

PHKL REC ANNUAL PROGRESS REPORT

A. Details of Principal Investigator	
Name	
Address	
Telephone	
Email	
Fax	
B. Details of Study	
PHKL REC reference no.	
Full study title	
Protocol number (if applicable)	
Date of PHKL REC initial approval	
Date of Last PHKL REC renewal	
Sponsor (if applicable)	
C. Commencement and Termination Dates	
Has the study started?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, what was the actual start date?	
If no, what is the expected start date?	
What are the reasons for the study not commencing?	
Has the study been completed?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If no, what is the expected completion date?	
D. Recruitment of Participants	
Proposed number of participants in the original application	
Actual number of participants recruited to date	
Number of participants withdrawn from study to date due to: (a) Withdrawal of consent (b) Loss to follow-up (c) Death	
Number of participants discontinued from study due to: (a) Adverse events (b) Lack of efficacy/ Disease progression	
E. Safety Report	
Have there been any Serious Adverse Events (SAE) reported to PHKL REC since the last REC initial approval/ renewal?	<input type="checkbox"/> Yes (Summarise in the table below) <input type="checkbox"/> No <input type="checkbox"/> N/A

Subject Study ID	Brief Description of SAE	Date Reported to PHKL REC

Have there been any Serious Unexpected Suspected Adverse Reactions (SUSARs) reported to PHKL REC since the last REC initial approval/ renewal?

Yes (Summarise in the table below)
 No
 N/A

Subject Study ID	Study Site Name	Brief Description of SUSAR	Date Reported to PHKL REC

F. Protocol Deviation/ Violation

Have there been any Protocol Deviations (PD) and/ or Protocol Violations (PV) reported to PHKL REC since the last REC initial approval/ renewal?

Yes (Summarise in the table below)
 No
 N/A

Subject Study ID	Brief Description of Protocol Deviation/ Protocol Violation	Date Reported to PHKL REC

G. Amendments

Have there been any changes in the study document since the last PHKL REC initial approval/ renewal?

Yes (Summarise in the table below)
 No
 N/A

Study Document with Version Number/ Date	Summary of Changes	Date Approved by PHKL REC

Have any co-investigators been added or removed since the last PHKL REC initial approval/ renewal?

Yes (Summarise in the table below)
 No

Investigator's Name	Role	Added/ Removed	Date Approved by PHKL REC

Have there been any other amendments since the last PHKL REC initial approval/ renewal? Yes (Summarise in the table below) No

Summary of Amendment	Date Approved by PHKL REC

F. Declaration

I declare that the information in this report is accurate to the best of my knowledge and belief, and I take full responsibility for it.

Principal Investigator:

Name:
Date:

G. For Office Use Only

Date of Received	
Received By	
Signature	
Annual Report ID:.	

H. Review by PHKL REC Chairman

Additional actions or information required?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, please specify	<p>_____</p> <p>_____</p>
Decision	<input type="checkbox"/> Approved. No action required <input type="checkbox"/> Decision deferred until further information is received <input type="checkbox"/> Table for full board meeting

Reviewed by:

Name:
Date: