



**UNIVERSITI  
MALAYA**

**PUSAT PERUBATAN UM**

**MEDICAL ETHICS COMMITTEE  
UNIVERSITY MALAYA MEDICAL CENTRE**

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

<b>NAME OF ETHICS COMMITTEE/IRB:</b> Medical Ethics Committee, University Malaya Medical Centre	<b>ETHICS COMMITTEE/IRB REFERENCE NUMBER:</b>  902.15
<b>ADDRESS:</b> LEMBAH PANTAI 59100 KUALA LUMPUR	
<b>PROTOCOL NO:</b>	
<b>TITLE:</b> Health Related Quality of Life (HRQoL) in biliary atresia: A comparative study	
<b>PRINCIPAL INVESTIGATOR:</b> Dr. Ong Sik Yong	<b>SPONSOR:</b>
<b>TELEPHONE:</b>	<b>KOMTEL:</b>

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

- ☒ Application Form
- ☒ Study Protocol
- ☐ Investigator Brochure
- ☒ Consent Form
- ☒ Patient Information Sheet
- ☐ Questionnaire
- ☒ Investigator(s) CV's (Dr. Ong Sik Yong)

Ver date: 03 Feb 12

Ver date:

Ver date:

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: 15<sup>th</sup> FEBRUARY 2012

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



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**MEDICAL ETHICS COMMITTEE COMPOSITION, UNIVERSITY MALAYA MEDICAL CENTRE**  
**Date: 15<sup>th</sup> FEBRUARY 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. Prof. Tan Chong Tin	Representative of Head Department of Medicine	Male	
3. Assoc. Prof. Stephen Thevananthan a/l Ambun	Representative of Head Department of Psychological Medicine	Male	✓
4. Assoc. Prof. Alizan Abdul Khalil	Head Department of Surgery	Male	✓
5. Dr. Poppy Rajan	Representative of Head Department of Pharmacology	Male	✓
6. Pn. Che Zuraini bt. Sulaiman	Representative of Head of Pharmacist Pharmacy Department University Malaya Medical Centre	Female	✓
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.

**PROF. DATUK LOOI LAI MENG**  
Chairman  
Medical Ethics Committee