Create and Submit a Modification for a PI Change

Use this job aid when the Principal Investigator (PI) on an active study needs to be changed in myUABResearch.

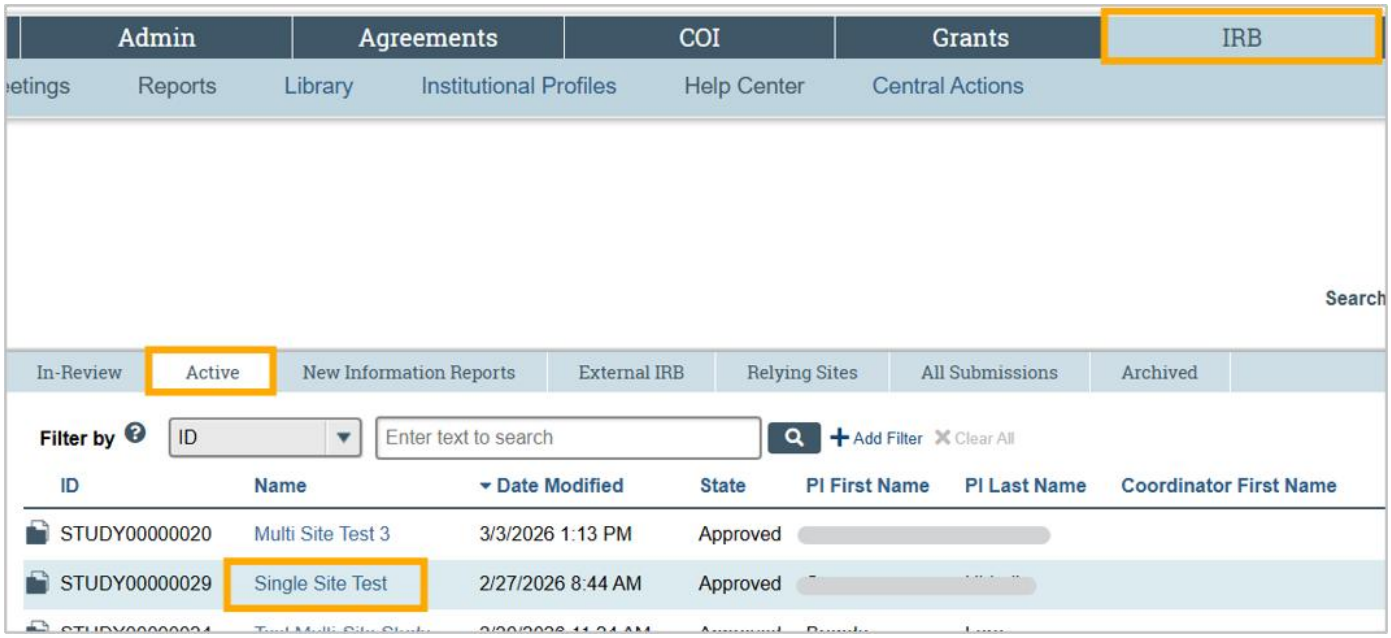
Important: A PI change is submitted as a Modification/Update. The modification scope you select determines which parts of the study application will be available for editing.

Before You Begin

- Determine whether the former PI will remain on the study in another study team role or will leave the study completely.
- Identify any study documents that list the PI, including the protocol and consent documents, because those documents must be updated as applicable.
- Prepare a memo documenting the PI change. The memo must include signatures from the former PI and the new PI and indicate that the former PI is relinquishing the PI role and the new PI is accepting the PI role.

Step 1: Open the active study

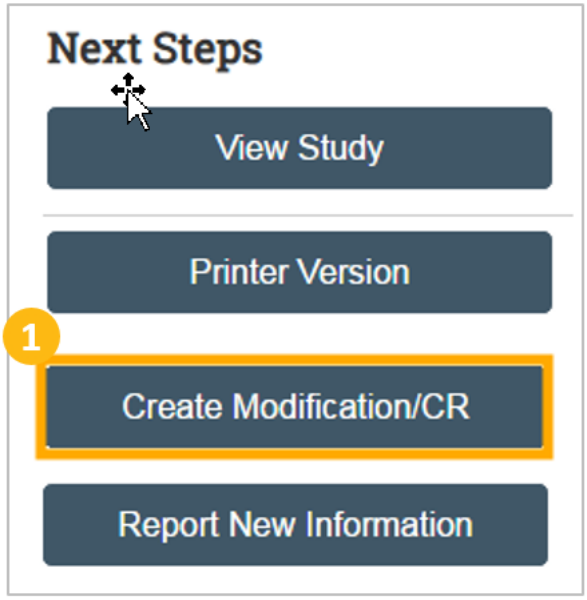
From the myUABResearch dashboard, select the IRB tab. Open the Active tab, then select the name of the study you need to modify.



