



Creating a Modification to a Relying Site (PSite)

This process should be used to revise information or documents specific to a relying site (PSite).

This may be an independent submission if the requested revisions are ONLY for relying site and do not require updates to the locally reviewed EForm or documents.

This request must be accompanied by a MOD submission to the overall study if the changes impact the locally reviewed EForm or documents.

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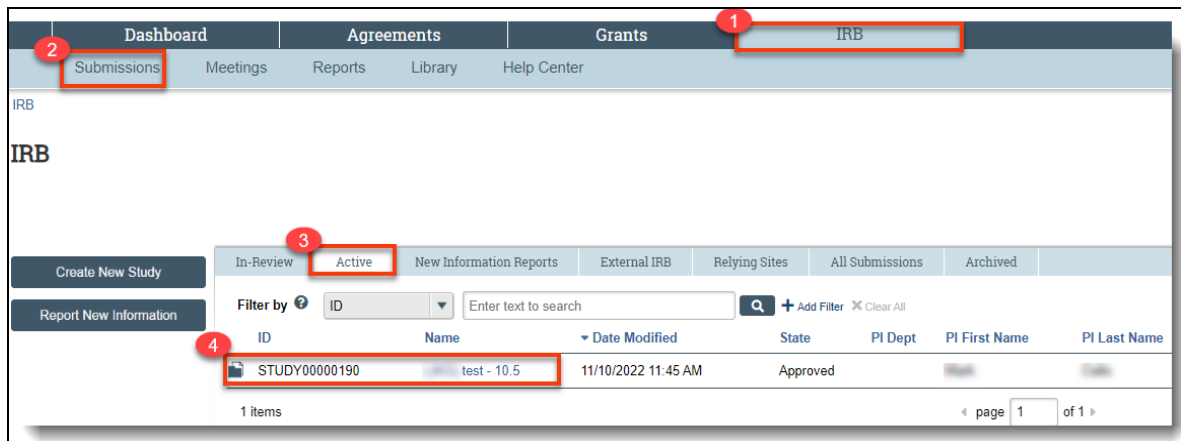
How to Access the System

1. The Huron submission system can be accessed at: <https://irb-era.brown.edu/>
2. When applicable, 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 Access the PSite

From the overall study record:

1. From the **IRB** tab,
2. Select **Submissions** tab,
3. Select **Active** tab,
4. Click on the **folder symbol** () or the **Name** of the submission to open.



From the Sites tab

1. From the **IRB** tab
2. Select **Relying Sites** tab
3. Click on the **folder symbol** () or the **Name** of the site to open.
 - a. Note: Sites are designated by institution and associated study. There may be multiple listings for an institution collaborating on different studies.

In-Review	Active	New Information Reports	External IRB	Relying Sites	All Submissions		
Filter by ? ID ▼ Enter text to search Q + Add Filter × Clear All							
ID	Name	▼ Date Modified	State	PI Dept	PI First Name	PI Last Name	Coordinator Name
 SITE00000026	Rutgers University Participating Site for TEAM300 Study	8/31/2026 11:53 AM	Active		Kristina	Jackson	
 SITE00000025	University of Florida Participating Site for TEAM300 Study	8/31/2026 11:52 AM	Active		Joy	Gabrielli	
 SITE00000083	Rutgers University (000606) Participating Site for Project CannTalk	12/22/2025 2:01 PM	Active		Kristina	Jackson	
 SITE00000019	La Trobe University Participating Site for Project POST	8/1/2023 11:55 AM	Active		Benjamin	Riordan	
 SITE00000018	University of Cincinnati Participating Site for Project POST	8/1/2023 11:45 AM	Active		Rose Marie	Ward	

Create the Modification

1. Select “Create Site Modification” from the left-hand menu

Next Steps

View Site

Printer Version

Create Site Modification

Report New Information

2. Select Modification/Update

- a. Complete the (1) **Modification Summary** tab. List each change and reason for change in the modification summary text box. If you are making multiple changes, number each item.

