



## 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:

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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**.