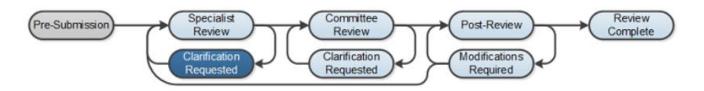# Clarification Requested and/or Reviewer Notes

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**.