**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

<table>
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<tr>
<th>How to: REQUEST A CLARIFICATION (HRPP / IRB ONLY)</th>
<th>Action to be taken</th>
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</table>

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.

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**Next Steps**

- **Pre-Review**
  - View Study
  - Printer Version
  - Submit Pre-Review
  - Request Pre-Review Clarification

- **IRB Review (committee review)**
  - Review Study
  - Printer Version
  - Submit Committee Review
  - Request Clarification by Committee Member

- **IRB Review (non-committee review)**
  - Review Study
  - Printer Version
  - Submit Designated Review
  - Request Clarification by Designated Reviewer
### How to: RESPOND TO A CLARIFICATION REQUEST (PI / PROXY)

<table>
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<tr>
<th>Step</th>
<th>Action to be taken</th>
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</table>
| 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]  
no-reply@huronclick.com  

Notification of Requested Clarifications  
To:  
Link: STUDY00000225  
PI:  
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. |
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.

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

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**.

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