



PUSAT PERUBATAN UM

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

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 Form | Ver date: 03 Feb 12 |
| <input checked="" type="checkbox"/> Study Protocol | Ver date: |
| <input type="checkbox"/> Investigator Brochure | Ver date: |
| <input checked="" type="checkbox"/> Consent Form | |
| <input checked="" type="checkbox"/> Patient Information Sheet | |
| <input type="checkbox"/> Questionnaire | |
| <input checked="" type="checkbox"/> Investigator(s) CV's (Dr. Ong Sik Yong) | |

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: 15th 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



MEDICAL ETHICS COMMITTEE COMPOSITION, UNIVERSITY MALAYA MEDICAL CENTRE
Date: 15th 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.

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PROF. DATUK LOOI LAI MENG
Chairman
Medical Ethics Committee