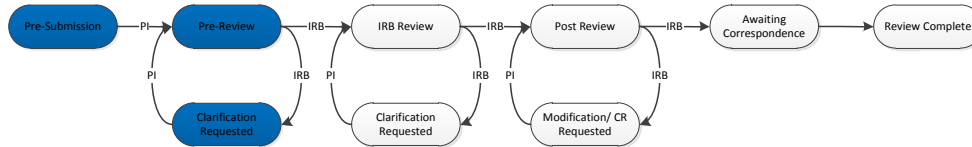




| | |
|-----------------------|---|
| Job Aid Title | Clarifications Requested |
| Relevant Users | Principal Investigator (PI), Study Staff, Additional Contact |
| Covered Topics | <ul style="list-style-type: none"> ○ Where to find the Clarifications Requested notification ○ How to respond to a request for clarifications |



1. Clarifications Requested notification

When the IRB requests information, a **Clarifications Requested** notification is sent to the PI and the additional contact.

- As PI or additional contact, you will receive an email message indicating that you need to take action on your submission. eIRB will send the email to the email address listed in your user profile, and the message will have a link to the corresponding submission.
- If you are already in the eIRB system, go to the **Under Review** tab and select the **Name** of the submission that requires clarifications. PI and study staff can also quickly find the submissions that require clarifications in their **Inbox**.

(Personnel listed as Additional Contacts will need to find the submission using the Under Review tab.)

| ID | Name | State | PI | Submission Type | Submission Date | IRB Owner | Last System Date |
|-------------|--------------|-------------------------------------|------|----------------------------|-------------------|-----------|-------------------|
| H00001448_2 | RNI 1 | In Non-Committee Review | Test | Reportable New Information | 2/26/2013 4:40 PM | Wang | 2/28/2013 4:35 PM |
| H00001447 | TEST STUDY 2 | Pre-Review | Test | Study | 2/26/2013 3:16 PM | Wang | 2/26/2013 4:16 PM |
| H00001446 | TEST STUDY | Pre-Review Clarifications Requested | Test | Study | 2/26/2013 3:05 PM | Wang | 3/12/2013 2:54 PM |

2. Review Clarifications Request

- To view the clarifications request, look under the **Clarifications Requested** tab in the submission workspace. The most common IRB clarifications request is a **Pre-Review Clarifications** request.



Home IRB

IRB > IRB Studies > TEST STUDY

H00001446: TEST STUDY

Principal Investigator PI Test
IRB Owner Sharon Wang
Submitted Date 2/26/2013
Approval Date
Expiration Date

Documents Project Personnel Follow-on submissions **Clarifications Requested** RNI Full History Summary History Respond to IRB Decision

| Pre-Review Clarifications | | Attached Document | Date |
|----------------------------|---|--------------------------------------|-----------|
| Request / Response | | | |
| Request By: Sharon Wang | Please see attached Word document for prereview clarifications requested. | prereview clarification 2.26.13.docx | 2/26/2013 |
| Response By: | | | 2/26/2013 |

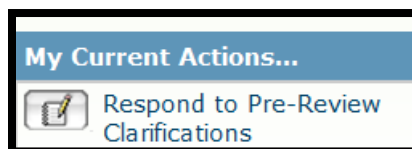
3. Update your submission, if needed, by selecting **EDIT STUDY** or **EDIT CR/MODIFICATION (PI or study staff)**

- Be sure to add any missing documents OR replace documents using update/upload revision in section **7.0 Attachments** of the study. Edit your submission before the next step.

! Note: Refer to the [How to Manage Files in eIRB](#) Job Aid that describes how to edit a study documents in Section 7.0 Attachments (PI or study staff only).

4. Respond to the Clarifications Request (PI or study staff)

- When you have finished editing your submission and you are ready to tell the IRB that you have responded, on the left side under **My Current Actions**, click on the button to respond. For a pre-review clarifications request, click on **Respond to Pre-Review Clarifications**.

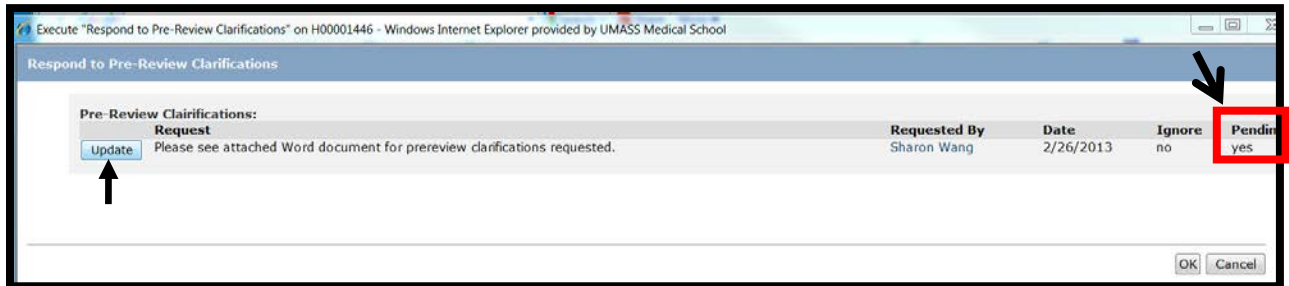


! TROUBLESHOOTING: If you are Study Staff and you are missing the button to Respond to Pre-Review Clarifications, then try the following steps:

