Responding to Issues & Modification Requests

How to respond when issues or modification requests are sent back to the study team to address

1. **Receive email from ARROW indicating issues or modifications were returned**
   All members of the study team that have edit/email access to the a protocol application – including the PI, Point(s) of Contact, and any other study team member that has been granted edit/email access – will receive an email from ARROW when issues or modifications are sent back to be addressed. Study team members will not be able to address any issues visible in the application until it is sent back by the IRB Staff Reviewer. Therefore, it is important to wait for the email from ARROW before trying to address issues.

2. **Review and respond to Reviewer Notes**
   Once the email has been received, access the appropriate protocol application from the ARROW Inbox by clicking on the appropriate protocol title to enter the protocol workspace.
Open the Reviewer Notes tab to view the issues or modifications to be addressed. **If issues or modifications are sent back for a Change of Protocol, please see pages 6 & 7 for additional instructions.**
Reviewer Notes may be in the form of IRB Requests, IRB Questions, or IRB Comments. Study team members can respond to the Reviewer Notes directly below each note. There is also a link provided to the specific page where the note was made (Jump To: [link]). **Study teams should respond to each Reviewer Note, and make the appropriate changes directly in the modified application and supporting research documents.**

**Please do not respond to Reviewer Notes with questions. Contact the Staff Reviewer, listed under the Application Details, to address any questions that come up when responding to notes and making changes to the application.**
Example of how to respond to Reviewer Notes:

A Study Team Response of "Done." is generally sufficient, unless the IRB asks the study team to confirm or clarify something in their response.
When all of the Reviewer Notes have been addressed, and the ARROW application and supporting documents updated as needed, the PI will need to press SUBMIT. This will not be possible until all of the required Reviewer Notes have been addressed.

Note: The Principal Investigator (PI), Point(s) of Contact (POC), and study team members with edit/email access all have the ability to respond to issues or modifications. However, only the PI has the ability to resubmit the application back to the IRB in ARROW.

The application is returned to the IRB office for review of the addressed issues or modifications made.
Responding to Issues for a Change

Responding to issues in ARROW regarding Changes to modify research procedures and/or documents is different than responding to issues or modifications from an Initial Review. A Change request involves two parts: a Change App to describe the proposed changes, and the Modified App where the proposed changes to the application are actually made.

Directions for reviewing issues for a Change:

Step 1

If there are issues or modifications that need to be addressed in the Change App, from the Change workspace, you can see the issues or modifications by clicking on the Change Form Reviewer Notes tab.

Note: The Principal Investigator (PI), Point(s) of Contact (POC), and study team members with edit/email access all have the ability to respond to issues or modifications. However, per normal IRB procedure, only the PI has the ability to resubmit the Change back to the IRB in ARROW.
Step 2

In addition to responding to issues or modifications listed in the Change App, if there are issues or modifications in the Modified App, those will also need to be addressed. To do this, click on the tab for the Modified App Reviewer Notes.

Once all issues or modifications have been addressed in the Change Form and/or Modified Application, refer to page 5 for how to submit. The SUBMIT activity will be in the Change workspace.