CREATING & SUBMITTING A STUDY

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

Please do not use Microsoft Internet Explorer or Microsoft Edge

<table>
<thead>
<tr>
<th>Step</th>
<th>Action to be taken</th>
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| 1    | 1. From the Dashboard within Huron,  
2. Click the Create menu,  
3. Click IRB,  
4. Select Create New Study. |

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).
3. Click **Save**.

4. Click **Continue** to move to the next page.

5. To exit the submission, click **Exit**.

   - *Note: these 3 actions are on every page throughout the submission.*

   ![Exit Save Continue.png](Exit%20Save%20Continue.png)

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4. After clicking **Continue** from the **International Research** page, the user lands on the **Final Page**.

5. Follow the instructions on this page by clicking **Finish** to exit the form.

   ![Exit Save Finish.png](Exit%20Save%20Finish.png)

   **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.**

   - *Note: Once the user clicks Finish, the user is brought back to the IRB workspace within the record.*

   - *The PI / proxy can continue to edit the study (Edit Study button) until it is submitted.*

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5. 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 Brown login credentials and click **Submit**.

   ![Next Steps.png](Next%20Steps.png)

   - *Note: the study has been submitted to HRPP and is now in the Pre-Review state.*

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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).

CHANGE STUDY DOCUMENTS (prior to submitting to HRPP)

Open the submission:

1. **Edit Study**.

2. Find the pages where documents need to be
   - Added - select **+Add**; and/or
   - 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.
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.