Closeout & Study Completion Checklist

Protocol Number: _____ **Site Name:** _____

Investigational Agent:		**Date**	**Comments**
❒	Collect all accountability log and review to ensure all discrepancies have been resolved		
❒	Confirm with Pharmacy that everything has been returned to sponsor or destroyed onsite		
Data Entry:			
❒	For DF/HCC managed protocols in InForm: • Notify ODQ and ask for confirmation that all data entry is complete.		
❒	Confirm all subjects are off treatment and off study in OnCore.		
Monitoring:			
❒	Schedule site closeout visit		
❒	Resolve all outstanding issues from closeout visit and receive final monitoring letter		
Supplies:			
❒	Return special equipment, if applicable		
❒	Return or release unused study supplies (i.e., tubes, packaging, shipping materials)		
Samples:			
❒	Inventory all research samples		
❒	Assure all samples have been shipped, if applicable		
Regulatory:			
❒	Delegation of authority logs updated and complete. (Do not add stop dates until all research activities have ceased.)		
❒	Obtain final documentation from the sponsor that all outstanding regulatory documents have been provided for all DF/HCC sites.		
❒	Organize study files (research subject files and regulatory files)		
❒	Verify all required regulatory documents have been collected, are up to date, and organized for storage		
Other:			
❒	Clinicaltrials.gov record is complete and results have been reported, if applicable		
❒	Assure final payment is received from sponsor		
❒	For trials that register subjects in OnCore, obtain ODQ sign off to complete the study		

The DF/HCC lead site must ensure all participating DF/HCC sites (and all external sites for investigator-sponsored, multi-center trials) have completed the above closeout activities before submitting a request to complete the study to the IRB.

After IRB Approves Study Completion:		**Date**	**Comments**
❒	Provide copy of IRB study completion approval to the sponsor.		
❒	Ensure delegation of authority log has stop dates entered.		
❒	Generate an inventory of files to be sent off site. The inventory and box identifies must be kept on site.		
❒	Review RCL-101 and ship regulatory files to offsite storage.		