PANTAI HOSPITAL Kuala Lumpur | A member of IHH Healthcare

PHKL REC AMENDMENT APPLICATION 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 - Amendment Details		
Type of Amendment(s): (Please tick where applicable)	☐ Research Protocol / Investigation Plan / Proposal ☐ Participant Recruitment Process ☐ Participant Sample / Population ☐ Patient Information Sheet / Informed Consent Form ☐ Investigator's Brochure ☐ Questionnaire ☐ Study Clinical Report Form / Data Collection Form ☐ Patient's Diary ☐ Advertisement for Subject Recruitment ☐ Trial Insurance Certificate ☐ Study Duration ☐ Investigator/s ☐ Sponsorship / Collaborators ☐ Others _____	
Describe the amendment(s) to the study using simple, non-technical language. Examples may include changes to study procedures, study objectives, recruitment, number of participants, study documents, or research personnel. *(The list of amended documents shall be provided in Section D and is not required in this section)*		
Explain the reason for the amendment(s) (including the impact on the research project and the participants).		
Do these changes raise any ethical issue?	☐ Yes ☐ No	
If yes, identify the ethical issues		

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Section D - Documents

No	Document Title	Version Number	Version Date

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	
Protocol Amendment ID	
Remarks	

Section G - Review by PHKL REC Chairman / Deputy Chairman

Any significant amendment(s) which affect the risk/ benefit ratio?	☐ Yes ☐ No
Additional actions or information required? If yes, please specify	☐ Yes ☐ No _____ _____
Decision	☐ Approved ☐ Decision deferred until further information is received ☐ Table for full board meeting

Reviewed by:

_____

Name :

Date : |__|__| |__|__| |__|__|