PANTAI HOSPITAL Kuala Lumpur | A member of IHH Healthcare

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)		☐ N/A
NMRR ID (if applicable)		☐ N/A
Sponsor (if applicable)		☐ N/A
Date of PHKL REC Initial Approval		
Section C - Subject's Information		
Subject ID (if applicable)		☐ N/A
Subject Recruitment Date (if applicable) (dd-mm-yyyy)		☐ N/A
Section D - Description of Protocol Deviation		
Type of Report	☐ Initial ☐ Follow-Up ☐ Final	
Type of Protocol Deviation	☐ Minor Protocol Deviation (*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*) ☐ Major Protocol Deviation or Protocol Violation *(persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients' safety at risk)*	
Description of Protocol Deviation	☐ Performance of a study procedure without PHKL REC approval ☐ Continuation of study activities during lapse of PHKL REC approval ☐ Enrolment of research subject who did not meet the protocol inclusion/ exclusion criteria ☐ 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) ☐ Study procedure was not performed as described in the currently approved protocol ☐ Study drug/ intervention errors (e.g., incorrect study drug/ intervention, incorrect dosage of the study drug given) ☐ Administrative non-compliance ☐ 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?	☐ No ☐ Yes, if yes has it been reported to PHKL REC? ☐ Yes ☐ No
How was the protocol deviation made aware?	
Does this protocol deviation affect the safety of the subject?	☐ No ☐ Yes, please explain: _____
Does this protocol deviation affect the scientific integrity of the study data?	☐ No ☐ Yes, please explain: _____
Was this protocol deviation unanticipated?	☐ No ☐ Yes
Does modification require to the data safety monitoring plan?	☐ No ☐ Yes, please explain: _____
Corrective action done for this event? (if any training is done, please submit supporting document)	☐ Not applicable ☐ No ☐ Yes, please explain: _____
Preventive action for this event?	☐ Not applicable ☐ No ☐ Yes, please explain: _____
Has the event been resolved?	☐ No ☐ 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	☐ No ☐ Yes, please explain: _____

Section E - Declaration

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:

_____

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?	☐ Yes ☐ No

If Yes, please specify	_____ _____
Decision	☐ Approved. No action required ☐ Decision deferred until further information is received ☐ Table for full board meeting
Reviewed by: _____ Name : Date : |__|__| |__|__| |__|__|	
Section H - Final Decision following the Full Board Meeting, or Decision Deferred Pending Further Information (where applicable)	
Decision	☐ Approved. No action required ☐ Decision deferred until further information is received
Reviewed by: _____ Name : Date : |__|__| |__|__| |__|__|	