Creating a Modification

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

Modifications to studies with relying sites may require an additional submission to revise site-specific materials within the PSite record.

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- How to Create a Modification
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- Submit a Modification

Create a Modification to a PSite
- 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.

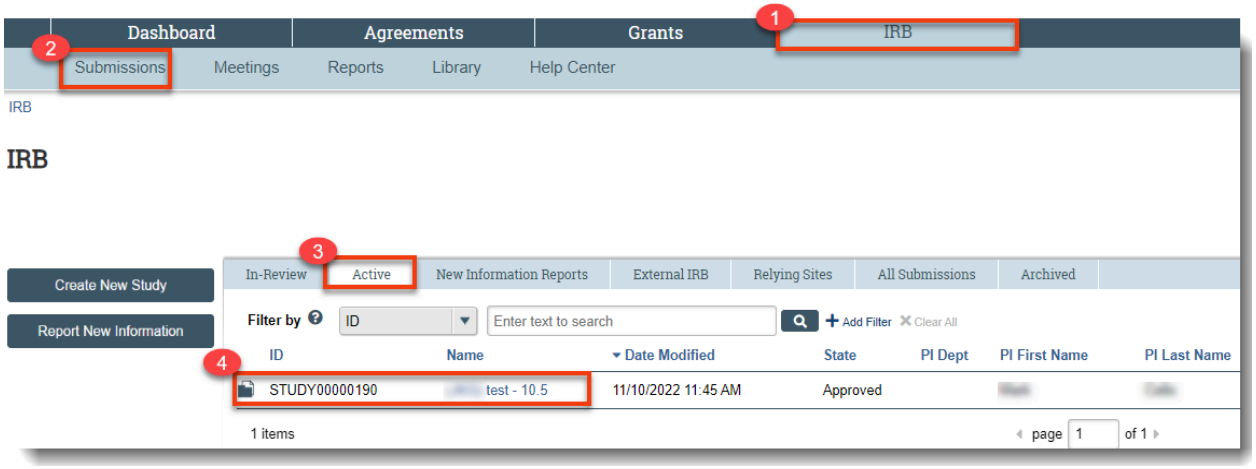
How to Create a Modification

1. From the **IRB** tab,

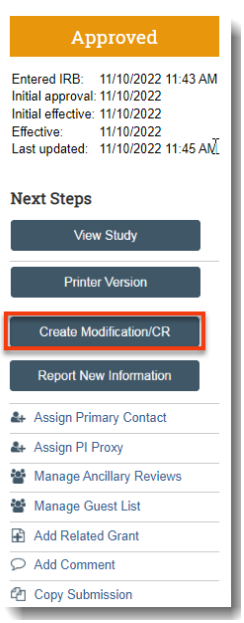
2. Select **Submissions** tab,

3. Select **Active** tab,

4. Click on the **folder symbol (** **)** or the **Name** of the submission to open.

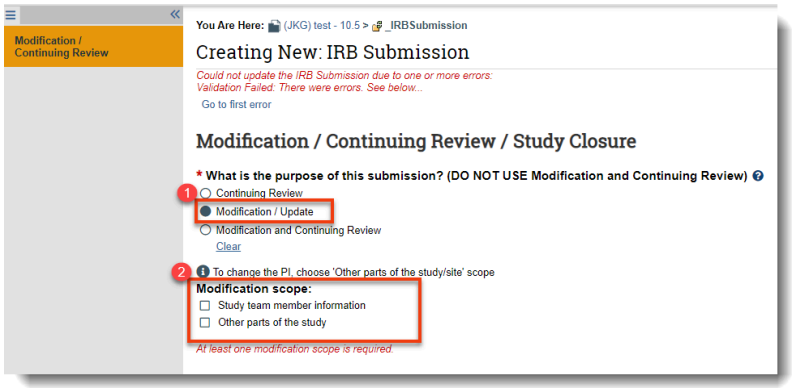


5. Select **Create Modification / CR**.



6. Select **Modification / Update**. Do not select Modification and Continuing Review. Once a response is made to "What is the purpose of this submission?," a logic driven question appears (Modification scope).

