Research Ethics Committee
(Kowloon Central / Kowloon East)

c/o Queen Elizabeth Hospital
30 Gascoigne Road Kowloon

Professor LEUNG Kai Shun

Department of Ophthalmology and Visual Sciences
The Chinese University of Hong Kong /
Honorary Consultant
Hong Kong Eye Hospital

31 May 2017

Ref: KC/KE-14-0198/FR-2

Dear Professor LEUNG,

REQUEST FOR AMENDMENTS / UPDATE

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 31 May 2017 by an expedited process. The approval decision was based on the documents submitted. You are required to adhere to the attached conditions:

Title of Study	Progressive lamina cribrosa deformation – A biomarker for fast progressors in glaucoma?
Principal Investigator	Professor LEUNG Kai Shun, Dept of Ophthalmology & Visual Sciences, CUHK / Honorary Consultant, HKEH
List of Co-investigators	Dr LEE Wai Yip, Associate Consultant, Dept of Ophthalmology, CMC
	Dr LI Chi Hong, Consultant, Dept of Ophthalmology, PWH
	Dr CHAN Li Jia, Assistant Professor, Dept of Ophthalmology and Visual Sciences, CUHK / Honorary Resident, HKEH
Protocol Amendments	REC(KC/KE) Protocol Amendment Application Form [KCKE SOP001F7] - Research Protocol [Version 4 dated 4 May 2017] - Participant Information Sheet [English and Chinese versions: Version 7 (dated 4 May 2017)]

Protocol Amendments (Cont'd)	- Informed Consent Form [English and Chinese versions: Version 7 (dated 4 May 2017)] - Increasing the target number of subjects from 97 to 168
Conditions	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): (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 for research projects approved on or after 1 September 2015. 6. Report the third study progress to REC by December 2017 and thereafter at 12 monthly intervals until study closure (use KCKE SOP001F9a)*. 7. Report study closure (use KCKE SOP001F9b)* by June 2020. 8. Report the study results and submit any relevant publications to REC(KC/KE).

** Download forms from the KCC/KEC intranet for use*

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

cc. Honorary Chief of Service, HKE

醫院管理局
HOSPITAL AUTHORITY

群策群力為病人・優質醫護滿杏林
Quality Patient-Centred Care Through Teamwork

Research Ethics Committee
(Kowloon Central / Kowloon East)

c/o Queen Elizabeth Hospital
30 Gascoigne Road Kowloon

Professor LEUNG Kai Shun

Department of Ophthalmology and Visual Sciences
The Chinese University of Hong Kong /
Honorary Consultant
Hong Kong Eye Hospital

16 March 2017

Ref: KC/KE-14-0198/FR-2

Dear Professor LEUNG,

REQUEST FOR AMENDMENTS / UPDATE

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 16 March 2017 by an expedited process. The approval decision was based on the documents submitted. You are required to adhere to the attached conditions:

Title of Study	Progressive lamina cribrosa deformation – A biomarker for fast progressors in glaucoma?
Principal Investigator	Professor LEUNG Kai Shun, Dept of Ophthalmology & Visual Sciences, CUHK / Honorary Consultant, HKEH
List of Co-investigators	Dr LEE Wai Yip, Associate Consultant, Dept of Ophthalmology, CMC
	Dr LI Chi Hong, Consultant, Dept of Ophthalmology, PWH
	Dr CHAN Li Jia, Assistant Professor, Dept of Ophthalmology and Visual Sciences, CUHK / Honorary Resident, HKEH
Protocol Amendments	REC(KC/KE) Protocol Amendment Application Form [KCKE SOP001F7] - Update of Principal Investigator's position - Research Protocol [Version 3 dated 23 Jan 2017]

Protocol Amendments (Cont'd)	- Participant Information Sheet [English and Chinese versions: Version 6 (dated 23 Jan 2017)] - Informed Consent Form [English and Chinese versions: Version 6 (dated 23 Jan 2017)]
Conditions	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): (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 for research projects approved on or after 1 September 2015. 6. Report the third study progress to REC by December 2017 and thereafter at 12 monthly intervals until study closure (use KCKE SOP001F9a)*. 7. Report study closure (use KCKE SOP001F9b)* by June 2020. 8. Report the study results and submit any relevant publications to REC(KC/KE).

