How to Request a 118 Determination for Delayed Onset Research

This guidance details how to request a 118 Determination (§46.118 Applications and proposals lacking definite plans for involvement of human subjects) for delayed onset research in Huron.

Certain research applications and proposals may be submitted to a federal sponsor with the knowledge that human subjects will be involved during the period of support, but definite plans for this involvement cannot be described in the proposal application. The NIH calls this "delayed onset research."

A PI may receive a Just-in-Time (JIT) notice, which is a procedure used by federal sponsors for certain programs and awards. This procedure allows specific elements of a study proposal to be submitted later in the application process - after review when the application is under consideration for funding. This includes certification of IRB approval for delayed onset research, which is required at least 30 days before any human subjects research takes place.

Before receiving a federal award, the HRPP may grant a 118 Determination to satisfy a federal sponsor's request documenting that a human subjects research protocol meets the requirements of 45 CFR 46.118. Under the HHS federal regulations, applications or proposals includes activities such as,

1. Institutional type grants when selection of specific projects is the institution's responsibility;
2. Research training grants in which the activities involving subjects remain to be selected; and
3. Projects in which human subjects' involvement will depend upon completion of instruments*, prior animal studies, or purification of compounds.

*Instruments, broadly, refer to tools used in assessment and/or evaluation and may include surveys, tests, and questionnaires, etc.

HRPP's 118 Determination will verify that

Submitting a 118 determination request results in an HRPP issued memo acknowledging that research activities involving human subjects are anticipated but are not prepared for IRB review. After receiving a 118 determination, investigators must submit a new submission with all

applicable materials including a complete Human Subjects Research Application, Consent Form(s) and data collection materials for review and approval before any research with human subjects can begin.

How to Access the System

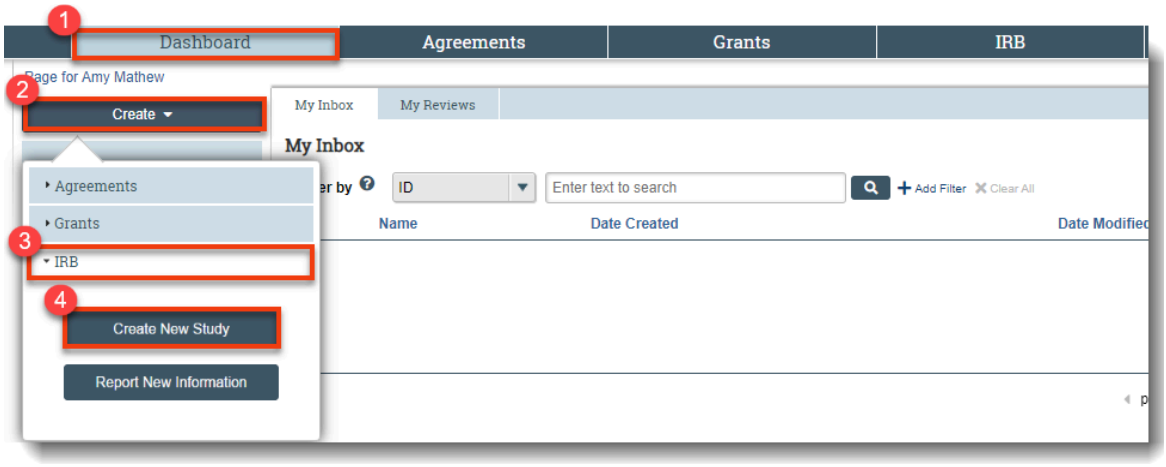
1. The Huron submission system URL can be found on the HRPP Huron webpage.

2. Brown affiliates will log in using the DUO Mobile two-factor authentication.

3. Huron can be accessed using Windows and Macintosh - Mozilla Firefox and Google Chrome. It cannot be accessed using Microsoft Internet Explorer or Microsoft Edge.

