



**JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN**

**(Medical Research & Ethics Committee)**

**KEMENTERIAN KESIHATAN MALAYSIA**

d/a Kompleks Institut Kesihatan Negara  
Blok A, No 1, Jalan Setia Murni U13/52,  
Seksyen U13, Bandar Setia Alam,  
40170 Shah Alam, Selangor.



Tel: 03-3362 8888/8205

Ruj.Kami:( 18 )KKM/NIHSEC/ P19-488

Tarikh: 30-September-2019

**Associate Professor Dr Yeong Chai Hong**  
**Taylor's University**

**Professor NORLISAH MOHD. RAMLI**  
**UNIVERSITY MALAYA MEDICAL CENTRE (UMMC)**

Dato'/ Tuan/ Puan,

**SURAT KELULUSAN ETIKA:**

**NMRR-19-379-46101 (ISR)**

**No Protokol : Exec B 1.1**

**Effect of High-Dose-Vitamin-B Multivitamin Supplement on Neural Connectivity and Oxidative Metabolism in Healthy Adults: A Randomised, Double-Blind, Placebo-Controlled, Phase II Clinical Trial**

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 dan lokasi kajian yang terlibat ialah:

Taylor's University

Associate Professor Dr Yeong Chai Hong (Penyelidik Utama)

Assoc. Prof Karuthan Chinna

Dr Wong Yin How

Dr. Anjan Kumar Das

Mr. Selvaraja a/l S Seerangam

Prof. Dr. Rusli bin Nordin

UNIVERSITY MALAYA MEDICAL CENTRE (UMMC)

Professor NORLISAH MOHD. RAMLI (Penyelidik Utama)

Dr Azlan bin Che Ahmad

Dr Tan Li Kuo

4. Adalah dimaklumkan bahawa kelulusan ini adalah sah sehingga **29-September-2020**. Tuan/Puan perlu menghantar dokumen-dokumen seperti berikut selepas mendapat kelulusan etika. Borang-borang berkaitan boleh dimuat turun daripada laman web Jawatankuasa Etika & Penyelidikan Perubatan (JEPP) (<http://www.nih.gov.my/mrec>).

- i. **Continuing Review Form** selewat-lewatnya dalam tempoh 2 bulan (60 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. Pihak JEPP mempunyai hak untuk menarik balik kelulusan etika sekiranya terdapat perubahan dokumen kajian yang tidak diisytiharkan.
  - 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.
5. Bilangan subjek yang disasarkan untuk menyertai kajian ini di Malaysia adalah **90 orang**.

Komen (jika ada) : Untuk mendapatkan kelulusan NPRA sebelum subject recruitment

Lokasi Kajian:

**Taylor's University**  
**UNIVERSITY MALAYA MEDICAL CENTRE (UMMC)**

Keputusan Jawatankuasa Etika dan Penyelidikan Perubatan:

(  ) Lulus

(  ) Tidak Lulus

Tarikh kelulusan : **30-September-2019**

Sekian terima kasih.

**BERKHIDMAT UNTUK NEGARA**

Saya yang menandatangani amanah,



.....  
**DR HJH SALINA ABDUL AZIZ**

Pengerusi

Jawatankuasa Etika & Penyelidikan Perubatan

Kementerian Kesihatan Malaysia

No. MPM: 27117



Ruj.Kami:( 19 )KKM/NIHSEC/ P19-488  
Tarikh: 30-September-2019

**Associate Professor Dr Yeong Chai Hong**  
**Taylor's University**

**Professor NORLISAH MOHD. RAMLI**  
**UNIVERSITY MALAYA MEDICAL CENTRE (UMMC)**

Dear Sir/ Mdm,

**ETHICS INITIAL APPROVAL:**

**NMRR-19-379-46101 (ISR)**

**Protocol No: Exec B 1.1**

**Effect of High-Dose-Vitamin-B Multivitamin Supplement on Neural Connectivity and Oxidative Metabolism in Healthy Adults: A Randomised, Double-Blind, Placebo-Controlled, Phase II Clinical Trial**

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 the Biological Resources and Benefit Sharing Act 2017.

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

Taylor's University

Associate Professor Dr Yeong Chai Hong (Penyelidik Utama)  
Assoc. Prof Karuthan Chinna  
Dr Wong Yin How  
Dr. Anjan Kumar Das  
Mr. Selvaraja a/l S Seerangam  
Prof. Dr. Rusli bin Nordin

UNIVERSITY MALAYA MEDICAL CENTRE (UMMC)

Professor NORLISAH MOHD. RAMLI (Penyelidik Utama)  
Dr Azlan bin Che Ahmad  
Dr Tan Li Kuo

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 1.2
- 2 Investigator's Brochure - Version 1.1
- 3 Patient Information Sheet (English) & Informed Consent Form (English) - Version 1.2
- 4 Patient Information Sheet Review Checklist – Version 1.1
- 5 Patient Information Sheet (BM) & Informed Consent Form (BM) – Version 1.2
- 6 Study Clinical Report Form (CRF) – Version 1.2
- 7 Advertisement for Subject Recruitment – Version 1.0
- 8 Trial Insurance Certificate (expired in December 2019)
- 9 Research Agreement / Clinical Trial Agreement (CTA) – Version 1.0
- 10 Investigators Documents: IA-HOD-IA form, CVs, GCPs and Conflict of Interest Declaration Form:

