'You Are Here: Interactions in Children', the title 'Editing: STUDY2023-0033', and the section 'Study Funding Sources'. Under this section, there are three numbered items: 1. Maestro Funding Source: with a search input field and a table with columns 'M-Number', 'Project Name', and 'PI Last Name' (containing 'There are no items to display'); 2. Radio buttons for 'This study has no funding.' and 'Project not set up in Maestro.' with a 'Clear' link; and 3. 'Additional Information or proposal number:'.

Adding Funding Sources

1. Complete the **Study Funding Source**:
 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.

The screenshot shows the Maestro web interface for editing study 'STUDY2023-0033'. The left sidebar contains navigation options: Basic Study Information, Study Funding Sources (highlighted), Local Study Team Members, Study Scope, Local Research Locations, and Local Site Documents. The main content area is titled 'Study Funding Sources' and includes the following sections:

- 1. Maestro Funding Source:** A search input field with a dropdown arrow. Below it is a table with columns 'M-Number', 'Project Name', and 'PI Last Name'. The table is empty with the text 'There are no items to display'.
- 2.** Two radio button options: 'This study has no funding.' and 'Project not set up in Maestro.' A 'Clear' link is located below the second option.
- 3. Additional Information or proposal number:** A large empty text area for input.
- 4. Upload any relevant Sponsor documentation:** An '+ Add' button above a table with columns 'Document' and 'Category'. The table is empty with the text 'There are no items to display'.

Adding Funding Sources continued

1. Complete the **Study Funding Source**:
 - **Q3** – If funding information is not available in Maestro Funding Source, provide sponsor and grant information (e.g., grant title, m number, sponsor number).
 - **Q4** – Attach a copy of the funding application, contract, agreement, or sponsor correspondence (e.g., just in time notice) for the listed funded sources.

2. Click **Save** and use the Page Navigator to jump to the **Study Scope** page (i.e., click on Study Scope on the left page navigator).

The screenshot shows the Maestro web application interface. On the left is a page navigator with the following items: Basic Study Information, Study Funding Sources (highlighted), Local Study Team Members, Study Scope, Local Research Locations, and Local Site Documents. The main content area is titled 'Editing: STUDY2023-0033' and 'Study Funding Sources'. It contains three sections:

1. **Maestro Funding Source:** A search input field with a dropdown arrow. Below it is a table with columns 'M-Number', 'Project Name', and 'PI Last Name'. The table is empty with the text 'There are no items to display'.
2. Radio button options:
 - This study has no funding.
 - Project not set up in Maestro.
 A 'Clear' link is below the second option.
3. **Additional Information or proposal number:** A large empty text area for input.
4. **Upload any relevant Sponsor documentation:** An '+ Add' button is above a table with columns 'Document' and 'Category'. The table is empty with the text 'There are no items to display'.

Study Scope

1. Complete the **Study Scope** (Note: these instructions are only to be used when requesting a 118 determination):
 1. **Q1** – Select **No**, even if your project involves the use 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 **Exit**

ATM | TEXAS A&M UNIVERSITY

Validate Compare

Basic Study Information

Study Funding Sources

Local Study Team Members

Study Scope

Local Research Locations

Local Site Documents

You Are Here: Interactions in Children

Editing: STUDY2023-0033

Study Scope

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](#)

Exit Save Continue

Submitting the 118 Determination Request

Once you click **Exit**, you will be brought back to the study workspace.

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

Note: Instructions on how to update study documents prior to submitting to the IRB can be found on the next slide.

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

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

Pre-Submission

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

Next Steps

1

Edit Study

2

Submit

Assign PI Proxy

Changing Study Documents prior to Submitting to the IRB

Open the submission:

1. Click **Edit Study**
2. Find the pages where documents need to be:
 - **Added** – click **+Add**; and/or
 - **Updated** – click Update

For updated documents, the version number changes confirming an update was completed.

1

Pre-Submission

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

Next Steps

[Edit Study](#)

[Printer Version](#)

2

7. * Attach the protocol: ?

+ Add

Click to **Add**

	Document	Category	Date Modified	Document History
<div style="border: 2px solid red; padding: 2px; display: inline-block;"> Update </div>	w TEMPLATE - Exempt protocol .docx(0.01)	IRB Protocol	5/22/2023	History ✕

Click to **Update**



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](#).