How to update a study with an “active” status

If your study that was migrated and now has an “active” status or if you selected “multisite/collaborative” and an external IRB is reviewing your study:

To seek IRB approval for changes to the basic site information, study team members, additional local funding sources and/or local site document pages, click on “Create Site Modification”

After clicking this option, follow these steps:

1. If you are modifying only team members, select “study team and research location information” under “modification scope”. If you are also changing other parts of the submission, check on “other parts of the site”.

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2. Provide information about current enrollment status. In addition, summarize what you are modifying.

3. Under “modification details” you will be able to go to your current submission and make the changes you need under the Basic Site information, Additional Local Funding Sources or Local Site Documents. For other changes, you need to submit an “Update Study” submission (see next section). Note that the Basic Site Information was be also modified with the “Update Study” submission.
4. Your PI or PI proxi can submit the modification.
You may update documents using the “Update Study Details” option. This does not represent Emory IRB Approval and you should use this function only after the external IRB has approved these changes you are about to submit. Make sure you include external IRB approval letters to the changes submitted. To update your study after the external IRB has approved changes to your study, follow these steps:

1. Click on “Update Study Details”

2. Describe all the changes you are submitting:
3. Update the information accordingly. With this submission, you can make changes to the basic study information, external IRB, study funding sources, study scope (and drug/device pages if selected), and study-related document sections of the smart form.

4. After all the changes are made, click finish and you will be taken back to the current MODs window. Click “finalize submission”. You do not need any action from the IRB to finalize the submission.
5. The submission will now read “Updates Finalized”. That ends this process.