04/05/2020 **Untitled Document**



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

MEDICAL CENTRE ADDRESS: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA

NAME OF ETHICS COMMITTEE/IRB Medical Research Ethics Committee, University Malaya Medical Centre	MREC ID NO: 20181029-6810
ADDRESS: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA	
PROTOCOL NO(if applicable):	
TITLE: The Efficacy of 20-Minute Mindful Breathing on the Dialysis Recovery Time (DRT) of Haemodialysis Patients: A Randomized Controlled Trial	
PRINCIPAL INVESTIGATOR: Lim Soo Kun	SPONSOR Lim Soo Kun

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

[✓]	Application to Conduct Research Project(form)	Ver.No:	Ver.Date: 29-10-2018
[✓]	Study Protocol	Ver.No: 1.0	Ver.Date: 29-10-2018
[✓]	Patient Information Sheet	Ver.No: 1.0	Ver.Date: 30-10-2018
[✓]	Consent Form	Ver.No: 1.0	Ver.Date: 30-10-2018
[]	Questionnaire	Ver.No:	Ver.Date:
[$Investigator's\ CV\ /\ GCP\ (\ Lim\ Soo\ Kun, MEA\ HING\ JUIN,\ YU\ DEYING,\ TAN\ SENG\ BENG,\)$	Ver.No:	Ver.Date:
[]	Insurance certificate	Ver.No:	Ver.Date:
[Other documents		
	1) DATA COLLECTION FORM	Ver.No:1	Ver.Date: 01-11-2018
	2) EQ-VAS	Ver.No:1	Ver.Date: 01-11-2018
	3) PSQI	Ver.No:1	Ver.Date: 01-11-2018
nd the	decision is []		
[\(\)	Approved (Full Board)		
г 1	Approved (Expedited)		

Comments:

The Investigators are required to:

- follow instructions, guidelines and requirements of the Medical Research Ethics Committee.
- 2) report any protocol deviations/violations to Medical Research Ethics Committee.
- provide annual and closure report to the Medical Research Ethics Committee. 3)

] Rejected(reasons specified below or in accompanying letter)

- comply with International Conference on Harmonization Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki. 4)
- obtain a permission from the Director of UMMC to start research that involves recruitment of UMMC patient. 5)
- 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 6) 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.
- ensure that the study does not take precedence over the safety of subjects.

Date of meeting: 23-01-2019 Date of approval : 23-01-2019

Approval By: PROF. DATUK DR. LOOI LAI MENG (Chairman, MREC)

This is a computer generated letter. No signature required.