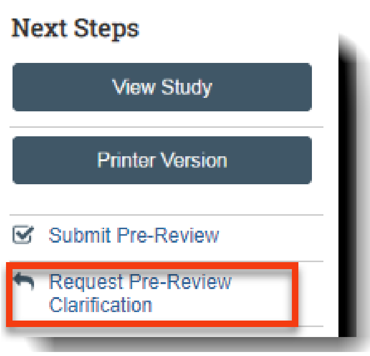
IRB CLARIFICATIONS:
REQUEST (HRPP / IRB), RESPONSE (PI / PROXY) & REVIEW (HRPP / IRB)

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

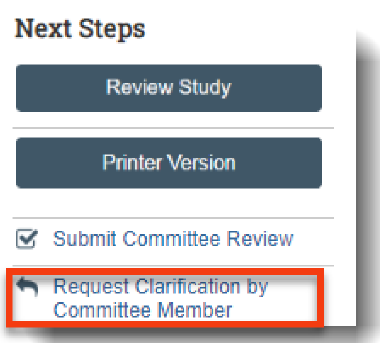
*Please **do not** use Microsoft Internet Explorer or Microsoft Edge*

How to:
REQUEST A CLARIFICATION (HRPP / IRB ONLY)

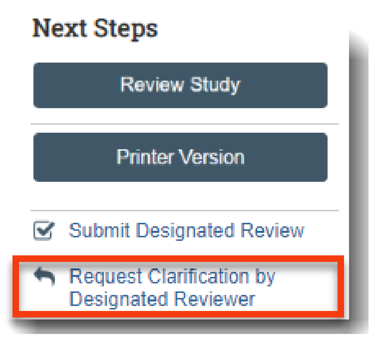
	Action to be taken
	If clarification is needed at any time during the review process: • Click **Request [Pre-Review] Clarification** or • Click **Request Clarification by [Committee Member, Designated Reviewer]**. • *Note: the PI / proxy will receive an email notification requesting clarification once requests are submitted. HRPP / IRB do not get an email notification when a PI responds back, but instead the submission will appear in My Inbox with the applicable submission state.* • *If further clarification is needed after the PI / Proxy submit their response, the IRB Coordinator can repeat this step.*



Pre-Review



IRB Review (committee review)

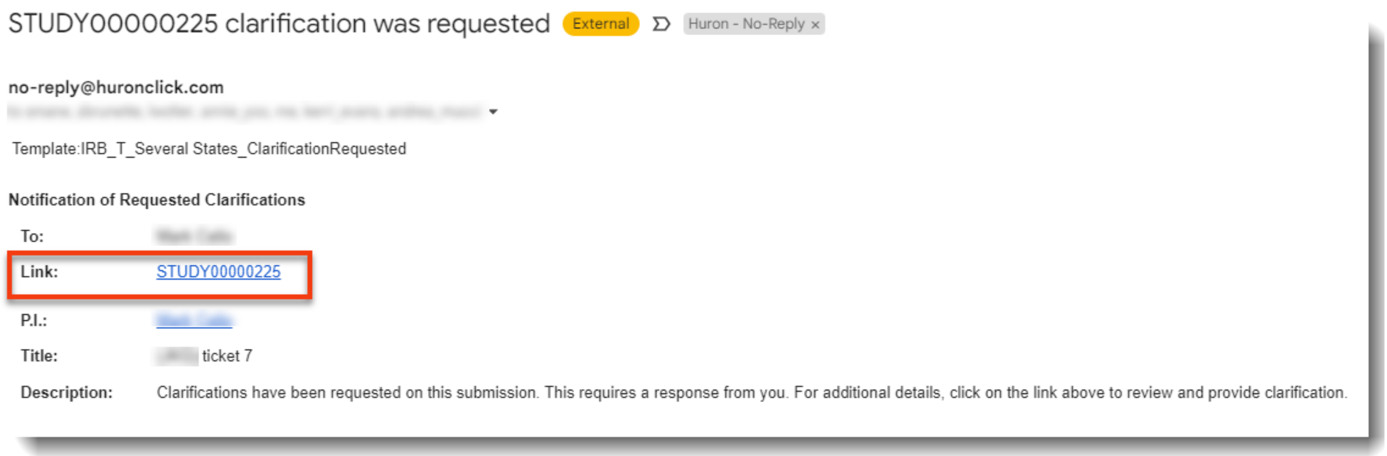


IRB Review (non-committee review)

<table>
<tr><th colspan="2">How to:
RESPOND TO A CLARIFICATION REQUEST (PI / PROXY)</th></tr>
<tr><th>Step</th><th>Action to be taken</th></tr>
<tr><td>1</td><td>

Click on the link from within the email notification received.

