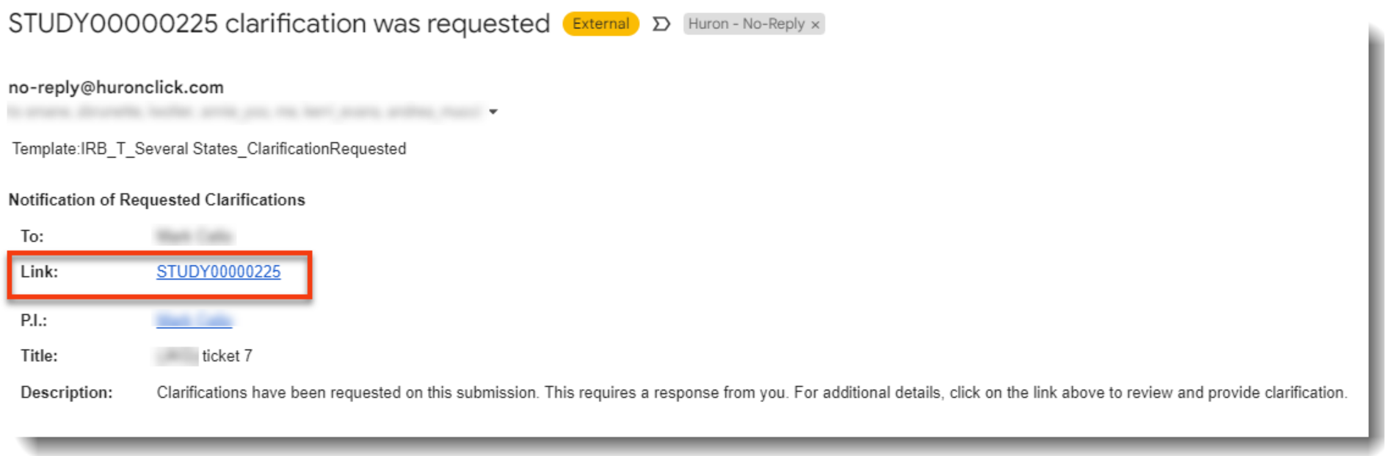
How to:
RESPOND TO A CLARIFICATION REQUEST (PI / PROXY)

<table>
<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.

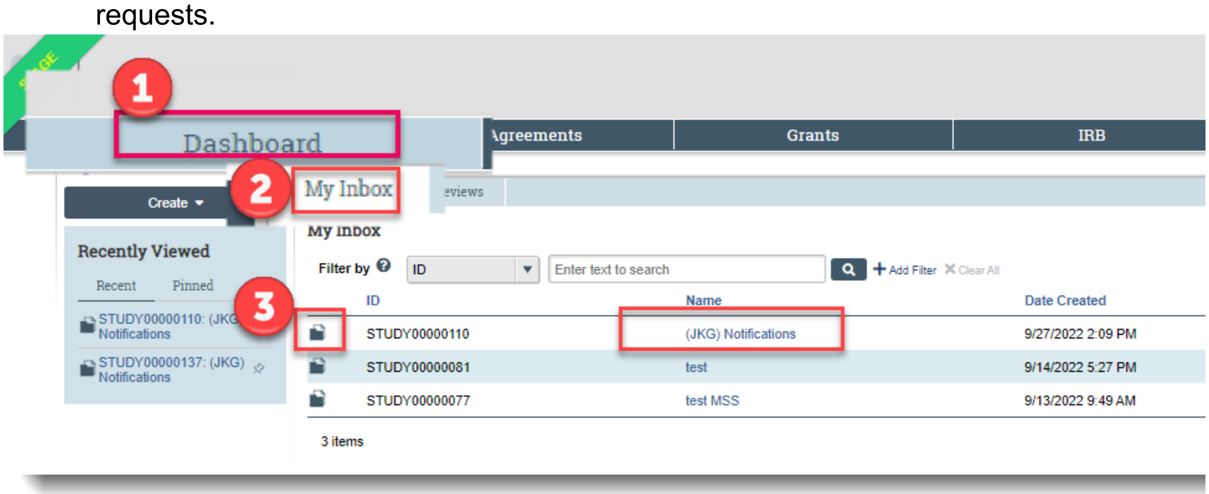
- *Note: if you are not logged in to Huron, you will automatically be directed to the login page.*
- *If you are not directed to the submission for review after logging in, see Step 2, below.*



</td></tr>
<tr><td>2</td><td>

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.



