

USM Human Research Ethic Committee Approval



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

23rd March 2017

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JEPeM Code : USM/JEPeM/16120597

Protocol Title : Prevalence and Associated Factors of Positive Chest X-Ray during TB Screening among High Risk Groups in Kedah 2016.

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/16120597**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **23rd March 2017** until **22nd March 2018**.

Study Site: Selected Hospitals and Health Clinics in Kedah.

The following researchers also involve in this study:

1. Assoc. Prof. Dr. Wan Mohd Zahiruddin Wan Mohammad
2. Dr. Zahariyah Yaacob
3. Dr. Maimunah Jamaluddin
4. Mr. Khairul Nizam Ibrahim

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. Data Collection Sheet (Proforma)

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) 2015: 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) 2015: Study Protocol Amendment Submission Form**.
3. Revisions in the informed consent form using the **JEPeM-USM FORM 3(A) 2015: 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**.