Taylor's University

Associate Professor Dr Yeong Chai Hong (Penyelidik Utama)  
Assoc. Prof Karuthan Chinna  
Dr Wong Yin How  
Dr. Anjan Kumar Das  
Mr. Selvaraja a/l S Seerangam  
Prof. Dr. Rusli bin Nordin

UNIVERSITY MALAYA MEDICAL CENTRE (UMMC)

Professor NORLISAH MOHD. RAMLI (Penyelidik Utama)  
Dr Azlan bin Che Ahmad  
Dr Tan Li Kuo

5. Please note that the approval is valid until **29-September-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 months (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.
  - 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. Total of **90 subjects** are targeted to enroll this study in Malaysia.
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): To obtain NPRA approval prior to subject recruitment

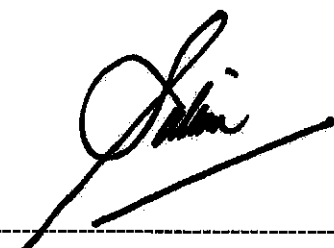
Project Sites:

*Taylor's University*  
UNIVERSITY MALAYA MEDICAL CENTRE (UMMC)

Decision by Medical Research & Ethics Committee:

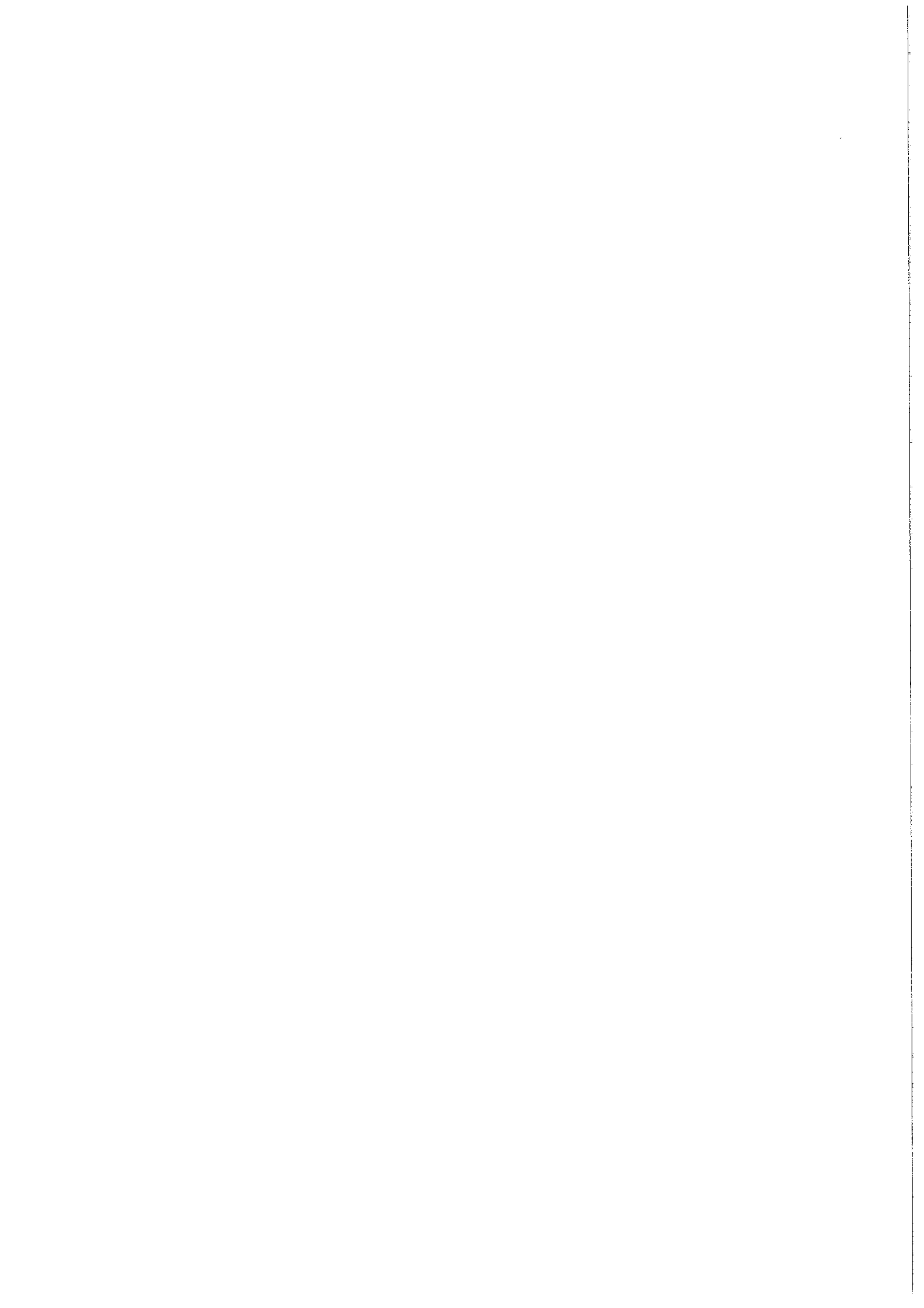
- Approved  
 Disapproved

Date of Approval : **30-September-2019**



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**DR HJH SALINA ABDUL AZIZ**  
Chairperson  
Medical Research & Ethics Committee (MREC)  
Ministry of Health  
MMC No.:27117



