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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

香港中文大學醫學院
Faculty Of Medicine
The Chinese University Of Hong Kong

醫院管理局
新界東醫院聯網
Hospital Authority
New Territories East Cluster

Joint Chinese University of Hong Kong-New Territories East Cluster Clinical Research Ethics Committee

香港中文大學-新界東醫院聯網 臨床研究倫理 聯席委員會

8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, Shatin, HK
Tel : (852) 2632 3935 / 2144 5926 Fax : (852) 2646 6653 Website : http://www.crec.cuhk.edu.hk

The Joint CUHK-NTEC CREC is an independent committee established by CUHK/NTEC and authorized to perform ethics and scientific review and oversight of clinical studies within the jurisdiction of CUHK/NTEC in accordance with its standard operating procedure and the principles of the Declaration of Helsinki and ICH Good Clinical Practice.

CREC Ref. No.: 2014.532

10 NOV '14

To: Prof. Christopher Kai Shun LEUNG
Dept. of Ophthalmology &
Visual Sciences
Hong Kong Eye Hospital

This notice is issued by the Joint CUHK-NTEC CREC with respect to the application/submission by you, being the principal investigator of the following study at your study site:

- **Study Protocol Title:** A randomized control trial evaluating the efficacy of additional intraocular pressure lowering treatment upon detection of lamina cribrosa deformation
- **Investigator(s):** Christopher Kai Shun LEUNG, Jacky Wai Yip LEE, Felix Chi Hong LI and Lijia CHEN

In accordance with our standard operating procedure, we have duly performed ethics and scientific review of your application/submission as detailed below:

- **Nature of Your Application/Submission:** ☒ Initial application ☐ Amendments/changes ☐ Others: ☐ Renewal
- **Mode of Review:** ☒ Full review ☐ Expedited review
- **Date of Initial/Renewal Approval:** 10 November 2014
- **Document(s) Reviewed:** See Schedule 1
- **Reviewer(s) :** See Schedule 2

After due review by our reviewer(s), we hereby write to inform you of our decision on your application /submission as follows:

- **Decision:**
  - ☒ Application/Submission approved
  - ☐ Application/Submission approved with condition(s) (see condition(s) below)
  - ☐ Application/Submission approved with remark(s) (see remark(s) below)
  - ☐ Application/Submission approved with condition(s) and remark(s) (see condition(s) and remark(s) below)
- **Regular Progress Report(s) Required:** Every 12 months from the date of initial/renewal approval and during the period of the study if required

香港中文大學醫學院
Faculty Of Medicine
The Chinese University Of Hong Kong

醫院管理局
新界東醫院聯網
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Tel : (852) 2632 3935 / 2144 5926 Fax : (852) 2646 6653 Website : http://www.crec.cuhk.edu.hk

10 NOV '14

You, being the principal investigator of the study at your study site, are reminded to comply with our requirements and to maintain communication with us during the period of the study by undertaking the principal investigator's responsibilities including (but not limited to):

- if the study is an industry-sponsored clinical study, submitting to us a copy of the fully executed indemnity agreement satisfying the Hospital Authority's requirement prior to commencement of the study (if it has not been submitted yet);
- observing and complying with all applicable requirements under our standard operating procedure ("IRB/REC SOP"), the Declaration of Helsinki and the ICH GCP (if applicable);
- submitting regular progress report(s) at the required intervals (as specified above) in accordance with the requirements in the IRB/REC SOP;
- not implementing any amendment/change to any approved study document/material without our written approval, except where necessary to eliminate any immediate hazard to the subjects or if an amendment/change is only of an administrative or logistical nature;
- notifying us of any new information that may adversely affect the rights, safety or well-being of the subjects or the proper conduct of the study;
- reporting any deviation from the study protocol or compliance incident that has occurred during the study and may adversely affect the rights, safety or well-being of any subject in accordance with the requirements in the IRB/REC SOP;
- submitting safety reports on all SAEs observed at your study site or SUSARs reported from outside your study site in accordance with the requirements in the IRB/REC SOP; and
- submitting a final report in accordance with the requirements in the IRB/REC SOP upon completion or termination of the study at your study site.

