INSTITUT JANTUNG NEGARA
National Heart Institute

RESEARCH AND DEVELOPMENT PROJECT REGISTRATION FORM

R&D PROJECT ID NO (For Office use only)	

RESEARCH AND DEVELOPMENT PROJECT REGISTRATION FORM

A. PROJECT INFORMATION

1. Title of Project

2. Principal Objective / Research Question

3. Investigators / Co-investigators

Name	Appointment	Department
1. 2. 3. 4. 5.		

4. Proposed dates (dd/mm/yyyy)

Start : End :

5. Study Design

Clinical trial		Economic evaluation	
Case-control study		Diagnostic test	
Cohort study			
Cross-sectional study			
Case note review			

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B. ETHICS APPROVAL

1. Will ethical approval be sought?

- ☐ YES
- ☐ NO
- ☐ Already obtained Ref: ☐

Please complete CRD Determination of Human Subject Research Checklist form CRD-QR-A13

2. If you will not be seeking ethical approval, please state why you consider this will not be required

C. SPONSOR / FUNDING DETAILS

Name	Address	Contact
1.		
2.		

D. RISK ASSESSMENT

Use the section below to identify hazards and indicate if adequate safety control measures are in place

a.	Drugs and chemicals	☐	NO	☐	Normal clinical practice	☐ YES
b.	Ionizing radiation	☐	NO	☐	Normal clinical practice	☐ YES
c.	Non-ionising radiation	☐	NO	☐	Normal clinical practice	☐ YES
d.	Lasers	☐	NO	☐	Normal clinical practice	☐ YES
e.	Display screen equipment	☐	NO	☐	Normal clinical practice	☐ YES
f.	Genetically modified microorganisms	☐	NO	☐	Normal clinical practice	☐ YES
g.	Solvent and flammable materials	☐	NO	☐	Normal clinical practice	☐ YES
h.	Medical devices and electrical equipment	☐	NO	☐	Normal clinical practice	☐ YES
i.	Other hazards (please specify)					

E. PROJECT AUTHORISATION

1. Investigator

Signature : _____

Name : _____

Department : _____

Date : _____

**** If applicant is external, all application must be co-signed by collaborator from Institut Jantung Negara***

2. Clinical Director / Head of Department

I confirm that the above-described project has been appropriately reviewed and that the project has my authorisation

Signature : _____

Name : _____

Department : _____

Date : _____

3. Director, Research and Development

I approve and fully support this application and confirm that I have considered all the service and resource implications related to undertaking this project.

Signature : _____

Name : _____

Department : _____

Date : _____

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RESEARCH AND DEVELOPMENT PROJECT REGISTRATION FORM

R&D PROJECT REGISTRATION CHECKLIST

1. Project Registration Form	
2. Study protocol	
3. Patient Information Sheet (if applicable)	
4. Consent Form (if applicable)	

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Date of Received : _____

Received by : _____

Signed : _____

INSTITUT JANTUNG NEGARA
National Heart Institute

Clinical Research Department
Determination of Human Subject Research Checklist

Research Programme Information

Project Registration Number	
Project Title/Study Project	
Sponsor	
Investigator	

	Yes	No	NA
Section A Does Your Activity Involve Human Subjects? • Is the data being obtained about living individuals? • Is the data collected through intervention or interactions with individuals? • Does the data contain identifiable private information? * *If any question in section A is "YES", go to section B.* *If all questions in section A are "NO", no review required.*			
Section B. Is it Research*? • Is the activity a systematic investigation, including research* development, testing and evaluation, designed to develop or contribute to generalizable knowledge? *** If any question in section A is "YES" and section B is "YES", submit IJNREC Application.*** *If section B is "NO", go to Section D.*			
Section C. Is IJNREC Review Required? • Does the activity involve secondary data sets with identifiable private information? • Does the activity use identified specimens or cell lines from other institutions or are they commercially available? • Is the data collected for administrative purposes with the intention of publication? • Does the activity involve the use of publicly available data that contains sensitive, personal, or identifiable data? • Does the interview or survey focus on experiences, opinions, and sensitive information about people? • Is the activity a biography that is generalizable? • Is the activity an oral history that is generalizable? • Does the activity involve case histories of multiple patients? • Is the activity a genetic study providing private information about live relatives? • Is the activity a class related project that will lead to publication or poster presentation? *** If any question in section C is "YES", submit IJNEC Application*** *If all questions in section C are "NO", go to section D.*			

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Determination of Human Subject Research Checklist

Section D. Is the Focus on a Specific Population? Does the activity intentionally focus on or include one or more specific populations? • If "YES", also check the box(s) below. ☐ Neonates/Fetuses ☐ Decisionally impaired ☐ Non-English speaking ☐ Institutionalized individuals ☐ Other _____ * *If any question in section D is "YES", submit IJNREC Application* *If all questions in section D are "NO", no IRB review required.*			

Signature : Date : (DD/MMM/YYYY)

Investigator :

FOR OFFICE USE ONLY

Date Received :

Name :

Signed :