How to Create a Study

1. From the **Dashboard**,

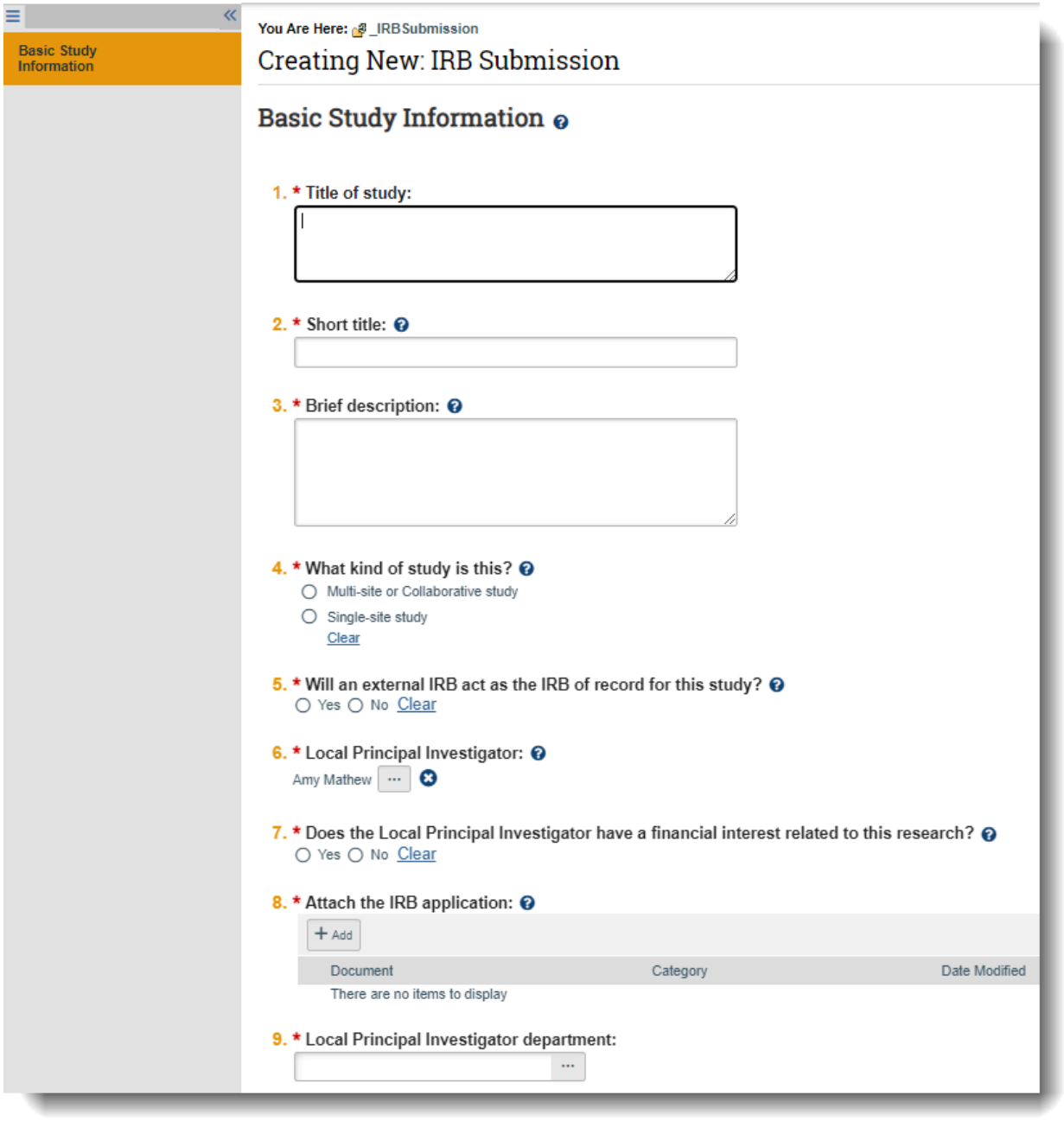


2. Click the **Create** menu,

3. Click **IRB**,

4. Select **Create New Study**. The Basic Information page must be completed and saved to create the study record.

Basic Study Information Page



1. **Title of the Study:** Add the title of the study. If this is for funding, consider adding the study title on the grant.

2. **Short Title:** Select a short title (50 characters max) that will be used to identify your study throughout the Huron system. For example, the study name used on recruitment materials or consent documents.

3. **Brief description:** In lay language, briefly describe the study and summarize the specific aims of the study (100 words max). For example, This is a <drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study> that will examine…by <using interviews, surveys, tasks, intervention>

4. **What kind of study is this?:** Select single site study.

