



UNIVERSITI
MALAYA

PUSAT PERUBATAN UM

**MEDICAL ETHICS COMMITTEE
UNIVERSITY MALAYA MEDICAL CENTRE**

ADDRESS: LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA
TELEPHONE: 03-79493209 / 2251 FAXIMILE: 03-79492030

NAME OF ETHICS COMMITTEE/IRB: Medical Ethics Committee, University Malaya Medical Centre		ETHICS COMMITTEE/IRB REFERENCE NUMBER: 975.7
ADDRESS: LEMBAH PANTAI 59100 KUALA LUMPUR		
PROTOCOL NO (if applicable):		VERSION NO.:
TITLE: Investigation of the role of the intestinal microflora in the aetiology of inflammatory bowel disease and the impact of helicobacter pylori status		
PRINCIPAL INVESTIGATOR: Prof. Lee Way Seah		SPONSOR: MOHE HIR

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

- [✓] Application to Conduct Research Project (form)
- [✓] Study Protocol
- [] Investigator Brochure
- [✓] Patient Information Sheet
- [✓] Consent Form Version 2
- [] Questionnaire
- [✓] Investigator's CV (Prof. Lee Way Seah)

Ver date: 21 Feb 13

Ver date:

Ver date:

Ver date:

Ver date: 13 Apr 12

Ver date:

and the decision is [✓] :

- [✓] Approved
- [] Modification requested (item specified below or in accompanying letter)
- [] Rejected (reasons specified 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 reports to the Medical Ethics Committee.
- 4) comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and the Declaration of Helsinki.
- 5) obtain permission from the Director of UMMC before starting research that involves recruitment of UMMC patients.
- 6) ensure that if the research is sponsored, the usage of consumable items and laboratory tests from UMMC services are not charged in the patient's hospital bills but are borne by the research grant.
- 7) note that he/she can appeal to the Chairman of MEC for studies that are rejected.
- 8) note that Medical Ethics Committee may audit the approved study.
- 9) ensure that the study does not take precedence over the safety of subjects.

Date of meeting: -

Date of approval: 07th MARCH 2013

c.c Head
Department of Paediatrics

Deputy Dean (Research)
Faculty of Medicine

Secretary
Medical Ethics Committee
University Malaya Medical Centre

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PROF. DATUK LOOI LAI MENG
Chairman
Medical Ethics Committee