Notification of Clinical Study Closure V2.0

Project Info

File No:
PI:
Project Title:
Submitted:
Submitted by:

Event Info

Event No:
Notes:

Common Questions

1. Notification of Clinical Study Closure

#	Question	Answer
1.1	Date of completion	
1.2	Has all participant data collection been completed?	
1.3	Total number of participants that were enrolled at the sites/institutions covered by this ethics approval:	
1.4	Enter the number of charts reviewed or samples collected:	
1.5	Final Date/Notice	
1.6	Enter the date of the study monitor's final visit or notice, if applicable.	
1.7	If not applicable please select not applicable below	
1.8	Data Biospecimen Storage/Destruction Describe plans for the final disposition of the data/biospecimens. Include, as applicable, how long the study data/biospecimens will be retained and where, and what plans there are for future use fo the data/biospecimens (if any) including who will have access to the data/biospecimens in the future and for what prupose. Please note that under Island Health policy, the PI must ensure that all study data is retained for at least three (3) years within an Island Health facility. For Clinical Trials, in accordance with Health Canada the retention period is at least 25 years. The applicable retention period must be confirmed in the response here.	
1.9	Reason for Completion -- Please provide the reason for the completion of the study (e.g. did the study run its course, of it if ended early, explain why; if the study involved enrollent of participants, comment about enrollment and whether enrollment goals were achieved.) Include any other	

	information required by the study sponsor to be submitted to the Research Ethics Board.	
1.10	If other, please describe:	
1.11	Reported Results and Sponsor Close-out Please note, once the Completion of Study form is reviewed, the REB will issue an Acknowledgement and the study will be automatically listed as 'Closed'. It will then show under your "Inactive" tab. The ONLY activity available from this point on is Request for Acknowledgement if needed. The study cannot be amended or reactivated. Are there any plans to provide a report of the results back to participants?	
1.12	Please describe how the results will be reported back to participants, or justify why you will not be reporting back.	
1.13	If other, please describe	
1.14	What have you undertaken and/or planned for disseminating results? (Please select all that apply)	
1.15	If other, please describe	
1.16	Please indicate if dissemination plans have been or will be targeted at specific knowledge users. Indicate all that apply:	
1.17	If other, please describe:	
1.18	NOTE, the REB requires at a minimum, an end-of-study report for all studies at study completion. The below survey meets this requirement when completed and attached.	