



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

- | | |
|--|---------------------|
| <input checked="" type="checkbox"/> Application to Conduct Research Project (form) | Ver date: 21 Feb 13 |
| <input checked="" type="checkbox"/> Study Protocol | Ver date: |
| <input type="checkbox"/> Investigator Brochure | Ver date: |
| <input checked="" type="checkbox"/> Patient Information Sheet | Ver date: |
| <input checked="" type="checkbox"/> Consent Form Version 2 | Ver date: 13 Apr 12 |
| <input type="checkbox"/> Questionnaire | Ver date: |
| <input checked="" type="checkbox"/> Investigator's CV (Prof. Lee Way Seah) | |

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:

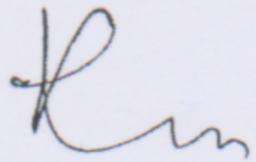
- 1) follow instructions, guidelines and requirements of the Medical Ethics Committee.
- 2) report any protocol deviations/violations to Medical Ethics Committee.
- 3) provide annual and closure reports to the Medical Ethics Committee.
- 4) comply with International Conference on Harmonization – Guidelines 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



PROF. DATUK LOOI LAI MENG
 Chairman
 Medical Ethics Committee