In addition to the above, you are also reminded to observe and comply with other applicable regulatory and management requirements including (but not limited to):

- if required by Hong Kong laws or regulations, obtaining a certificate for clinical trial through the Hong Kong Department of Health and complying with the associated requirements;
- obtaining the necessary consent from the management of your institution/department in accordance with the requirements of your institution/department;
- if required by local laws or regulations at conducting site out of IRB/REC's jurisdiction, obtaining an approval and complying with associated requirements;
- not representing to any third party or in any way likely to mislead any third party forming the view that the approval from the IRB/REC has any extraterritorial effect; and
- with due diligence ensuring your teams, staff, agents or whosoever connected with you to comply with the preceding requirements.

Yours sincerely,

Jenny Ng (Secretary)
for and on behalf of
The Joint CUHK-NTEC CREC

JN/ci

CREC Ref. No.: 2014.532

Schedule 1
Documents Reviewed

The documents reviewed by with respect to the said application/submission include:

- Protocol, Version 2, dated 06 November 2014
- Participant Information Sheet and Informed Consent Form, English Version 2, dated 06 November 2014
- Participant Information Sheet and Informed Consent Form, Chinese Version 2, dated 06 November 2014
- FIG.1 A-E, English Version 1, dated 09 October 2014
- FIG.2 Flow Chart of study design and schedule of follow-up examination and investigations, English Version 1, dated 09 October 2014

Schedule 2
Reviewers List
Joint CUHK-NTEC Clinical Research Ethics Committee

Title and Name	Occupation	Qualification	Male / Female (M/F)	Study Reviewed by	Present in CREC meeting on 04 Nov 2014
Chairman: Prof. Benny C.Y. ZEE	Professor, School of Public Health, CUHK	BSc(Manitoba), MSc(Manitoba), PhD(Pittsburgh)	M	√	√
Vice/Deputy Chairman: Dr. Chi Kong LI	Consultant Paediatrician, Department of Paediatrics, PWH	MBBS, MD(CUHK), MRCP(UK), DCH(Lond), FHKCPaed, FHKAM(Paed), FRCP(Edin), FRCPCH(UK)	M	√	√
Prof. Alice Pik Shan KONG	Associate Professor, Department of Medicine and Therapeutics, CUHK	MBChB(CUHK), MRCP(UK), FHKCP, FHKAM(Medicine), FRCP(Glasgow)	F		
Prof. Brigette MA	Associate Professor, Department of Clinical Oncology, CUHK	FRACP(Australia),FHKCP, FHKAM(Medical Oncology)	F		
Prof. Vincent C.T. MOK	Associate Professor, Department of Medicine and Therapeutics, CUHK	MBBS(U Sydney), MRCP(UK), FHKCP, FHKAM, MD(CUHK), FRCP(Edin)	M		√
Prof. Cheuk Chun SZETO	Professor, Department of Medicine and Therapeutics, CUHK	MBChB(CUHK), MRCP(UK), FHKCP, FHKAM, DM(CUHK), FRCP(Edin)	M	√	√
Prof. Wai Kwong TANG	Professor, Department of Psychiatry, CUHK	MBChB(CUHK), MD (CUHK), MRCP(UK), FHKCP, FHKAM	M	√	√
Prof. Brian TOMLINSON	Professor, Department of Medicine and Therapeutics, CUHK	BSc, MBBS, MD, MRCP(UK), FHKCP, FRCP, FRC(E), FRCP(G), FHKAM(Med), FCP, FACP	M	√	√

