

# IRB CREATING & SUBMITTING A MODIFICATION


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

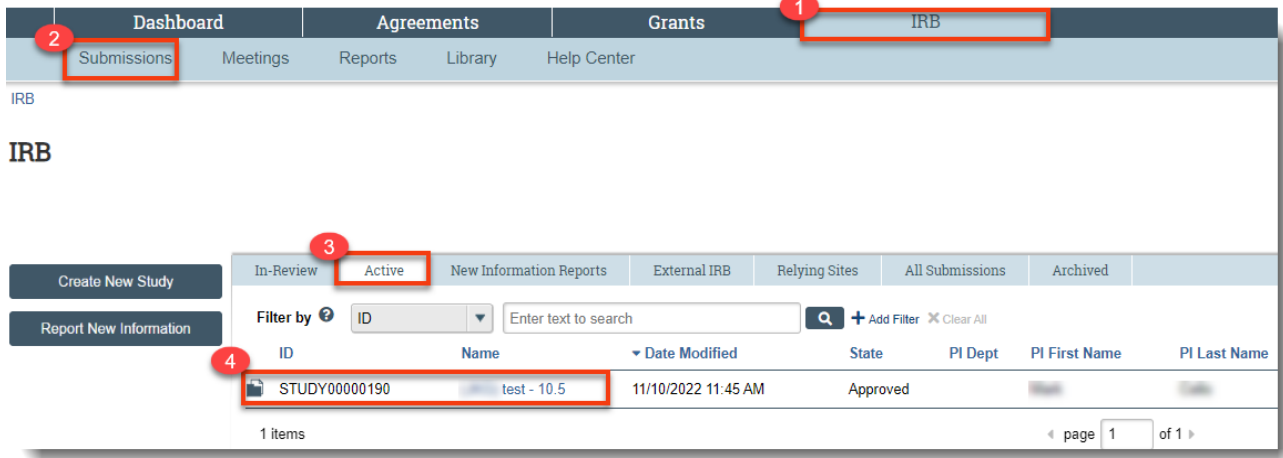
Please **do not** use Microsoft Internet Explorer or Microsoft Edge

When you [log in](#) with your Brown credentials, your landing page will be your Dashboard.

Step	Action to be Taken with Screenshot
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1

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



- Select **Create Modification / CR**.

**Approved**

Entered IRB: 11/10/2022 11:43 AM  
Initial approval: 11/10/2022  
Initial effective: 11/10/2022  
Effective: 11/10/2022  
Last updated: 11/10/2022 11:45 AM

**Next Steps**

View Study

Printer Version

**Create Modification/CR**

Report New Information

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Related Grant

Add Comment

Copy Submission

### IMPORTANT

#### When creating / editing a Modification:

- 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**.

