Clarification Requested and/or Reviewer Notes

At several points during the review process, the Safety Specialist or Committee members may request clarifications or require modifications from the protocol team prior to making a determination.

**WORK INSTRUCTIONS – CLARIFICATION REQUESTED:**

1. Log into the Click Portal and click on the Safety tab in the top navigation bar.

2. Find the submission requiring clarifications or modifications in which the state is defined as Clarification Requested (Specialist Review) or Clarification Requested (Committee Review). Click on the protocol’s Name to navigate to the protocol Workspace.
   - Principal Investigators can also navigate directly to the protocol Workspace by clicking on the link in the email notification and logging into the system.

3. Review the requested information by clicking on the Clarification Requested activity on the History tab.

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 then click OK.

5. The response submitted will display in the History log and state of the protocol will return back to either Specialist Review or Committee Review.
The Safety Specialist or Committee members may also ask for additional information by adding a Reviewer Note to specific SmartForm pages.

**WORK INSTRUCTIONS – REVIEWER NOTES:**

1. Log into the Click Portal and click on the **Safety** tab in the top navigation bar.

2. Find the submission requiring clarifications or modifications in which the state is defined as **Clarification Requested (Specialist Review)** or **Clarification Requested (Committee Review)**. Click on the protocol’s **Name** to navigate to the protocol Workspace.
   - Principal Investigators can also navigate directly to the protocol Workspace by clicking on the link in the email notification and logging into the system.

3. Review the requested information by clicking on the **Clarification Requested** activity on the **History** tab.

4. To edit the protocol in response to the reviewer’s requests, click on the **Reviewer Notes** tab. Click on the **Jump To:** link which will direct you to the SmartForm that has the Reviewer Notes.
   - The Reviewer Notes tab will only be present if the reviewer has elected to attach notes to the protocol.

5. From the protocol SmartForm pages, click the **Click here to respond** link.

6. Select a **Type** of response from the list and enter your explanation in the **Response** text box. Click **OK**.

7. Exit the protocol and navigate to the protocol Workspace. Click on **Submit Response**.

8. In the **Comments** box, explain your response to the reviewer and click **OK**.

9. The response submitted will display in the **History** log and state of the protocol will return back to either **Specialist Review** or **Committee Review**.