5. **Will an external IRB act as the IRB of record for this study?:** Select **No**.

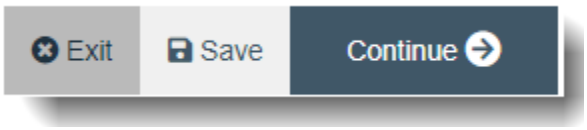
6. **Local Principal Investigator:** This will default to the individual creating the record. Revise the Local Principal Investigator to the Brown PI if you are creating the record on behalf of another study team member.

7. **Does the Local Principal Investigator have a financial interest related to this research?:** Review the help text for specific guidance on what constitutes a financial interest.

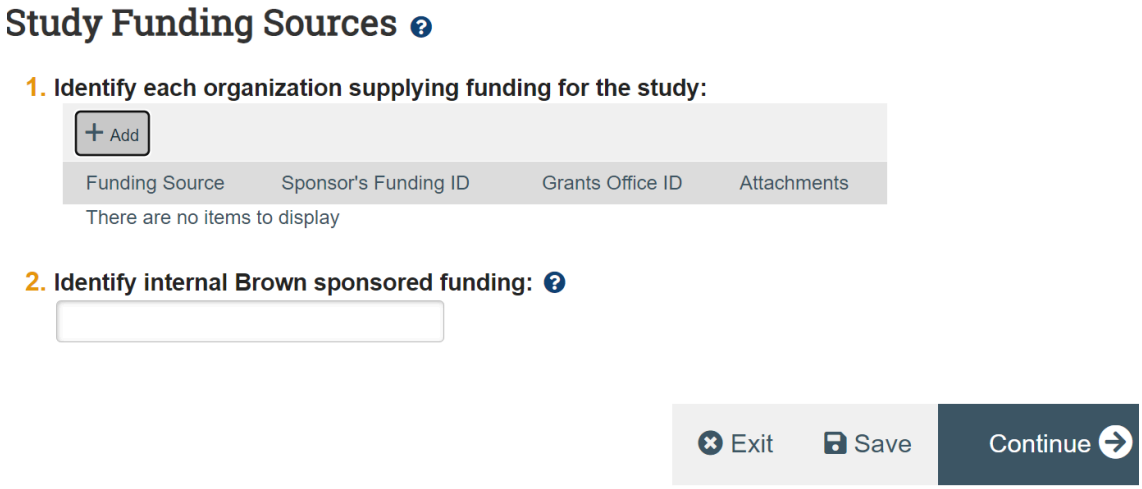
8. **Attach the IRB application:** Upload HRP-503-Template Protocol or HRP-503a-Template SBS Protocol as a Word document. Within the protocol, provide brief descriptions of the project background, aims and procedures. When describing study procedures and recruitment, confirm no research activities with human subjects, including recruitment, will be conducted until full IRB approval is obtained. The remaining sections will have a response of "N/A" or "Finalized [*recruitment procedures/consent procedures/etc.*] will be submitted to the IRB for review prior to implementation."

9. **Local Principal Investigator department:** Select the department of the Local Principal Investigator. If the PI is affiliated with more than one department, select the department the study is being conducted from. See the list of HRPP Department contacts for additional reference.

