



**UNIVERSITY  
OF MALAYA  
MEDICAL CENTRE**

**MEDICAL RESEARCH ETHICS COMMITTEE  
(Formerly known as Medical Ethics Committee)  
UNIVERSITY OF MALAYA MEDICAL CENTER**

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

<b>NAME OF ETHICS COMMITTEE/IRB</b> Medical Research Ethics Committee, University Malaya Medical Center	<b>MREC ID NO:</b> 201512-1945
<b>ADDRESS :</b> LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA	
<b>PROTOCOL NO</b> (if applicable) :	
<b>TITLE:</b> Paediatric Colonoscopy in Malaysia: a 10-year Experience in a Tertiary Center	
<b>PRINCIPAL INVESTIGATOR :</b> Prof. LEE WAY SEAH	<b>SPONSOR</b> -

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

<input checked="" type="checkbox"/> Application to Conduct Research Project(form)	Ver.No :	Ver.Date : 14-12-2015
<input checked="" type="checkbox"/> Study Protocol	Ver.No :	Ver.Date :
<input type="checkbox"/> Patient Information Sheet	Ver.No :	Ver.Date :
<input type="checkbox"/> Consent Form	Ver.No :	Ver.Date :
<input type="checkbox"/> Questionnaire	Ver.No :	Ver.Date :
<input checked="" type="checkbox"/> Investigator's CV / GCP ( Prof. LEE WAY SEAH, )	Ver.No :	Ver.Date :
<input type="checkbox"/> Insurance certificate	Ver.No :	Ver.Date :
<input checked="" type="checkbox"/> Other documents		

and the decision is [☒]

- ☐ Approved (Full Board)  
☒ Approved (Expedited)  
☐ Rejected(reasons specified below or in accompanying letter)

Comments:

Retrospective study

*The Investigators are required to:*

- 1) follow instructions, guidelines and requirements of the Medical Research Ethics Committee.
- 2) report any protocol deviations/violations to Medical Research Ethics Committee.
- 3) provide annual and closure report to the Medical Research Ethics Committee.
- 4) comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.
- 5) obtain a permission from the Director of UMMC to start research that involves recruitment of UMMC patient.
- 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 research grant.
- 7) note that he/she can appeal to the Chairman of Medical Research Ethics Committee for studies that are rejected.
- 8) note that Medical Research Ethics Committee may audit the approved study.
- 9) ensure that the study does not take precedence over the safety of subjects.

Date of expedited approval : 08-01-2016

*This is a computer generated letter. No signature required.*