JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(Medical Research & Ethics Committee)
KEMENTERIAN KESIHATAN MALAYSIA
d/a Institut Pengurusan Kesihatan
Jalan Rumah Sakit, Bangsar
59000 Kuala Lumpur

Tel.: 03-2287 4032/2282 0491/2282 9085
03-2282 9082/2282 1402/2282 1449
Faks: 03-2282 0015

Ruj.Kami : KKM/NIHSEC/P18-1307(11)
Tarikh : **21-Ogos-2018**

DR MUHAMMAD ZAHID IQBAL
ASIAN INSTITUTE OF MEDICINE, SCIENCE & TECHNOLOGY (AIMST) UNIVERSITY

Dato'/ Dr/ Tuan/ Puan,

SURAT KELULUSAN ETIKA:

NMRR-17-2381-38042 (IIR)
NO. PROTOKOL : N/A
EFFECT OF PHARMACIST INVOLVEMENT IN DIABETES MEDICATION THERAPY ADHERENCE PROGRAM (DMTAC) ON THE CLINICAL OUTCOMES, QUALITY OF LIFE, COST OF TREATMENT AND PROGRESSION OF DIABETIC COMPLICATIONS OF DIABETES IN DIFFERENT HOSPITALS OF MALAYSIA

Dengan hormatnya perkara di atas adalah dirujuk.

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 termasuk Akta Akses kepada Sumber Biologi dan Perkongsian Faedah 2017.

3. Penyelidik- penyelidik yang terlibat ialah:

Hospital Sultan Abdul Halim, Sungai Petani
Dr Muhammad Zahid Iqbal (Penyelidik Utama)

Hospital Pulau Pinang
Dr. Amer Hayat Khan

Hospital Sultanah Bahiyah, Alor Setar
Dr. Amer Hayat Khan

4. Adalah dimaklumkan bahawa kelulusan ini adalah sah sehingga **20-Ogos-2019**. Tuan/Puan perlu menghantar dokumen-dokumen seperti berikut selepas mendapat kelulusan etika. Borang-borang berkaitan boleh dimuat turun daripada laman web Jawatakuasa Etika & Penyelidikan Perubatan (JEPP) (http://www.nih.gov.my/mrec).

i. ***Continuing Review Form*** selewat-lewatnya dalam tempoh 1 bulan (30 hari) sebelum tamat tempoh kelulusan ini bagi memperbaharui kelulusan etika.
ii. ***Study Final Report*** pada penghujung kajian.
iii. Mendapat kelulusan etika sekiranya terdapat pindaan ke atas sebarang dokumen kajian/ lokasi kajian/ penyelidik.
iv. Kajian berkenaan intervensi klinikal sahaja: Laporan mengenai ***all Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSARs)*** dan ***Protocol***

.../2-

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.

5. Bilangan subjek/ pesakit/ responden yang disasarkan untuk menyertai kajian ini di Malaysia adalah **600 orang**.

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

Sekian terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

.....
DR. HJH SALINA BINTI ABDUL AZIZ
Pengerusi
Jawatankuasa Etika & Penyelidikan Perubatan
Kementerian Kesihatan Malaysia
E-mel: mrecsec@nih.gov.my

s.k:

HRRC Hospital Pulau Pinang

HRRC Hospital Sultan Abdul Halim

HRRC Hospital Sultanah Bahiyah

JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(Medical Research & Ethics Committee)
KEMENTERIAN KESIHATAN MALAYSIA
d/a Institut Pengurusan Kesihatan
Jalan Rumah Sakit, Bangsar
59000 Kuala Lumpur

Tel.: 03-2287 4032/2282 0491/2282 9085
03-2282 9082/2282 1402/2282 1449
Faks: 03-2282 0015

Ref:KKM/NIHSEC/P18-1307(12)
Date: **21-August-2018**

DR MUHAMMAD ZAHID IQBAL
ASIAN INSTITUTE OF MEDICINE, SCIENCE & TECHNOLOGY (AIMST) UNIVERSITY

Dear Dato'/ Dr/ Sir/ Madam,

ETHICS INITIAL APPROVAL:

NMRR-17-2381-38042 (IIR)
PROTOCOL NO. : N/A
EFFECT OF PHARMACIST INVOLVEMENT IN DIABETES MEDICATION THERAPY ADHERENCE PROGRAM (DMTAC) ON THE CLINICAL OUTCOMES, QUALITY OF LIFE, COST OF TREATMENT AND PROGRESSION OF DIABETIC COMPLICATIONS OF DIABETES IN DIFFERENT HOSPITALS OF MALAYSIA

This letter is made in reference to the matter above.

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 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 the Biological and Benefit Sharing Act 2017.

3. The investigators involved in this study are:

Hospital Sultan Abdul Halim, Sungai Petani
Dr Muhammad Zahid Iqbal (Principal / Coordinating Investigator)

Hospital Pulau Pinang
Dr. Amer Hayat Khan

Hospital Sultanah Bahiyah, Alor Setar
Dr. Amer Hayat Khan

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. Cover letter to MREC (Version DC2018.11, dated 21-08-2018)
2. Declaration of Conflict of Interest (COI) (Version DC2017.00, dated 03-10-2017)
3. Protocol (Version DC2018.03, dated 20-08-2018)
4. Patient Information Sheet (Version DC2018.04, dated 20-08-2018)
5. Informed Consent Form (Version DC2018.04, dated 20-08-2018)

.../2-

6. Questionnaire (Version DC2017.00, dated 23-10-2017)
7. Data Collection Form (Version DC2018.05, dated 12-06-2018)
8. Follow-up Review Report (Version DC2018.09, dated 20-08-2018)
9. IA-HOD-IA, CV and GCP Certification of:
    - Dr. Amer Hayat Khan
10. IA-HOD-IA and CV of:
    - Dr Muhammad Zahid Iqbal

5. Please note that the approval is valid until **20-August-2019**.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 1 month (30 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**.
iv. **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. There will be **600** subjects/ patients/ respondents targeted to be enrolled in this study within Malaysia.

7. 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.

Project Sites:
HOSPITAL PULAU PINANG
HOSPITAL SULTAN ABDUL HALIM, SUNGAI PETANI
HOSPITAL SULTANAH BAHIYAH, ALOR SETAR

Decision by Medical Research & Ethics Committee:
(√) Approved
( ) Disapproved

Date of Approval : **21-August-2018**

.....
DR. HJH SALINA BINTI ABDUL AZIZ
Chairperson
Medical Research Ethics Committee
Ministry of Health Malaysia
E-mel: mrecsec@nih.gov.my

c.c:

HRRC Hospital Pulau Pinang

HRRC Hospital Sultan Abdul Halim

HRRC Hospital Sultanah Bahiyah