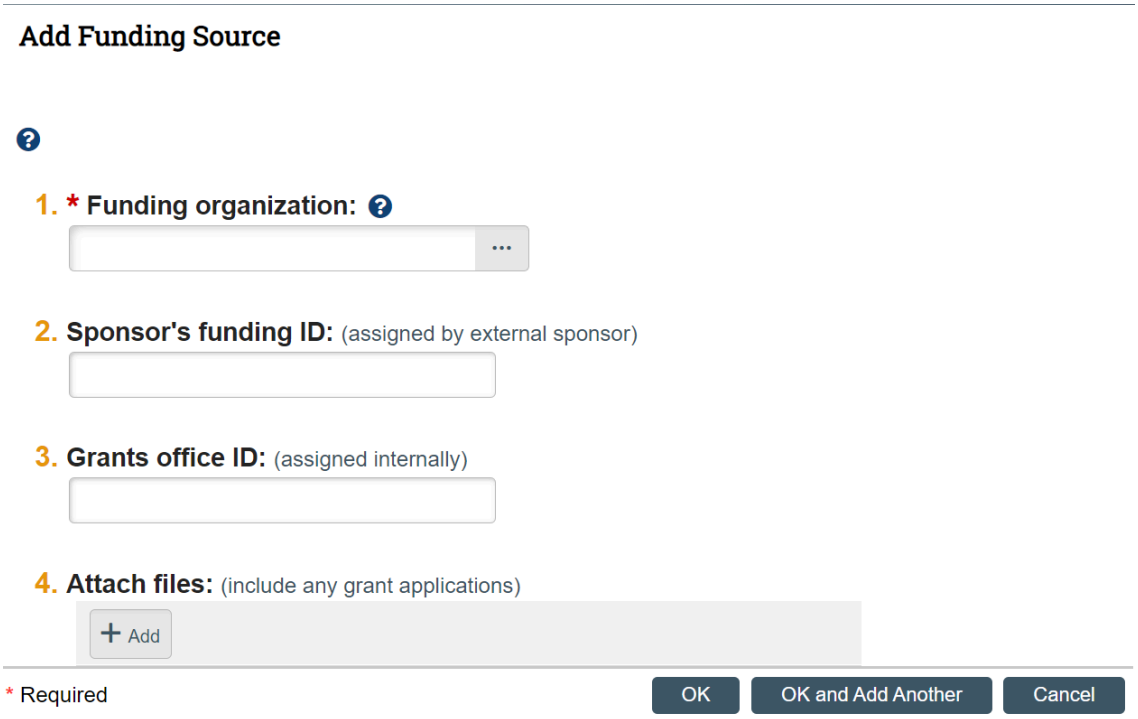
5. Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.



Study Funding Sources Page



1. **Identify each organization supplying funding for the study**: If there is external funding for the study, select the +Add button to access the details.



    1. **Funding Organization:** You can start typing the name of the organization (e.g. NIH) or select the three ellipses to access the full list of organizations. If you cannot locate the funding organization, contact the HRPP by email.

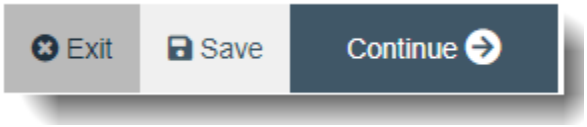
2. **Sponsor's funding ID:** If there is a funding ID, include this information. This information is not required.

3. **Grant's office ID:** If there is a grant office ID, include this information. This information is not required.

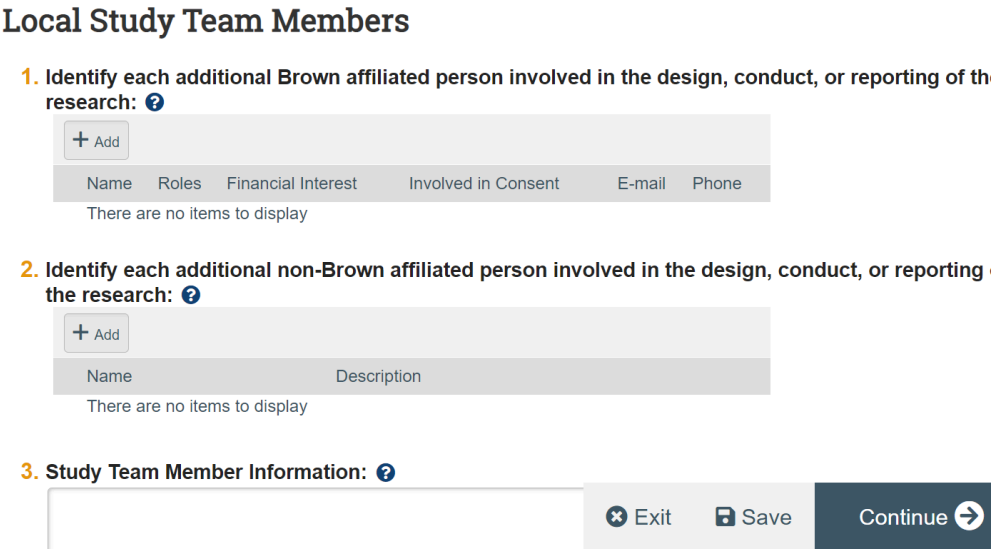
4. **Attach files:** No documentation is required to be uploaded to this space.

