



Creating a Modification

This guidance should be used for submitting changes to an approved study, including updates to both study personnel and materials.

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How to Access the System

How to Create a Modification

Change Study Documents

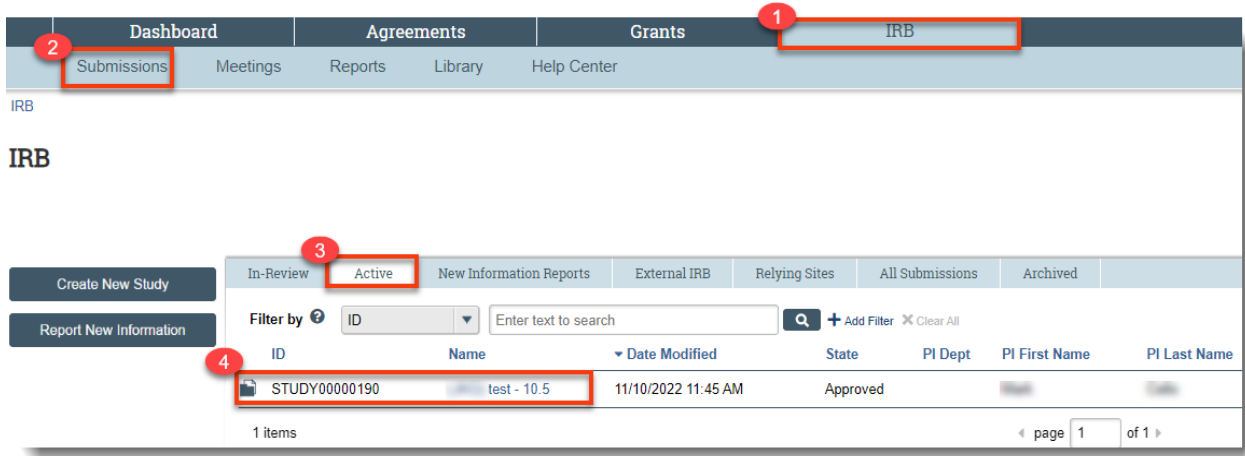
Submit a Modification

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 Create a Modification

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.



The screenshot shows the IRB system interface. At the top, there are tabs: Dashboard, Agreements, Grants, and IRB (highlighted with a red box and number 1). Below these are sub-tabs: Submissions (highlighted with a red box and number 2), Meetings, Reports, Library, and Help Center. The main content area is titled 'IRB'. Below this, there are buttons: 'Create New Study' and 'Report New Information'. To the right, there are tabs: In-Review, Active (highlighted with a red box and number 3), New Information Reports, External IRB, Relying Sites, All Submissions, and Archived. Below these tabs is a search bar with 'Filter by' and 'ID' selected. A search button with a magnifying glass icon is next to it. Below the search bar is a table with columns: ID, Name, Date Modified, State, PI Dept, PI First Name, and PI Last Name. The first row of the table is highlighted with a red box and number 4, showing the submission 'STUDY00000190' with the name 'test - 10.5'. At the bottom right, there is a pagination control showing 'page 1 of 1'.

5. Select **Create Modification / CR**.



9. 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**.

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.

Validate Compare

Basic Study Information

Study Funding Sources

Study Scope

Local Research Locations

Study-Related Documents

Local Site Documents

International Research

You Are Here:

Editing: II

Basic Stu

1. * Title of s

2. * Short titl

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.

9. * Attach the protocol: ?



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



Submit a Modification

To submit a modification, 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**.

