Clarification Requested/Modifications Required/Deferral Process

At several points during the review process, the IRB may request clarifications or require modifications from the study team prior to making a determination.

**Work Instructions:**

1. Log into the Click Portal and navigate to My Inbox.

2. Find the submission requiring clarifications or modification in which the state is defined as Clarification Requested (Pre-Review), Clarification Requested (IRB Review) or Modifications Required (Post-Review). Click on the study’s Name to navigate to the Study Workspace.
   - Principal Investigators can also navigate directly to the Study 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, or by reviewing the Determination Letter.

4. Edit the submission by navigating to the SmartForm - click on the Edit Study, Edit Modification/CR, or Edit RNI button under My Current Actions. Save your changes and Exit the study.

5. To provide a response, return to the Study 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.
   - The Principal Investigator must execute the Submit Response activity to send the submission back to the IRB for review.
   - Anyone listed on the study can execute the Submit Response activity for RNI submissions.

6. The response submitted will display in the History log and state of the study will return back to Pre-Review, In Review or Post-Review.