**MEMBERS OF THE MEDICAL RESEARCH & ETHICS COMMITTEE WHO  
ATTENDED THE MEETING ON 14<sup>th</sup> May 2019**

No	NAME	GENDER	EXPERTISE	DESIGNATION/ AFFILIATION	ROLES	TICK (✓) IF PRESENT
1	<b><u>MREC Chairperson</u></b> Dr. Salina binti Abdul Aziz	F	Psychiatry & Clinical Epidemiology	Hospital Kuala Lumpur	Medical member	✓
2	<b><u>Deputy Chairperson</u></b> Datin Dr Noriah bt Bidin	F	Public Health	Institute of Health Management	Medical member	X
3	<b><u>MREC Secretary</u></b> Dr Lee Keng Yee	F	Bioethics/ Epidemiology	Clinical Research Centre	Secretary	✓
4	Dato' Dr Ong Loke Meng	M	Nephrology	Head, Clinical Research Centre, Hospital Pulau Pinang	Medical member	✓
5	Dr Goh Pik Pin	F	Ophthalmology	Director, Network of Clinical Research Centre	Medical member	✓
6	Dr Sondi Sararaks	F	Public Health	Institute for Health System Research (MOH)	Medical member	✓
7	Dr Hung Liang Choo	F	Paediatric Cardiology	Dept of Paediatrics Institute of Paediatrics, Hospital Kuala Lumpur	Medical member	X
8	Dr Peter Gan Kim Soon	M	Law and Ethics	Hospital Ampuan Afzan, Kuantan	Medical member	✓
9	Dr Norharlina Bahar	F	Psychiatry	Dept. of Psychiatry, Selayang Hospital	Medical member	X
10	Dr Kalaiarasu M. Peariasamy	M	Dental	CRC, Sg Buloh Hospital	Medical member	✓

No	NAME	GENDER	EXPERTISE	DESIGNATION/ AFFILIATION	ROLES	TICK (✓) IF PRESENT
11	Dr Leong Huey Yin	F	Medical Member	Hospital Kuala Lumpur	Clinical genetics & Paediatrics	✓
12	Dr Ho Tze Ming	M	Senior Researcher (Acarology)	Retired	Scientific member	X
13	Ms Shahidah bt Mohamed Makki	F	Clinical Psychology	Dept of Psychiatry and Mental Health Kuala Lumpur Hospital	Scientific member	X
14	Chew Chun Keat	M	Pharmacy	Clinical Research Centre, Ampang Hospital	Scientific member	✓
15	Pn Ching Shan Lii	F	Pharmacy	Dept. of Pharmacy,	Scientific member	X
16	Dr Murizal Zainol	M	Molecular Pathology & Toxicology	Institute for Medical Research	Scientific member	✓
17	Ms Komathi Perialathan	F	Health Education	Institute of Health Systems Research	Scientific member	X
18	Pn Teo Jau Shya	F	Clinical Data Management	ClinData Consult Sdn Bhd	Scientific member	X
19	Pn Ooi Phak Hong	F	Layperson	-	Non-medical Non Scientific member	X
20	Pn Ong Mei Ching	F	Layperson	MaxStation Malaysia Sdn Bhd	Non-medical Non Scientific member	✓
21	Ms Tan Yi Wan	F	Layperson	-	Non-medical Non Scientific member	X
22	Mr Yong Yoke Choon	M	Layperson	Max Family Society	Non-medical Non	✓



No	NAME	GENDER	EXPERTISE	DESIGNATION/ AFFILIATION	ROLES	TICK (✓) IF PRESENT
					Scientific member	
23	Ms Juliyana Junaidi	F	Layperson	IDRISSI International School	Non-medical Non Scientific member	✓
24	Dr Goh Cheng Soon	F	Traditional and complementary medicine	Traditional and complementary medicine Division, Ministry of Health	Medical member	✓
25	Dr Asyraf Syahmi Bin Mohd Noor	M	Medical officer	Secretariat of the National Institutes of Health	Secretariat of MREC	✓
26	Halimah Mustafa	F	-	CRM	Secretariat of MREC	✓
27	En Nicholas Leow Chun Wei	M	Pharmacy	National Pharmaceutical Regulatory Agency	Independent Expert (Non-voting member)	X

The MREC is constituted in compliance with ICH GCP and local regulatory requirements. Any member of the MREC who is involved in the study / project under review will not participate in the approval of the study / project

