Untitled Document



UNIVERSITY OF MALAYA UNIVERSITY OF MALAYA MEDICAL CENTRE

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: 2019610-7501
ADDRESS : LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA	NMRR.ID: 19-379-46101
PROTOCOL NO(if applicable) :	
TITLE: Effect of High-Dose-Vitamin-B Multivitamin Supplement on Neural Connectivity and Oxidative Metabolism in Healthy Adults	
PRINCIPAL INVESTIGATOR : PROF. DR. NORLISAH BT MOHD RAMLI	SPONSOR TAYLOR'S UNIVERSITY

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 : 10-06-2019
Study Protocol		Ver.No : 1.1	Ver.Date : 08-10-2019
[✓] Patient Information Sheet		Ver.No : 1.0	Ver.Date : 18-06-2019
[✓] Consent Form		Ver.No : 1.0	Ver.Date : 18-06-2019
[] Questionnaire		Ver.No :	Ver.Date :
	MOUD DAMELOUZDELAU DINITI	ver.ino :	ver.Date :
Investigator's CV / GCP (PROF. DR. NORLISAH BT NAWAWI , AZLAN BIN CHE AHMAD, TAN LI KU OO CHENG YEOW, WONG YI JIET, ASSOCIATE I WONG YIN HOW,)		Ver.No :	Ver.Date :
[/] Insurance certificate		Ver.No : 1.0	Ver.Date : 08-10-2019
[VI Other documents			

and the decision is $[\checkmark]$

[] Approved (Full Board)

- [] Approved (Expedited)
- [] Rejected(reasons specified below or in accompanying letter)

Comments:

Revised satisfactorily.

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.
- 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 6) 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 : 25-09-2019 Date of approval : 21-11-2019 Approval By : LOOI LAI MENG (Chairman, MREC)

This is a computer generated letter. No signature required.