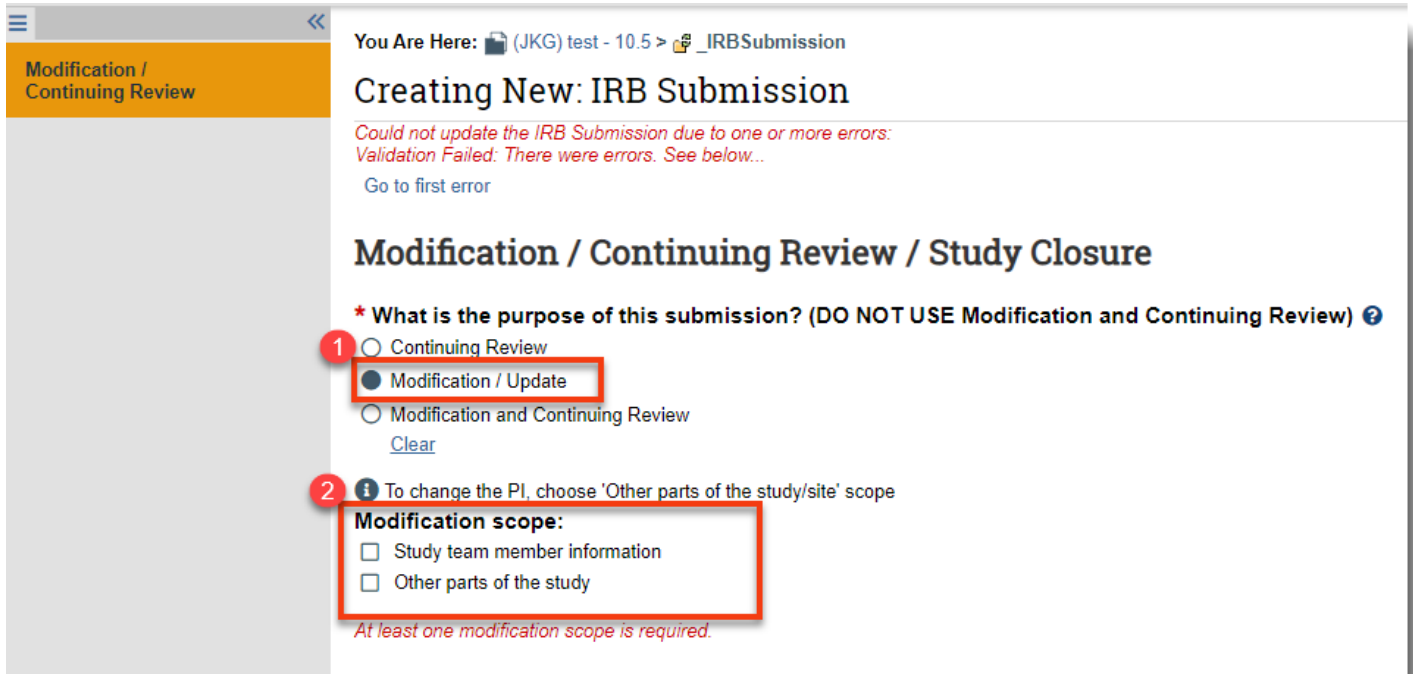
3

1. Select **Modification / Update**.

- *Note: Do not select Modification and Continuing Review as this function has been disabled per HRPP policy.*
- *Once a response is made to “What is the purpose of this submission?,” a logic driven question appears (Modification scope).*

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

- *Note: At least 1 response is needed for this section to generate the modification needed for the study.*

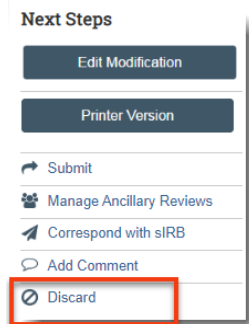


4

1. Select **Save**.

- *Note: If an incorrect response was chosen for “What is the purpose of this submission?” and it has been saved, then click **Exit** to leave the submission and select **Discard** from the study record workspace.*

*Screenshot of Note:*



- *A new Modification/CR request can be resubmitted once the incorrect version has been*

discarded.