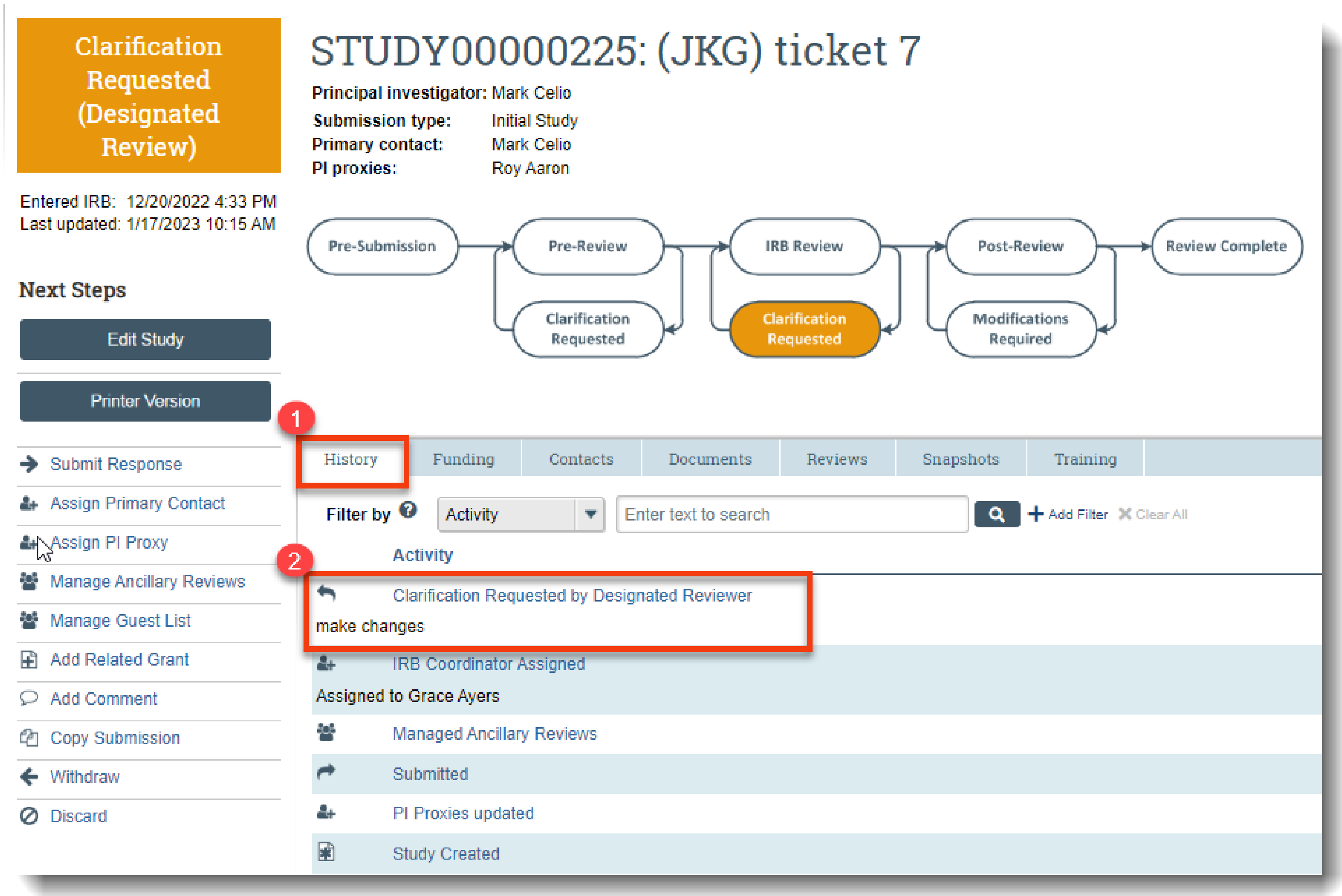
</td></tr>
</table>

<table>
<tr>
<td>3</td>
<td>

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.*

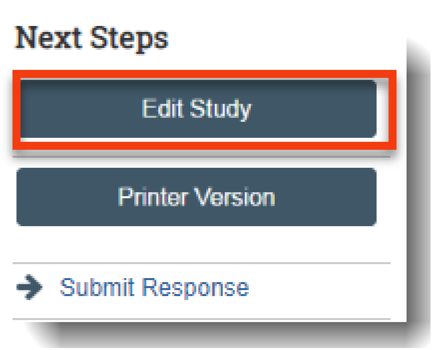


</td>
</tr>
<tr>
<td>4</td>
<td>

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

On the Smartform pages where documents need to be uploaded

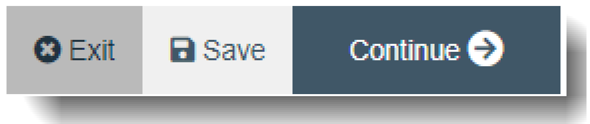
- Select “+Add” for a new document.
- Select “Update” to make a change to an existing document. This will replace the previous version. The study record should maintain the most current version of the documents.
    - Use track changes in Word to document any revisions to the updated material being uploaded. At the time of upload, review the document title for any additional edits to the title such as the date or version number.

