



Research Ethics Committee  
(Kowloon Central / Kowloon East)

c/o Queen Elizabeth Hospital  
30 Gascoigne Road Kowloon

Professor THAM Chee Yung Clement

S.H. Ho Professor of Ophthalmology and Visual Sciences  
Department of Ophthalmology and Visual Sciences  
The Chinese University of Hong Kong /  
Honorary Consultant  
Hong Kong Eye Hospital

18 January 2022

Ref: KC/KE-09-0121/ER-3

Dear Professor THAM,

**REQUEST FOR AMENDMENTS / UPDATE  
AND EXTENSION OF STUDY PERIOD**

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 18 January 2022 by an expedited process. The approval decision was based on the documents submitted. You are required to adhere to the attached conditions:

<b>Title of Study</b>	Correlation between clinic-measured intraocular pressure (IOP) and disease progression in primary angle closure glaucoma (PACG)
<b>Principal Investigator</b>	Professor THAM Chee Yung Clement, S.H. Ho Professor of Ophthalmology and Visual Sciences, Dept of Ophthalmology and Visual Sciences, CUHK / Honorary Consultant, HKE
<b>New List of Co-investigators</b>	Dr BAIG Nafees Begum, Honorary Associate Professor, Dept of Ophthalmology and Visual Sciences, CUHK
	Miss CHAU Ming Chung Christy, Medical Student, HKU
	Dr KWONG Yuen Ying Yolanda, Associate Consultant, HKE
	Professor LAM Shun Chiu Dennis, Honorary Professor, Dept of Ophthalmology and Visual Sciences, CUHK

<p><b>New List of Co-investigators (Cont'd)</b></p>	<p>Professor LEUNG Kai Shun Christopher, Clinical Professor and Head, Dept of Ophthalmology, HKU</p>
	<p>Dr LEUNG Yu Lung Dexter, Honorary Associate Professor, Dept of Ophthalmology and Visual Sciences, CUHK</p>
	<p>Dr LI Chi Hong Felix, Part-time Consultant, Dept of Ophthalmology and Visual Sciences, AHNH</p>
	<p>Dr POON Shuet Yan Agnes, Medical Officer, Dept of Ophthalmology and Visual Sciences, PWH</p>
	<p>Dr SO Fei Sophia, Resdient, Dept of Ophthalmology and Visual Sciences, PWH</p>
	<p>Dr YUEN Shi Yin Nancy, Honorary Associate Professor, Dept of Ophthalmology and Visual Sciences, CUHK</p>
<p><b>Protocol Amendments</b></p>	<p>REC(KC/KE) Protocol Amendment Application Form [KCKE SOP001F7]</p> <ul style="list-style-type: none"> <li>- Research Protocol [Version 7 (dated 29 Dec 2021)]</li> <li>- Update of Co-investigator, Professor LEUNG Kai Shun Christopher's position and affiliation</li> <li>- Extended the study period to December 2023</li> </ul>
<p><b>Conditions</b></p>	<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> </ol> </li> <li>5. (iv) new information that may be relevant to a subject's willingness to continue participation in the study.</li> <li>6. Report the date of the first study subject recruited to REC (use KCKE SOP001F10)*.</li> </ol>

<b>Conditions (Cont'd)</b>	<ol style="list-style-type: none"><li>7. Report the fourteenth study progress to REC by December 2022 (use KCKE SOP001F9a)*.</li><li>8. Report study closure (use KCKE SOP001F9b)* by December 2023.</li><li>9. Report the study results and submit any relevant publications to REC(KC/KE).</li></ol>
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*\* Download forms from the KCC/KEC website for use*

# *Principal Investigators(PI) are reminded to submit amendment application to REC(KC/KE) before leaving the original institution. Department heads/COSs concerned may coordinate the PI's replacement as needed.*



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Dr LEUNG Wing Cheong  
Panel Chairman of REC(Operation)  
(Kowloon Central/Kowloon East)

cc. Chief of Service, HKE