



**JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(MEDICAL RESEARCH & ETHICS COMMITTEE)**

**KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA**

Kompleks Institut Kesihatan Negara (NIH)
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Tel.: +(6)03-33628888/ 33628205

Ruj.Kami/ Ref.: **23-02155-HJV**

Tarikh/ Date : **25-09-2023**

**LEELAVATHI A/P MUTHUPALANIAPPEN
UNIVERSITI KEBANGSAAN MALAYSIA (UKM)**

Dato'/ Dr/ Tuan/ Puan,

SURAT KELULUSAN ETIKA/ LETTER OF ETHICAL APPROVAL:

NMRR ID-23-02155-HJV (IIR)

**EFFECTIVENESS OF THE PAUSE© FLIPCHART COMPARED TO CONVENTIONAL METHOD OF
PREMARITAL HIV COUNSELLING: A RANDOMIZED CONTROL STUDY**

Dengan hormatnya perkara di atas adalah dirujuk.

This letter is made in reference to the matter above.

2. Bersama dengan surat ini dilampirkan surat kelulusan saintifik dan etika bagi projek ini. Segala rekod dan data subjek adalah SULIT dan hanya digunakan untuk tujuan kajian dan semua isu serta prosedur mengenai *data confidentiality* mesti dipatuhi. Kebenaran daripada Pengarah Hospital / Institusi di mana kajian akan dijalankan mesti diperolehi terlebih dahulu sebelum kajian dijalankan. Dato'/ Tuan/ Puan perlu akur dan mematuhi keputusan tersebut dan undang-undang lain yang berkaitan.

*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 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.*

3. Penyelidik- penyelidik dan lokasi penyelidikan yang terlibat ialah:

The investigators and sites involved in this study are:

Klinik Kesihatan Sultan Ismail

Leelavathi A/P Muthupalaniappen (Penyelidik Utama/ *Principal Investigator*)

Klinik Kesihatan Bukit Indah

Leelavathi A/P Muthupalaniappen (Penyelidik Utama/ *Principal Investigator*)

Klinik Kesihatan Mahmoodiah

Magaletchumi A/P Chelladorai

Klinik Kesihatan Larkin

Magaletchumi A/P Chelladorai

Klinik Kesihatan Kampung Majidee

Magaletchumi A/P Chelladorai

Klinik Kesihatan Ulu Tiram

Aznida Firzah Abdul Aziz

Klinik Kesihatan Tampoi

Aznida Firzah Abdul Aziz

Klinik Kesihatan Taman Universiti

Aznida Firzah Abdul Aziz

4. Dokumen- dokumen kajian berikut telah diterima dan disemak dengan merujuk kepada kajian di atas:

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

Senarai dokumen yang diterima dan disemak/ *List of documents received and reviewed:*

1. Surat iringan kepada JEPP
Cover letter to MREC
(Versi/ *Version 3*, bertarikh/ *dated 12-09-2023*)
2. Pengisytiharan Konflik Kepentingan
Declaration of Conflict of Interest (COI)
(Versi/ *Version 1*, bertarikh/ *dated 03-07-2023*)
3. Protokol
Protocol
(Versi/ *Version 3*, bertarikh/ *dated 10-09-2023*)
4. Lembaran maklumat pesakit & borang persetujuan
Participant information sheet & informed consent form
Versi Bahasa Melayu/ *Malay version (Versi/ Version 3*, bertarikh/ *dated 10-09-2023*)
5. Borang pengumpulan data
Data collection form
(Versi/ *Version 1*, bertarikh/ *dated 04-07-2023*)
6. Borang soal selidik
Questionnaire
(Versi/ *Version 1*, bertarikh/ *dated 03-07-2023*)
7. Carta Gantt
Gantt Chart
(Versi/ *Version 1*, bertarikh/ *dated 03-07-2023*)
8. Borang IA-HOD-IA, *Curriculum Vitae (CV)* dan sijil *Good Clinical Practice (GCP)*
IA-HOD-IA form, Curriculum Vitae (CV) and Good Clinical Practice (GCP) certificate of:
 - Leelavathi A/P Muthupalaniappen
 - Aznida Firzah Abdul Aziz
9. Borang IA-HOD-IA dan *Curriculum Vitae (CV)*
IA-HOD-IA form, Curriculum Vitae (CV) of:
 - Magaletchumi A/P Chelladorai

5. Adalah dimaklumkan bahawa kelulusan ini adalah sah sehingga **24-09-2024**. Tuan/ Puan perlu menghantar dokumen-dokumen seperti berikut selepas mendapat kelulusan etika. Borang-borang berkaitan boleh dimuat turun daripada laman web *National Medical Research Registry (NMRR)*.

