

PHKL REC AMENDMENT APPLICATION FORM

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	
Sponsor (if applicable)	
C. Amendment Details	
Type of Amendment(s): (Please tick where applicable)	<input type="checkbox"/> Research Protocol/ Investigation Plan/ Proposal <input type="checkbox"/> Participant Recruitment Process <input type="checkbox"/> Participant Sample/ Population <input type="checkbox"/> Patient Information Sheet/ Informed Consent Form <input type="checkbox"/> Investigator's Brochure <input type="checkbox"/> Questionnaire <input type="checkbox"/> Study Clinical Report Form/ Data Collection Form <input type="checkbox"/> Patient's Diary <input type="checkbox"/> Advertisement for Subject Recruitment <input type="checkbox"/> Trial Insurance Certificate <input type="checkbox"/> Study Duration <input type="checkbox"/> Investigator/s <input type="checkbox"/> Sponsorship/ Collaborators <input type="checkbox"/> Others _____
Explain the amendment(s) to the study using language comprehensible to a lay person (may include changes in procedure, direction of project, source/ manner of recruitment, number of participants or changes to research personnel)	
Reason for the amendment(s) (include a comment on the impact on the research project and the participants at sites for which the reviewing of PHKL REC is responsible)	
Do these changes raise any ethical issue?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, identify the ethical issues	

D. Documents

No	Document Title	Version Number	Version Date

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:

F. For Office Use Only

Date of Received	
Received By	
Signature	
Protocol Amendment ID	

G. Review by PHKL REC Chairman

Any significant amendment(s) which affect the risk/ benefit ratio?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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 <input type="checkbox"/> Decision deferred until further information is received <input type="checkbox"/> Table for full board meeting

Reviewed by:

Name:

Date: