

12<sup>th</sup> September 2022

**Assoc. Prof. Dr. Balamurugan Tangiisuran**  
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**JEPeM Code : USM/JEPeM/22050296**  
**Protocol Title : Evaluation of Community Pharmacist-Led Fall Prevention Program (CAREFREE) among Community-Dwelling Older Adults – A Randomised Controlled 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/22050296**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **12<sup>th</sup> September 2022** until **11<sup>th</sup> September 2023**.

Study Site: Selected community pharmacies in Malaysia

The following researchers are also involved in this study:

1. Dr. Fatimatu Zahra' Abd. Aziz
2. Miss Nur Izzati Shahabuddin

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

1. Research Proposal

In addition to the abovementioned document, the following technical documents were included in the review on which this approval is based:

1. Participant Information Sheet and Consent Form (English version)
2. Participant Information Sheet and Consent Form (Malay version)
3. Advertisement
4. Knowledge Questionnaire
5. Standard Referral Form

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 that you 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](http://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.

“WAWASAN KEMAKMURAN BERSAMA 2030”

“BERKHIDMAT UNTUK NEGARA”

Sincerely,



**b/p**  
**ASSOC. PROF. DR. NORZARINA MOHD ZAHARIM**  
Deputy Chairperson  
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM  
Universiti Sains Malaysia

Date of meeting : 21<sup>st</sup> July 2022  
Venue : Through WEBEX Application  
Time : 9.00 a.m – 1.00 p.m  
Meeting No : 551

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Members 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
<b>Advisor:</b> Prof. Dr. Narazah Mohd Yusoff	Advisor of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	F	✓ (Advisor)
<b>Deputy Chairperson:</b> Assoc. Prof. Dr. Norzarina Mohd Zaharim	Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	F	✓ (Deputy Chairperson)
<b>Deputy Chairperson:</b> Assoc. Prof. Dr. Shahrom Mahmud	Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Deputy Chairperson)
<b>Member Secretary:</b> Dr. Nik Norma Nik Hasan	Member secretary of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	F	✓ (Member Secretary)
<b>Secretariat:</b> Mdm. Nor Amira Khurshid Ahmed	Research Officer	F	✓
<b>Members :</b>			
1.	Mr. Abdul Hamid Ibrahim Naina	Community Representatives	M ✓
2.	Mr. Anuar Omar	Community Representatives	M ✓
3.	Mdm. Chin Khuan Sui	Community Representatives	F ✓
4.	Dr. Goh Yen Nee	Lecturer, Graduate School of Business	F ✓
5.	Assoc. Prof. Dr. Loke Yiing Jia@ Loke Weng Kah	Lecturer, School of Social Sciences	F ✓
6.	Dr. Muhamad Yusri Musa	Lecturer, Advanced Medical and Dental Institute	M ✓
7.	Mr. Yahya Amir	Community Representatives	M ✓

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.



**ASSOC. PROF. PROF. DR. NORZARINA MOHD ZAHARIM**  
Deputy Chairperson  
Jawatankuasa Etika Penyelidikan (Manusia), JEPeM  
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