7. Choose a response for **Modification scope** (a checkbox will appear when selected).

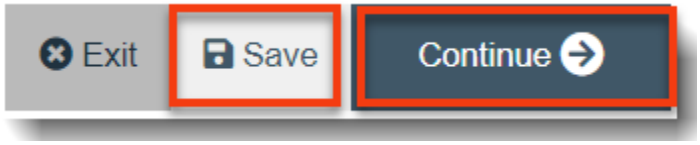


a. **Study team member information:** Use only to make changes (adding or removing) to study personnel listed on the study team members page. No other changes can be made, including changes to the PI, if this response is selected.

b. **Other parts of the study:** This option opens all pages of the study Smartform for revision except the study team member page.

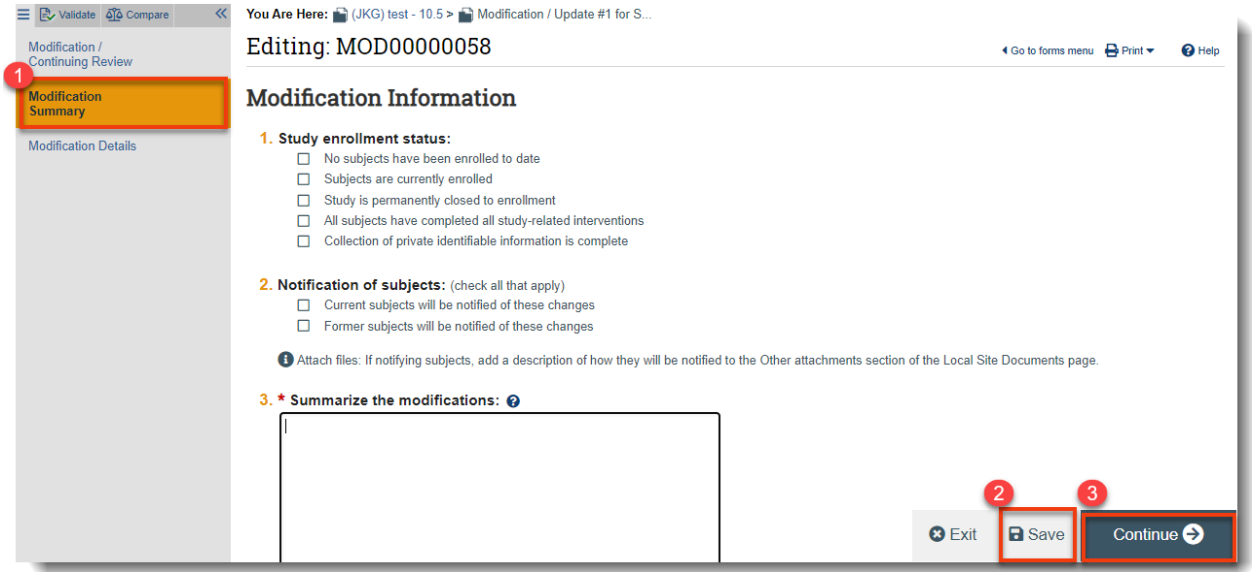
c. **Study team member information** and **Other parts of the study:** This option opens all pages of the study Smartform for revision.

8. Select Save and Continue.



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.
   **Requests for reliance agreement should only include revisions directly related to the reliance. Additional revisions must be submitted independently.*
   Select (2) **Save**. Select (3) **Continue.**

   To revise information or documents specific to a relying site (PSite), this modification request must be accompanied by a MOD submission from the PSite record.



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.



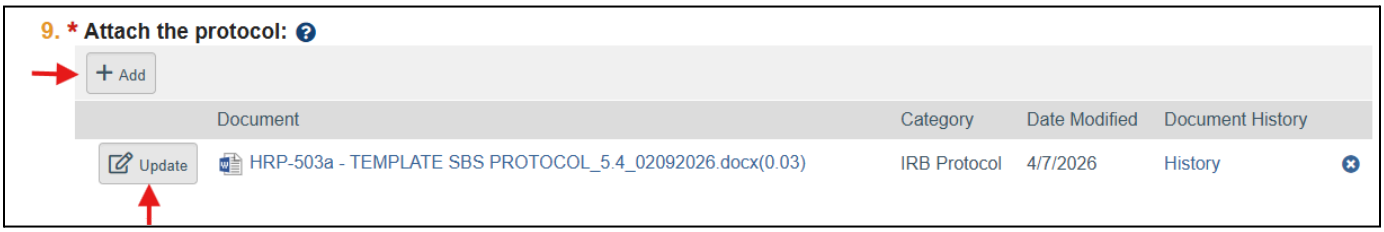
If you select **Save and Exit** on the previous Modification Information screen, you will be brought back to the main Modification workspace. In the Modification workspace, click

the blue **Edit Modification/CR** on the left hand side to access the editable Smartform pages.