2. **Identify internal Brown sponsored funding:** Write the name of any internal Brown University funding sources that support this research (e.g., Global Health Scholarship, Research Seed Funding, Salomon Faculty Research Awards, Research Achievement Awards).

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.



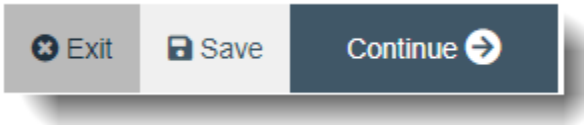
Local Study Team Members Page



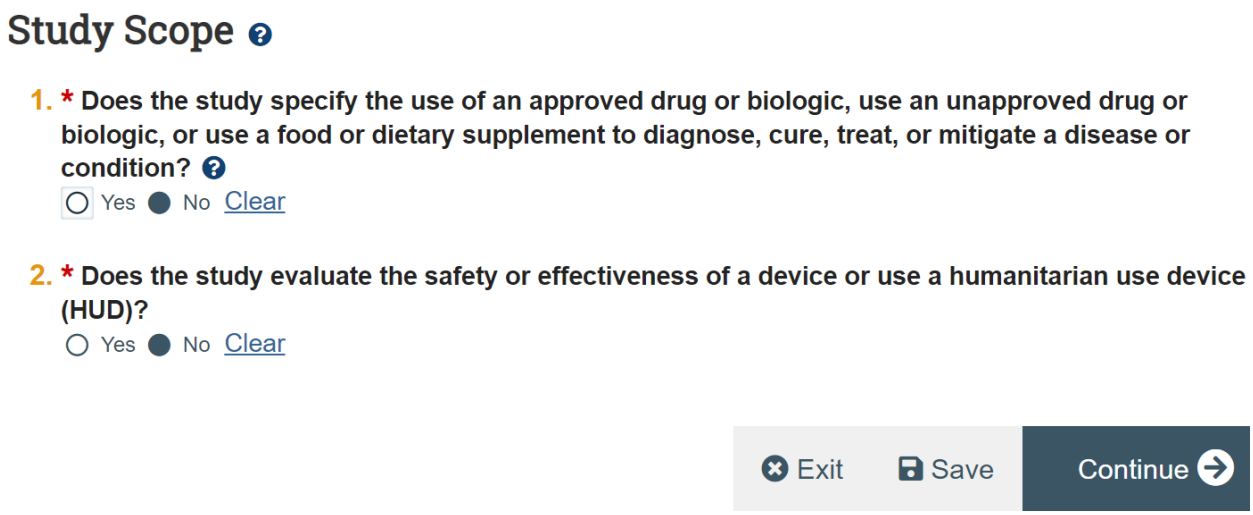
1. **Identify each additional Brown affiliated person involved in the design, conduct, or reporting of the research:** Study team member information is not required at this time.

Adding individuals that may assist in the submission of the complete human subjects research application once finalized would be helpful to add and assign as PI Proxies at this time.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.



