

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:

Active

Entered IRB: 7/9/2019 5:00 AM Last updated: 2/20/2020 12:50 PM

To seek IRB approval for changes to the 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".



Image: Weight of the second	You Are Here: WIRB - > Modification / Update #1 for Editing: SITEMOD001-IRB00			
Modification Summary	Modification			
Modification Details	 What is the purpose of this submission? Modification / Update 			
	To change the PI, choose 'Other parts of the study/site' scope			
	Study team and research location information			
	✓ Other parts of the site			
	Active Modification For This Study			

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

Modification / Continuing Review	You Are Here: WIRB - → Modification / Update #1 for Editing: SITEMOD001-IRB0
Modification Summary	Modification Information
Modification Details	 Study enrollment status: No subjects have been enrolled to date Subjects are currently enrolled Study is permanently closed to enrollment All subjects have completed all study-related interventions Collection of private identifiable information is complete
	 2. Notification of subjects: (check all that apply) Current subjects will be notified of these changes Former subjects will be notified of these changes Attach files: If notifying subjects, add a description of how they will be notified to the
	3. * Summarize the modifications: 😧

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.



Basic Site Information	You Are Here: B WIRB Editing: IRB00
Additional Local Funding Sources Local Site Documents	Euriffig. INDOO Basic Local Site Information 1. * Local principal investigator: ?

4. Your PI or PI proxi can submit the modification.

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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" Active Entered IRB: 7/9/2019 5:00 AM Last updated: 2/20/2020 12:50 PM Next Steps IRB00 Principal invest Lead principal Submission type Primary contact PI proxies: PI p

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	Entered IRB: 7/9/2019 5:00 AM Last updated: 2/20/2020 12:50 PM	Principal investigator: Lead principal investigator: Submission type:	IRB Site
	Next Steps	Primary contact: Pl proxies: Pl proxies (Lead site):	
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	Report New Information	History Funding	Conta
	Assign Primary Contact	Filter by 2 Activity	

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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.