- *Note: if you are not logged in to Huron, you will automatically be directed to the login page.*
- *If you are not directed to the submission for review after logging in, see Step 2, below.*



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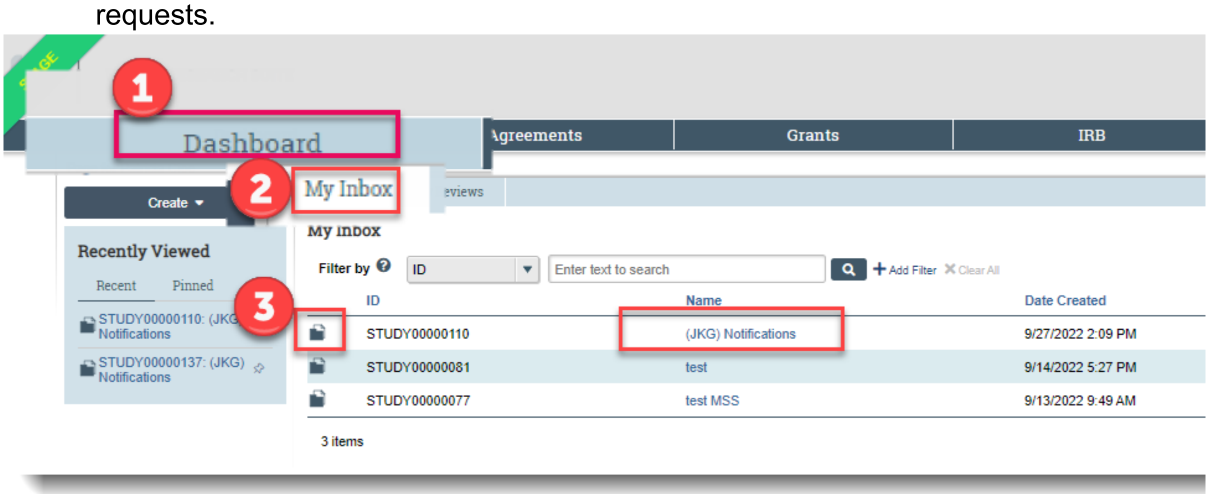
If you are not directed to the submission from step 1, log in to Huron:

1. From the **Dashboard,**
2. Click on **My Inbox**
3. Select the **folder symbol (** **)** or the **Name** of the submission to open and review clarification requests.



