



May 13, 2025

How to Submit a Modification to Update a Study

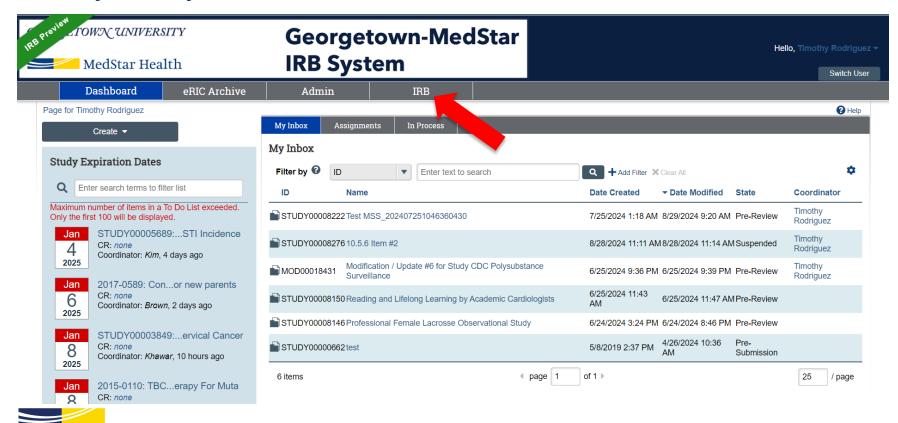
Who can submit modifications?

Only the PI and PI proxies

- Any approved team member may <u>create</u> edit modifications in presubmission state but **cannot submit**.
- Study team members, other than the PI, must be assigned as proxies to submit.

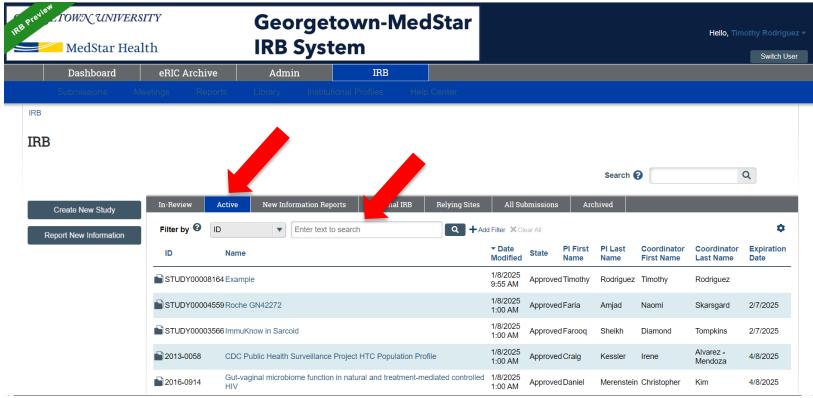


 When you log into the system, you will be brought to your inbox. Select the IRB tab to find your study.



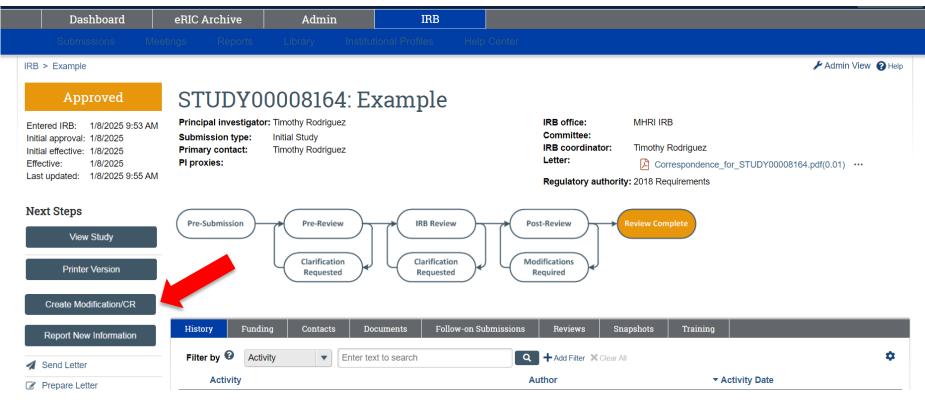
MedStar Health

 Select the Active tab to show your currently approved studies. Then use the search box to find the study you would like to modify.



