

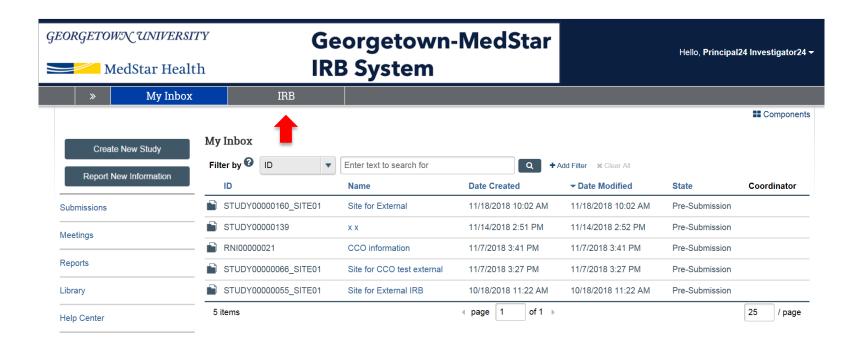
Georgetown-MedStar IRB System

How to Close a Study in the Georgetown-MedStar IRB System



Georgetown-MedStar IRB System

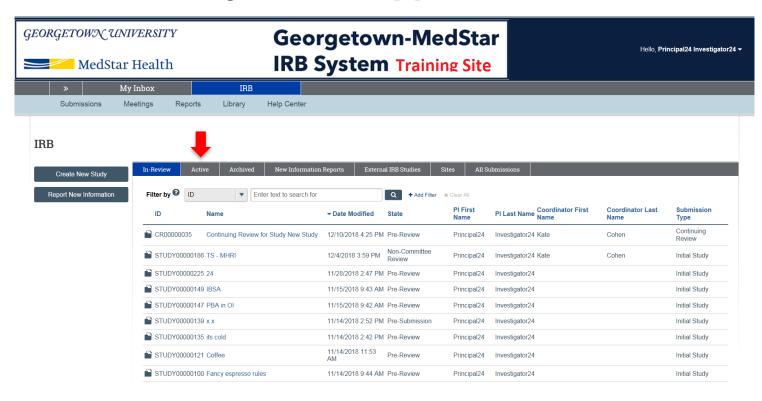
When you log into the system, you will be brought to your inbox. Select the IRB tab on the top of the screen.





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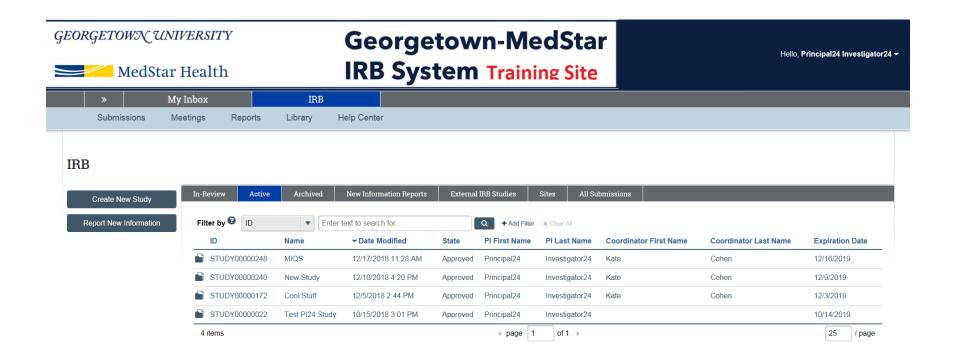
Once in the IRB tab, click on the Active studies tab to see the list of your IRB approved studies





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Once on the Active studies tab, click on the name of the study you would like to close.





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You will arrive on the study workspace page. Click on the Create Modification/CR option on the left.





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To close your study, select Continuing Review as the purpose of the submission.

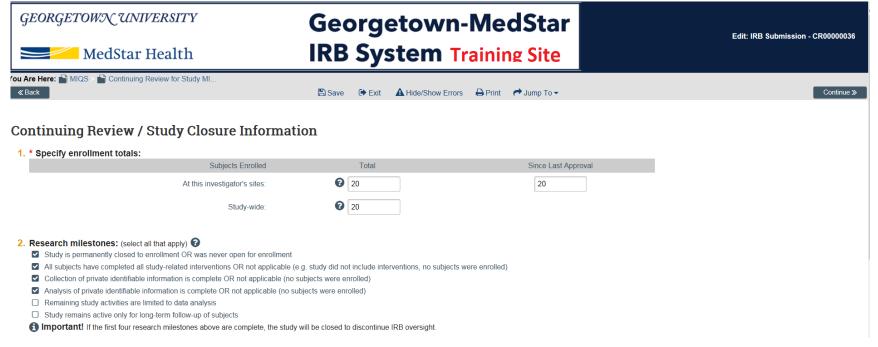




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In the CR/Study Closure Information page, enter the requested information.

Note: The first four research milestones must be selected to close the study. If the first four research milestones cannot be selected, your study is not ready to be closed.





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You will be prompted to acknowledge the study will be closed once you select the first four research milestones.

Complete the rest of the page with the requested information.

