



Study Closeout Checklist

Study Title	
Principal Investigator	
Reason for Study Closeout	<input type="checkbox"/> Recruitment Complete <input type="checkbox"/> Premature Termination, please specify:

Task/Item	Target Completion Date	Complete
Project Leader formulates project closeout plan, including milestones for closeout activities		<input type="checkbox"/>
Notify research sites the study is entering the closeout phase, including activities and timelines		<input type="checkbox"/>
Research site closeout		<input type="checkbox"/>
Final investigational product accountability and return/destruction		<input type="checkbox"/>
Storage or destruction of laboratory specimens		<input type="checkbox"/>
Data query resolution		<input type="checkbox"/>
Database lock		<input type="checkbox"/>
Data analysis		<input type="checkbox"/>
Final study report / manuscript preparation		<input type="checkbox"/>
Preparation of records for archiving		<input type="checkbox"/>
Notify Health Canada of study completion		<input type="checkbox"/>
Notify other governing regulators of study completion, if applicable		<input type="checkbox"/>
Other:		<input type="checkbox"/>
Other:		<input type="checkbox"/>
Other:		<input type="checkbox"/>
If Study Terminated or Suspended Prematurely (in addition to the above):		
Notify Health Canada within 15 days of official discontinuance of the study		<input type="checkbox"/>
Notify other governing regulators of official discontinuance of the study, if applicable		<input type="checkbox"/>
Notify research sites of official discontinuance of the study		<input type="checkbox"/>
Provide instruction for research sites regarding informing study participants of treatment and follow-up plan		<input type="checkbox"/>
Other:		<input type="checkbox"/>
Other:		<input type="checkbox"/>

All study closeout activities have been completed as indicated above.

Project Leader

Date