Modification for a PI Change

Step 2: Create the modification

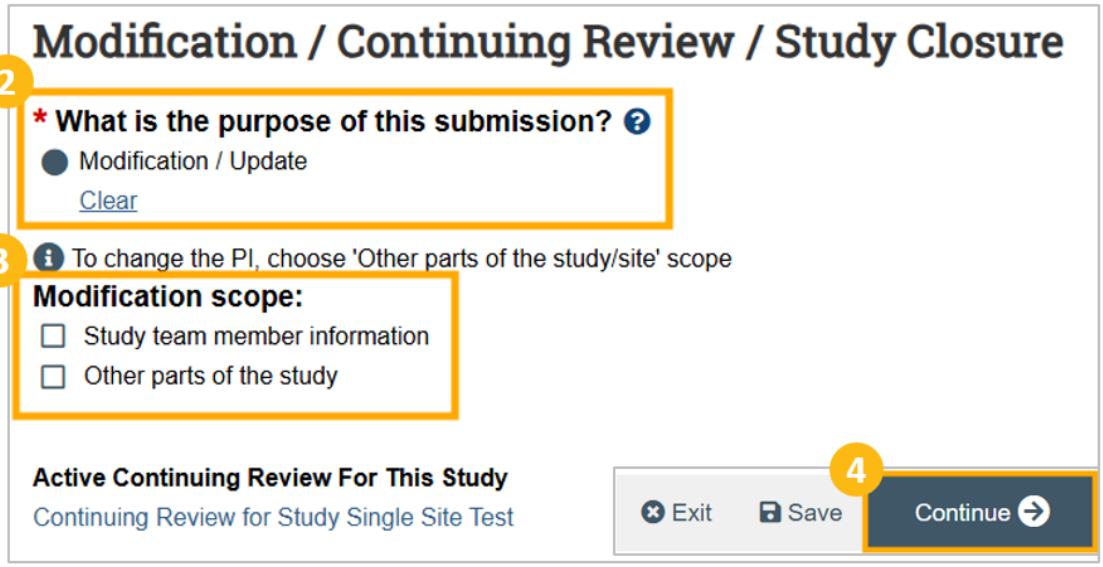
From the study workspace, click Create Modification/CR.



Step 3: Select the submission purpose and modification scope

For What is the purpose of this submission?, select Modification / Update. Under Modification scope, select the part(s) of the study you need to modify, then click Continue.

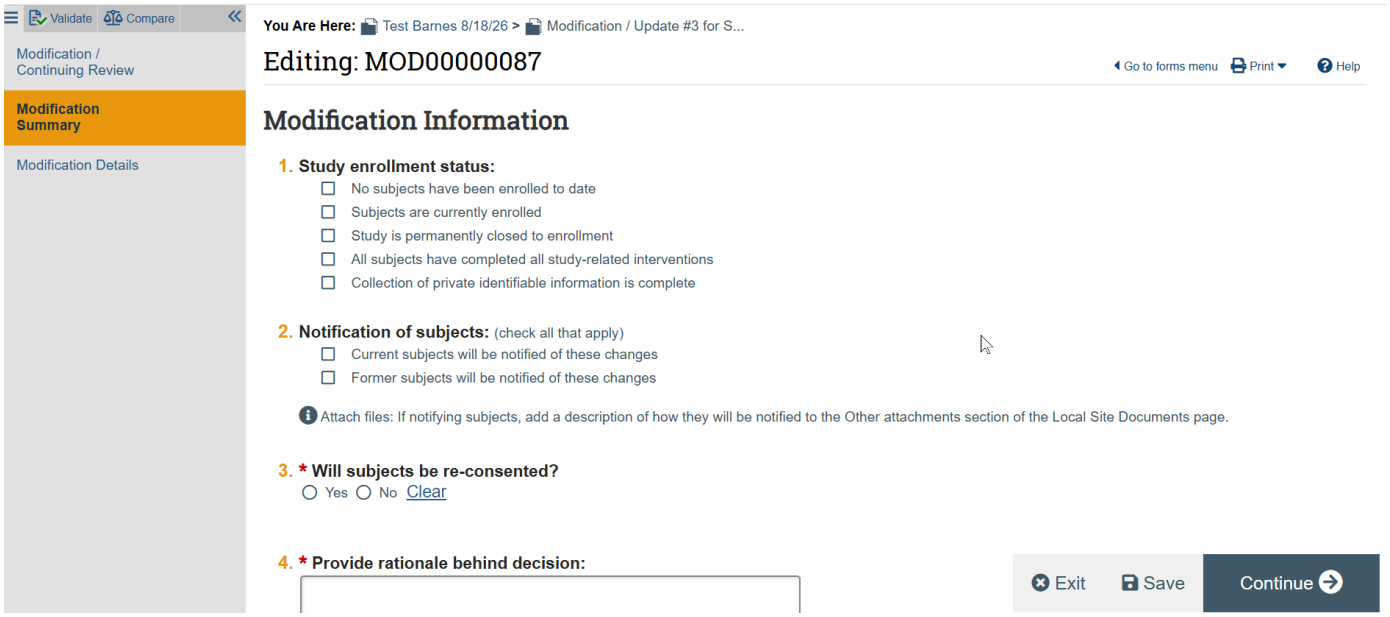
PI change scope: Select Other parts of the study to change the PI. ***If the former PI will remain on the study in another role, also select Study team member information.*** If the former PI is leaving the study completely, do not select Study team member information solely for the PI change.