E.g. (1) Adding new study procedures - Adding a follow up survey about x, y and z. An updated HRP-503-Template Protocol or HRP-503a-Template SBS Protocol, Consent Addendum and follow up survey are uploaded. (2) Change to Phase 1 Interview Guide - A revised Phase 1 Interview guide is uploaded. Minor formatting changes and a new question have been added.

Select (2) **Save**. Select (3) **Continue**.

Modification / Update #1 for S...

You Are Here: (JKG) test - 10.5 > Modification / Update #1 for S...

Editing: MOD00000058

Go to forms menu | Print | Help

Modification Information

1. Study enrollment status:

- ☐ No subjects have been enrolled to date
- ☐ Subjects are currently enrolled
- ☐ Study is permanently closed to enrollment
- ☐ All subjects have completed all study-related interventions
- ☐ Collection of private identifiable information is complete

2. Notification of subjects: (check all that apply)

- ☐ Current subjects will be notified of these changes
- ☐ Former subjects will be notified of these changes

Attach files: If notifying subjects, add a description of how they will be notified to the Other attachments section of the Local Site Documents page.

3. * Summarize the modifications: ?

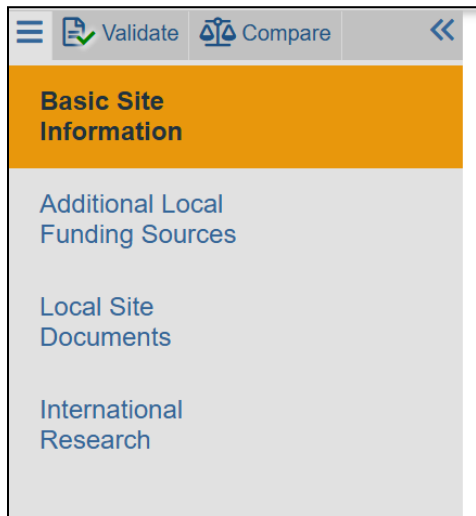
Exit | Save | Continue

Change Study Documents

1. After selecting **Continue** on the Modification Information screen, you will be able to access the pages of the Smartform starting with the Basic Information page. Use the left

hand navigation menu to select the page you would like to modify or select **Continue** on the bottom right corner to navigate through each Smartform page.

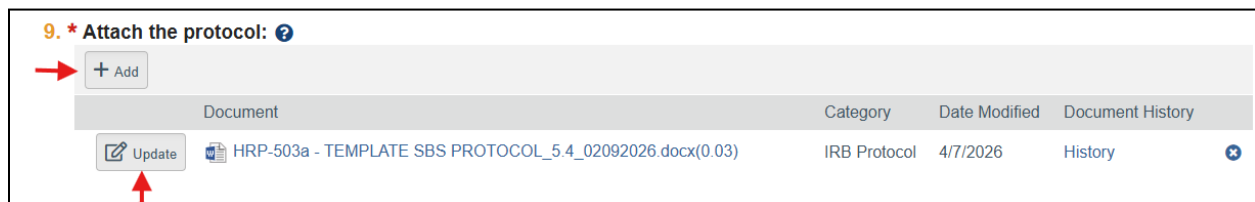
If you select **Save and Exit** on the previous Modification Information screen, you will be brought back to the main Modification workspace. In the Modification workspace, click the blue **Edit Modification/CR** on the left hand side to access the editable Smartform pages.



2. On the Smartform pages where documents need to be uploaded:
 - a. For new document - select **+Add**
 - b. To make a change to an existing document - select **Update**

When updating an existing document, use the “Update” button to replace the previous version. The study record should maintain the most current version of the documents.

Use track changes in Word to document any revisions to the updated material being uploaded. At the time of upload, review the document title for any additional edits to the title such as the date or version number. If the document still contains track changes from a previous review, please accept all previously-approved changes, so that only the current requested changes remain.



3. After completing the modifications, click **Save** and **Continue** to move to the next page.

To exit the submission, click **Exit**. The final page will offer **Finish** rather than **Continue**.



Submit a Modification

To submit a modification, within the study record workspace:

1. Click **Submit**.
2. Click **OK** to agree to the terms.

