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**
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.
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.
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/
Saving your work

1. Click **Save**
2. Click **Continue** to navigate to the next page of the application
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.
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.
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).
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 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 Exit
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.
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.*
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.