



**JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(MEDICAL RESEARCH & ETHICS COMMITTEE)
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA**
Kompleks Institut Kesihatan Negara (NIH)
No.1, Jalan Setia Murni U13/52,
Seksyen U13 Bandar Setia Alam,
40170 Shah Alam, Selangor.

Tel: 03-3362 8398/8399/8404/8408

Ref : 22-01199-TGT
Date : 23-February-2024

**LAW ZHE KANG
PUSAT PERUBATAN UNIVERSITI KEBANGSAAN MALAYSIA (PPUKM)**

Dear Dato'/ Dr. / Mr/ Miss,

**AMENDMENTS FOR STUDY: NMRR ID 22-01199-TGT (IIR)
Protocol No : 1.0
Tranexamic acid for hyperacute spontaneous IntraCerebral Haemorrhage (TICH-3)**

Your amendment submission date **19-02-2024** is referred.

2. Amendments of the following have been received and reviewed with reference to the above study:

Documents received and reviewed with reference to the above study:

1. Declaration of Conflict of Interest (COI form)_version_3 16-Feb-2024\
2. Research Protocol_version_2.0 07-Oct-2022
3. Change of Principal Investigator at Hospital Sultanah Bahiyah to:
 - a. Dr Muhammad Yasin
4. Addition of new co/sub-investigator:
 - a. Dr Hor Khai Yng - study site Hospital Sultanah Bahiyah, Alor Setar Kedah
 - b. Dr Ng Yong Kai - study site Hospital Sultanah Bahiyah, Alor Setar Kedah
 - c. Dr Hardawani binti Mohd Hussain - study site Hospital Sultanah Bahiyah, Alor Setar Kedah
 - d. Dr Sharifah Ummu A'idah Syed Hamid - study site Hospital Kuala Lumpur
 - e. Dr Nadiyah Ahmad Fuad - study site Hospital Kuala Lumpur
 - f. Dr Lim Mei Sin - study site Hospital Kuala Lumpur
 - g. Dr Lee King Peng - study site Hospital Kuala Lumpur

The Medical Research & Ethics Committee, Ministry of Health Malaysia operates in accordance to the International Council for Harmonization of Technical Requirement for Pharmaceutical for Human Use (ICH) and Malaysia Guideline for Good Clinical Practice

Decision by Medical Research & Ethics Committee:

- () Approved via Expedited Review by MREC Chairperson/ Deputy Chairperson/ Secretary
() Disapproved

Date of Decision: 23-February-2024

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DR NURAIN BINTI MOHD NOOR
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia