



Research Ethics Committee  
(Kowloon Central / Kowloon East)

c/o Queen Elizabeth Hospital  
30 Gascoigne Road Kowloon

Professor THAM Chee Yung Clement

Honorary Chief of Service  
Hong Kong Eye Hospital /  
Chairman  
Department of Ophthalmology and Visual Sciences,  
Chinese University of Hong Kong

23 November 2017

Ref: KC/KE-17-0107/FR-4

Dear Professor THAM,

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 22 August 2017 at a review panel meeting. The approval decision was based on the documents submitted and the information presented by Dr CHAN Pui Man Poemen at the meeting. You are required to adhere to the attached conditions:

<b>Title of Study</b>	An investigation of the effectiveness of Paul Glaucoma Implant (PGI) – a pilot study
<b>Principal Investigator</b>	Professor THAM Chee Yung Clement, Honorary Chief of Service, HKE / Chairman, Dept of Ophthalmology and Visual Sciences, CUHK
<b>List of Co-investigator</b>	Dr CHAN Pui Man Poemen, Associate Consultant, HKE
<b>Protocol title and version</b>	An investigation of the effectiveness of Paul Glaucoma Implant (PGI) – a pilot study [Hong Kong Eye Hospital Version 1 dated 24 Oct 2017]
<b>Consent Form versions</b>	Informed Consent Form [English and Chinese Versions: Hong Kong Eye Hospital Version 1 dated 8 Nov 2017]
<b>Information Sheet versions</b>	Participant Information Sheet [English and Chinese Versions: Hong Kong Eye Hospital Version 1 dated 8 Nov 2017]

<b>Certificate of indemnity/insurance</b>	<ul style="list-style-type: none"> <li>- Copy of Liability Insurance [Policy No.: SCM0000087 from Chubb Insurance Singapore Limited dated 22 Aug 2017]</li> </ul>
<b>Other Documents</b>	<ul style="list-style-type: none"> <li>- Clinical Research Ethics Review Application Form</li> <li>- EC Certificate [Registration No.: HD 60118700 0001; Report No.: 12031321 001; dated 20 July 2017]</li> <li>- CVs of Principal Investigator and Co-investigator</li> </ul>
<b>Study site approved</b>	Hong Kong Eye Hospital
<b>Conditions</b>	<ol style="list-style-type: none"> <li>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.</li> <li>2. Apply a clinical trial certificate from Department of Health if indicated and submit a copy to this committee before the study begins.</li> <li>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.</li> <li>4. Report the followings to REC(KC/KE):       <ol style="list-style-type: none"> <li>(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</li> <li>(ii) study protocol or consent document change (use KCKE SOP001F7)*</li> <li>(iii) protocol deviation within 30 calendar days from the first awareness of the deviation/incident</li> <li>(iv) new information that may be relevant to a subject's willingness to continue participation in the study.</li> </ol> </li> <li>5. Report the date of the first study subject recruited to REC (use KCKE SOP001F10)* within 1 month.</li> <li>6. Report the first study progress to REC by November 2018 (use KCKE SOP001F9a)*.</li> <li>7. Report study closure (use KCKE SOP001F9b)* by March 2019.</li> <li>8. Report the study results and submit any relevant publications to REC(KC/KE).</li> </ol>

\* All post-approval activities such as protocol amendment, progress report, supplementary information and final report submissions should be made via HA CRER Portal.

**Review Panel (for full review only)**

	Title and Name	Affiliation
Chairperson:	Dr Victoria WONG	HA Staff
Members:	Professor TANG Shiu Keung	Non-Scientific Member / Independent Member
	Dr HUI LO Man Chun Jenny	Non-Scientific Member / Independent Member
	Dr LEUNG Kin Ping	Non-Scientific Member
	Dr LEUNG Wing Cheong	HA Staff
	Dr CHO Chi Shing William	HA Staff
	Ms Jess LO	HA Staff



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Dr Victoria WONG  
Panel Chairman of REC (Operation)  
(Kowloon Central/Kowloon East)

cc. Deputy Hospital Chief Executive, HKE