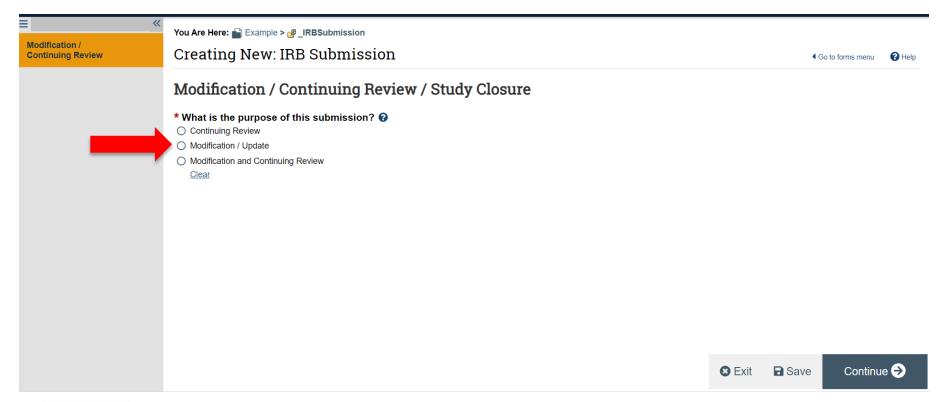


 This is a study home page. Select Create Modification/CR to begin the modification application.



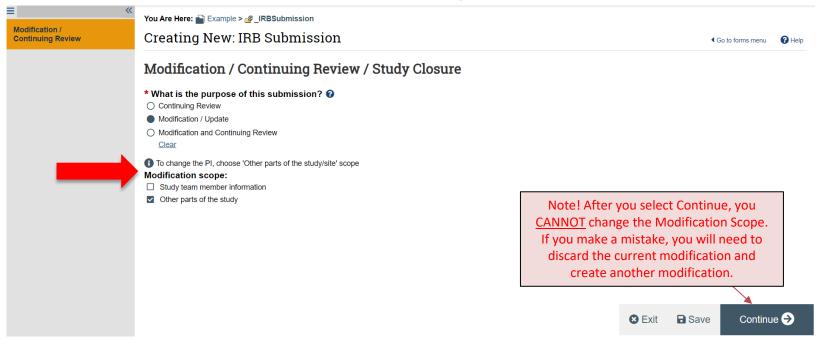


Select Modification/Update.



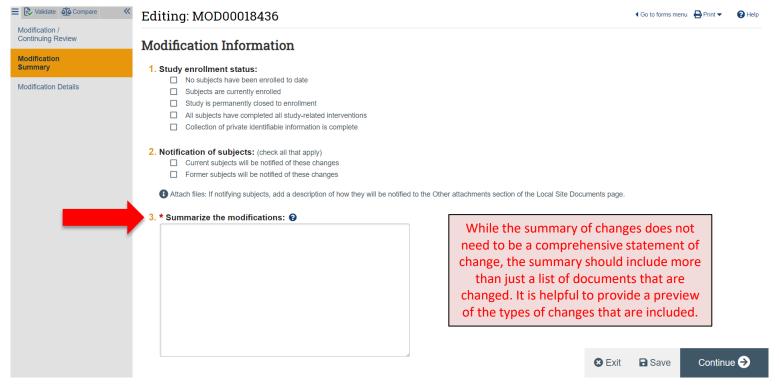


- Select Other Parts of the Study under Modification Scope.
- The Modification Scope determines what can be updated in this modification.
- If you would like to add additional team members, please also select Study Team
 Member Information under Modification Scope.



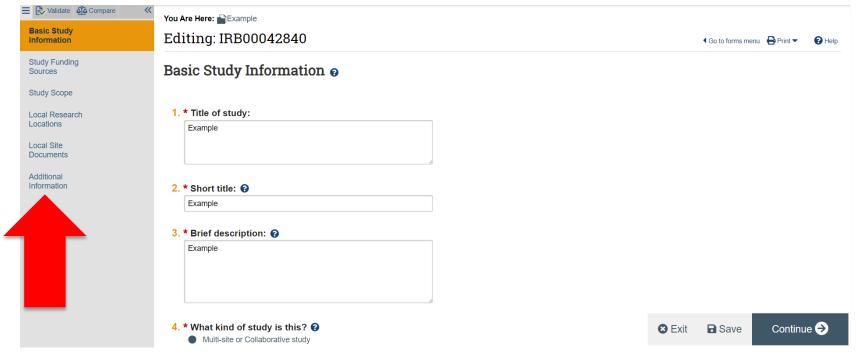


 Complete this page. For item #3, please include a summary list of all changes to the study.





