



Research Site Closeout Document Checklist

Study Title:	
Principal Investigator:	
Research Site:	
Qualified Investigator:	

Document	Located in:			Comments
	MC	Site	N/A	
Study Protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Protocol Amendment(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Investigator's Brochure / Product Monograph	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Health Canada – Letter(s) of no objection	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Clinical Trials Site Information Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Qualified Investigator Undertaking Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
REB Attestation Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
REB Approval(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
REB Membership List	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
REB Annual Approval(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
REB Approved ICF(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Financial Disclosure Form	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Inter-Institutional Agreement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
CVs for Qualified Investigators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Medical Licenses for Qualified Investigators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Signature and Delegation List	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Site Laboratory Reference Ranges	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Site Laboratory Accreditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Central Laboratory Reference Ranges	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Central Laboratory Accreditation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Training Log	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participant Screening/Enrolment Logs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participant Identification Code List	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Investigational Product Shipping Records				
Investigational Product Accountability Logs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Investigational Product Return/Destruction Records	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Return of Treatment Allocation and Decoding Documentation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Final Report by Research Site to REB	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participant CRFs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Participant Originally Signed & Dated ICFs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
SAE Reports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

The presence of all regulatory and study documentation has been confirmed by:

Name

Date