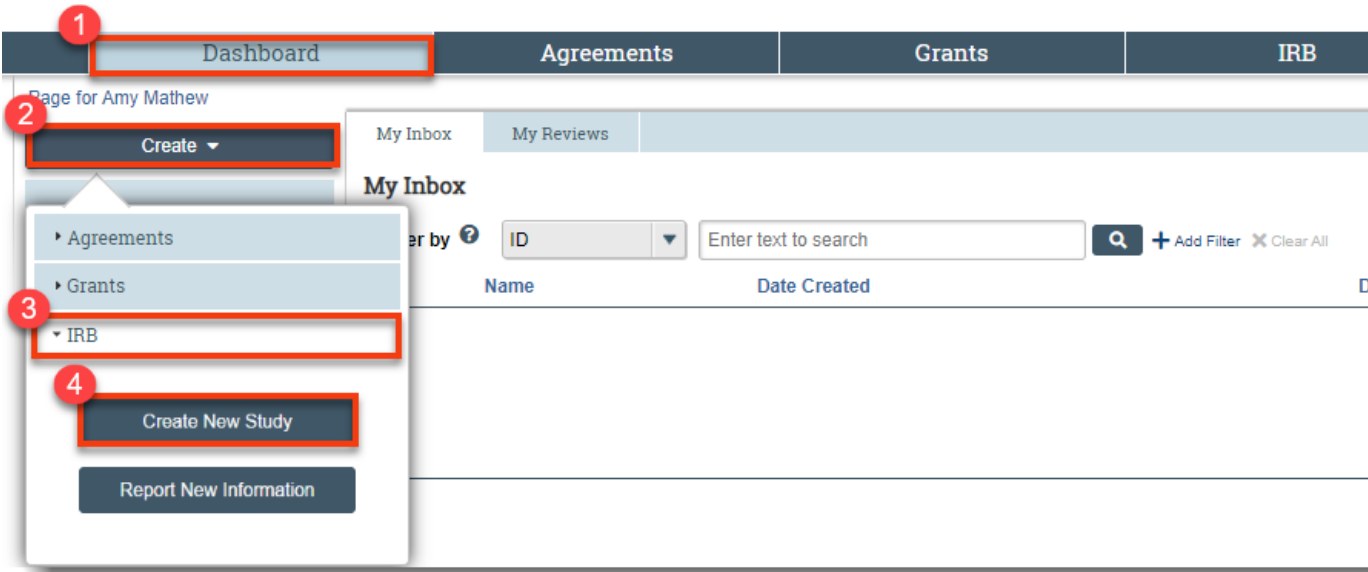


CREATING & SUBMITTING A STUDY

Browsers Currently Supported: Windows and Macintosh - Mozilla Firefox; Google Chrome

Please **do not** use Microsoft Internet Explorer or Microsoft Edge

Step	Action to be taken
1	<ol style="list-style-type: none">1. From the Dashboard within Huron,2. Click the Create menu,3. Click IRB,4. Select Create New Study.  <p>The screenshot shows a user interface with a top navigation bar containing 'Dashboard', 'Agreements', 'Grants', and 'IRB'. Below this is a 'Page for Amy Mathew' header with 'My Inbox' and 'My Reviews' tabs. A 'Create' dropdown menu is open, showing options for 'Agreements', 'Grants', and 'IRB'. The 'IRB' option is selected, and its sub-menu is visible, containing 'Create New Study' and 'Report New Information'. Red boxes and numbers 1-4 highlight the 'Dashboard' tab, the 'Create' dropdown, the 'IRB' option, and the 'Create New Study' button respectively.</p>

IMPORTANT

When creating / editing a submission:

- All questions marked with a red asterisk require a response.
- If a response is changed on any question, and there is a 'clear' option, 'clear' needs to be selected before changing to a different response (this applies to ALL pages of the submission).
- When uploading a document, please disregard the **Show Advanced Option**.

Complete the **Basic Study Information** page.

- *Note: The **Basic Study Information** page needs to be completed and saved for the study shell to be created.*
- *The user's responses to the questions on this page will generate other pages to be completed within the submission (e.g., Drugs, Devices).*

Basic Study Information

You Are Here: [Home](#) > [IRBSubmission](#)

Creating New: IRB Submission

Basic Study Information [?](#)

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: [?](#)

Amy Mathew



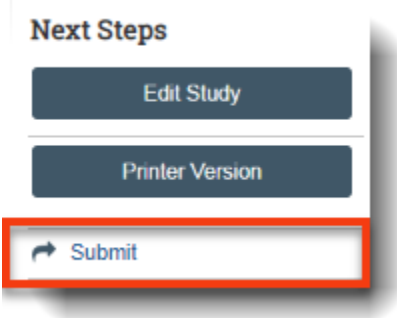
7. * Does the Local Principal Investigator have a financial interest related to this research? [?](#)

