



<b>NAME OF ETHICS COMMITTEE/IRB:</b> Medical Ethics Committee, University Malaya Medical Centre  <b>ADDRESS:</b> LEMBAH PANTAI 59100 KUALA LUMPUR	<b>ETHICS COMMITTEE/IRB REFERENCE NUMBER:</b>  975.7
<b>PROTOCOL NO (if applicable):</b>  <b>TITLE:</b> Investigation of the role of the intestinal microflora in the aetiology of inflammatory bowel disease and the impact of helicobacter pylori status	<b>VERSION NO.:</b>
<b>PRINCIPAL INVESTIGATOR:</b> Prof. Lee Way Seah	<b>SPONSOR:</b> 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: 07<sup>th</sup> 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