



**UNIVERSITY
OF MALAYA**
MEDICAL CENTRE

MEDICAL RESEARCH ETHICS COMMITTEE
(Formerly known as Medical Ethics Committee)
UNIVERSITY OF MALAYA MEDICAL CENTER

ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE : 03-79493209/2251 FAXIMILE : 03-79492030

NAME OF ETHICS COMMITTEE/IRB Medical Research Ethics Committee, University Malaya Medical Center	MREC ID NO: 20161-2097
ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA	NMRR.ID : 29523
PROTOCOL NO (if applicable) :	
TITLE: Effects of Functional Electrical Stimulation (FES)-Cycling Exercise Plus Progressive Resistance Training on Muscle Strength And Cardiovascular Response After Incomplete Spinal Cord Injury	
PRINCIPAL INVESTIGATOR : Associate Professor Nazirah Hasnan	SPONSOR -

The following item have been received and reviewed in connection with the above study to conducted by the above investigator.

<input checked="" type="checkbox"/> Application to Conduct Research Project(form)	Ver.No :	Ver.Date : 27-01-2016
<input checked="" type="checkbox"/> Study Protocol	Ver.No :	Ver.Date :
<input checked="" type="checkbox"/> Patient Information Sheet	Ver.No : 1.1	Ver.Date : 01-06-2015
<input checked="" type="checkbox"/> Consent Form	Ver.No :	Ver.Date :
<input type="checkbox"/> Questionnaire	Ver.No :	Ver.Date :
<input checked="" type="checkbox"/> Investigator's CV / GCP (Associate Professor Nazirah Hasnan, Dr Mohd Haidzir Bin Abd Manaf, NUR AZAH HAMZAID, Nurhaida Rosley,)	Ver.No :	Ver.Date :
<input type="checkbox"/> Insurance certificate	Ver.No :	Ver.Date :
<input checked="" type="checkbox"/> Other documents		
1) STUDY PROTOCOL	Ver.No : 1	Ver.Date : 06-01-2015

and the decision is

- Approved (Full Board)
 Approved (Expedited)
 Rejected(reasons specified below or in accompanying letter)

Comments:

-

The Investigators are required to:

- 1) *follow instructions, guidelines and requirements of the Medical Research Ethics Committee.*
- 2) *report any protocol deviations/violations to Medical Research Ethics Committee.*
- 3) *provide annual and closure report to the Medical Research Ethics Committee.*
- 4) *comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.*
- 5) *obtain a permission from the Director of UMMC to start research that involves recruitment of UMMC patient.*
- 6) *ensure that if the research is sponsored, the usage of consumable items and laboratory tests from UMMC services are not charged in the patient's hospital bills but are borne by research grant.*
- 7) *note that he/she can appeal to the Chairman of Medical Research Ethics Committee for studies that are rejected.*
- 8) *note that Medical Research Ethics Committee may audit the approved study.*
- 9) *ensure that the study does not take precedence over the safety of subjects.*

Date of meeting : 17-02-2016

Date of approval : 17-02-2016

This is a computer generated letter. No signature required.