SingHealth
Defining Tomorrow's Medicine

Tel: (65) 6225 0488
Fax: (65) 6557 2138
Singapore Health Services Pte Ltd
31 Third Hospital Avenue
#03-03 Bowyer Block C
Singapore 168753
www.singhealth.com.sg
UEN No. 200002698Z

CIRB Ref: **2012/358/E**

17 May 2012

Dr Christina Ong
Department of Gastroenterology
KK Women's and Children's Hospital

Dear Dr Ong

SINGHEALTH CENTRALISED INSTITUTIONAL REVIEW BOARD (CIRB) APPROVAL

Study Title: Cap polyposis in children - a 10 year review

We are pleased to inform you that the SingHealth CIRB E has approved the above research project to be conducted in KKH.

The documents reviewed are:

a) CIRB / DSRB Application Form dated 30 April 2012
b) Data Collection Form dated 24/04/2012

The CIRB has approved your request for waiver of informed consent.

The SingHealth CIRB operates in accordance with the ICH/ Singapore Guideline for Good Clinical Practices, and with the applicable regulatory requirement(s).

The approval period is from **17 May 2012 to 16 May 2013**. The reference number for this study is CIRB Ref: 2012/358/E. Please use this reference number for all future correspondence.

The following are to be observed upon CIRB Approval:

1. No subject should be admitted to the trial before the Health Sciences Authority issues the Clinical Trial Certificate (only applicable for drug-related studies).

2. The Principal Investigator should ensure that this study is conducted in compliance with the Singapore Guideline for Good Clinical Practice, the ethical guidelines of which are applicable to all studies to be carried out, and to ensure that the study is carried out in accordance to the guidelines and the submitted protocol. The Principal Investigator should meet with his collaborator(s) regularly to assess the progress of the study, and be familiar and comply with all applicable research policies in the Institution.

3. No deviation from, or changes of, the protocol should be initiated without prior written CIRB approval of an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or when the change(s) involve(s) only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone number(s).

4. Only the approved Patient Information Sheet and Consent Form should be used. It must be signed by each subject prior to enrolling in the study and initiation of any protocol procedures. Two copies of the Informed Consent Form should be signed and dated. Each subject or the subject's legally accepted representative should be given a copy of the signed consent form. The remaining copy should be kept by the PI / medical record.

5. The Principal Investigator should report promptly to the SingHealth Centralised IRB of:
   i. Deviations from, or changes to the protocol including those made to eliminate immediate hazards to the trial subjects.
   ii. Changes increasing the risk to subjects and/or affecting significantly the conduct of the trial.
   iii. All serious adverse events (SAEs) and adverse drug reaction (ADRs) that are both serious and unexpected.
   iv. New information that may affect adversely the safety of the subjects or the conduct of the trial.
   v. Completion of the study.

6. Study Status Report should be submitted to the SingHealth Centralised IRB for the following:
   i. Annual review: Status of the study should be reported to the CIRB at least annually using the Study Status Report.
   ii. Study renewal: the Study Status Report is to be submitted at least one month prior to the expiry of the approval period. A valid CIRB renewal is essential, as any research performed outside of an approved time frame is not legal, and thus not covered by the hospital's research insurance in case of unexpected adverse reactions.
   iii. Study completion or termination: the Final Report is to be submitted within three months of study completion or termination.

Yours sincerely

A/Prof Agnes Ng
Chairman
SingHealth Centralised Institutional Review Board E

Cc: Institution Representative, KKH
Head, Department of Gastroenterology, KKH