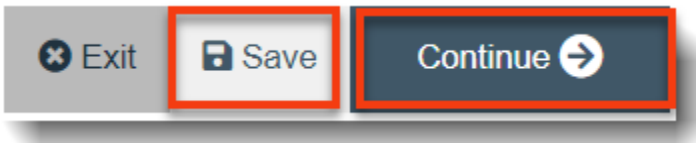
2. On the Smartform pages where documents need to be uploaded:
    a. For new document - select **+Add**
    b. To make a change to an existing document - select **Update**

    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.

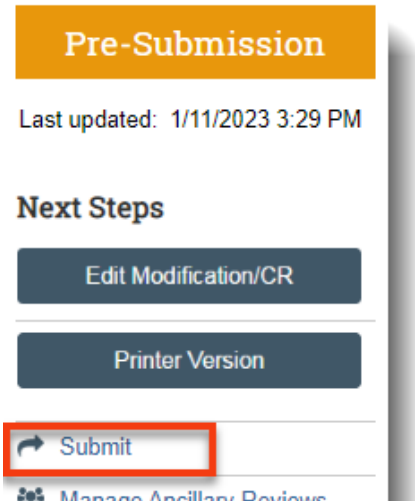


3. After completing the modifications, click **Save** and **Continue** to move to the next page. To exit the submission, click **Exit**. These 3 actions are on every page.



Submit a Modification

To submit a modification, within the study record workspace:



1. Click **Submit**.

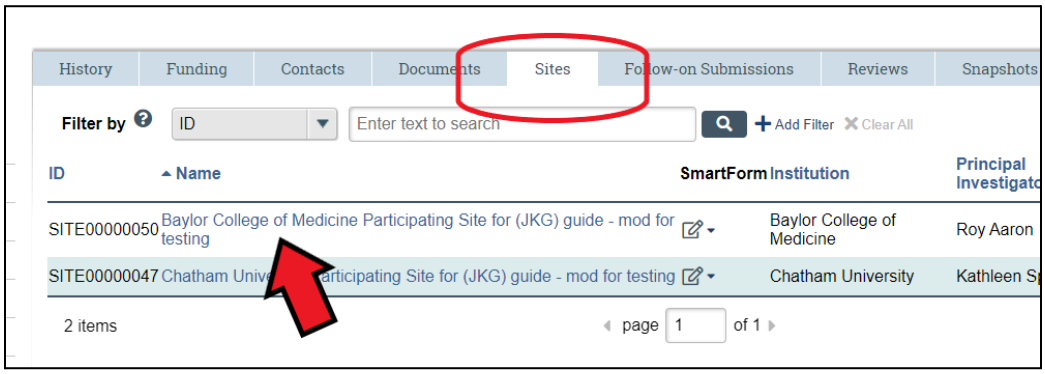
2. Click **OK** to agree to the terms.

