PANTAI HOSPITAL
Kuala Lumpur

PHKL REC RESEARCH APPROVAL APPLICATION FORM

(Please complete all sections and attach all supporting documents before submission)

A. General Information

Full Research Title:

Protocol Number:

NMRR ID:

Research Type

- ☐ Clinical
- ☐ Health Management
- ☐ Health System
- ☐ Health Policy Research
- ☐ Action Research
- ☐ Basic/ Biomedical
- ☐ Public Health/ Epidemiology
- ☐ Health Social Science/ Behavioural
- ☐ Systematic Review
- ☐ Case Study/ Report/ Clinical Audit

Research Subtype

- ☐ Interventional Study: BA/ BE
- ☐ Interventional Study: Community Trial
- ☐ Observational Study: Basic/ Biomedical
- ☐ Observational Study: Clinical Epidemiology
- ☐ Observational Study: Questionnaire
- ☐ Interventional Study: Clinical Trial
- ☐ Interventional Study: Quasi Experimental
- ☐ Observational Study: Clinical Economics
- ☐ Observational Study: Patient Registry/ Database

Therapeutic Area

- ☐ Accident & Emergency
- ☐ Anaesthesiology
- ☐ Cardiology
- ☐ Dermatology
- ☐ Diabetes Mellitus
- ☐ Endocrine / Metabolic
- ☐ ENT
- ☐ Gastroenterology
- ☐ Haematology
- ☐ Hypertension
- ☐ Infectious Disease
- ☐ Neonatology
- ☐ Neurology
- ☐ Neurosurgery
- ☐ Oncology
- ☐ Ophthalmology
- ☐ Orthopaedics
- ☐ Primary Care
- ☐ Rheumatology
- ☐ Surgery
- ☐ Transplantation
- ☐ Traumatology
- ☐ Urology
- ☐ Nephrology
- ☐ Others _____

B. Investigator Details

Name of Principal Investigator:

Tel:	**Fax:**

H/P Number:

Email:

Department:

Good Clinical Practice Certification ☐ Yes ☐ No

List of Co-Investigators:

Name	Position	Institution	Signature

C. Project Information

Project Summary

Not >500 words including introduction, methodology, objectives and expected research outcomes

Research Objectives

Primary Objectives

1.
2.

Secondary Objectives

1.
2.

Time Frame

Expected Start Date	:	(Day/Month/Year)
Expected End Date	:	(Day/Month/Year)
Research Duration	:	(Months)

Research Funding

☐ No Funding
☐ Industrial sponsor
Name of funder:
Amount of funding:
☐ Research Grant
Name of funder:
Amount of funding:

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Kuala Lumpur

D. Ethical Consideration

How many research subjects planning to be enrolled into your study?

Will you seek written consent from the research subjects before they are recruited into your study?

☐ Not applicable
☐ Yes (*Please attach Patient Information Sheet and Informed Consent Form)*

What are the benefits of the study to the research subjects?

What are the potential risks and burdens to the research subjects?

Will the research subject(s) receive financial reimbursement or other compensations for participating in your research?

☐ Not applicable
☐ Yes. Please state the amount
☐ No

Does this study have insurance coverage to cover potential injury to the participants?

☐ Not applicable
☐ Yes
☐ No

Will participants' details be anonymised?

☐ Yes
☐ No. Please explain why and what you will do to ensure participants' confidentiality is protected.

Where will the data be kept? How long will the data be retained?

Do any of the investigators in this study have conflict of interest to declare?

☐ No
☐ Yes. Please state the conflict of interest

E. Declaration

Declaration

I declare that the information in this application form is accurate to the best of my knowledge and belief and I take full responsibility for it.

I understand it is my responsibility to obtain approval where appropriate from PHKL Research and Ethics Committee before the project takes place. I agree to inform PHKL Research and Ethics Committee of any variations to the research during the application period or during the conduct of my research.

Principal Investigator:

_____

Name:
Date:

F. For Office Use Only

Date of Received	
Received By	
Signature	
PHKL REC Ref No.	

G. Review by PHKL REC Chairman

Additional actions or information required?	☐ Yes ☐ No
If Yes, please specify	_____ _____

Reviewed by:

_____

Name:
Date:

Please attach supporting documents *(please tick if applicable)*

No.	Items	
1.	Study Protocol/ Proposal - Protocol shall include detailed description on introduction, objective(s), methodology, data analysis plan and a Gantt chart ** Compulsory. Version number and version date are required*	☐
2.	Investigator's CV ** Compulsory*	☐
3.	Good Clinical Practice (GCP) Certificate ** Required for clinical trials*	☐
3.	Patient Information Sheet and Informed Consent Form (English) ** Required for projects involved human subjects*	☐
4.	Patient Information Sheet and Informed Consent Form (BM) ** Required for projects involved human subjects. Version number and version date are required*	☐
5.	Patient Information Sheet and Informed Consent Form (Other applicable language) ** Required for projects involved human subjects. Version number and version date are required*	☐
6.	Questionnaire/ Surveys/ Interview ** Required when applicable only*	☐
7.	Case Report Form/ Data Collection Form ** Required when applicable only*	☐
8.	Patient's Diary ** Required when applicable only*	☐
9.	Investigator's Brochure ** Required for clinical trial only*	☐
10.	Trial Insurance Certificate ** Required for clinical trial only*	☐
11.	Clinical Trial Agreement ** Required for clinical trial only*	☐
12.	Decision Letter from other Ethics Committees/ Regulatory Authorities (Including negative decision, or any modifications/ amendments during initial submission submitted to other Ethics Committee and/or Regulatory Authority)	☐
13.	Advertisement Materials ** Required when applicable only*	☐
14.	Other Relevant Documents for this Study *(please list down)* -	☐

Please submit a signed electronic copy of the form and all supporting documents to my.phkl.rec@pantai.com.my.

For further enquiries, kindly call the PHKL Research and Ethics Committee Secretariat at 03-2781 4519/ 4520.