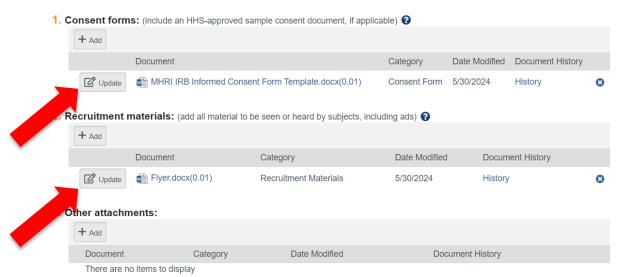
- Update sections of the application as needed. Use the left-hand column to navigate.
- If you have questions that are not addressed in this guide, you may refer to the New Submission Guide which includes additional detail. You may also contact ORI staff for additional guidance.





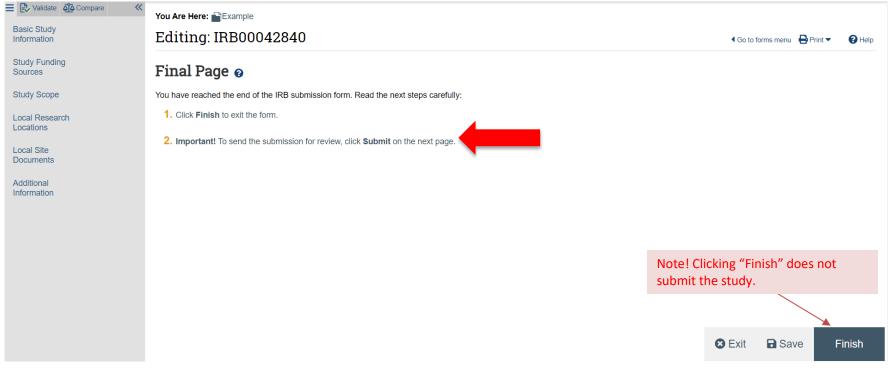
- When uploading a revised document:
 - Do not delete documents
 - Use the Update button
 - This will stack newer versions on top of an older and preserve the document history.
 - This also allow the IRB to easily recognize edits between the new and older version.

Local Site Documents o



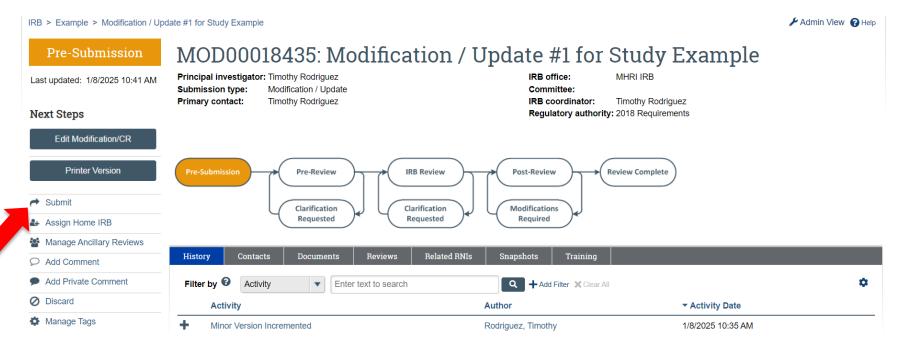


- On the final page of the modification, click Finish.
- This will send you to the study homepage.
- This <u>does not</u> submit the study.



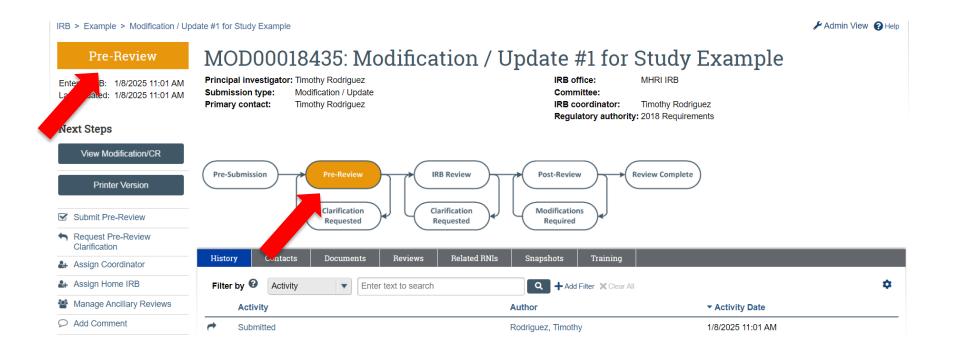


- After clicking Finish, you will be returned to the modification home page.
- Once on the home page, click Submit to submit your modification for review.
- Only the PI or the PI proxies can submit.
 - If you are not the PI or PI Proxy, you will not see the Submit option.





After clicking Submit, the status in the orange box should indicate "Pre-Review".





Congratulations! You have successfully submitted to the MHRI IRB.

It's how we treat people.