** Download forms from the KCC/KEC intranet for use*

Dr Daniel CHAN
for Chairman of REC (Governing)
(Kowloon Central/Kowloon East)

cc. Honorary Chief of Service, HKE

醫院管理局
HOSPITAL
AUTHORITY

Research Ethics Committee
(Kowloon Central / Kowloon East)

c/o Queen Elizabeth Hospital
30 Gascoigne Road Kowloon

Professor LEUNG Kai Shun

Department of Ophthalmology and Visual Sciences
The Chinese University of Hong Kong /
Honorary Consultant
Hong Kong Eye Hospital

16 March 2017

Ref: KC/KE-14-0198/FR-2

Dear Professor LEUNG,

REQUEST FOR AMENDMENTS / UPDATE

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 16 March 2017 by an expedited process. The approval decision was based on the documents submitted. You are required to adhere to the attached conditions:

Title of Study	Progressive lamina cribrosa deformation – A biomarker for fast progressors in glaucoma?
Principal Investigator	Professor LEUNG Kai Shun, Dept of Ophthalmology & Visual Sciences, CUHK / Honorary Consultant, HKEH
List of Co-investigators	Dr LEE Wai Yip, Associate Consultant, Dept of Ophthalmology, CMC
	Dr LI Chi Hong, Consultant, Dept of Ophthalmology, PWH
	Dr CHAN Li Jia, Assistant Professor, Dept of Ophthalmology and Visual Sciences, CUHK / Honorary Resident, HKEH
Protocol Amendments	REC(KC/KE) Protocol Amendment Application Form [KCKE SOP001F7] - Update of Principal Investigator's position - Research Protocol [Version 3 dated 23 Jan 2017]

484

Research Ethics Committee
(Kowloon Central / Kowloon East)

c/o Queen Elizabeth Hospital
30 Gascoigne Road Kowloon

Prof LEUNG Kai Shun

Honorary Associate consultant
Department of Ophthalmology
Hong Kong Eye Hospital

2 December 2014

Ref: KC/KE-14-0198/FR-2

Dear Prof LEUNG,

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 20 November 2014 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	Progressive lamina cribrosa deformation – A biomarker for fast progressors in glaucoma?
Principal Investigator	Prof LEUNG Kai Shun, Honorary Associate consultant, Dept of Ophthalmology, HKE
List of Co-investigators	Dr LEE Wai Yip, Associate Consultant, Dept of Ophthalmology, CMC
	Dr LI Chi Hong, Consultant, Dept of Ophthalmology, PWH
	Dr CHAN Li Jia, Assistant Professor, Dept of Ophthalmology and Visual Sciences, CUHK
Protocol title and version	Progressive lamina cribrosa deformation – A biomarker for fast progressors in glaucoma? [Version 2 dated 15 Oct 2014]
Informed Consent Form versions	Informed Consent Form [English Version: Version 5(dated Oct 30, 2014)] [Chinese Version: Version5(dated Oct 30, 2014)]

Certificate of indemnity/insurance	N/A
Other Documents	- KCC/KEC Cluster REC Clinical Research Ethics Review Application Form [HA RE001F3] - Fig 1 [Version 1 (dated Oct 30, 2014)] - FIG.2 Flow chart of study design and schedule of follow-up examination and investigations [Version 1 (dated Oct 30, 2014)] - CVs of Principal Investigator and Co-investigators
Study site approved	Hong Kong Eye Hospital
Conditions	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): (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) new information that may be relevant to a subject's willingness to continue participation in the study. 5. Report the first study progress to REC by December 2015 and thereafter at 12 monthly intervals until study closure (use KCKE SOP001F9a)*. 6. Report study closure (use KCKE SOP001F9b)* by June 2020. 7. Report the study results and submit any relevant publications to REC(KC/KE).

* *Download forms from the KCC/KEC intra-net for use*

Review Panel (for full review only)

	Title and Name	Affiliation
Chairperson:	Dr MOK Ka Ming	HA Staff
Members:	Dr NG Kin Sun	Lay Member
	Dr FU Kin Hang	HA Staff
	Dr KAM Yee Wai Grace	HA Staff
	Dr CHO Chi Shing William	HA Staff
	Mr CHUI Hok Shing Andrew	HA Staff

Mr Emmanuel KAO
Chairman of REC(KC/KE)

cc. Honorary Chief of Service, Department of Ophthalmology, HKE