

Clarification Requested/Modifications Required



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 SUNY RF PACS portal and click on the **IRB** tab in the top navigation menu.
- 2. Find the submission requiring clarifications or modification and 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.
- 4. To edit the submission, click on the **Edit Study**, **Edit Modification/CR**, or **Edit RNI** button under **My Current Actions**. Make the requested changes. **Save** your changes and **Exit** the study.
- 5. Provide a response by clicking on **Submit Response** under **My Current Actions**. Write your response in the box provided 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 the state of the study will return to **Pre-Review**. In **Review** or **Post-Review**.