

30<sup>th</sup> November 2022

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**JEPeM Code : USM/JEPeM/22050315**

**Protocol Title : Randomized Control Trial on Efficacy and Safety of Oral Paracetamol versus Intravenous Paracetamol on Premature Neonates with Patent Ductus Arteriosus.**

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/22050315**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **30<sup>th</sup> November 2022** until **29<sup>th</sup> November 2023**.

Study Site: Hospital Universiti Sains Malaysia.

The following researchers are also involved in this study:

1. Dr. Mohd Rizal Mohd Zain
2. Prof. Dr. Hans Van Rostenberghe
3. Dr. Anis Munirah Mohd Kori
4. Assoc. Prof. Dr. Noraida Ramli
5. Dr. Nor Rosidah Ibrahim
6. 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. Patient Information Sheet and Consent Form (English version)
2. Patient Information Sheet and Consent Form (Malay version)
3. Data collection form (Proforma)

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](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,



**DR. NOOR AMAN A. HAMID**

Deputy Chairperson

Jawatankuasa Etika Penyelidikan (Manusia), JEPeM  
Universiti Sains Malaysia

Date of meeting : 27<sup>th</sup> July 2022  
Venue : Through WEBEX Application  
Time : 9.00 a.m – 2.00 p.m  
Meeting No : 553

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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	
<b>Deputy Chairperson:</b> Dr. Noor Aman A. Hamid	Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Deputy Chairperson)	
<b>Advisor:</b> Assoc. Prof. Siti Hawa Ali	Advisor of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	F	✓ (Advisor)	
<b>Secretary:</b> Mr. Mohd Bazlan Hafidz Mukrim	Senior Science Officer	M	✓	
<b>Secretariat:</b> Miss Siti Fatimah Ariffin	Research Officer	F	✓	
<b>Members :</b>				
1.	Assoc. Prof. Dr. Adibah Ibrahim	Lecturer, School of Medical Sciences	F	✓
2.	Assoc. Prof. Dr. Garry Kuan Pei Ern	Lecturer, School of Health Sciences	M	✓
3.	Dr. Juhaida Daud	Representative for Director of Hospital USM	F	✓
4.	Prof. Dr. Mohtar Ibrahim	Lecturer, School of Medical Sciences	M	✓
5.	Dr. Mujahid Bakar	Lecturer, School of Health Sciences	M	✓
6.	Mrs. Norleha Mohd Noor	Executive Secretary, Office of Director of Hospital USM	F	✓
7.	Dr. Saedah Ali	Scientific, Non-Institutional Member	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.



**DR. NOOR AMAN A. HAMID**  
Deputy Chairperson  
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