



DR AHMAD HANIS BIN AHMAD SHUSHAMI
PEJABAT KESIHATAN DAERAH BARAT DAYA

HASLINDA BINTI SUMERY
PEJABAT KESIHATAN DAERAH BARAT DAYA

Dear Sir/ Mdm,

ETHICS INITIAL APPROVAL: NMRR-19-3044-50759 (IIR)
A RETROSPECTIVE CROSS-SECTIONAL STUDY ON FACTORS ASSOCIATED WITH POOR
PAP SMEAR QUALITY IN BARAT DAYA DISTRICT, PENANG

This letter is made in reference to the above matter.

2. The Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (MOH) has provided ethical approval for this study. Please take note that all records and data are to be kept strictly **CONFIDENTIAL** and can only be used for the purpose of this study. All precautions are to be taken to maintain data confidentiality. Permission from the District Health Officer / Hospital Administrator / Hospital Director and all relevant heads of departments / units where the study will be carried out must be obtained prior to the study. You are required to follow and comply with their decision and all other relevant regulations, including the Access to Biological and Benefit Sharing Act 2017.

3. The investigators and study sites involved in this study are:

KLINIK KESIHATAN BAYAN BARU

Dr Ahmad Hanis bin Ahmad Shushami (Principal Investigator)
Haslinda Binti Sumery (Principal Investigator)

KLINIK KESIHATAN BAYAN LEPAS

Dr Ahmad Hanis bin Ahmad Shushami (Principal Investigator)
Haslinda Binti Sumery (Principal Investigator)

Klinik Kesihatan Ibu Dan Anak Ayer Puteh

Dr Ahmad Hanis bin Ahmad Shushami (Principal Investigator)
Haslinda Binti Sumery (Principal Investigator)

KLINIK KESIHATAN TELUK BAHANG

Dr Ahmad Hanis bin Ahmad Shushami (Principal Investigator)
Haslinda Binti Sumery (Principal Investigator)

4. The following study documents have been received and reviewed with reference to the above study:

Documents received and reviewed with reference to the above study:

1. Study Protocol_Version 1.0, dated 01-November-2019
2. Data Collection Form_Version 1, dated 01-November-2019

3. Investigator's documents : Declaration of Conflict of Interest (COI), IA-HOD-IA, and CV:
- a) Dr Ahmad Hanis bin Ahmad Shushami (Principal Investigator)
 - b) HASLINDA BINTI SUMERY (Principal Investigator)

5. Please note that ethical approval is valid until **05-December-2020**. The following are to be reported upon receiving ethical approval. Required forms can be obtained from the Medical Research Ethics Committee (MREC) website (<http://www.nih.gov.my/mrec>).
- i. **Continuing Review Form** has to be submitted to MREC within 2 month (60 days) prior to the expiry of ethical approval.
 - ii. **Study Final Report** upon study completion to the MREC.
 - iii. Ethical approval is required in the case of **amendments / changes** to the **study documents/ study sites/ study team**. MREC reserves the right to withdraw ethical approval if changes to study documents are not completely declared.
6. This study involves the following methods:
- i. **Retrospective**
 - ii. **Secondary data**
7. Please take note that the reference number for this letter must be stated in all correspondence related to this study to facilitate the process.

Comments (if any): **NIL**

Project Sites:

KLINIK KESIHATAN BAYAN BARU
KLINIK KESIHATAN BAYAN LEPAS
KLINIK KESIHATAN IBU DAN ANAK AYER PUTEH
KLINIK KESIHATAN TELUK BAHANG

Decision by Medical Research & Ethics Committee:

- (☒) Approved
(☐) Disapproved

Date of Approval : 06-December-2019



DR HJH SALINA ABDUL AZIZ
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia
MMC No: 27117

s.k. HRRC Hospital Pulau Pinang