INSTITUT JANTUNG NEGARA
National Heart Institute

IJN Research Ethics Committee

APPLICATION FORM

IJNREC ID NO :

SECTION A – PROJECT / STUDY SUMMARY

1. Project Title/ Study Title :

1.2 Name of Investigator :
(Please attach CV)

Department		MMC Registration No :
Contact Details	Telephone : Email :	Trained in GCP : ☐ Yes ☐ No

1.3 Name of all Sub-Investigator /Co-Investigator :
(Please attach CV)

Name		MMC Registration No :
Department/Institution		Trained in GCP : ☐ Yes ☐ No
Contact Details	Telephone : Email :	
Name		MMC Registration No :
Department/Institution		Trained in GCP : ☐ Yes ☐ No
Contact Details	Telephone : Email :	
Name		MMC Registration No :
Department/Institution		Trained in GCP : ☐ Yes ☐ No
Contact Details	Telephone : Email :	

2. Please provide a summary of the project written in language accessible for a non-expert audience (approximately 350 words).

2.1 Does this project require IJNREC approval? Yes ☐ No ☐

2.2 IRB (Independent Review Board) Application from Other Institutions.
If the research project submits to any other IRBs, please provide the following information:

Name of the IRB	
Submission reference number	
Date of submission	
Decision	☐ Approved ☐ Modification required prior to approval ☐ Disapproved
Copy of the decision letter if any	

2.3 NMRR Registration (National Medical Research Register)
If the research project has registered with NMRR, please provide the following information:

Date of registration	
Registration reference number	

2.4 Date start and end date of the project

Proposed start date	dd/mmm/yyyy
Proposed completion date	dd/mmm/yyyy
Duration of project	

2.5 Sponsorship/grant of the project/study
List all sources of funds e.g. grants, commercial sponsorship, university's funds etc.

Is there any sponsor/grant?	☐ Yes (please fill up information below) ☐ No
Name of the sponsor/grant	
Address	
Contact Details	

2.6 Type of research

☐ Clinical Trial ☐ Fundamental Research	Phase of study ☐ Phase I ☐ Phase II ☐Phase III ☐ Phase IV
☐ Industry-sponsored ☐ Investigator initiate	Site : ☐ Single Centre ☐ Multi Centre
☐ Collaboration/Academic Research	

2.7 Category of research

☐	**Interventional** *Participant may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random.* ☐ **Drug** ☐ **Device (e.g. Defibrillators, Implantable)** ☐ **Others (Explain)**
☐	Observational *Participant may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the participant*
☐	Retrospective Medical Record Review
☐	Human tissue/stem cell research
☐	Questionnaire/Survey
☐	Others (Specify) :

SECTION B – PROJECT PROPOSAL AND PROTOCOL

Please complete the template below ensuring you answer all the questions comprehensively. Your protocol should also be included in this template.

3. What is the purpose/objective of this study? Please clearly state the aims of the study or hypothesis to be tested

4. What is the research methodology?

SELECTION OF PARTICIPANT (S)

5. What category of participants will be involved? (i.e. gender, ages, type of disease)

Gender	☐ Male ☐ Female ☐ Both
Ages	☐ 18 years and above ☐ Below 18 years (assent) ☐ Others (specify) :
Type of disease (Specify)	
Others (Specify)	

5.1 Number of participants

The number of participant expected to be enrolled at sites	
Total number of participant to enroll at all sites	

5.2 Please state the rationale for your participant choice?

5.3.Vulnerable participants in the study involvement (if applicable)
If vulnerable and disadvantaged groups (i.e. children, incapacitated adults, populations in low income countries) will be involved please give full details and outline the steps that will be taken to protect them.

Vulnerable participants including children, pregnant women, economically and educationally disadvantaged, decisionally impaired	☐ YES ☐ NO
Number of vulnerable participants	
Rationale involvement of vulnerable participants	
Additional safeguards to protect their rights and welfare	

5.4 What are the inclusion/exclusion criteria?

Inclusion Criteria	
Exclusion Criteria	

5.5 Describe how potential participants will be identified and recruited?
Please specify all channels which you intend to use to advertise to potential participants.