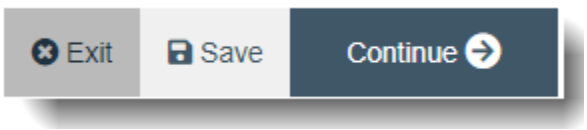
Study Scope Page



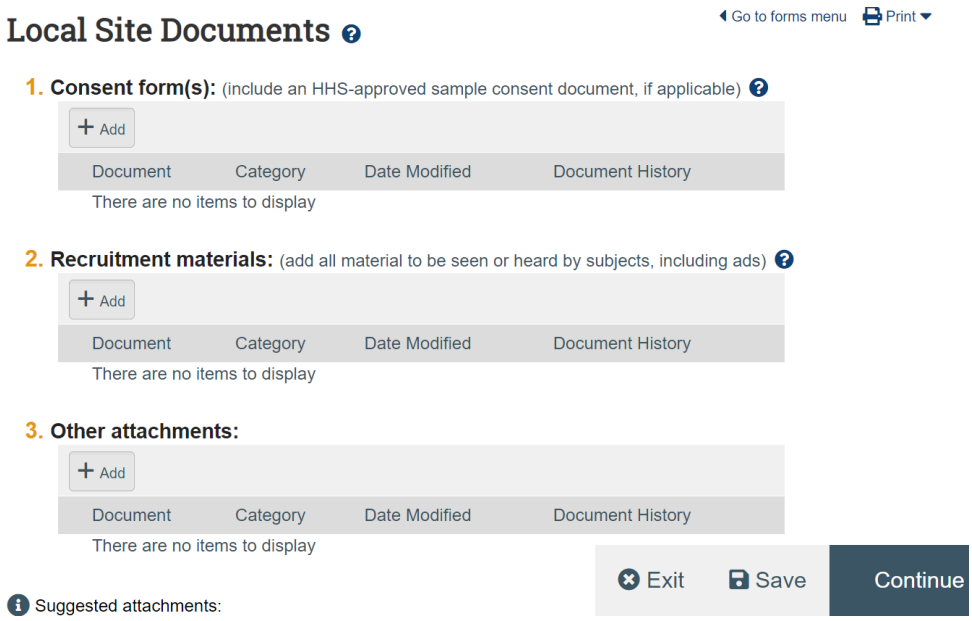
1. **Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?:** Select No.

2. **Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?:** Select No.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.



Local Site Documents Page

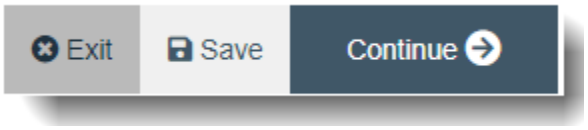


1. **Consent form(s):** Do not attach anything.

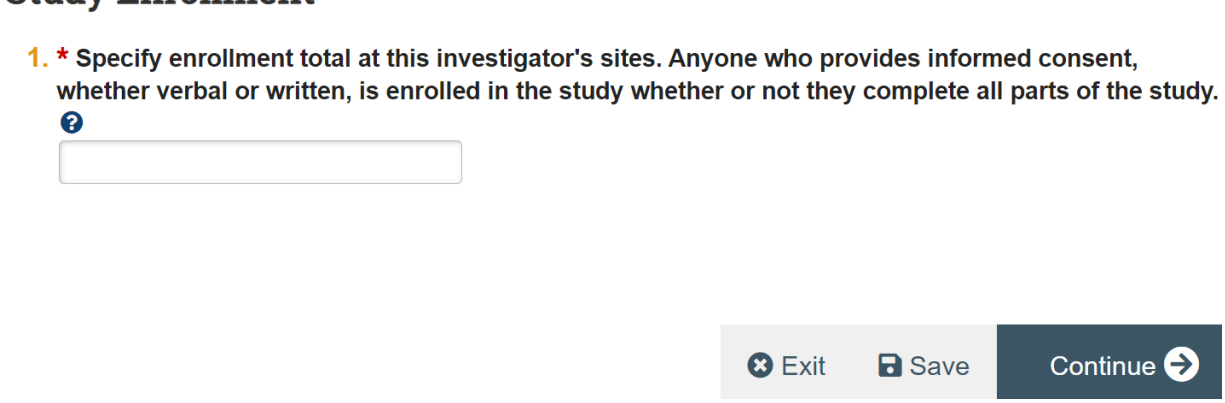
2. **Recruitment materials:** Do not attach anything.

3. **Other attachments:** Attach documentation of the 118 memo request e.g. the funder (email or letter is sufficient).