3. Type in your login credentials and click **Submit**.

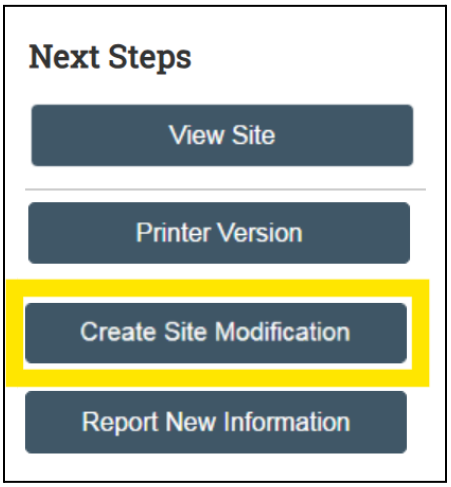
Create a Modification to a PSite

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

1. Go to the Sites tab from the main study record
    a. Click on the site that needs revision



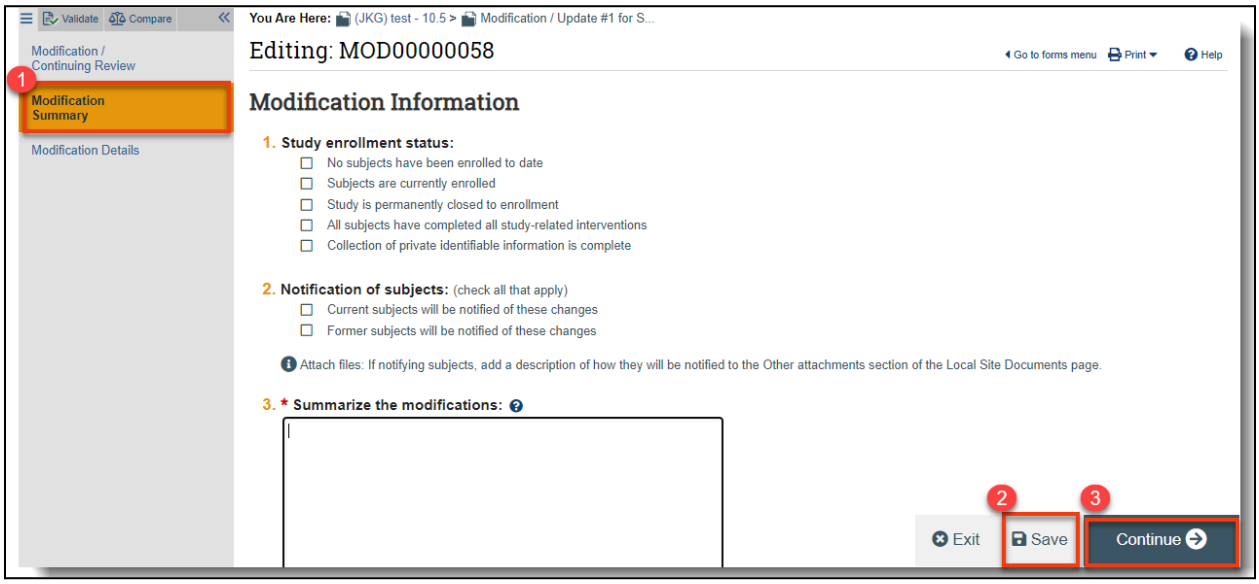
    b. Select “Create Site Modification” from the left-hand menu



    c. 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 -

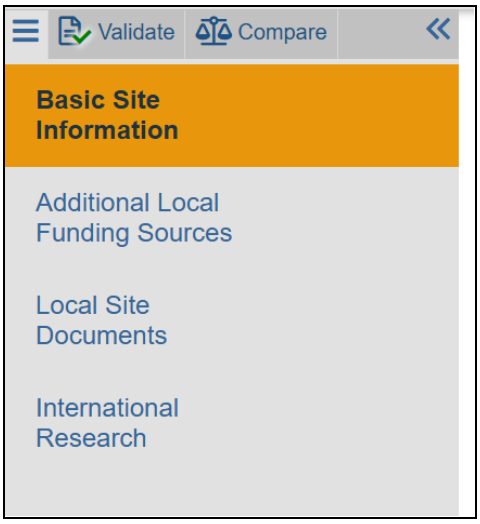
A revised Phase 1 Interview guide is uploaded. Minor formatting changes and a new question have been added.
Select (2) **Save**. Select (3) **Continue.**



Change Study Documents

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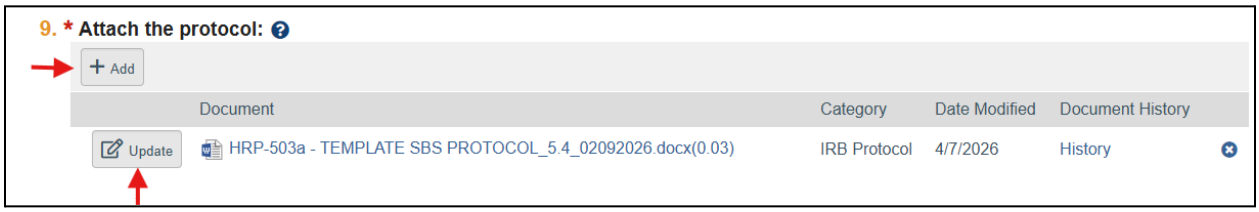
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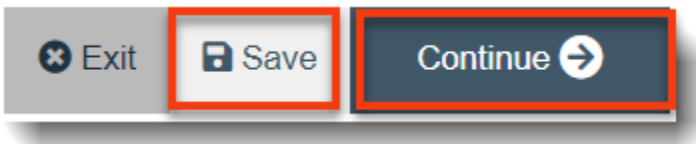
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3. After completing the modifications, click **Save** and **Continue** to move to the next page. To exit the submission, click **Exit**. The final page will offer **Finish** rather than **Continue**.



Submit a Modification

To submit a modification, within the study record workspace:

1. Click **Submit**.

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