2.	Research milestones: (select all that apply)
	Study is permanently closed to enrollment OR was never open for enrollment
	All subjects have completed all study-related interventions OR not applicable (e.g. study did not include interventions, no subjects were enrolled)
	Collection of private identifiable information is complete OR not applicable (no subjects were enrolled)
	Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled)
	Remaining study activities are limited to data analysis
	☐ Study remains active only for long-term follow-up of subjects
	1 Important! If the first four research milestones above are complete, the study will be closed to discontinue IRB oversight.
	* Lacknowledge that this study will be closed: \$\Bar{\chi}\$
	* I acknowledge that this study will be closed:
	*B
5.	* Do any investigators or research staff have a financial interest related to the research that was not described in a previous application?
	O Yes No Clear
4	Charlette items that are two since the last IDD annuaval for all sites involved in the study ("Tallette in the study ("Tallett
4.	Check the items that are true since the last IRB approval for all sites involved in the study: (initial review or last continuing review)
	No subjects experienced unexpected harm
	Anticipated adverse events have NOT taken place with greater frequency or severity than expected
	NO subjects withdrew from the study
	NO unanticipated problems involving risks to subjects or others
	□ NO complaints about the study
	□ NO publications in the literature relevant to risks or potential benefits
	□ NO interim findings
	□ NO multi-center trial reports
	□ NO data safety monitoring reports
	□ NO regulatory actions that could affect safety and risk assessments



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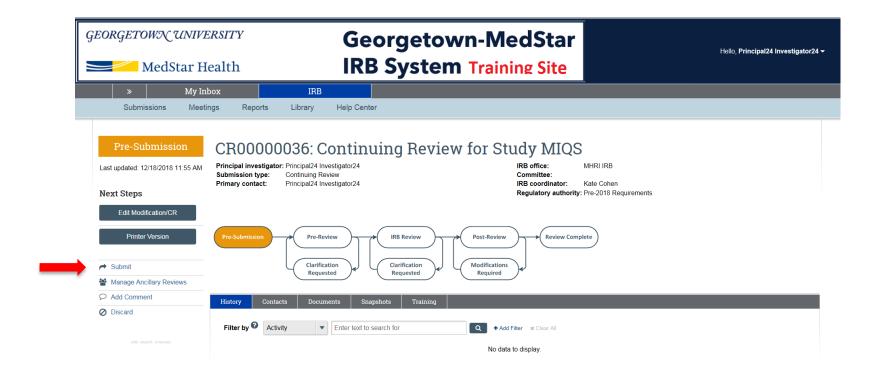
Once you have completed the required continuation page, you should reach the Final Page. Click Finish.





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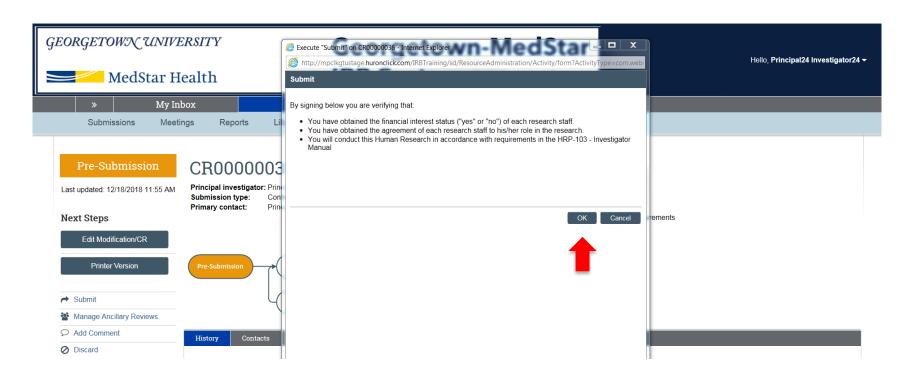
You will then arrive on the study workspace page, where you will see your continuation submission. Click submit on the left side of the page.





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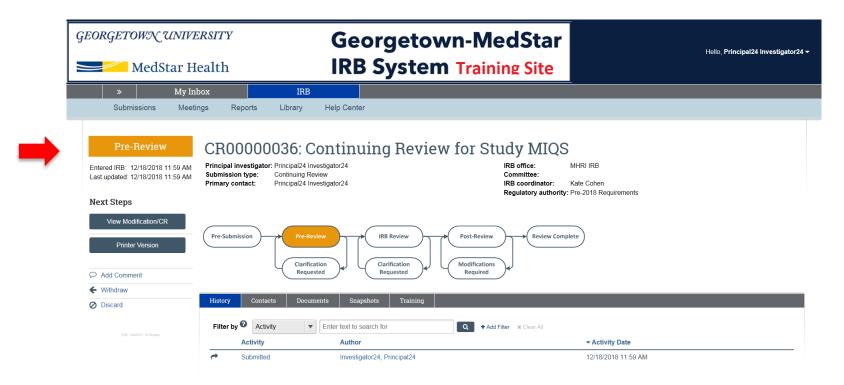
You will be prompted to confirm the verifications listed. Click OK.





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You will see your submission is now in the pre-review status. The IRB will review your final continuing review and closure request.





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Once the IRB has closed your study, you will receive the closure communication. You will then be able to find your closed study record in the IRB tab, under the Archived tab.





Georgetown-MedStar IRB System

Congratulations!

You have successfully submitted a study for closure in the new Georgetown-MedStar IRB System!

If you have any questions about the steps described, please contact the Office of Research Integrity at MHRI-ORIHelpDesk@medstar.net.