Researcher's Guide

UCI IRB is the Relying IRB (External IRB Reliance)

Version September 2025

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How to create and submit in ZOT IRB?

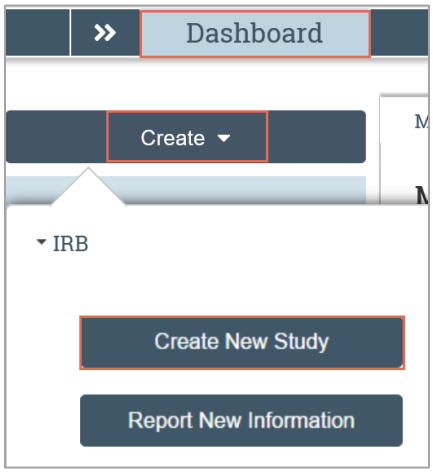
Access the Researcher's guide from the HRP toolkit to learn about Navigation and Basic Tasks for ZOT IRB.

Create and Submit an External Reliance Study

Before you begin, gather files and information about your study.
All submissions reviewed by an external IRB are always found on the **External IRB tab**.

To create a study

1. From the Dashboard, click the **Create** menu and then select **Create New Study**.



2. Complete the pages. Click **Continue** to move to the next page.
3. Pay attention to the following pages:
   a. **Basic Study Information**: use the following questions to indicate whether the study is a single - or multiple-site study and it will be externally reviewed. [***Note:*** *Majority of external reliance studies will be* ***multi-site studies****.]*

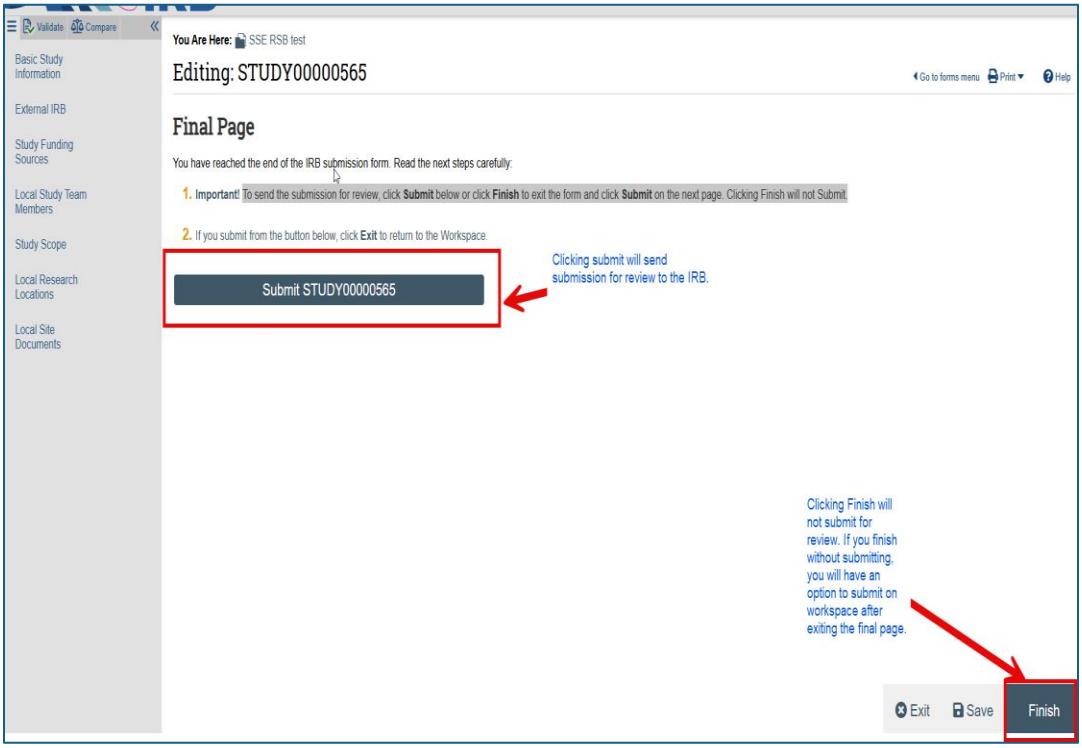
What kind of study is this?

Will an external IRB act as the IRB of record for this study?

   b. Basic Study Information: Under item#8:
      - **Attach** HRP-832-PI-Worksheet- Consideration for Relying on an External IRB
      - **Attach the protocol**: the study protocol is a mandatory document to include.
   a. **Local Site Documents**: add local consent forms, recruitment materials and other documents such as LOAs specific to your study.
   b. **Study-Related Documents**: if the study is a multi-site study use this page to add: templates for consent forms, recruitment materials, and other from the IRB

of record.

4. On the final page, to send the submission for review, click **Submit** below or click **Finish** to exit the form and click **Submit** on the next page. Clicking Finish will not Submit.



5. If you only click finish, you are taken to the study workspace. You can continue to edit the study (Edit Study button) until you **submit** it.

Important! Clicking **Finish** does not send the study to the IRB office. It remains in the Pre- Submission state. When the study is ready for IRB review, the PI or PI proxy must **submit** the study.

Modification of Multi-Site External Studies

Note: Create Site Modification is only available for Multi-Site External Studies.

There are two activities that can be used to modify a multi-site external review study: (1) **Create Site Modification**; and (2) **Update Study Details**. Create Site Modification allows the PI to edit only site information, and Update Study Details allows the PI to edit only study information. For all 3 activities, the local IRB is notified after the submission. What happens after that depends on the type.

