

18th September 2023

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JEPeM Code : USM/JEPeM/KK/23030212

Protocol Title: Perioperative Characteristics and Outcomes of Colorectal Cancer in Elderly Patients in a Tertiary Hospital in Malaysia.

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/23030212**, which should be used for all communications to JEPeM-USM in relation to this study. This ethical approval is valid from **18th September 2023** until **17th September 2024**.

Study Site: Hospital Universiti Sains Malaysia.

The following researchers are also involved in this study:

1. Prof. Dr. Andee Dzulkarnaen Zakaria

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

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”

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A U . PROF. DR. AZLAN HUSIN
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia