



## Research Site Closeout Report

<b>Study Title:</b>	
<b>Principal Investigator:</b>	
<b>Research Site:</b>	
<b>Qualified Investigator:</b>	
<b>Date Site Closeout Performed:</b>	
<b>Site Closeout Visit Performed By:</b>	

### Key Research Site Personnel Involved with the Study

Name	Title	Available During Discussions (Y/N)
	Qualified Investigator	
	Research Coordinator	
	Pharmacist	
	Etc...	

Activity	Y	N	N/A	Comments
<b>Case Report Forms (electronic or paper based)</b>				
Ensure there is a completed CRF for each participant enrolled in the study.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Verify that all CRF data has been entered into the electronic system by the research site OR forms submitted to the Methods Centre.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Verify that all CRF queries/corrections are resolved.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Verify all source documentation is filed as appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Site Study Files and Regulatory Documentation</b>				
Verify that a signed and dated ICF is on file for each study participant.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Confirm the REB has been informed of study closure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
All study files and regulatory documentation are up to date and on file.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Complete the Research Site Study Document Checklist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Attached
Verify the qualified investigator has plans to complete the site closeout report and forward to the methods centre.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Investigational Product Accountability and Return/Destruction</b>				
Ensure that all required investigational product accountability is complete and documentation is filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	



Verify that unused investigational product is returned/destroyed as per methods centre instructions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Verify investigational product return/destruction documentation is filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If blinded investigational product was used, confirm that blinding code was not broken. If it was broken, ensure the presence of documentation regarding rationale for breaking the code.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Laboratory Specimens</b>				
Ensure all participant samples have been shipped according to study procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Determine disposition of samples, including plans for future shipments, on-site storage and destruction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Administrative Items</b>				
Ensure all site payments are disbursed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Ensure all study materials are returned/destroyed as per methods center instructions (i.e. CRFs, lab kits, etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Ensure access to electronic data capture systems (eCRFs) has been removed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Record Retention</b>				
Provide instructions and confirm the research site has a plan for record retention.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Ensure record retention storage documentation is filed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Summary**

Post study-critique including:

- Site recruitment activities (numbers, time frame from enrolment to completion)
- SAEs
- Protocol violations, deviations
- Issues, resolution and lessons learned

Was the overall experience with the site favourable?

Should this site be considered for future studies?

Written by:

\_\_\_\_\_ Name

\_\_\_\_\_ Date