To Create a Site Modification for an External Study

1. In the Top Navigator, click **IRB** and then **Submissions**.
2. Click the **External IRB** tab and open the study.
   Note: Active external IRB studies are in the Active state.
3. Click **Create Site Modification**.

For **Create Site Modification**, the PI can select to modify either Study Team Members, or Other Parts of the Study or both.

a. If Study Team Members is selected – The local IRB either accepts the site updates or requests a pre-review clarification.
b. If Other Parts of the Study selected – The local IRB either accepts the site updates or request a pre- review clarification.

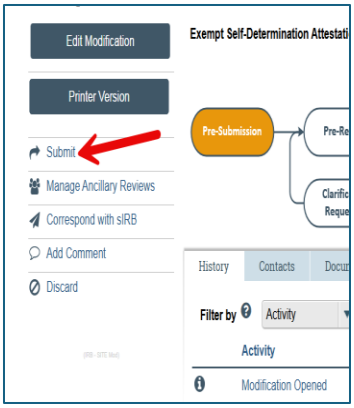
Use create Site Modification for local context changes that affect institutional requirement such as changes to personnel, conflicts of interest, funding, HIPAA, or changes to institutionally required consent language. Select both options if applicable. These will be reviewed by your local IRB.

Note: Once an option is selected and you save and continue to next page, you cannot go back and edit the options.

4. On the **Modification Information** page, summarize the updates and complete the form.

Note: If you have a **Modification along with a Continuing Renewal (CR)**, you can use **Create Site Modification** activity to submit a combined transaction. Ensure to complete and attach HRP-832a-PI Worksheet-Continuing Review. This worksheet can be attached under "other" in the Local Site Documents section along with other renewal documents as applicable.

5. Click **Finish** to exit the modification application. This should bring you back to the study workspace.
6. From the study workspace, click **Submit**.
7. Click **OK** to agree to the terms.



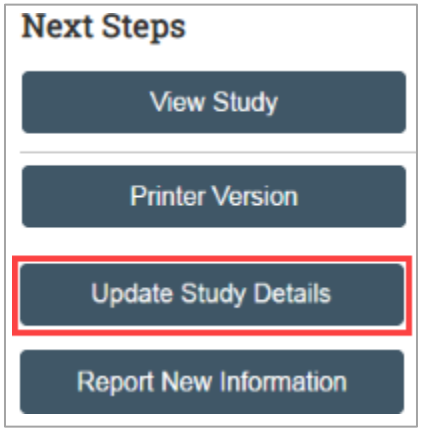
Update Study Details for a Single-Site/Multi-Site External Study

Use Update Study Details to make changes to an approved, single-site/multi-site external study based on what the external IRB approved. The resulting External Update will be found in the study's Follow-on Submissions tab.

For Update Study Details – The local IRB is only notified. The study update does not go through sIRB (IRB of record) Review.

To update study details for an external study

1. In the Top Navigator, click **IRB** and then **Submissions**.
2. Click the **External IRB** tab and open the study.
   Note: The active external studies are in the External IRB state.



3. Click **Update Study Details**.

Note: PI can choose to track CR data via "Report CR data" tab/activity for reference, however, this activity does not provide any notification to IRB Coordinators. The IRB does not require PIs to complete CR data activity. Utilizing the "Report Continuing Review Data" activity is optional. The IRB requires this information to be collected via HRP-832a PI

worksheet attached with Update Study Details.

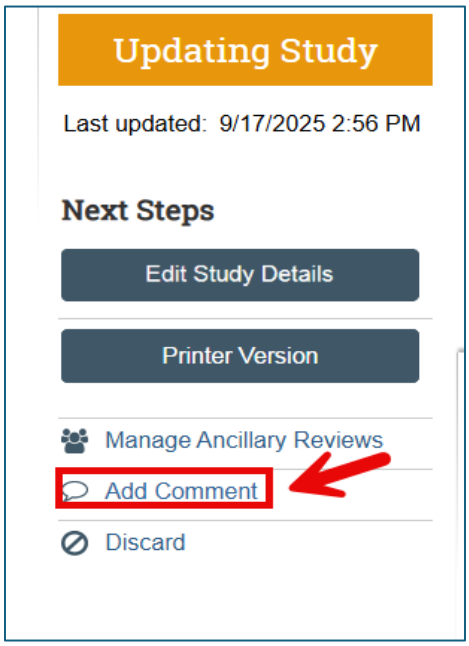
4. If you are **closing the study**, provide this information in the summary section and attach closing letter from the Reviewing IRB in 'study-related documents' section.

   Note: If closing is linked to a modification, then use 'create site modification' activity.

5. Summarize the updates, click **Continue**, then make changes to the study.
6. Complete the HRP-832a-PI Worksheet-Continuing Review for relying on External IRB and attach to the 'Basic Study Information' Section.
7. Attach the approval letter from the IRB of record in the Study-related documents tab.
8. Once all updates are complete to send the submission for review, click **Submit** on the final page or click **Finish** to exit the form and click **Submit** on the workspace. Clicking finish itself will not submit.

Note: The submit button is only available for PI/PI Proxy. In case research team members other that PI/PI Proxy are completing this activity, they can use the comment section (see #9 below) to inform the IRB Coordinator to finalize documents.

9. **IMPORTANT!** From the study workspace, click **Add Comment** to notify the IRB Coordinator. This will send an email to IRB Coordinators.



10. In the **Comment** box, ask the IRB office to **finalize** the updates.
11. Select the **IRB Coordinator** checkbox to send a notification to them.
12. Click **OK**.