

## Clarification Requested and/or Modifications Required



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

### WORK INSTRUCTIONS

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1. Log into Click Portal and navigate to **My Inbox**
2. Find the submission requiring clarifications or modifications and click on the submission name to navigate to the submission workspace
  - Investigators can also navigate directly to the submission 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 in the history log, 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**
5. When the changes have been made, the study PI 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