Modification for a PI Change

Step 4: Complete Modification Information

Complete the Modification Information page as it applies to the study, including all required questions, and click Continue.

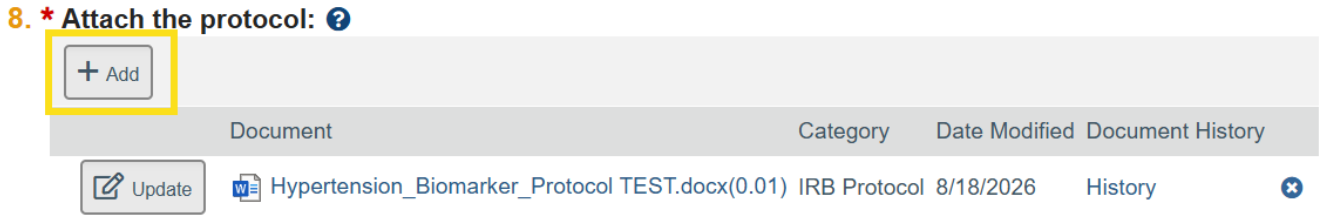


Step 5: Change the PI on Basic Study Information

Continue through the study application to Basic Study Information. Update Question 7 to identify the new PI.



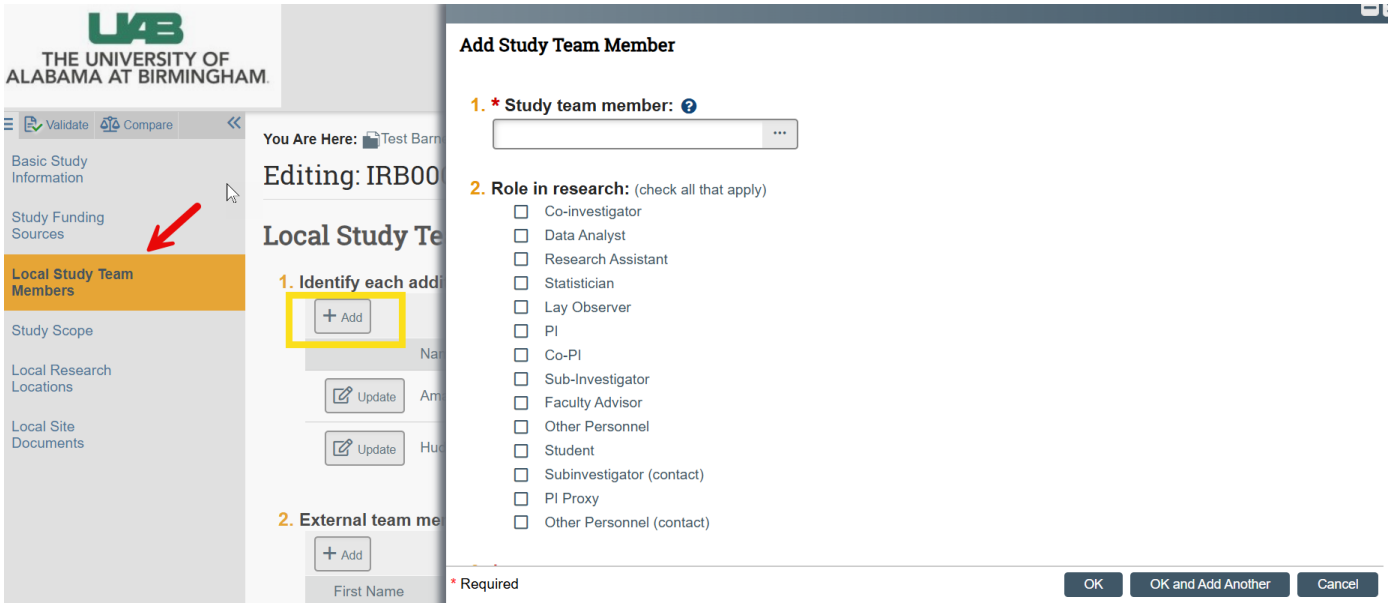
Also review the protocol and other study documents for references to the former PI. If the protocol lists the PI, update the protocol and upload the revised protocol at Question 8 on the Basic Study Information page.