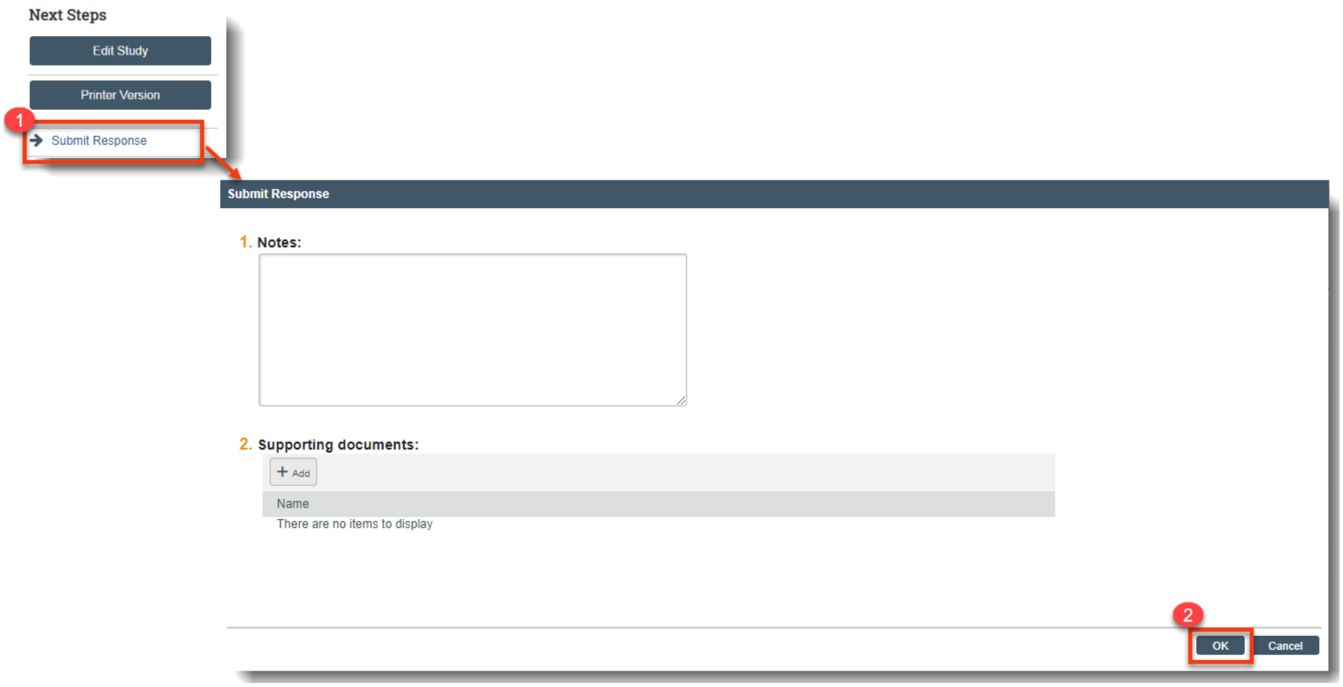


</td>
</tr>
<tr>
<td>5</td>
<td>

1. Click **Save**.

</td>
</tr>
</table>

	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**. a. A textual response is required in the Notes field b. Do not upload new or revised documents in the response window. To submit new or revised documents, you must "Edit Study" (See 4. above) and navigate to the appropriate page. 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.*

	Next Steps Edit Study Printer Version 1 Submit Response Submit Response 1. Notes: 2. Supporting documents: Add Name There are no items to display 2 OK Cancel