

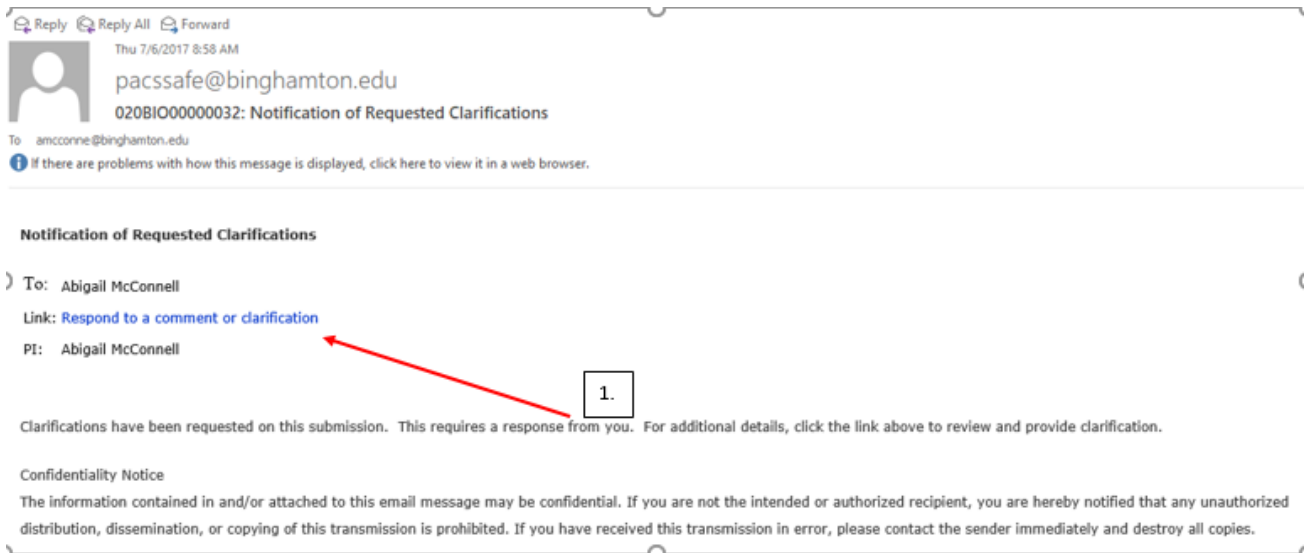
## Clarification Requested and/or Modifications Required by the PI in PACS



At several points during the review process, the Safety review team may request clarifications or require modifications from the research team (PI) prior to making a determination.

### WORK INSTRUCTIONS: THESE DIRECTIONS ARE FOR THE PI TO RESPOND TO REQUESTS MADE BY THE BSO OR COMMITTEE MEMBERS AND TO MAKE MODIFICATIONS DURING THE APPROVAL PROCESS IF NEEDED

- As the PI of a protocol that needs to respond to requests from approvers during the approval process of a protocol, click on the link to your protocol in the email that you receive from PACS.



- Find the submission requiring clarifications or modifications in which the state is defined as **Clarification Requested (Specialist Review)** and click on the submission name to navigate to the protocol workspace.

- Review the requested information by clicking on the **Clarification Requested** activity in the history log.

<< Return to Workspace

< Prev

1 / 3

**Activity Details (Clarification Requested by Specialist)** Pre-reviewer sends the submission back to the protocol team for clarifications

**Author:** Abigail McConnell (020 Binghamton University)  
**Logged For (Click Safety Submission):** Respond to a comment or clarification  
**Activity Date:** 7/6/2017 8:57 AM

**Activity Form** Property Changes Documents Notifications

3.

1. **Assigned specialist:**  
Abigail McConnell
2. **Make the following changes or provide the requested information:**  
Please update to BSL-2
3. **Supporting documents:**  

Document Name	Date Modified
There are no items to display	

**Reviewer Notes**

You have added 0 reviewer notes to this submission. To add specific notes in context (recommended), view the submission forms and click **Add** in the Reviewer Notes bar.

<< Return to Workspace

4. To provide a response, return to the protocol workspace and click on **Submit Response** under My Current Actions. Write your response in the box provided and/or add any additional supporting documentation and click OK.

The screenshot shows the 'Submit Response' dialog box in the IRB system. The dialog has a 'Comments' section with a text area containing 'I have updated the Protocol to reflect BSL 2'. Below it is a 'Supporting documents' section with an 'Add' button, which is highlighted with a box containing the number '4.'. The background shows the 'Respond to a comment or clarification' page with a workflow diagram and a list of activities.

- To edit the protocol in response to the reviewer's note, click on the **Edit Protocol** and then click on the **Jump To** link within the protocol which will direct you to the SmartForm that has the reviewer's note.

*Note: The Reviewers' Note tab will only be present if there are notes made by the reviewer.*

The activity is documented under the History tab and the state goes back to Specialist Review.