Modification for a PI Change

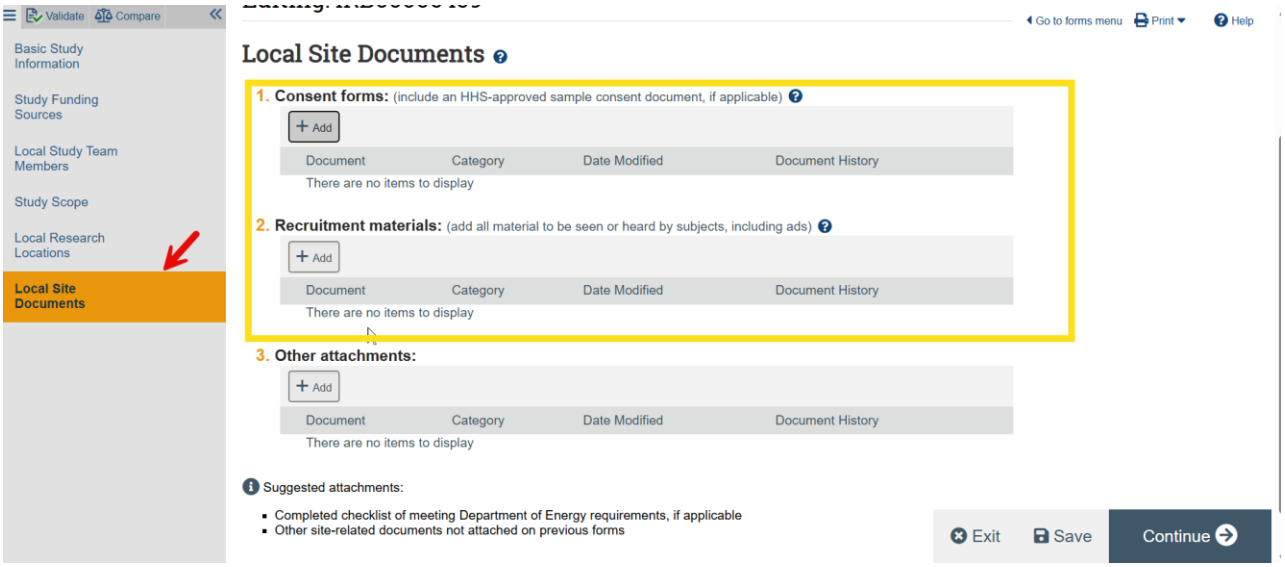
Step 6: Add the former PI to the study team, if applicable

Complete this step only if you selected Study team member information because the former PI will remain on the study in another role. If the former PI is leaving the study: Do not add the former PI as a study team member. Continue through the application.



