

14th July 2020

Dr. Lee Lai Kuan

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JEPeM Code : USM/JEPeM/20030183

Protocol Title : Efficacy of Low Glycaemic Index Instant Multigrain Supplementation in Type II Diabetes Mellitus: A Randomized, Open-Labelled Intervention Trial.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/20030183**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **14th July 2020** until **13th July 2021**.

Study Site: Advanced Medical and Dental Institute (AMDI), Universiti Sains Malaysia, Pulau Pinang

The following researchers are also involved in this study:

1. Dr. Mastura Mohd Sopian
2. Assoc. Prof. Dr. Foo Keng Yuen
3. Dr. Mohamad Hafizi Abu Bakar
4. Miss Nur Anis Mohd Ariffin

The following document has been approved for use in the study:

1. Research Proposal

In addition to the above mentioned document, the following technical documents were included in the review on which this approval was based:

1. Participant Information Sheet and Consent Form (English version)
2. Participant Information Sheet and Consent Form (Malay version)
3. Questionnaire
4. Flyers

The list of JEPeM-USM members present during the full board meeting reviewing your protocol is attached.

While the study is in progress, we request you to submit to us the following documents:

1. Application for renewal of ethical approval 60 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2019: Continuing Review Application Form**.
2. Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be

submitted or reported using **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**

3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2019: Study Protocol Amendment Submission Form.**
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2019: Adverse Events Report.**
5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2019.**
6. Any event which may have ethical significance.
7. Any information which is needed by the JEPeM-USM to do ongoing review.
8. Notice of time of completion of the study using **JEPeM-USM FORM 3(C) 2019: Final Report Form.**

Please note that forms may be downloaded from the JEPeM-USM website: www.jepem.kk.usm.my

JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

Sincerely,

Narazah

PROF. DR. NARAZAH MOHD YUSOFF

Deputy Chairperson

Jawatankuasa Etika Penyelidikan (Manusia) JEPeM

Universiti Sains Malaysia

Date of meeting : 21st May 2020
Venue : Through WEBEX Application.
Time : 9.00 a.m – 1.00 p.m
Meeting No : 463

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Members of Committee of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia who reviewed the protocol/documents are as follows:

Member (Title and Name)		Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items, were reviewed
Deputy Chairperson: Prof. Dr. Narazah Mohd Yusoff		Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	F	✓ (Deputy Chairperson)
Secretariat: Miss Nor Amira Khurshid Ahmed		Research Officer	F	✓
Members :				
1.	Mr. Anuar Omar	Community Representatives	M	✓
2.	Assoc. Prof. Dr. Baharudin Ibrahim	Lecturer, School of Pharmaceutical Sciences	M	✓
3.	Mdm. Chin Khuan Sui	Community Representatives	F	✓
4.	Dr. Chong Soon Eu	Lecturer, Advanced Medical and Dental Institute	M	✓
5.	Dr. Husnaida Abdul Manan @ Sulong	Lecturer, Advanced Medical and Dental Institute	F	✓
6.	Mr. Mohd Jasmie Ikhrum Ab Rahaman	Senior Clerk, Advanced Medical and Dental Institute	M	✓
7.	Assoc. Prof. Dr. Khairiah @ Salwa Mokhtar	Lecturer, School of Distance Education	F	✓
8.	Dr. Muhamad Yusri Musa	Lecturer, Advanced Medical and Dental Institute	M	✓
9.	Assoc. Prof. Dr. Norzarina Mohd Zaharim	Lecturer, School of Social Sciences	F	✓
10.	Assoc. Prof. Dr. Premalatha Karupiah	Lecturer, School of Social Sciences	F	✓
11.	Assoc. Prof. Dr. Shahrom Mahmud	Lecturer, School of Physics	M	✓
12.	Prof. Dr. Suriati Ghazali	Lecturer, School of Humanities	F	✓
13.	Assoc. Prof. Dr. Tan Cheng Ling	Lecturer, Graduate School of Business	F	✓

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Narazah

PROF. DR. NARAZAH MOHD YUSOFF

Deputy Chairperson
Jawatankuasa Etika Penyelidikan (Manusia), JEPeM
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