*Please note that the approval is valid until **24-09-2024**. The following are to be reported upon receiving ethical approval. Required forms can be obtained from the National Medical Research Registry (NMRR) website.*

- i. **Continuing Review Form** harus dihantar kepada JEPP selewat-lewatnya dalam tempoh 2 bulan (60 hari) sebelum tamat tempoh kelulusan ini bagi memperbaharui kelulusan etika.

Continuing Review Form has to be submitted to MREC within 2 months (60 days) prior to the expiry of ethical approval.

- ii. **Study Final Report (Closure Notification)** harus dihantar kepada JEPP pada penghujung kajian.

Study Final Report (Closure Notification) has to be submitted to MREC upon study completion.

- iii. Mendapat kelulusan etika sekiranya terdapat **pindaan ke atas sebarang dokumen kajian/ lokasi kajian/ penyelidik**. Pihak JEPP mempunyai hak untuk menarik balik kelulusan etika sekiranya terdapat perubahan dokumen kajian yang tidak diisytiharkan.

*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.*

- iv. **Kajian berkenaan intervensi klinikal sahaja**: Laporan mengenai **all Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSARs)** dan **Protocol Deviation/Violation** di lokasi kajian yang diluluskan oleh JEPP jika berkenaan. SAE perlu dilaporkan dalam tempoh 15 hari kalender dari kesedaran kejadian (*awareness of event*) oleh penyelidik. Laporan awal SUSAR perlu dikemukakan seawal mungkin tapi tidak melewati 7 hari calendar dari kesedaran kejadian oleh penyelidik, disusuli dengan laporan lengkap dalam tempoh tambahan 8 hari kalender.

*Applicable for Clinical interventional Studies only: Report occurrences of **all Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSARs)** and **Protocol Deviation/Violation** at all MREC approved sites to MREC. SAEs are to be reported within 15 calendar days from awareness of event by investigator. Initial report of SUSARs are to be reported as soon as possible but not later than 7 calendar days from awareness of event by investigator, followed by a complete report within 8 additional calendar days.*

6. Bilangan **subjek/ pesakit/ responden** yang akan terlibat dalam kajian ini di Malaysia adalah seramai **180 orang**.

*There will be **180 subjects/ patients/ respondents** involved in this study within Malaysia.*

7. Sila ambil maklum bahawa sebarang urusan surat-menyurat berkaitan dengan penyelidikan ini haruslah dinyatakan nombor rujukan surat ini untuk melicinkan urusan yang berkaitan.

Please take note that the reference number of this letter must be stated in all future correspondence related to this study to facilitate the administrative processes.

8. Jawatankuasa Etika & Penyelidikan Perubatan, Kementerian Kesihatan Malaysia, beroperasi mengikut *Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)*. Mana-mana ahli JEPP yang terlibat dalam kajian/ projek yang dinilai tidak akan mengambil bahagian dalam kelulusan kajian/ projek.

The Medical Research & Ethics Committee, Ministry of Health Malaysia, operates in accordance to the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). Any member of the MREC who is involved in the study/ project under review will not participate in the approval of the study/ project.

Lokasi kajian/ *Project Sites*:

KLINIK KESIHATAN MAHMOODIAH
KLINIK KESIHATAN LARKIN
KLINIK KESIHATAN BUKIT INDAH
KLINIK KESIHATAN KAMPUNG MAJIDEE
KLINIK KESIHATAN SULTAN ISMAIL
KLINIK KESIHATAN ULU TIRAM
KLINIK KESIHATAN TAMPOI
KLINIK KESIHATAN TAMAN UNIVERSITI

Keputusan Jawatankuasa Etika & Penyelidikan Perubatan/
Decision by Medical Research & Ethics Committee:

() Lulus/ *Approved*

() Tidak lulus/ *Disapproved*

Tarikh Kelulusan Etika/ *Date of Ethical Approval*: **25-09-2023**

Sekian terima kasih.
Thank you.

"MALAYSIA MADANI"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,
I who carry out the trust,



.....
DR. NURAIN BINTI MOHD NOOR

Pengerusi/ *Chairperson*

Jawatankuasa Etika & Penyelidikan Perubatan/ *Medical Research & Ethics Committee*

Kementerian Kesihatan Malaysia/ *Ministry of Health Malaysia*

(No. MPM/ MMC No: 31576)