

**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

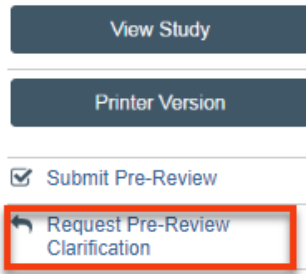
**How to:
REQUEST A CLARIFICATION (HRPP / IRB ONLY)**

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.*

Next Steps



View Study

Printer Version

Submit Pre-Review

Request Pre-Review Clarification

Pre-Review

Next Steps



Review Study

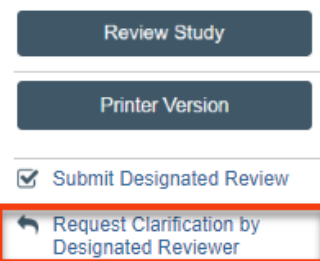
Printer Version

Submit Committee Review

Request Clarification by Committee Member

IRB Review (committee review)

Next Steps



Review Study

Printer Version

Submit Designated Review

Request Clarification by Designated Reviewer

IRB Review (non-committee review)

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

Step

Action to be taken

1

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.*

STUDY00000225 clarification was requested External Huron - No-Reply x

no-reply@huronclick.com

Template:IRB_T_Several States_ClarificationRequested

Notification of Requested Clarifications

To:


Link: [STUDY00000225](#)

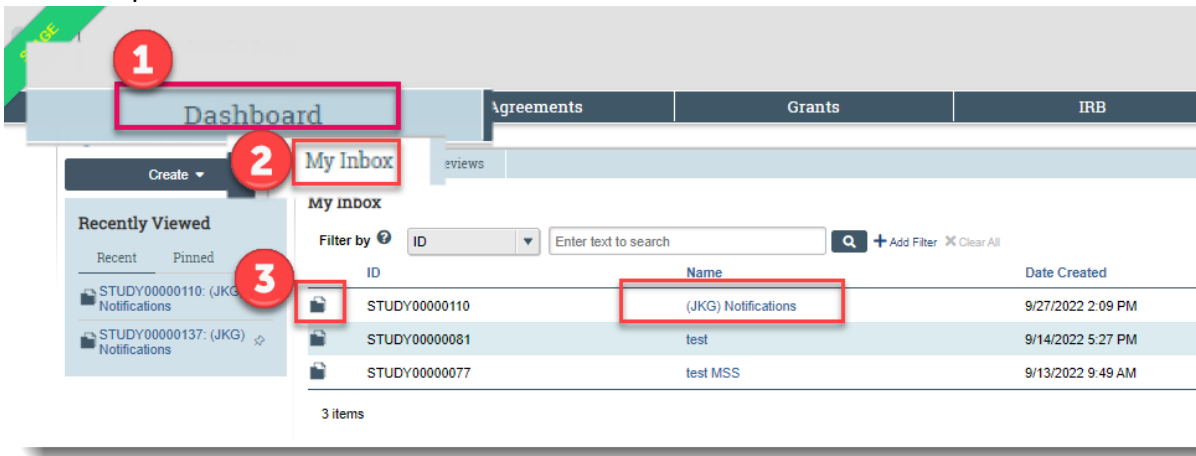
P.I.:

Title: ticket 7

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.

2 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.



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

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

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.

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.*



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- 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.*

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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.

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

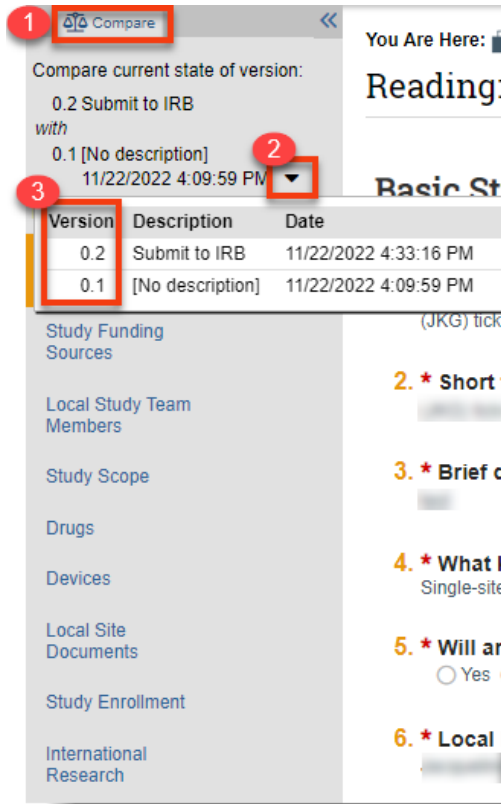
OK

Cancel

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