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

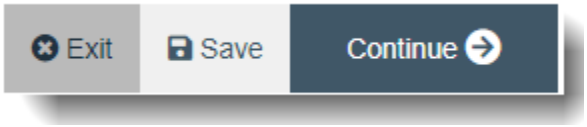


Study Enrollment Page

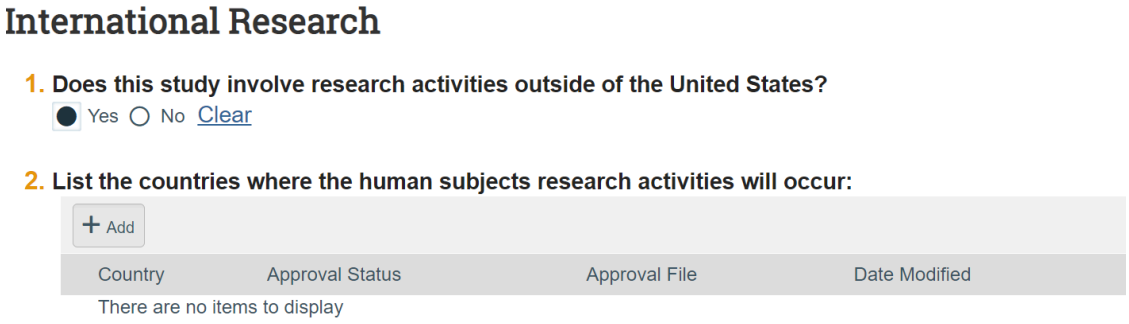


1. **Specify enrollment total at this investigator's sites. Anyone who provides informed consent, whether verbal or written, is enrolled in the study whether or not they complete all parts of the study.:** Input zero.

Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.



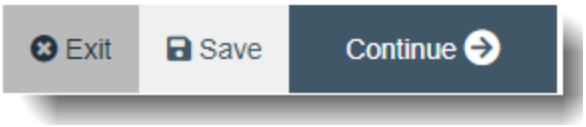
International Research Page



a. Does this study involve research activities outside of the United States?: Select "**No**."

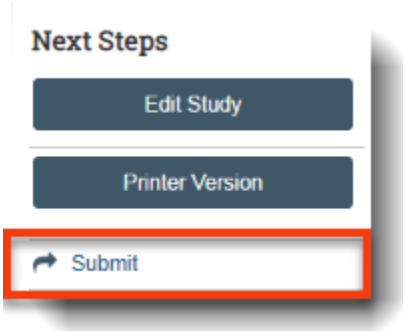
Click **Save**. Click **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.

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



Once the user clicks **Finish**, the user is brought back to the IRB workspace within the record. The study record is editable until it is submitted.

To Submit the Study



To submit a study for review, within the study record workspace:

1. Click **Submit**.
2. Click **OK** to agree to the terms.
3. Type in your login credentials and click **Submit**.

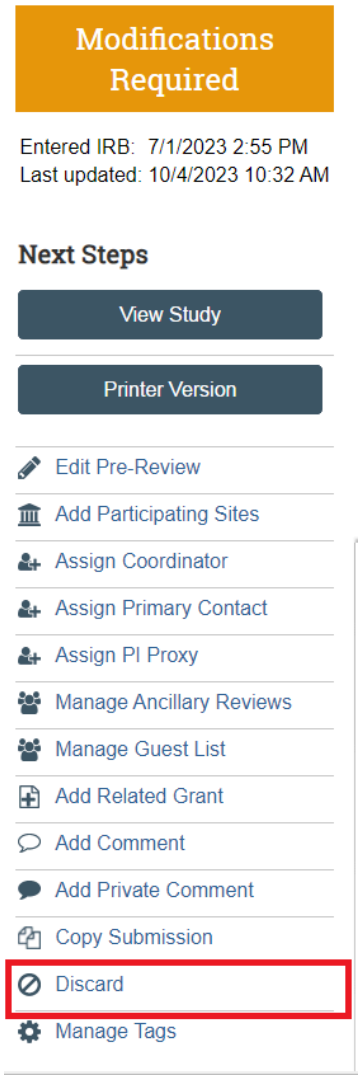
Once you select **Submit**, the study has been submitted to HRPP and is now in the Pre-Review state.

Use "Add Comment" under Next Steps to inform the IRB the submission is requesting a 118 determination. Include a deadline for when this letter needs to be provided by.

After 118 Memo is Provided

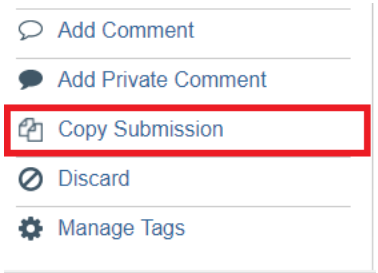
Once the submission has received the 118 memo, the research team is responsible for the following next steps:

Once the full protocol and materials under this study title are created and ready for IRB/HRPP **review**, **Discard** the 118 submission. The **Discard** button is found under **Next Steps** on the left-hand side of the study's main page.



Once Discarded, Copy the submission to create a new record for the human subjects research submission. The **Copy Submission** button is also found under **Next Steps** on the left-hand side of the main study's page.

