

26th October 2023

Dr. Lee Ling Hong
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JEPeM Code : USM/JEPeM/KK/23060438

Protocol Title: Randomized Control Trial on Short Term Effect of High Versus Low Position of Umbilical Catheter in Neonates.

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/KK/23060438**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **26th October 2023** until **25th October 2024**.

Study Site: Hospital Universiti Sains Malaysia.

The following researchers are also involved in this study:

1. Assoc. Prof. Dr. Noraida Ramli
2. Dr. Farohah Che Mat Zain
3. Dr. Nor Rosidah Ibrahim
4. Dr. Anis Munirah Mohd Kori
5. Assoc. Prof. Dr. Kueh Yee Cheng

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

1. Research Proposal

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

1. Parental Information Sheet and Consent Form (Malay version)
2. Baseline Data

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 45 days before the expiration date of this approval through submission of **JEPeM-USM FORM 3(B) 2022: 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) 2022: Study Protocol Amendment Submission Form**.
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2022: Study Protocol Amendment Submission Form**.
4. Reports of adverse events including from other study sites (national, international) using the **JEPeM-USM FORM 3(G) 2022: Adverse Events Report**.

5. Notice of early termination of the study and reasons for such using **JEPeM-USM FORM 3(E) 2022**.
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) 2022: Final Report Form**.

Please note that forms may be downloaded from the JEPeM-USM website: <https://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.

“MALAYSIA MADANI”

“BERKHIDMAT UNTUK NEGARA”

Sincerely,



ASSOC. PROF. DR. AZLAN HUSIN

Chairperson

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM
Universiti Sains Malaysia

Date of meeting : 23rd August 2023
Venue : Through WEBEX Application
Time : 9.00 a.m – 2.00 p.m
Meeting No : 605
Panel : Panel A

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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 (✓) present during review process	
Chairperson: Assoc. Prof. Dr. Azlan Husin	Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Chairperson)	
Deputy Chairperson: Dr. Noor Aman A. Hamid	Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Deputy Chairperson)	
Secretary: Mr. Mohd Bazlan Hafidz Mukrim	Senior Science Officer	M	✓	
Secretariat: Miss Siti Fatimah Ariffin	Research Officer	F	✓	
Members:				
1.	Prof. Dato' Dr. Jafri Malin Abdullah	Lecturer, School of Medical Sciences	M	✓
2.	Tuan Haji Mohamad Zahari Awang	Community Representatives	M	✓
3.	Prof. Dr. Nik Hazlina Nik Hussain	Lecturer, School of Medical Sciences	F	✓
4.	Assoc. Prof. Dr. Norsarwany Mohamad	Lecturer, School of Medical Sciences	F	✓
5.	Dr. Surianti Sukeri	Lecturer, School of Medical Sciences	F	✓
6.	Assoc. Prof. Dr. Garry Kuan Pei Ern	Lecturer, School of Health Sciences	M	✓
7.	Dr. Sharifah Zubaidiah Syed Jaapar	Lecturer, School of Medical Sciences	F	✓
8.	Prof. Dr. Tengku Muzaffar Tengku Shihabudin	Lecturer, School of Medical Sciences	M	✓
9.	Assoc. Prof. Dr. Nor Azwany Yaacob	Lecturer, School of Medical Sciences	F	✓
10.	Prof. Dr. Oleksandr Krasilshchikov	Scientific, Non-Institutional Member	M	✓
11.	Assoc. Prof. Dr. Rhendra Hardy Mohd Zaini	Lecturer, School of Medical Sciences	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.



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Chairperson
Jawatankuasa Etika Penyelidikan (Manusia), JEPeM
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