Step 7: Update Local Site Documents

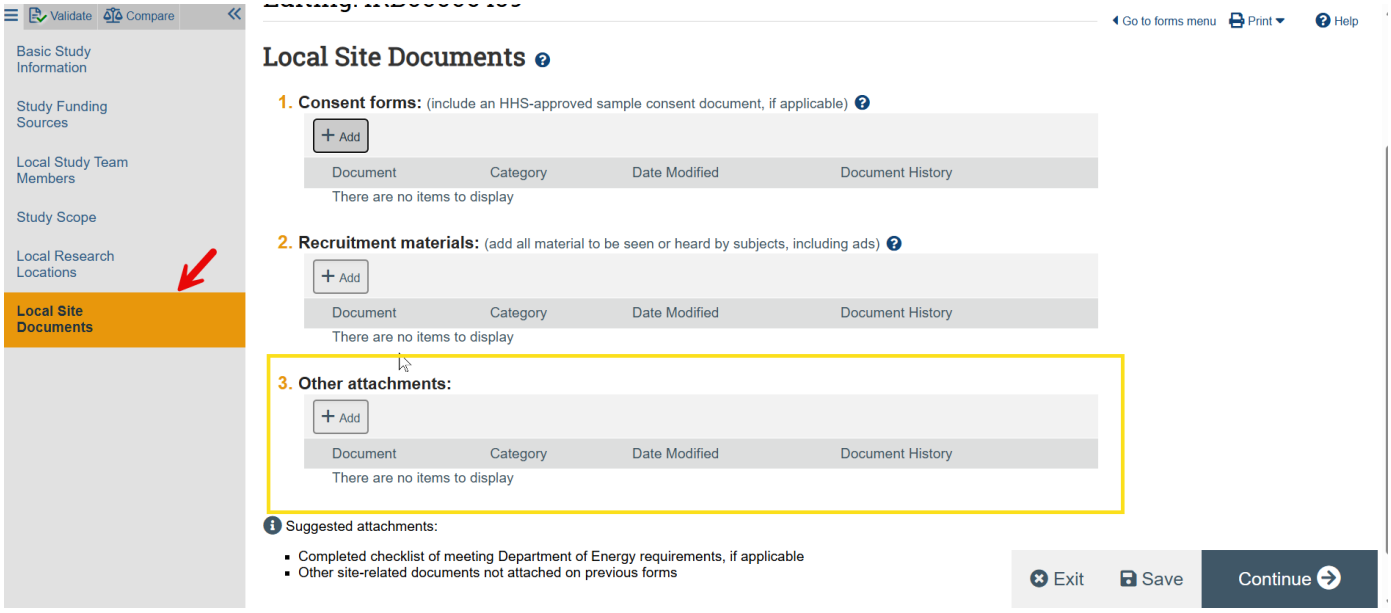
Continue to the Local Site Documents page. Update any documents that identify the PI. For example, if a consent form lists the PI, revise the consent form to identify the new PI and upload the updated version.



Modification for a PI Change

Step 8: Upload the PI change memo

On the Local Site Documents page, upload the signed PI change memo under Other attachments. The memo should document the change in PI and include the signatures of both the former PI and the new PI.



Document review: Before continuing, verify that all documents that identify the PI have been updated consistently.

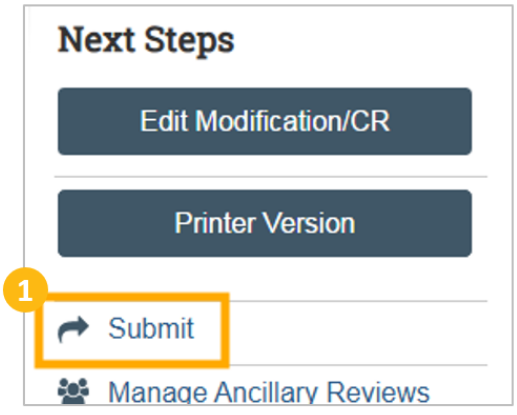
Step 9: Finish the modification

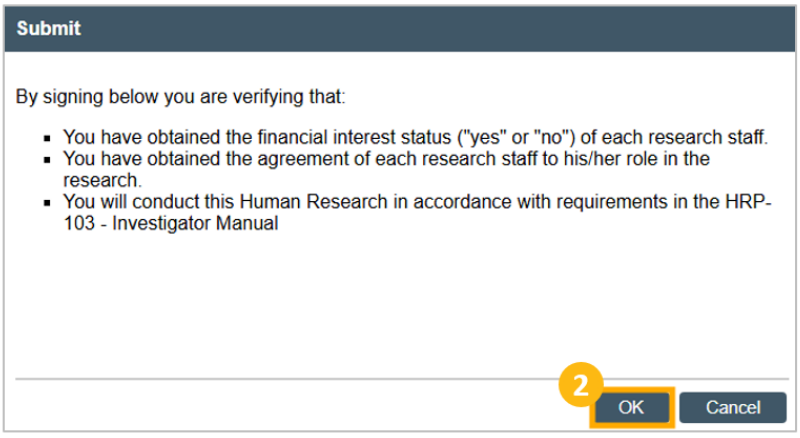
Continue through the remaining pages of the study application. When all changes are complete, click Finish. You will be returned to the modification workspace.



Step 10: Submit the modification to the IRB

From the modification workspace, click Submit under Next Steps. Review and verify the required statements to complete submission.





Modification for a PI Change

After submission, the modification moves to the Pre-Review state. The PI change has now been submitted to the IRB for review.

PI Change Scope Quick Reference

Situation	Modification Scope
Change the PI	Other parts of the study
Change the PI and keep the former PI on the study in another role	Other parts of the study + Study team member information
Change the PI and remove the former PI from the study	Other parts of the study