5.6 What results/end points are to be measured/noted?

PRIVACY AND CONFIDENTIALITY PROTECTIONS

6. What and how precautions will be taken to ensure confidentiality, privacy and data protection?
Data should be secured against unauthorized access and comply with data protection legislation. Where possible the data should be anonymised, where this is not possible confidentiality should be maintained.

6.1. Data Collection
Please include a copy of any questionnaire that will be used, or sample questions (e.g. a topic guide), in

structured or semi-structured interviews.

How the data will be collected?	
Where the data will be collected?	
When the data will be collected?	
Who will collect the data?	
Any specific form use?	

6.2. Data re-labelling or data de-identified including x-rays or other digital images

How the data will be re-labelling or de-identified?	
Who will responsible for the identification?	

6.3. Access of the data

Who will have the access to the data?	
Describe levels of access control.	

6.4. Data sharing

How the data will be transferred or transmitted?	
Describe how you will secure the data while transit?	

6.5. Data / result analysis

How will the data/result will be analysed?	
Who will analysed the data/result?	

6.6. Result dissemination

How the data/result will be disseminated?	
Arrangements for participants access to the results?	
Publications/Presentations	☐ Yes ☐ No If presentation, ☐ Oral presentation ☐ Poster presentation

<u>INFORMED CONSENT (To complete the Informed Consent Checklist)</u>

7 Adult Informed Consent

Who is obtaining the consent?	
When the consent will be taken?	
Where the consent will be taken?	
How much time given to participant given for decision-making?	
How is the process/procedure obtaining informed consent?	

If it is not possible to obtain consent, full reason must be given.	

7.1. Assent Consent (18 years and below) if applicable.

Who is obtaining child assent?	
When and where will assent be obtained?	
Will a parent or guardian be present?	☐ Yes ☐ No Provide a rationale if only one parent will consent.

This checklist of 21 elements to help in determining that the required information is in the Patient Information Sheet and Informed Consent Form to assures compliance with research guideline and regulations.
Reference : ICh-GCP, Malaysia Guidelines for Good Clinical Practice,3rd edition, 2011

No	Informed Consent Elements	Yes	No	Not applicable
1	That the trial involves research.			
2	The purpose of the trial			
3	The trial treatments(s) and the probability for random assignment to each treatment			
4	The trial procedures to be followed, including all invasive procedures			
5	The subject responsibilities			
6	Those aspects of the trial that is experimental			
7	The reasonable foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant			
8	The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.			
9	The alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks			
10	The compensation and/or treatment available to the subject, in the event of trial-related injury			
11	The anticipated prorated payment, if any, to the subject for participating in the trial *If Yes, please state amount per visit.			
12	The anticipated expenses, if any, to the subject for participating in the trial			
13	That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled			

14	That the monitor(s), the auditor (s), the IJNREC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access			
15	That record identifying the subject will be kept confidential and, to the extent permitted by applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential			
16	That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in this trial			
17	The person(s) to contact for further information regarding the trial and the rights of trial subjects (e.g. representative of Ethics Committee), and whom to contact in the event of the trial-related injury (e.g. Investigator)			
18	The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated			
19	The expected duration of the subject's participation in the trial			
20	The approximate number of subjects involved in the trial			
21	The source of the investigational product that may be culturally unacceptable			

8. RISK OF THE STUDY

What are the risks to participants, and how will these managed?	
What are the risks to researchers, and how will these be managed?	

9. BENEFIT OF THE STUDY

What are the expected benefits of the research to participants?	
What are the expected benefits of the research to researchers?	