2. Select **Continue**.

- *Note: Continue will move the user to the next page.*



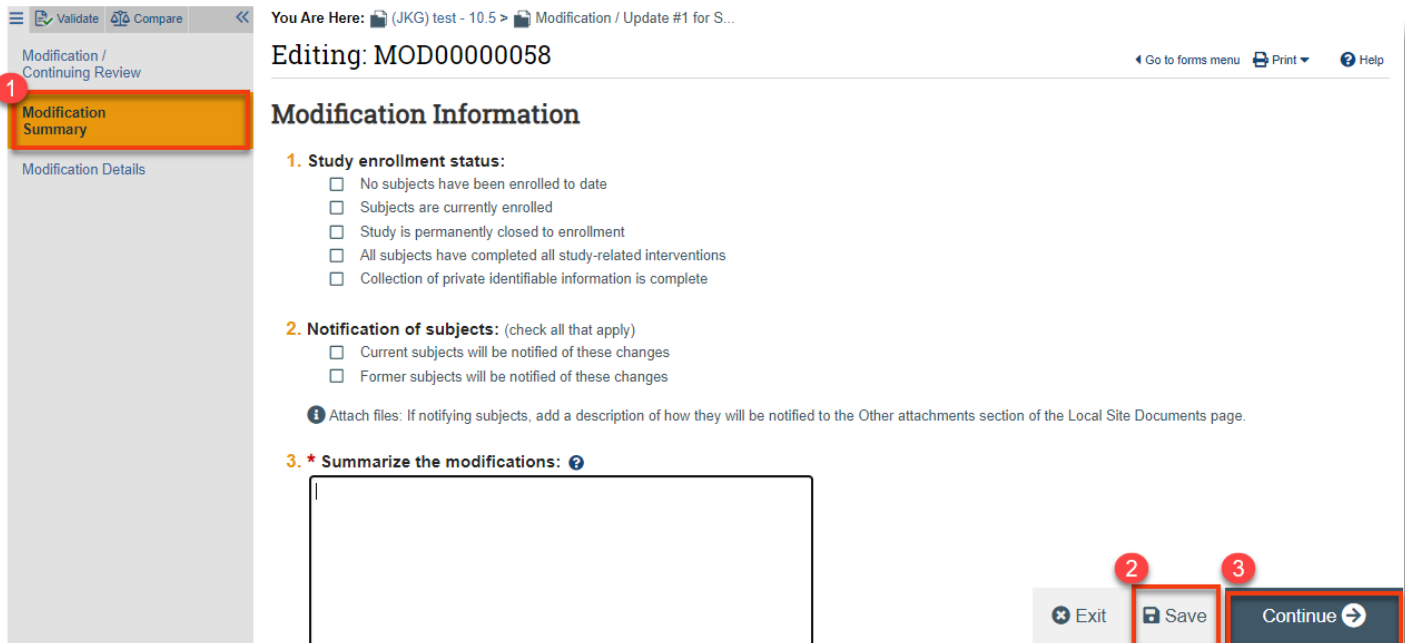
5

3. Complete the **Modification Summary** tab.

4. Select **Save**.

5. Select **Continue**.

- *Note: Once Continue is clicked, the user will be brought to the original submission to make edits.*
- *Remember to attach an updated protocol to the **Basic Study Information** page.*



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To submit a modification, 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**.

- *Note: Edits to the modification request cannot be made if the request has been submitted to the HRPP for review.*

## Pre-Submission

Last updated: 1/11/2023 3:29 PM

### Next Steps

Edit Modification/CR

Printer Version

Submit

Manage Ancillary Reviews

Add Comment

Discard

## OPTIONAL STEPS

### Study Response Validation, Change Study Documents

optional

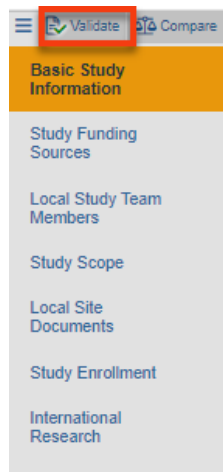
#### STUDY RESPONSE VALIDATION

To validate to ensure required information is included before submitting, either:

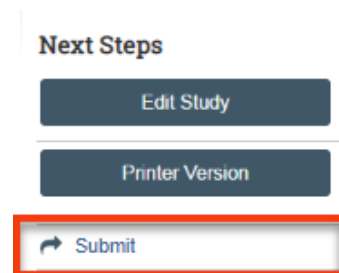
- Click **Validate** within the study itself

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).



or



## CHANGE STUDY DOCUMENTS

Open the submission:

1. **Edit Study**.
2. Find the pages where documents need to be
  - a. Added - select **+Add**; and/or
  - b. Updated - select **Update**
3. For updated documents, the version number changes confirming an update was completed.
  - *Note: To change study documents, the user can update the study documents at any time prior to submitting the study to the HRPP for review.*
  - *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 in the current modification (or if a new modification is submitted following the study approval).*