Yes No [Clear](#)

8. * Attach the IRB application: [?](#)

Document	Category	Date Modified
There are no items to display		

9. * Local Principal Investigator department:

3	<ul style="list-style-type: none"> • Click Save. • Click Continue to move to the next page. • To exit the submission, click Exit. • <i>Note: these 3 actions are on every page throughout the submission.</i> 
4	<ul style="list-style-type: none"> • After clicking Continue from the International Research page, the user lands on the Final Page. • Follow the instructions on this page by clicking Finish to exit the form.  <p><i>Important! Clicking Finish does not send the submission to the HRPP. When the study is ready for HRPP review, the PI or proxy must submit from the study record workspace.</i></p> <ul style="list-style-type: none"> • <i>Note: Once the user clicks Finish, the user is brought back to the IRB workspace within the record.</i> • <i>The PI / proxy can continue to edit the study (Edit Study button) until it is submitted.</i>
5	<p>To submit a study for review, within the study record workspace:</p> <ol style="list-style-type: none"> 1. Click Submit. 2. Click OK to agree to the terms. 3. Type in your Brown login credentials and click Submit.  <ul style="list-style-type: none"> • <i>Note: the study has been submitted to HRPP and is now in the Pre-Review state.</i>

OPTIONAL STEPS

optional

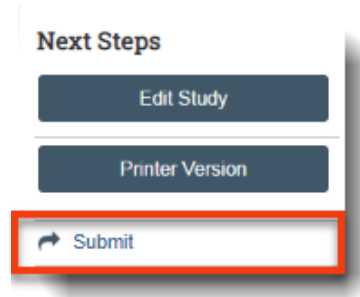
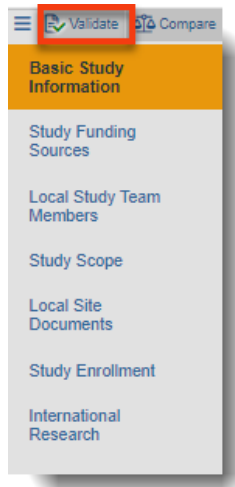
STUDY RESPONSE VALIDATION

To validate to ensure required information is included before submitting, either:

- Click **Validate** within the study itself

Or

- Click **Submit** from the IRB workspace within a record and if there are unanswered required questions, they will appear in a pop-up window (only choose this option if the user is ready to submit).



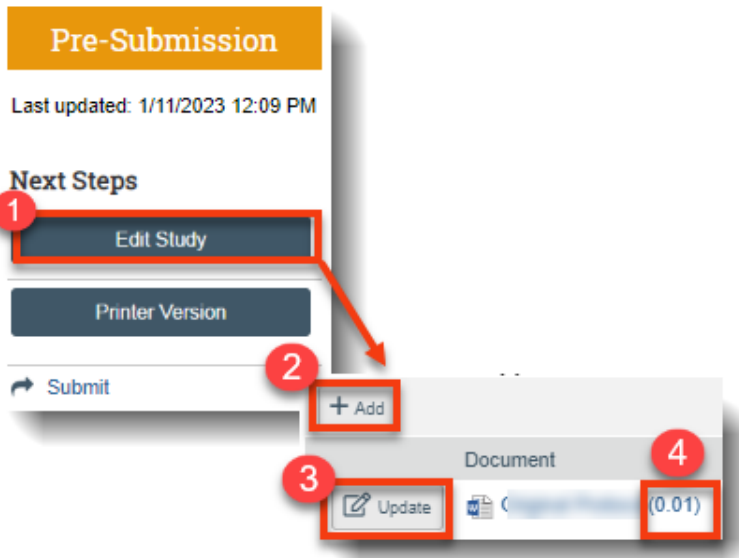
or

optional

CHANGE STUDY DOCUMENTS (prior to submitting to HRPP)

Open the submission:

1. **Edit Study.**
 2. Find the pages where documents need to be
 - a. Added - select **+Add**; and/or
 - b. Updated - select **Update**
 3. For updated documents, the version number changes confirming an update was completed.
- *Note: Once the study is in the review process (submitted to HRPP), documents are only able to be updated if the IRB Coordinator or Committee Member requests clarifications (or if a modification is submitted following the study approval). See guidance on Submitting a Modification.*



optional

MULTI-SITE STUDY

If the study is a multi-site study, before submitting for review:

1. Select **Manage Participating Sites** to add the other institutions/sites conducting research under this protocol.
2. Click **+Add** to add the institution & collaborating investigator to the study.
3. Click **OK**.

Note: If the institution and/or the collaborating investigator is not available for you to select from step 2, contact HRPP.

