



Research Ethics Committee
(Kowloon Central / Kowloon East)

c/o Queen Elizabeth Hospital
30 Gascoigne Road Kowloon

Dr CHENG Ching Hei James Wesley

Medical Officer
Department of Paediatrics and Adolescent Medicine
United Christian Hospital

7 April 2017

Ref: KC/KE-16-0187/FR-2

Dear Dr CHENG,

The REC(KC/KE) members are appointed by the Cluster Chief Executives to review and monitor clinical research independently according to the guidance of Declaration of Helsinki and ICH GCP Guidelines in order to safeguard the rights, safety and well-being of research subjects. It has the authority to approve, require modifications (to secure approval), or disapprove research. This committee has power to terminate/suspend a research at any time if there is evidence to indicate that the above principles and requirements have been violated.

The Committee has reviewed and approved your research application on 23 November 2016 at a review panel meeting. The approval decision was based on the documents submitted and the information presented by you at the meeting. You are required to adhere to the attached conditions:

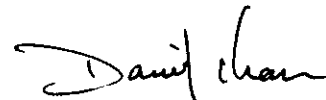
Title of Study	Randomized Control Trial: Can topical Timolol reduce the use of Propranolol for the treatment of infantile haemangioma?
Principal Investigator	Dr CHENG Ching Hei James Wesley, Resident, Dept of Paediatrics and Adolescent Medicine, UCH
List of Co-investigators	Dr FUNG Po Gee Genevieve, Associate Consultant, Dept of Paediatrics and Adolescent Medicine, UCH
	Dr LUK Chi Kong David, Associate Consultant, Dept of Paediatrics and Adolescent Medicine, UCH
	Ms CHAN Yuk Hing, Advanced Practice Nurse, Dept of Paediatrics and Adolescent Medicine, UCH
	Ms TONG Pui Lin, Registered Nurse, Dept of Paediatrics and Adolescent Medicine, UCH
Protocol title and version	Randomized Control Trial: Can topical Timolol reduce the use of Propranolol for the treatment of infantile haemangioma? [Version 1 (17 February 2017)]
Consent Form versions	English and Chinese Versions [Version 1 (17 February 2017)]

Information Sheet versions	English and Chinese Versions [Version 1 (17 February 2017)]
Certificate of indemnity/insurance	N/A
Other Documents	<ul style="list-style-type: none"> - KCC/KEC Cluster REC Clinical Research Ethics Review Application Form [HA RE001F3] - Data Collection Booklet [Version 1 17 February 2017] - Urgent Contact Card [Version 1 dated 17Feb2017] - CVs of Principal Investigator and Co-investigators
Study site approved	United Christian Hospital
Conditions	<ol style="list-style-type: none"> 1. Be compliant with the applicable laws and regulations (including Hong Kong laws), HA policy, professional code of conduct, guidance of ICH GCP and Declaration of Helsinki. 2. Apply a clinical trial certificate from Department of Health if indicated and submit a copy to this committee before the study begins. 3. Not deviate from, or make changes to the study protocol without prior written REC approval, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues. 4. Report the followings to REC(KC/KE): <ol style="list-style-type: none"> (i) unexpected and serious adverse event (use KCKE SOP001F8)* within 7 calendar days for life-threatening or fatal event and within 15 calendar days for others from the date of first knowledge of the event (ii) study protocol or consent document change (use KCKE SOP001F7)* (iii) protocol deviation within 30 calendar days (iv) new information that may be relevant to a subject's willingness to continue participation in the study. 5. Report the date of the first study subject recruited to REC (use KCKE SOP001F10)* within 1 month. 6. Report study closure (use KCKE SOP001F9b)* by February 2018. 7. Report the study results and submit any relevant publications to REC(KC/KE).

* Download forms from the KCC/KEC intranet for use

Review Panel (for full review only)

	Title and Name	Affiliation
Chairperson:	Dr Daniel CHAN	HA Staff
Members:	Dr NG Kin Sun	Independent Member / Non-Scientific Member
	Professor TANG Shiu Keung	Independent Member / Non-Scientific Member
	Dr MOK Ka Ming	HA Staff
	Dr NG Chun Kong	HA Staff
	Dr AU Kwok Hung	HA Staff
	Mr CHAN Hin Cheong	HA Staff
	Dr Au Wing Cheong Raymond	HA Staff



Dr Daniel CHAN
Panel Chairman of REC (Operation)
(Kowloon Central/Kowloon East)

cc. Chief of Service, Department of Paediatrics and Adolescent Medicine, UCH