



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

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 Centre	MREC ID NO: 2019131-7084
ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA	
PROTOCOL NO (if applicable) :	
TITLE: The Values in Shared Interactions Tool (VISIT) for integrating patient agendas into consultations: A single-center block-randomization trial	
PRINCIPAL INVESTIGATOR : Dr Lee Yew Kong	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 : 31-01-2019
<input checked="" type="checkbox"/> Study Protocol	Ver.No : 1	Ver.Date : 24-01-2019
<input checked="" type="checkbox"/> Patient Information Sheet	Ver.No : 1	Ver.Date : 09-01-2019
<input checked="" type="checkbox"/> Consent Form	Ver.No : 1	Ver.Date : 18-01-2019
<input checked="" type="checkbox"/> Questionnaire	Ver.No :	Ver.Date :
<input checked="" type="checkbox"/> Investigator's CV / GCP (Dr Lee Yew Kong,NG CHIRK JENN, LEE PING YEIN, CHIEW THIAM KIAN, ADINA BINTI ABDULLAH , CHARITY LEE CHIN AI, TUN FIRZARA BINTI ABDUL MALIK,)	Ver.No :	Ver.Date :
<input type="checkbox"/> Insurance certificate	Ver.No :	Ver.Date :
<input checked="" type="checkbox"/> Other documents		
1) Patient information sheet (Doctor's copy)	Ver.No : 1	Ver.Date : 10-01-2019
2) Consent Form (Doctor's copy)	Ver.No : 1	Ver.Date : 18-01-2019
3) Pre & Post Questionnaires for Patients	Ver.No : 1	Ver.Date : 31-01-2019
4) Consultation Time & Agenda Form for Doctors	Ver.No : 1	Ver.Date : 31-01-2019

and the decision is

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

Comments:

Note: Prof. Ng Chirk Jenn is co-investigator and not involved in decision of MREC.

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 : 27-02-2019

Date of approval : 27-02-2019

Approval By : LOOI LAI MENG (Chairman,MREC)

This is a computer generated letter. No signature required.