PANTAI HOSPITAL Kuala Lumpur | A member of IHH Healthcare

PHKL REC RESEARCH APPROVAL APPLICATION FORM

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

Section A - General Information

(i) Full Research Title:

(ii) Protocol Number (if applicable): ☐ N/A

(iii) NMRR ID (if applicable): ☐ N/A

(iv) **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

(v) **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

(vi) **Therapeutic Area**

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

Section B - Investigator Details

Name of Principal Investigator:

Tel:

H/P Number:

Email:

Designation:

Department:

Institution:

Good Clinical Practice Certification ☐ Yes ☐ No

List of Co-Investigators:

Name	Designation	Institution	Signature

Section C - Project Information

(i) **Project Summary**

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

(ii) **Research Objectives**

Primary Objectives

1.
2.

Secondary Objectives

1.
2.

(iii) **Time Frame** *(The starting date of the study should be after ethics approval)*

Expected Start Date : (Day/Month/Year)

Expected End Date : (Day/Month/Year)

Research Duration : (Months)

(iv) **Research Funding**

☐ No Funding

☐ Industrial Sponsor

Name of Funder : _____

Amount of Funding : _____

☐ Research Grant

Name of Funder : _____

Amount of Funding : _____

Section D - Ethical Consideration

(i) How many research subjects are you planning to enrol into your study?

(ii) Will you seek written consent from the research subject(s) before they are recruited into your study?

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

(iii) What are the benefits of the study to the research subject(s)?

(iv) What are the potential risks and burdens to the research subject(s)?

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

- ☐ Not Applicable
- ☐ Yes. Please state the amount
- ☐ No

(vi) Does this study have insurance coverage for potential injury to the participants?

- ☐ Not Applicable
- ☐ Yes
- ☐ No

(vii) Will participants' details be anonymised?

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

(viii) Where will the data be kept? How long will the data be retained?

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

- ☐ No
- ☐ Yes. Please state the conflict of interest

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Section 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 the PHKL Research and Ethics Committee before the project takes place. I agree to inform the 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 :

Section F - For Office Use Only

Date of Received	
Received By	
Signature	
PHKL REC Ref No.	
Remarks	

Section G - Review by PHKL REC Chairman / Deputy Chairman

Additional actions or information required? If Yes, please specify	☐ Yes ☐ No, table in full board meeting _____ _____
Independent Expert to review If Yes, name of Independent Expert Reason for Appointment Independent Expert to attend full board meeting?	☐ Yes ☐ No _____ _____ _____ _____ ☐ Yes ☐ No

Reviewed by:

_____

Name :

Date :

Section H - Supporting Documents

No.	Items	Document Name	Version Number	Version Date	Please mark (x) if applicable
1.	**Study Protocol/ Proposal** Study Protocol/Proposal shall include detailed description on introduction, objective(s), methodology, data analysis plan, and a Gantt chart ** Compulsory for all studies*				☐ Mandatory
2.	**Investigator's CV** ** Compulsory for all studies*				☐ Mandatory
3.	**Good Clinical Practice (GCP) Certificate** ** Compulsory for clinical trials*				☐ Applicable ☐ Not applicable ☐ To be submitted once available
4.	**Patient Information Sheet and Informed Consent Form (English)** ** Required for projects involving human subjects*				☐ Applicable ☐ Not applicable ☐ To be submitted once available
5.	**Patient Information Sheet and Informed Consent Form (Bahasa Malaysia)** ** Required for projects involving human subjects*				☐ Applicable ☐ Not applicable ☐ To be submitted once available
6.	**Patient Information Sheet and Informed Consent Form (Other applicable language)** ** Required for projects involving human subjects*				☐ Applicable ☐ Not applicable ☐ To be submitted once available
7.	**Questionnaire/ Surveys/ Interview** ** Required only when applicable*				☐ Applicable ☐ Not applicable ☐ To be submitted once available
8.	**Case Report Form/ Data Collection Form** ** Required only when applicable*				☐ Applicable ☐ Not applicable ☐ To be submitted once available
9.	**Patient's Diary** ** Required only when applicable*				☐ Applicable ☐ Not applicable ☐ To be submitted once available
10.	**Investigator's Brochure** ** Required only for clinical trials*				☐ Applicable ☐ Not applicable ☐ To be submitted once available
11.	**Trial Insurance Certificate** ** Required only for clinical trials*				☐ Applicable ☐ Not applicable ☐ To be submitted once available
12.	**Clinical Trial Agreement** ** Required only for clinical trials. Draft agreement is acceptable.*				☐ Applicable ☐ Not applicable ☐ To be submitted once available
13.	**Decision Letter from Other Ethics Committees/ Regulatory Authorities** ** Including negative decisions, or any modifications/ amendments during initial submission submitted to other Ethics Committees and/or Regulatory Authorities*				☐ Applicable ☐ Not applicable ☐ To be submitted once available
14.	**Subject Facing Materials** ** Required only when applicable*				☐ Applicable ☐ Not applicable ☐ To be submitted once available

15.	**Other Relevant Documents for this Study** *(please list below)* -				☐ Applicable ☐ Not applicable ☐ To be submitted once available

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 03-2280 1320 / 1321.