

**PHKL REC PROTOCOL DEVIATION REPORTING FORM**

Section A. Details of Principal Investigator		
Name		
Address		
Telephone		
Email		
Section B. Details of Study		
PHKL REC Reference No.		
Full Study Title		
Protocol Number (if applicable)		<input type="checkbox"/> N/A
NMRR ID (if applicable)		<input type="checkbox"/> N/A
Sponsor (if applicable)		<input type="checkbox"/> N/A
Date of PHKL REC Initial Approval		
Section C. Subject's Information		
Subject ID (if applicable)		<input type="checkbox"/> N/A
Subject Recruitment Date (if applicable) (dd-mm-yyyy)		<input type="checkbox"/> N/A
Section D. Description of Protocol Deviation		
Type of Report	<input type="checkbox"/> Initial <input type="checkbox"/> Follow-Up <input type="checkbox"/> Final	
Type of Protocol Deviation	<input type="checkbox"/> Minor Protocol Deviation <i>(non-systematic protocol noncompliance with minor consequences, in terms of its effect on the participant's/subject's rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature)</i>  <input type="checkbox"/> Major Protocol Deviation or Protocol Violation <i>(persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk)</i>	
Description of Protocol Deviation	<input type="checkbox"/> Performance of a study procedure without PHKL REC approval <input type="checkbox"/> Continuation of study activities during lapse of PHKL REC approval <input type="checkbox"/> Enrolment of research subject who did not meet the protocol inclusion/ exclusion criteria <input type="checkbox"/> Deviation in the consent process (e.g., failure to obtain informed consent prior to initiation of study procedures, use of an invalid consent form, missing date of consent, missing signature) <input type="checkbox"/> Study procedure were not performed as described in the currently approved protocol <input type="checkbox"/> Study drug/ intervention errors (e.g., incorrect study drug/ intervention, incorrect dosage of the study drug given) <input type="checkbox"/> Administrative non-compliance <input type="checkbox"/> Others _____	

Date of Protocol Deviation (dd-mmm-yyyy)	
Date of Awareness (dd-mmm-yyyy)	
Protocol Deviation Narratives:	
Has this type of protocol deviation (or similar deviations) previously occurred in this study or this study site?	<input type="checkbox"/> No <input type="checkbox"/> Yes, if yes has it been reported to PHKL REC? <input type="checkbox"/> Yes <input type="checkbox"/> No
How was the protocol deviation made aware?	
Does this protocol deviation affect the safety of the subject?	<input type="checkbox"/> No <input type="checkbox"/> Yes, please explain:
Does this protocol deviation affect the scientific integrity of the study data?	<input type="checkbox"/> No <input type="checkbox"/> Yes, please explain:
Was this protocol deviation unanticipated?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Does modification require to the data safety monitoring plan?	<input type="checkbox"/> No <input type="checkbox"/> Yes, please explain:
Corrective action done for this event? (if any training is done, please submit supporting document)	<input type="checkbox"/> Not applicable <input type="checkbox"/> No <input type="checkbox"/> Yes, please explain:
Preventive action for this event?	<input type="checkbox"/> Not applicable <input type="checkbox"/> No <input type="checkbox"/> Yes, please explain:
Has the event been resolved?	<input type="checkbox"/> No <input type="checkbox"/> Yes, please explain:
If this report was submitted more than 30 days after awareness of the event, please explain why and how late submission will be avoided in the future	<input type="checkbox"/> No <input type="checkbox"/> Yes, please explain:
<b>Section E. Declaration</b>	
I declare that the information in this form is accurate to the best of my knowledge and belief, and I take full responsibility for it.	
Principal Investigator:	
<hr/> Name: Date:	

Section F. For Office Use Only	
Date of Received	
Received By	
Signature	
PD ID	
Remarks	
Section G. Review by PHKL REC Chairman/ Deputy Chairman	
Additional actions or information required?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, please specify	<hr/> <hr/>
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:  <hr/> Name: Date:	