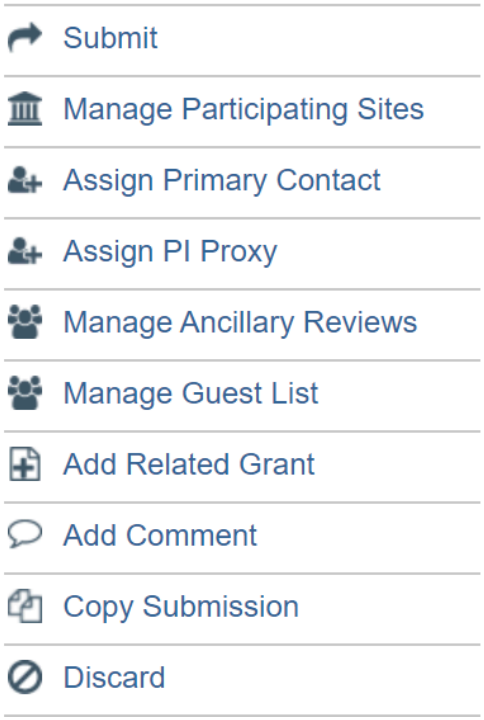
Only those who have editing rights in the record (i.e. PI or PI Proxy) can Copy Submission.

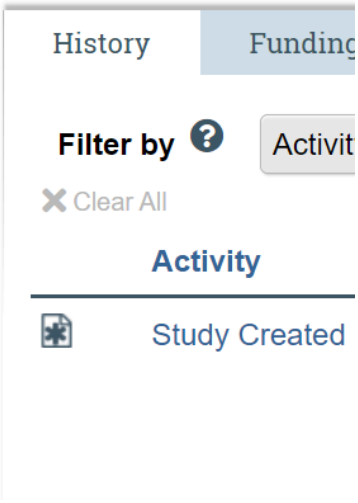


Once Copied, populate the Copied human subjects research record using the "PI Guidance: New Submission."

Make sure that the **"title of study"** and **"short title"** of the Copied submission matches the 118 submission's study title.

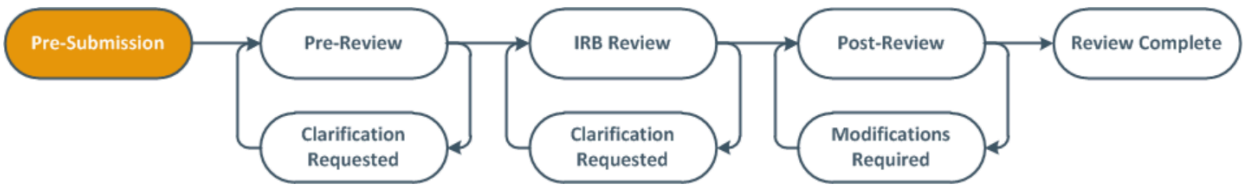
Study Record Menu Navigation





The left hand menu is available to the Principal Investigator, Primary Contact, PI Proxy and other study team members.

Submit: Will be removed as a menu option once the study record progresses to Pre-Review in the study timeline.



Assign Primary Contact: The primary contact will receive all email notifications related to the submission and be able to create new Modifications, Continuing Reviews and Reportable New

Information. The Principal Investigator will need to review and "Submit" the Modifications and Continuing Reviews before they are moved to Pre-Review.

Assign PI Proxy: PI Proxy is able to submit a study record on behalf of the PI. The PI Proxy must be a Study Team Member listed in the study record. Only the study's PI or an assigned PI proxy can submit a record for review. PI Proxy is on a study by study basis. If you are serving as a PI's proxy for their research portfolio, this must be done in each of their study records.

Manage Guest List: Guest list can be used to give view-only access to other relevant parties such as grant or department administrators. Individuals on the guest list cannot modify the study record.

Add Comment: Add comment allows you to add information for the PI, study team or HRPP staff. Note, your comment is visible to anyone with access to this submission and will remain in the submission History. Use the **Who should receive an e-mail notification?** to send a notification to recipients. If a checkbox is not selected, no individual will be notified of the comment.

Discard: This activity will permanently remove the submission. Discard will close the study record. The record will remain in Huron but you will not be able to take any further action such as submitting a modification, continuing review, etc.