

2nd December 2015

Prof. Dr. Zabidi Azhar Mohd Hussin
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*→ Dr. Huzaimah
with permission
of - **

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JEPeM Code : USM/JEPeM/15070242

Protocol Title : Development and Evaluation of a Community-Based One-Stop Feeding Centre as a 'NeuroNutritional Rehabilitation' Hub for Children with Neurological Disabilities.

Dear Prof.,

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/15070242**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **December 2015** until **November 2016**.

The following documents have been approved for use in the study.

1. Research Proposal

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

1. Participant Information Sheet and Consent Form (Malay version) – Phase I
2. Participant Information Sheet and Consent Form (Malay version) – Phase II
3. Participant Information Sheet and Consent Form (Malay version) – Phase III
4. Disabled Child Feeding Questionnaires
5. Content Validation Form - Disabled Child Feeding Questionnaires
6. Semi-Structured Interview Protocol
7. Content Validation Form - Semi-Structured Interview Protocol
8. Feeding Training Module
9. Content Validation Form - Feeding Training Module

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

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) 2014: Continuing Review Application Form**. Subsequently this need to be done yearly as long as the research goes on.
- * 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) 2014: Study Protocol Amendment Submission Form**.
- * 3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2014: Study Protocol Amendment Submission Form**.
- * 4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2014: Adverse Events Report**.



5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2014**.
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) 2014: Final Report Form**.

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

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.

Thank you.

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

PROF. DR. HANS AMIN VAN ROSTENBERGHE

Chairperson

Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia



Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM)
Human Research Ethics Committee USM (HREC)

Date of meeting : 10 September 2015
Venue : Meeting Room, Centre for Research Initiatives,
Clinical and Health Sciences, USM Kampus Kesihatan.
Time : 9.00 a.m – 3.00 p.m
Meeting No : 316


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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	
Chairperson : Professor Dr. Hans Amin Van Rostenberghe	Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Chairperson)	
Deputy Chairperson : Professor Dr. Mohd Shukri Othman	Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Deputy Chairperson)	
Secretary: Mr. Mohd Bazlan Hafidz Mukrim	Research Officer	M	✓	
Members :				
1.	Dato' Haji Elias Zakaria	Lecturer, School of Humanities	M	✓
2.	Professor Wan Abdul Manan Wan Muda	Lecturer, School of Health Sciences	M	✓
3.	Associate Professor Oleksandr Krasilshchikov	Lecturer, School of Health Sciences	M	✓
4.	Associate Professor Dr. Mohtar Ibrahim	Lecturer, School of Medical Sciences	M	✓
5.	Associate Professor Siti Hawa Ali	Lecturer, School of Health Sciences	F	✓
6.	Dr. Azlan Husin	Lecturer, School of Medical Sciences	M	✓
7.	Dr. Nik Min Ahmad	Deputy Director (Clinical), Hospital USM	M	✓
8.	Mr. Haji Ismail Hassan	Community Representative	M	✓
9.	Mrs. Zawiah Abu Bakar	Community Representative	F	✓

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