535

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

14 February 2019

Ref: KC/KE-15-0232/ER-1

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 14 February 2019 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 retinal nerve fiber layer (RNFL) thinning as a biomarker to guide intraocular pressure (IOP) lowering treatment in ocular hypertensives (OHT)
Principal Investigator	Professor LEUNG Kai Shun, Dept of Ophthalmology and Visual Sciences, CUHK / Honorary Consultant, HKE
List of Co-investigators	Dr CHAN Pui Man Poemen, Assistant Professor, Dept of Ophthalmology and Visual Sciences, CUHK
	Dr LI Chi Hong Felix, Consultant, Dept of Ophthalmology and Visual Sciences, PWH / AHNH
Protocol Amendments	REC(KC/KE) Protocol Amendment Application Form [KCKE SOP001F7] - Participant Information Sheet [English and Chinese Versions: Version 5 (dated 28 Dec 2018)]

Protocol Amendments (Cont'd)	- Informed Consent Form [English and Chinese Versions: Version 5 (dated 28 Dec 2018)] - Increased the target number of subjects from 250 to 274
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 from the first awareness of the deviation/incident (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 March 2019 and thereafter at 12 monthly intervals until study closure (use KCKE SOP001F9a)*. 7. Report study closure (use KCKE SOP001F9b)* by October 2022. 8. Report the study results and submit any relevant publications to REC(KC/KE).

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

Dr KWAN Chung Kong
Panel Chairman of REC(Operation)
(Kowloon Central/Kowloon East)

cc. Honorary Chief of Service, HKE

醫院管理局
HOSPITAL AUTHORITY

群策群力爲病人・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

30 April 2018

Ref: KC/KE-15-0232/ER-1

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 30 April 2018 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 retinal nerve fiber layer (RNFL) thinning as a biomarker to guide intraocular pressure (IOP) lowering treatment in ocular hypertensives (OHT)
Principal Investigator	Professor LEUNG Kai Shun, Dept of Ophthalmology and Visual Sciences, CUHK / Honorary Consultant, HKE
List of Co-investigators	Dr CHAN Pui Man Poemen, Assistant Professor, Dept of Ophthalmology and Visual Sciences, CUHK
	Dr LI Chi Hong Felix, Consultant, Dept of Ophthalmology and Visual Sciences, PWH / AHNH
Protocol Amendments	REC(KC/KE) Protocol Amendment Application Form [KCKE SOP001F7] - Change of Co-investigator, Dr CHAN Pui Man Poemen's position and working location - Research Protocol [Version 3 dated 26 March 2018] - Participant Information Sheet [English and Chinese Versions: Version 4 (dated 26 March 2018)]

Protocol Amendments (Cont'd)	- Informed Consent Form [English and Chinese Versions: Version 4 (dated 26 March 2018)] - Increasing the target number of subjects from 62 to 250
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 from the first awareness of the deviation/incident (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 March 2019 and thereafter at 12 monthly intervals until study closure (use KCKE SOP001F9a)*. 7. Report study closure (use KCKE SOP001F9b)* by October 2022. 8. Report the study results and submit any relevant publications to REC(KC/KE).

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Dr KWAN Chung Kong
Panel Chairman of REC(Operation)
(Kowloon Central/Kowloon East)

cc. Honorary Chief of Service, HKE

535

Research Ethics Committee
(Kowloon Central / Kowloon East)

c/o Queen Elizabeth Hospital
30 Gascoigne Road Kowloon

Professor LEUNG Kai Shun

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

23 March 2016

Ref: KC/KE-15-0232/ER-1

Dear Professor 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 23 March 2016 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 retinal nerve fiber layer (RNFL) thinning as a biomarker to guide intraocular pressure (IOP) lowering treatment in ocular hypertensives (OHT)
Principal Investigator	Professor LEUNG Kai Shun, Professor, Dept of Ophthalmology and Visual Sciences, CUHK / Honorary Consultant, HKE
List of Co-investigators	Dr CHAN Pui Man Poemen, Associate Consultant, HKE
	Dr LI Chi Hong Felix, Consultant, Dept of Ophthalmology and Visual Sciences, PWH / AHNH
Protocol title and version	Progressive retinal nerve fiber layer (RNFL) thinning as a biomarker to guide intraocular pressure (IOP) lowering treatment in ocular hypertensives (OHT) [Version 1 dated 8 Jan 2016]
Consent Form versions	Informed Consent Form [English and Chinese Versions: Version 1 (dated 16 Mar 2016)]
Information Sheet versions	Participant Information Sheet [English and Chinese Versions: Version 1 (dated 16 Mar 2016)]

Certificate of indemnity/insurance	N/A
Other Documents	- KCC/KEC Cluster REC Clinical Research Ethics Review Application Form [HA RE001F3] - REC(KC/KE) Clinical Study Categorization Form [Version No: 01] - 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) 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 the first study progress to REC by March 2017 and thereafter at 12 monthly intervals until study closure (use KCKE SOP001F9a)*. 7. Report study closure (use KCKE SOP001F9b)* by October 2022. 8. Report the study results and submit any relevant publications to REC(KC/KE).

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

Dr AU Siu Kie
for Chairman of REC (Governing)
(Kowloon Central/Kowloon East)

cc. Honorary Chief of Service, HKE