



**UNIVERSITI
MALAYA**

**MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTRE**

ADDRESS: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE: 03-79493209 FAXIMILE: 03-79494638

PUSAT PERUBATAN UM

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|--|---|
| NAME OF ETHICS COMMITTEE/IRB: Medical Ethics Committee, University Malaya Medical Centre | ETHICS COMMITTEE/IRB REFERENCE NUMBER: 938.10 |
| ADDRESS: LEMBAH PANTAI 59100 KUALA LUMPUR | |
| PROTOCOL NO: | |
| TITLE: Comparison of split- dose versus whole- dose reduced volume Polyethylene Glycol Electrolyte Lavage Solution (PEG-ELS) for bowel preparation in adult patients undergoing colonoscopy | |
| PRINCIPAL INVESTIGATOR: Dr. Chan Wah Kheong | SPONSOR: |
| TELEPHONE: | KOMTEL: |

The following item [✓] have been received and reviewed in connection with the above study to be conducted by the above investigator.

- | | |
|--|---------------------|
| <input checked="" type="checkbox"/> Application Form | Ver date: 04 Jul 12 |
| <input checked="" type="checkbox"/> Study Protocol | Ver date: |
| <input type="checkbox"/> Investigator Brochure | Ver date: |
| <input type="checkbox"/> Patient Information Sheet | |
| <input type="checkbox"/> Consent Form | |
| <input type="checkbox"/> Questionnaire | |
| <input checked="" type="checkbox"/> Investigator(s) CV's (Dr. Chan Wah Kheong) | |

and have been [✓]

- Approved
 Conditionally approved (identify item and specify modification below or in accompanying letter)
 Rejected (identify item and specify reasons below or in accompanying letter)

Comments:

Investigator are required to:

- 1) follow instructions, guidelines and requirements of the Medical Ethics Committee.*
- 2) report any protocol deviations/violations to Medical Ethics Committee.*
- 3) provide annual and closure report to the Medical Ethics Committee.*
- 4) comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.*
- 5) note that Medical Ethics Committee may audit the approved study.*

Date of approval: 15th AUGUST 2012

Head
Department of Medicine

Deputy Dean (Research)
Faculty of Medicine

Secretary
Medical Ethics Committee
University Malaya Medical Centre

PROF. KULENTHRAN ARUMUGAM
Deputy Chairman
Medical Ethics Committee

MEDICAL ETHICS COMMITTEE COMPOSITION, UNIVERSITY MALAYA MEDICAL CENTRE
Date: 15th AUGUST 2012

| Member (Title and Name) | Occupation (Designation) | Male/Female (M/F) | Tick (✓) if present when above items were reviewed |
|---|--|----------------------|---|
| Chairperson: Y. Bhg. Prof. Datuk Looi Lai Meng | Senior Consultant Department of Pathology | Female | |
| Deputy Chairperson: Prof. Kulenthiran Arumugam | Senior Consultant Medical Education Research and Development Unit (MERDU) | Male | ✓ |
| Secretary (non-voting): Cik Norashikin Mahmood | Scientific Officer Department of Quality | Female | ✓ |
| Members: 1. Y. Bhg. Prof. Dato' Patrick Tan Seow Koon | Deputy Director (Professional) University Malaya Medical Centre | Male | |
| 2. Y. Bhg. Prof. Datin Zahurin Mohamed | Head Department of Pharmacology | Female | ✓ |
| 3. Prof. Tan Chong Tin | Representative of Head Department of Medicine | Male | ✓ |
| 4. Assoc. Prof. Jesjeet Singh Gill | Representative of Head Department of Psychological Medicine | Male | ✓ |
| 5. Assoc. Prof. Alizan Abdul Khalil | Head Department of Surgery | Male | |
| 6. Tuan Haji Amrahi Buang | Chief Pharmacist Pharmacy Centre University Malaya Medical Centre | Male | ✓ |
| 7. Y. Bhg. Assoc. Prof. Datin Grace Xavier | Representative of Dean (Research Fellow) Faculty of Law University Malaya | Female | ✓ |
| 8. Y. Bhg. Datin Aminah bt. Pit Abdul Rahman | Public Representative | Female | ✓ |
| 9. Madam Ong Eng Lee | Public Representative | Female | ✓ |

Comments: The MEC of University Malaya Medical Centre is operating according to ICH-GCP guidelines and the Declaration of Helsinki. Member's no. 7, 8 & 9 are representatives from Faculty of Law in the University Malaya and the public. They are independent of the hospital or trial site.



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PROF. KULENTHRAN ARUMUGAM
Deputy Chairman
Medical Ethics Committee