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CIRB Ref: **2015/2519**

03 July 2015

Dr Andrew Kwek Boon Eu
Department of Gastroenterology & Hepatology
Changi General Hospital

Dear Dr Kwek

**SINGHEALTH CENTRALISED INSTITUTIONAL REVIEW BOARD (CIRB) APPROVAL**

**Protocol Title**: **Benefits of Premedication with Small Volume Simethicone Solution before Diagnostic Gastroscopy: A Randomized Endoscopist-blinded Prospective Study (Protocol No.: CGH-QIPSMJ)**

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

The documents reviewed are:

a) CIRB Application Form dated 26 Jun 2015
b) Research Protocol: Version 1.1 dated 10 Jun 2015
c) Participant Information Sheet and Consent Form: Version 1.1 dated 24 Jun 2015
d) Data Collection Form: Version 1 dated 15 May 2015
e) Product Insert (ridwind baby drops)
f) Reference for Endoscopic Visibility Scoring

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 **03 July 2015 to 17 June 2016**. The reference number for this study is CIRB Ref: **2015/2519**. Please use this reference number for all future correspondence.

The following are to be observed upon SingHealth 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 SingHealth 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 Participant 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 CIRB 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 CIRB for the following:
   i. Annual review: Status of the study should be reported to the SingHealth CIRB at least annually using the Study Status Report.
   ii. Study renewal: the Study Status Report is to be submitted at least two months prior to the expiry of the approval period. A valid SingHealth 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

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cc: Institution Representative, CGH
Head, Department of Gastroenterology & Hepatology, CGH

Annex 1

| LIST OF CIRB E MEMBERS INVOLVED IN THE REVIEW ON 18 JUN 2015 | | | |
|---|---|---|---|
| **Name** | **CIRB Membership** | **Designation, Institution** | **Gender** |
| A/Prof Agnes Ng | Chairman | Senior Consultant, Paediatric Anaesthesia, KKWCH | Female |
| Dr Paul Goh Soo Chye | Dy Chairman | Director, Tampines Polyclinic, SHP | Male |
| Dr Swah Teck Sin | Member | Director, Bedok Polyclinic, SHP | Male |
| Dr Kelvin Xu Shaorong | Member | Senior Clinical Pharmacist, Pharmacy, KKWCH | Male |
| Ms Ang Su-Lin | Member | Community Member | Female |
| Dr Low Kah Tzay | Member | Paediatrician, Anson International Paediatric & Child Development Clinic | Male |
| Ms Kwek Koon Roan | Member | Asst Director, Nursing Development Unit, NHC | Female |