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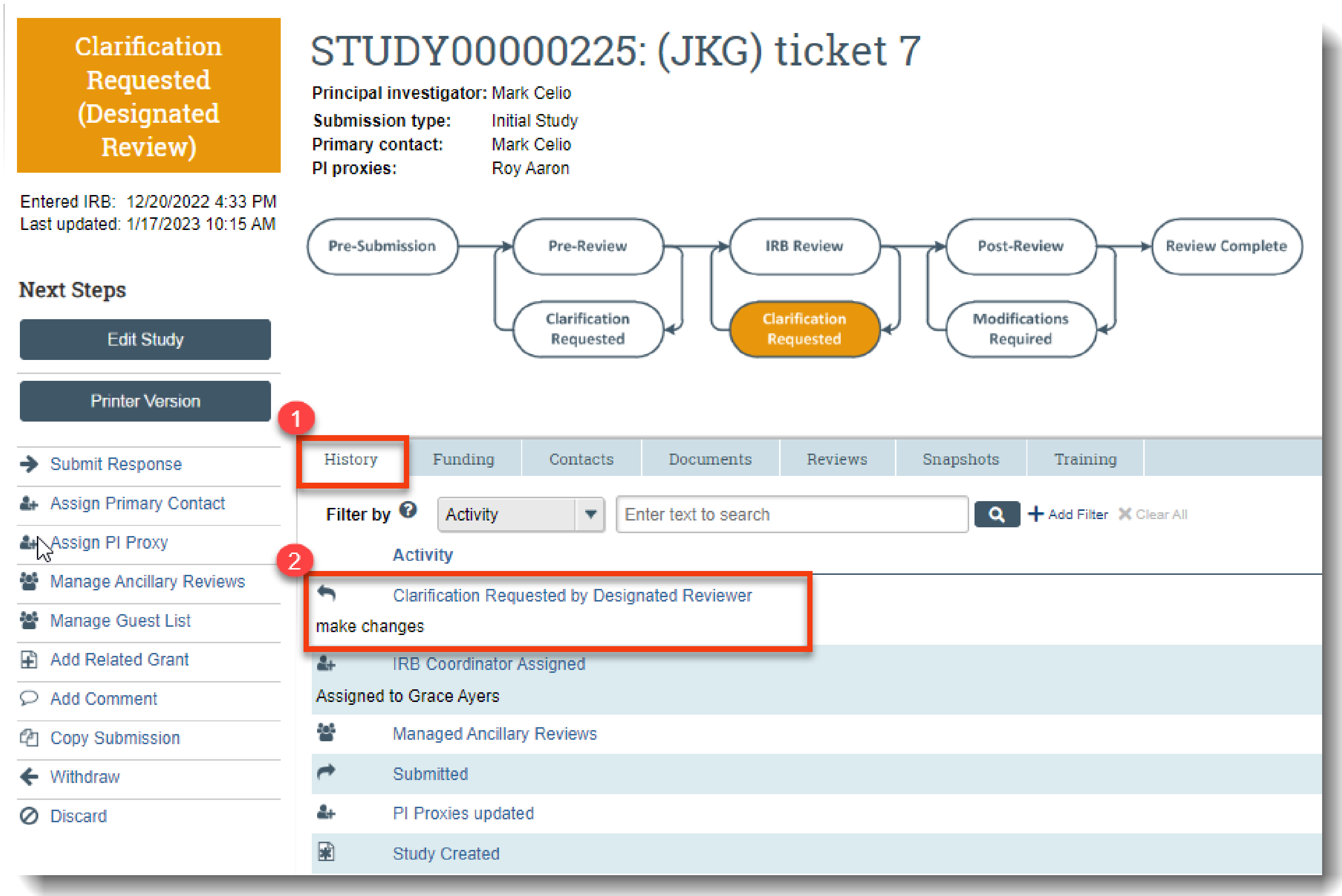
1. Review the **Clarification Requested** from **History** menu,
2. under **Activity** within the study record.

*Note: the clarification will be directly embedded in this location, but you can also click on the blue link labeled with **Clarification Requested [by Designated Reviewer, Committee Member, Pre-Review]** to open the requests in a separate window.*



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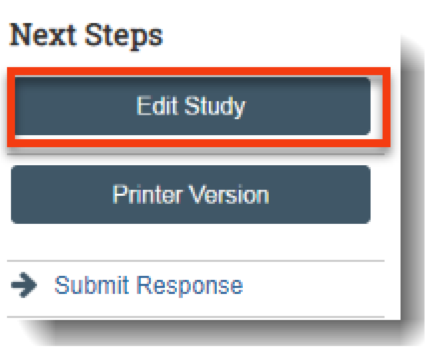
If changes are needed, click **Edit Study** to make the necessary changes within the submission form.



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1. Click **Save**.

