Research Ethics Amendment Application

Project Info

File No:
PI:
Project Title:
Submitted: N/A
Submitted by: N/A

Event Info

Event No:
Notes:

Common Questions

1. Proposed Study Amendment

#	Question	Answer
1.1	Please include the study title here:	
1.2	Has there been any change to the Principal Investigator or Principal Investigator contact information since the last submission to the Research Ethics Board?	
1.3	If there is a new PI, or PI contact information has changed, please provide name and all contact information below:	
1.4	If this is a clinical trial with a new Principal Investigator, has evidence of GCP training within the past 2 years been attached to this submission?	
1.5	Has there been any change to the primary contact information or to members of the research team since the last submission to the Research Ethics Board?	
1.6	If study team members have been removed or added, or there is new contact information, please descibe below:	
1.7	If this is a clinical trial with a new Co-Investigator(s), has evidence of GCP training within the past 2 years been attached to this submission?	
1.8	Please provide a summary of the proposed amendment, including rationale:	
1.9	Is this study still in the recruitment phase?	
1.10	Does the proposed amendment change the study design (e.g. collect additional data, change the study objectives, research design, sample size, inclusion/exclusion criteria, treatment/intervention procedures/dosage)?	
1.11	Does the proposed amendment increase the risk to participants?	
1.12	Does the proposed amendment change the study sponsor or funder?	
1.13	Does the proposed amendment change the study end date?	

1.14	Does the proposed amendment change any of the study or consent documentation? If Yes, ensure you attach a both a 'tracked changes' and a 'clean' copy of any documents you are changing.	
1.15	Please describe any other changes proposed by this amendment:	
1.16	For study participants already enrolled, the Principal Investigator recommends:	
1.17	If Other, please describe:	
1.18	Is a Health Canada No Objection Letter (NOL) required for this amendment?	
1.19	Operational Changes: Please indicated if there are any changes or additions to Island Health supports required to conduct this research (choose all that apply):	
1.20	Operational Changes: Please summarize your amended requirements for Island Health services/supports here:	
1.21	Other: please describe	
1.22	Please confirm your study team and all contact information to update all study team profiles in the Research Services Portal:	