新界西·醫院聯網
New Territories West Cluster
聯網辦事處 Cluster Office
屯門醫院 Tuen Mun Hospital
23 Tsing Chung Koon Road, Tuen Mun, New Territories, Hong Kong. Tel: (852) 2468 5111 Fax: (852) 2455 1911
新界屯門青松觀路23號 電話：(852) 2468 5111 傳真：(852) 2455 1911

新界西醫院聯網 研究倫理委員會
New Territories West Cluster Research Ethics Committee (NTWC REC)

5/F, Rehabilitation Block, Tuen Mun Hospital Tel: (852) 2468 6118

REC is an independent committee established by New Territories West Cluster and authorized to perform ethics and scientific review and oversight of clinical studies in accordance with its standard operating procedure and the principles of the Declaration of Helsinki and ICH Good Clinical Practice.

REC Ref. No.: NTWC/CREC/17087 Date: 22 January 2019

To: Prof Christopher LEUNG Kai-shun
Professor
Department of Ophthalmology
The Chinese University of Hong Kong

This notice is issued by NTWC REC with respect to the application/submission by you, being the principal investigator of the following study at your study site:

- Study Protocol Title: Progressive retinal nerve fiber layer (RNFL) thinning as a biomarker to guide intraocular pressure (IOP) lowering treatment in ocular hypertensives (OHT)
- Study Protocol No.: N/A
- Lead Principal Investigator: Prof Christopher LEUNG Kai-shun, Professor, Department of Ophthalmology, The Chinese University of Hong Kong
- Local Principal Investigator: Dr Kelvin WAN Ho-nam, Resident, Department of Ophthalmology, Tuen Mun Hospital
- Study Site: Tuen Mun Hospital

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 ☐ Regular reporting ☒ **Amendments/changes** ☐ Others:
- Mode of Review: ☐ Full review ☒ **Expedited review**
- Date of Review/Decision: 21 January 2019
- Document(s) Reviewed:
  1. Protocol Amendment Application Form dated 15 November 2018;
  2. Research Protocol Version 2 dated 27 November 2017 (with clean and tracked changes versions);
  3. English Version Informstion Sheet and Informed Consent Form Version 2 dated 27 November 2018 (with clean and tracked changes versions);
  4. Traditional Chinese Version Informstion Sheet and Informed Consent Form Version 2 dated 27 November 2018 (with clean and tracked changes versions).

醫院管理局 HOSPITAL AUTHORITY
與民攜手 Helping People Stay Healthy 保健安康
HA 1110/NTWC

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

- Decision:
  - ☒ **Application approved**
  - ☐ Application approved with condition(s) (see condition(s) below)
  - ☐ Receipt of submission acknowledged without comment
  - ☐ Application disapproved (see opinion(s) below)
  - ☐ Others (see opinion(s) below)
- Regular Progress Report(s) Required: Every 12 months from the date of initial approval and during the period of the study

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 ("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 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 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 REC SOP; and
- submitting a final report in accordance with the requirements in the 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; and
- obtaining the necessary consent from the management of your institution/department in accordance with the requirements of your institution/department.

Yours sincerely,
for and on behalf of
NTWC REC

Ms Sonnia WONG
Secretary, NTWC REC

cc Dr Kelvin WAN, TMH Resident(OPH) (Local PI)

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新界西醫院聯網 臨床及研究倫理委員會
New Territories West Cluster Clinical & Research Ethics Committee (NTWC CREC)

5/F, Rehabilitation Block, Tuen Mun Hospital Tel: (852) 2468 6118

CREC is an independent committee established by New Territories West Cluster and authorized to perform ethics and scientific review and oversight of clinical studies in accordance with its standard operating procedure and the principles of the Declaration of Helsinki and ICH Good Clinical Practice.

CREC Ref. No.: NTWC/CREC/17087 Date: 22 September 2017

To: Prof Christopher LEUNG Kai-shun
Professor
Department of Ophthalmology
The Chinese University of Hong Kong

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

- Study Protocol Title: Progressive retinal nerve fiber layer (RNFL) thinning as a biomarker to guide intraocular pressure (IOP) lowering treatment in ocular hypertensives (OHT)
- Study Protocol No.: N/A
- Lead Principal Investigator: Prof Christopher LEUNG Kai-shun, Professor, Department of Ophthalmology, The Chinese University of Hong Kong
- Local Principal Investigator: Dr Kelvin WAN Ho-nam, Resident, Department of Ophthalmology, Tuen Mun Hospital
- Study Site: Tuen Mun Hospital

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** ☐ Regular reporting ☐ Amendments/changes ☐ Others:
- Mode of Review: ☐ Full review ☒ **Expedited review**
- Date of Review/Decision: 21 September 2017
- Document(s) Reviewed:
  1. Clinical Research Ethics Review Application Form;
  2. Research Protocol Version 1 dated 9 August 2017;
  3. Information Sheet and Informed Consent Form Version 1 dated 18 September 2017 (English and Traditional Chinese Version);
  4. Investigator's Curriculum Vitae:
     - Prof Christopher LEUNG Kai-shun (Lead PI),
     - Dr Kelvin WAN Ho-nam (Local PI);
  5. Copies of approval letter granted by KC/KE REC dated 29 April 2017 and Joint CUHK-NTEC CREC dated 13 June 2017.

醫院管理局 HOSPITAL AUTHORITY
與民攜手 Helping People Stay Healthy 保健安康
HA 1110/NTWC

- Reviewer(s): Vice-Chairman :
  Dr Frank WONG Chi-sing, Consultant, Department of Clinical Oncology, Tuen Mun Hospital

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

- Decision:
  - ☒ **Application approved**
  - ☐ Application approved with condition(s) (see condition(s) below)
  - ☐ Receipt of submission acknowledged without comment
  - ☐ Application disapproved (see opinion(s) below)
  - ☐ Others (see opinion(s) below)
- Regular Progress Report(s) Required: Every 12 months from the date of initial approval and during the period of the study

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 ("CREC 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 CREC 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 CREC 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 CREC SOP; and
- submitting a final report in accordance with the requirements in the CREC SOP upon completion or termination of the study at your study site.

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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; and
- obtaining the necessary consent from the management of your institution/department in accordance with the requirements of your institution/department.

Yours sincerely,
for and on behalf of
NTWC CREC

Ms Winnie WONG
Secretary, NTWC CREC

cc Dr Kelvin WAN, TMH Resident(OPH) (Local PI)
Dr P F YIU, TMH/POH COS(OPH)