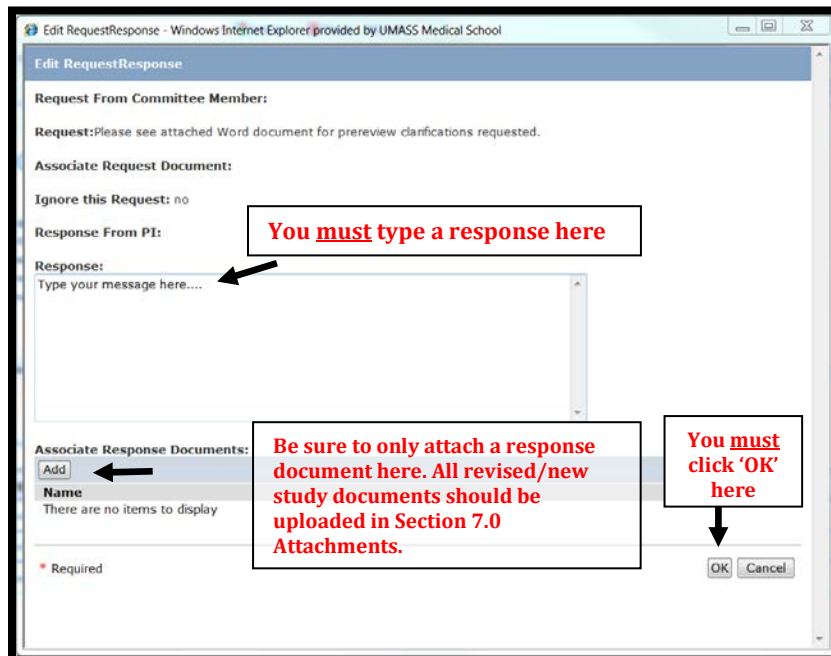
- Check first that you are listed as the PI or Study Staff. Additional Contacts do not have editing privileges in eIRB.
 - Go to the main study (parent) and click on Edit Research Staff. Click OK at the bottom of the window.
 - Then, return to your submission and you should see the button to respond (i.e., Respond to Pre-Review Clarifications) under My Current Actions.
- Try the above steps before contacting the IRB office. If you continue to have issues, contact the IRB office.



- Once the **Respond to Pre-Review Clarifications** pop-up opens, click on the **Update** button to enter comments. If there have been multiple clarification requests, click Update next to the request that says “Yes” under Pending. Do not respond to a request that is no longer pending. **The most recent (pending) request is usually at the top of the pop-up window.**



- Once the update page pops open, you **must** type a message into the **Response** text box that either addresses brief clarifications directly or points the IRB to an associated response document attached (e.g., *see attached clarifications response letter*). If you have a clarifications response letter, select the **Add** button to upload the response letter and follow instructions in the pop-up page to upload the document.





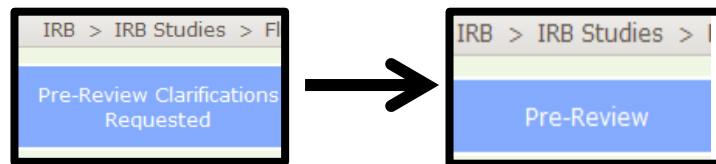
Respond to Pre-Review Clarifications

Pre-Review Clarifications:

| | Request | Requested By | Date | Ignore | Pending |
|---------------------------------------|-----------|--------------|-----------|--------|---------|
| <input type="button" value="Update"/> | test prcr | Sharon Wang | 3/25/2013 | no | no |

You must click 'OK' here

- Click **OK** twice – once to close the response box and once to send the study back to the IRB (refer to screen shots above)
- Once you have successfully completed the above steps, the state will change (e.g., from “Pre-Review Clarifications Requested” to “Pre-Review”) and the IRB will review the response.
- You will know that you have responded successfully when the submission’s “state” in the upper left-hand of the screen has changed from **Pre-Review Clarifications Requested** to **Pre-Review**.



! Notes:

- All active study staff and the PI have the ability to respond to clarifications requested.
- Responding to a clarifications request is a different process than responding to an IRB decision. Refer to the [How to Respond to IRB Decision](#) Job Aid which describes how to respond to an IRB determination.