

Protocol Deviation Report Form

Project Info

File No:

PI:

Project Title:

Submitted:

Submitted by:

Event Info

Event No: Notes:

Common Questions

1. Protocol Deviation

#	Question	Answer
1.1	Date the deviation occurred:	
1.2	Date sponsor notified:	
1.3	Report Type	
1.4	If this is a follow up report, please provide report number, and date of initial report.	
1.5	Did the deviation occur in order to eliminate an apparent hazard?	
1.6	Affected participant ID(s)	
1.7	Is (are) the participant(s) still enrolled in the study?	
1.8	Reason for Submission: (If the Protocol Deviation does not meet at least one of the criteria listed below, do not submit the report to the Island Health Research Ethics Board.)	

2. Type of Deviation

#	Question	Answer
2.1	What is the type of deviation?	
2.2	If Other, please describe:	
2.3	Description of major protocol deviation:	
2.4	Explain the reason for the major protocol deviation:	
2.5	Has this type of deviation occurred before or could it occur again?	

3. Recommendations of Principal Investigator

#	Question	Answer
3.1	Based on this deviation, do you recommend a change to the protocol?	
3.2	Do you recommend a change to the site's consent form?	
3.3	Do you recommend a change to the study-wide consent form?	
3.4	If a change to the consent form is recommended, do you plan to re-consent current participants?	