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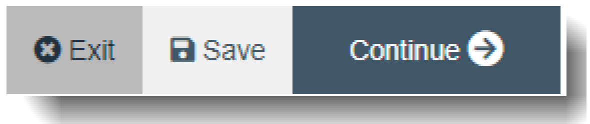
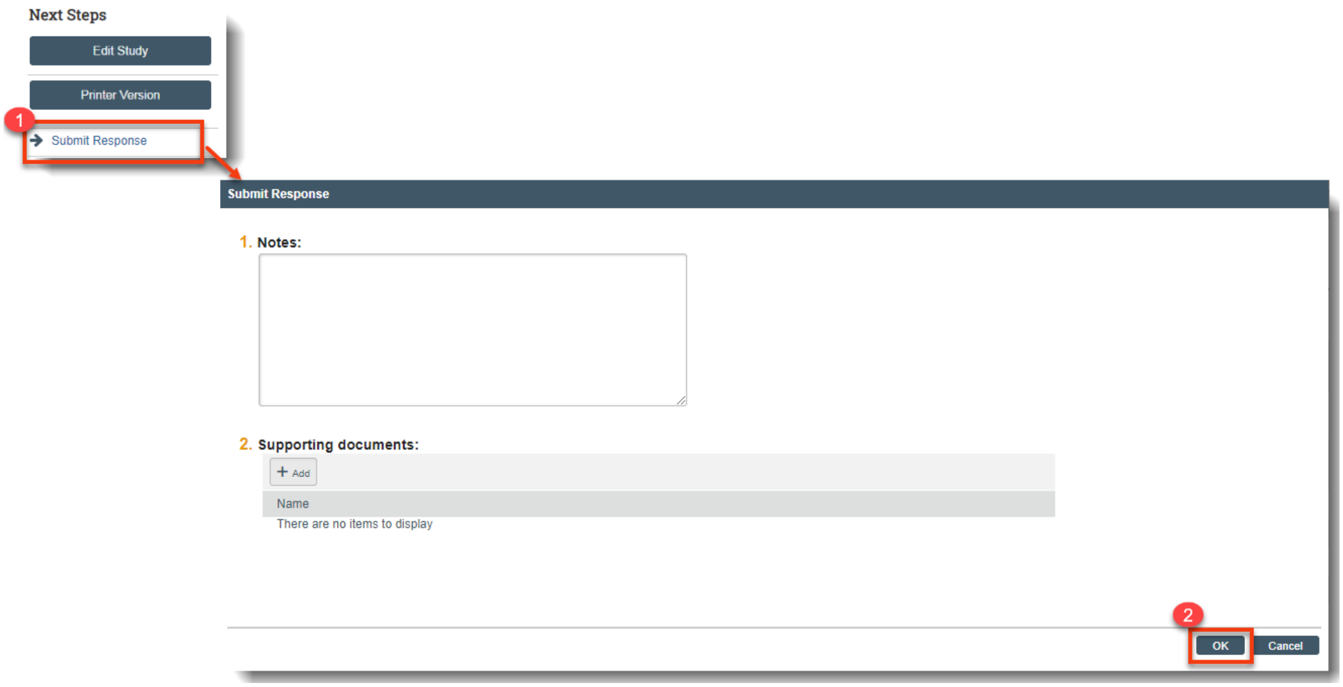
	2. Click **Continue** to move to the next page. 3. To exit the submission, click **Exit**. ● *Note: these 3 actions are on every page throughout the submission.* 
6	● After clicking **Continue** from the **International Research** page (if changes are needed here), the user lands on the **Final Page**. ● Follow the instructions on this page by clicking **Finish** to exit the form.  ● *Note: Once the user clicks Finish, the user is brought back to the IRB workspace within the record.* ● *Clicking Finish does not send the submission to the HRPP. When the study is ready for HRPP review, the PI or proxy must submit from the study record workspace.* ● *The PI / proxy can continue to edit the study (Edit Study button) until it is submitted.*
7	To submit a response to the clarifications requested by the HRPP / IRB: 1. Click **Submit Response**. 2. Click **OK**. *Note: once OK is selected from Submit Response, the response immediately appears under Activity within the History menu and is public to all with access to the submission.*

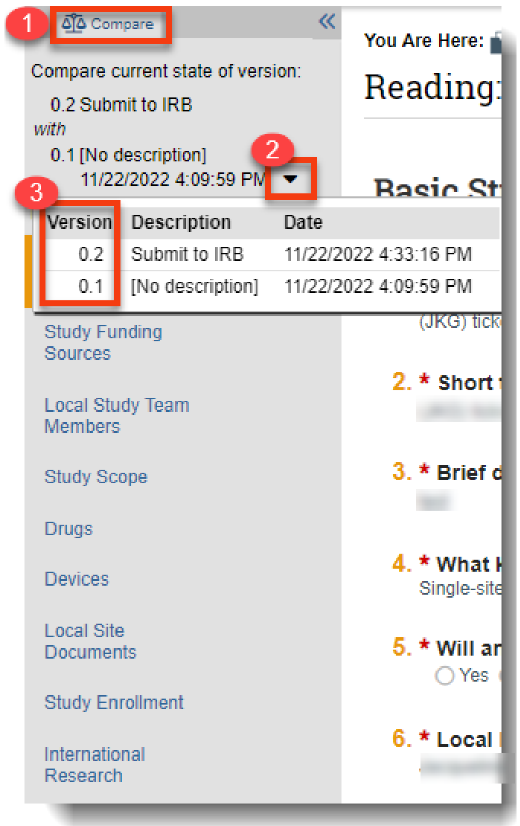


REVIEW STUDY RESPONSE (HRPP / IRB only)

After the study team submits their response to the clarification request at Pre-Review or Designated Review, you can compare versions to see the changes that were made.

1. Click **Compare**.
2. Click the down arrow to show the versions that you can compare against.
3. Select a version to compare the current version.

- *Note: if a change was made to the form, a pencil icon will appear. Click the pencil icon to view the change made. New information is highlighted in green.*



OPTIONAL
Validation of Response

optional	The user can choose to validate before submitting their response by clicking **Validate** within the study itself