There are five (5) major types of risk :

1	Physical risk (for example, pain, bruising and infection associated with venipuncture, muscle soreness and pain as a consequence of exercise testing, heart attack induced by maximal exercise tests)
2	Psychological risk (for example, stress associated with experiments and testing, feelings of guilt or discomfort because of sensitive survey topics)
3	Social risk (for example, invasion of privacy, loss of community standing)
4	Legal risk (for example, criminal prosecution or revocation of parole)
5	Economic risk (for example, loss of employment, loss of potential monetary gain)

Definition of minimal risk : Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

RISK CATEGORIES

Check the appropriate risk category of your research :

Type	Risk	Yes	No
1	The research involves no more than minimal risk to subjects.		
2	The research involves minimal risk to subjects.		
3a	The research involves more than minimal risk to subjects. The risk(s) represents a minor increase over minimal risk, or		
3b	The risk(s) represents more than a minor increase over minimal risk, or		
3c	The risk (s) represents a major increase over minimal risk		

Definition of benefit : A research benefit is considered to be something of a health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participating in research is not considered to be a benefit.

BENEFITS CATEGORIES

Check the appropriate risk category of your research :

Type	Benefits	Yes	No
1	The research provides no prospects of direct benefit to individual subjects, but likely will yield generalizable knowledge about subject's disorder or condition.		
2	The research provides no prospect of direct benefits to individual subjects, but likely will yield generalizable knowledge to further society's understanding of the disorder or condition under study.		
3	The research provides the prospect of direct benefits to individual subjects.		
4	The research provides no prospects of direct benefits to individual subjects, to science or to society.		

Risk/Benefit Matrix

Risk / Benefit	1	2	3a	3b	3c
1	Exempt if not involves vulnerable subjects	Exempt if not involves vulnerable subjects	Expedited/Full-board	Expedited/Full-board	Rejected

2	Exempt if not involves vulnerable subjects	Exempt if not involves vulnerable subjects	Expedited/Full-board	Expedited/Full-board	Rejected
3	Exempt if not involves vulnerable subjects	Exempt if not involves vulnerable subjects	Expedited/Full-board	Expedited/Full-board	Rejected
4	Rejected	Rejected	Rejected	Rejected	Rejected

**Vulnerable subjects is refer to children, prisoners, mentally disabled persons, economically or educationally disadvantaged persons, pregnant women, fetuses and neonates.*

STUDY PROCEDURE

10. Explain all procedures, from screening through closeout which to undergo by research participant including study visit and the procedures that are part of standard of care.

10.1 Explain alternative procedures or courses of treatment, if any, that might be advantage to the participant.

11. Will participants be reimbursed for expenses or given any inducements? If so, please give details.

Reimbursement to participant	☐ Yes ☐ No
If yes, please specify	

12. What facilities will be needed and who will provide them?

13. Do any researchers have any financial interests in this research or its outcomes or any relevant affiliations?

If 'Yes' please give details and include an appropriate comment on the Participant Information Sheet.

Any Financial interest	☐ Yes ☐ No
If 'Yes' please specify	

14. Monitoring, auditing or inspection
Please explain on the monitoring, auditing or inspection measures taken for this study.

15. Insurance

☐ YES ☐ NO

If 'YES' please give details.

Policy Number	
Period of Coverage	
Scope of Coverage	
Limit of Insurance	

Investigator :

- I certify that the information provided in this application is complete and accurate.
- I understand that as Investigator, I have ultimate responsibility for the conduct of IJNREC approved studies, the ethical performance of protocols, the protection of the rights and welfare of human subjects, and strict adherence to the study's protocol and any stipulation imposed by IJNREC
- I agree to comply with all IJN's policies and procedures, as well as with all applicable regulatory requirements and laws, regarding the protection of human participants in research.

Signature : _____

Name : _____ Date :_____*(dd/mmm/yyyy)*

Head of Department :

- I have reviewed this application and determined that all applicable departmental requirements are met.
- The investigator is qualified by education, training, and experience to assume responsibility for the proper conduct of the study.
- The investigator has adequate resources to conduct the study in terms of time, facilities, staff, access to a subject population, and resources for care subjects may need.

HOD Signature : _____

Name : _____ Date : _____*(dd/mmm/yyyy)*

FOR OFFICE USE ONLY

Date of Received : _____

Received by : _____

Signature : _____