How to update a study with an “external IRB” status

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

If you are seeking Emory IRB approval of study documents (for example, if changes are made to the CIRB addendum), or if the change to the study may require a new ancillary review or changes to our local context information, you need to click on “Add Comment” and send an email to the IRB staff (IRB coordinator in the system) with the tracked document and a clean copy instead.

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. Please remember that if your study was migrated, you need to update the financial interest question for each of the study team members. In addition, if your submission has a drug section, please attach the IBs and FDA correspondence (if any) for each drug. Answer the questions on the last page of the submission.

**NOTE**: If your study was migrated, you are not required to upload the HIPAA attestation and waiver form.
4. After all the changes are made, click finish and you will be taken back to the current MODs window.

5. Only the PI or the PI proxy will be able to click on Finalize Updates. If you missed something, click on “edit study details” to keep updating.

6. If you do not see the option to “finalize updates”, log a comment to the study submission for our staff to do it for you.