Title and Name	Occupation	Qualification	Male / Female (M/F)	Study Reviewed by	Present in CREC meeting on 04 Nov 2014
Dr. Simon K.C. CHAN	Consultant, Department of Anaesthesia and Intensive Care, PWH	MBBS (UNSW), FANZCA(Aust), FHKCA, FHKAM, Dip Pain Mgt(HKCA), MHSM(UNSW)	M		
Dr. Ernest H.M. MA	Senior Medical Officer, Medicine & Geriatics, TPH	MBChB, MRCP(UK), Msc Resp Med(Lond), FRCP(Lond, Edin, Ire), FHKCP, FHKAM, MBA, EdD(UTS)	M	√	√
Dr. Kevin Ka Hang OR	Consultant, Department of Medicine and Geriatrics, SH	MBBS(UNSW), MRCP(UK), FHKCP, FHKAM(Med), FRCP(Edin), BChinMed(HKU)	M		
Dr. Keary ZHOU	Instructor, School of Pharmacy, CUHK	BS(UCLA), PharmD(USC)	F		
Ms. Alexandra Dak Wai LO	Chinese Medicine Practitioner, Part-time lecturer and adjunct tutor, Dept of Anatomical and Cellular Pathology, PWH, CUHK	LLB, Hons.(HKU), PCLL(HKU), LLB, Hons.(Peking), LLM (CityU), BchinMed(HKU)	F	√	
Ms. Emily May Ling CHAN	Retired	DSW(HKPU), RSW Certified Hypnotherapist CISM, UMBC	F		√
Mr. Wilson SO	Retired	Bachelor of Social Science, Master of Town and Country Planning	M		
Mr. Ping Hei TAO	Retired	MHRM(MQU), Dip Soc Sci(HKBU)	M	√	√
Mr. Foster YIM	Barrister-at-Law	PCLL(CUHK), JD(CUHK), Msc in Marketing (CUHK),MA in Philosophy (UK), BA (Hons) in Translation (LU)	M	√	√

KOWLOON WEST CLUSTER
九龍西醫院聯網

醫院管理局
HOSPITAL AUTHORITY

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Prof LEUNG Kai Shun, Christopher,
Honorary Associate Consultant,
Department of Ophthalmology,
The Chinese University of Hong Kong

19 January, 2015

Dear Prof LEUNG,

KWC-REC Reference: KW/EX-14-216(82-23)

Title: Progressive lamina cribrosa deformation – A biomarker for fast progressors in glaucoma?

The Kowloon West Cluster Research Ethics Committee (KWC-REC) is authorized by the Cluster Chief Executive to review and monitor clinical research. It serves to ensure that research complies with the Declaration of Helsinki, ICH GCP Guidelines, local regulations and HA policy. It has the authority to approve, require modifications in (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.

KWC-REC has approved your research application on 19 January, 2015 by expedited review process, and reached the following decision on the documents submitted as shown below. You are required to adhere to the attached conditions.

Study site(s)	Caritas Medical Centre
Document(s) approved	I. Clinical Research Ethics Review Application Form (revised on 19 November, 2014) II. One-Page Summary Form (revised on 30 December,2014) III. Protocol Version 1 dated 16 Oct 2014 IV. Participant Information Sheet and Informed Consent Form - English Version 3 dated Dec 30, 2014 V. Participant Information Sheet and Informed Consent Form - Chinese Version 3 dated 8 Jan, 2015 VI. FIG.1 A-E, English Version 1 dated 16Oct2014 VII. FIG.2 Flow Chart of study design and schedule of follow-up examination and investigations, English Version 1, dated 16Oct2014
Document(s) reviewed	I. Approval Letter issued by Joint CUHK-NTEC CREC dated 10 November, 2014 II. Approval Letter issued by REC KC/KE dated 2 December, 2014 III. CV of all Investigators (received on 3 November, 2014)
Conditions	1. Do 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. 2. Apply a clinical trial certificate from Department of Health if indicated. 3. Report the followings to KWC-REC* : (i) study protocol or consent document changes, (ii) serious adverse event, (iii) study progress (iv) new information that may be relevant to a subject's willingness to continue participation in the study. 4. Report first study progress to KWC-REC at **12-monthly intervals** until study closure. [*Forms are available from KWC-REC intranet webpage]

Please quote the REC Reference **KW/EX-14-216(82-23)** in all your future correspondence with the KWC-REC, including submission of progress reports and requesting for amendments to the research protocol.

Yours sincerely,

(Dr Ashley CHENG)
Chairperson
Research Ethics Committee
Kowloon West Cluster

c.c. COS(Ophthalmology), CMC

(AY)

Secretariat of
Research Ethics Committee,
Kowloon West Cluster

Room 533, 5/F, Block J,
Princess Margaret Hospital

Tel: (852) 29901017 / 29901047
Fax: (852) 29903438

Princess Margaret Hospital
2-10 Princess Margaret
Hospital Road, NT
Tel: (852) 2990 1111
Fax: (852) 2786 3629

瑪嘉烈醫院
新界瑪嘉烈醫院道2-10號
電話：(852) 2990 1111
傳真：(852) 2786 3629