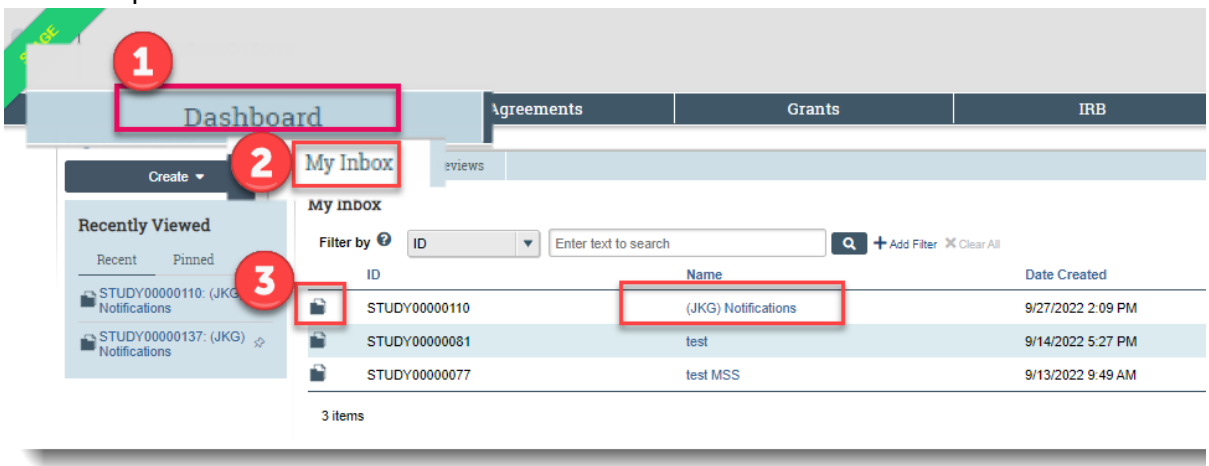


How to: RESPOND TO A CLARIFICATION REQUEST (PI / PROXY)

Step	Action to be taken
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1	<p>Click on the link from within the email notification received.</p> <ul style="list-style-type: none"> <i>Note: if you are not logged in to Huron, you will automatically be directed to the login page.</i> <i>If you are not directed to the submission for review after logging in, see Step 2, below.</i> <p>STUDY00000225 clarification was requested External Huron - No-Reply x</p> <p>no-reply@huronclick.com</p> <p>Template: IRB_T_Several States_ClarificationRequested</p> <p>Notification of Requested Clarifications</p> <p>To: [Redacted]</p> <p>Link: STUDY00000225</p> <p>P.I.: [Redacted]</p> <p>Title: [Redacted] ticket 7</p> <p>Description: Clarifications have been requested on this submission. This requires a response from you. For additional details, click on the link above to review and provide clarification.</p>
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2	<p>If you are not directed to the submission from step 1, log in to Huron:</p> <ol style="list-style-type: none"> From the Dashboard, Click on My Inbox Select the folder symbol () or the Name of the submission to open and review clarification requests.  <p>The screenshot shows the Huron system interface. At the top, there is a navigation bar with 'Dashboard', 'Agreements', 'Grants', and 'IRB'. Below this is a 'My Inbox' section with a search bar and a table of items. The table has columns for ID, Name, and Date Created. The first row is highlighted, and a folder icon is visible next to it. Red circles and boxes highlight the 'Dashboard' link, the 'My Inbox' link, and the folder icon next to the first submission entry.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th>ID</th> <th>Name</th> <th>Date Created</th> </tr> </thead> <tbody> <tr> <td>STUDY00000110</td> <td>(JKG) Notifications</td> <td>9/27/2022 2:09 PM</td> </tr> <tr> <td>STUDY00000081</td> <td>test</td> <td>9/14/2022 5:27 PM</td> </tr> <tr> <td>STUDY00000077</td> <td>test MSS</td> <td>9/13/2022 9:49 AM</td> </tr> </tbody> </table>	ID	Name	Date Created	STUDY00000110	(JKG) Notifications	9/27/2022 2:09 PM	STUDY00000081	test	9/14/2022 5:27 PM	STUDY00000077	test MSS	9/13/2022 9:49 AM
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STUDY00000077	test MSS	9/13/2022 9:49 AM											

3

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.*

Clarification Requested (Designated Review)

STUDY00000225: (JKG) ticket 7

Principal investigator: Mark Celio
Submission type: Initial Study
Primary contact: Mark Celio
PI proxies: Roy Aaron

Entered IRB: 12/20/2022 4:33 PM
Last updated: 1/17/2023 10:15 AM

Next Steps

Edit Study
Printer Version

Submit Response
Assign Primary Contact
Assign PI Proxy
Manage Ancillary Reviews
Manage Guest List
Add Related Grant
Add Comment
Copy Submission
Withdraw
Discard

History Funding Contacts Documents Reviews Snapshots Training

Filter by Activity Enter text to search + Add Filter X Clear All

Activity

Clarification Requested by Designated Reviewer
make changes

IRB Coordinator Assigned
Assigned to Grace Ayers

Managed Ancillary Reviews

Submitted

PI Proxies updated

Study Created

4

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.

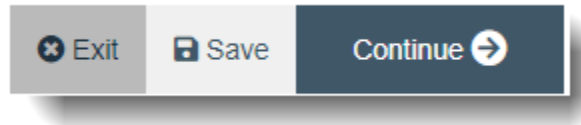
Next Steps

Edit Study
Printer Version
Submit Response

5

1. Click **Save**.

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