PANTAI HOSPITAL Kuala Lumpur | A member of IHH Healthcare

PHKL REC ANNUAL PROGRESS REPORT

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		
Date of last PHKL REC Renewal		
Section C - Study Details		
Has the study started?	☐ Yes ☐ No	
If yes, what was the actual start date?		
If no, reasons for the study not commencing?		
Study Status	☐ Ongoing (Expected completion: ____ / ____ / _____) ☐ Completed (Date: ____ / ____ / _____) ☐ Terminated before commencement (Date: ____ / ____ / _____) ☐ Terminated after commencement (Date: ____ / ____ / _____)	
Reason for early termination (if applicable)		
Section D - Recruitment of Participants		
Proposed number of participants in the original application		
Actual number of participants recruited to date		
Number of participants withdrawn or discontinued from study		
Section E - Safety Report		
Have there been any Serious Adverse Events (SAE) 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 SAE reported to PHKL REC	Date Reported to PHKL REC	Date reported as SUSAR (if applicable)

Have there been any Safety Report (DSUR, SUSAR Line Listing) reported to PHKL REC since the last REC initial approval/ renewal?	☐ Yes (Summarise in the table below) ☐ No ☐ N/A

List of Safety Report	Date Reported to PHKL REC

Section 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

Section G - Amendments and Notification

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 submissions or notifications since the last PHKL REC initial approval/ renewal?	☐ Yes (Summarise in the table below) ☐ No

Summary of Notification	Date Submitted to PHKL REC

Section H - Summary of Results (applicable to study closure)
Provide a brief written summary of your study results and attach support documentation such as publication abstract, journal, articles, clinical trial summary, documents or communication as applicable.

Section I - 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 : |__|__| |__|__| |__|__|

Section J - For Office Use Only	
Date of Received	
Received By	
Signature	
Annual Report ID	
Remarks	

Section K - 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 : |__|__| |__|__| |__|__|	