Research Ethics Committee
(Kowloon Central / Kowloon East)

c/o Queen Elizabeth Hospital
30 Gascoigne Road Kowloon

Dr Mårten Erik BRELÉN

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

12 January 2016

Ref: KC/KE-15-0192/FR-3

Dear Dr BRELÉN,

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 15 December 2015 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	Subthreshold micropulse yellow (577 nm) laser versus half-dose photodynamic therapy for central serous chorioretinopathy : a randomized controlled pilot study
Principal Investigator	Dr Mårten Erik BRELÉN, Assistant Professor, Dept of Ophthalmology and Visual Sciences, CUHK / Honorary Resident, HKE
List of Co-investigators	Dr NG Siu Chun Danny, Clinical Assistant Professor, Dept of Ophthalmology and Visual Sciences, CUHK / Honorary Resident, HKE
	Dr LAI Hiu Ping Frank, Resident, Department of Ophthalmology and Visual Sciences, PWH
	Dr SIN Pui Yee Helena, Resident Specialist, Department of Ophthalmology and Visual Sciences, PWH
	Dr Mary HO, Resident, Department of Ophthalmology and Visual Sciences, PWH
Protocol title and version	Subthreshold micropulse yellow (577 nm) laser versus half-dose photodynamic therapy for central serous chorioretinopathy : a randomized controlled pilot study [Version 1 dated 24 November 2015]

Consent Form versions	[English Version: Version 1 (dated 24 November 2015)] [Chinese Version: Version 1 (dated 18 December 2015)]
Information Sheet versions	Participant Information Sheet [English Version: Version 1 (dated 24 November 2015)] [Chinese Version: Version 1 (dated 18 December 2015)]
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 study closure (use KCKE SOP001F9b)* by January 2017. 7. Report the study results and submit any relevant publications to REC(KC/KE).

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

Review Panel (for full review only)

	Title and Name	Affiliation
Chairperson:	Dr NG Man Kin Roger	HA Staff
Members:	Dr Winnie CHAN	HA Staff
	Dr LEUNG Kwok Yin	HA Staff
	Miss Alice KAN	Lay Member
	Mr TANG King Yan	Lay Member

Mr Emmanuel KAO
Chairman of REC (Governing)
(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

Dr Mårten Erik BRELÉN

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

23 October 2018

Ref: KC/KE-15-0192/FR-3

Dear Dr BRELÉN,

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 23 October 2018 by an expedited process. The approval decision was based on the documents submitted. You are required to adhere to the attached conditions:

New Title of Study	A Randomized Controlled Clinical Trial Comparing Subthreshold Micropulse Yellow (577 nm) Laser versus Half-dose Photodynamic Therapy for Central Serous Chorioretinopathy
Principal Investigator	Dr Mårten Erik BRELÉN, Assistant Professor, Dept of Ophthalmology and Visual Sciences, CUHK / Honorary Resident, HKE
List of Co-investigators	Dr NG Siu Chun Danny, Clinical Assistant Professor, Dept of Ophthalmology and Visual Sciences, CUHK / Honorary Resident, HKE
	Dr LAI Hiu Ping Frank, Associate Consultant, Dept of Ophthalmology and Visual Sciences, PWH
	Dr SIN Pui Yee Helena, Resident Specialist, Dept of Ophthalmology and Visual Sciences, PWH
	Dr Mary HO, Associate Consultant, Dept of Ophthalmology and Visual Sciences, PWH

List of Co-investigators (Cont'd)	Dr TSANG Chi Wai, Consultant, HKE
	Dr Shaheeda MOHAMED, Associate Consultant, HKE
	Dr FONG Hon Chi Angie, Associate Consultant, HKE
	Dr FOK Chung Tin Andrew, Associate Consultant, HKE
	Dr WONG Lai Man Raymond, Associate Consultant, HKE
	Dr LOK Ka Hing, Resident, HKE
	Dr SZETO Ka Ho Simon, Resident, HKE
Protocol Amendments	REC(KC/KE) Protocol Amendment Application Form [KCKE SOP001F7] - Change of Project Title - Update of Co-investigators List - Research Protocol [Version 5 dated 3 Sep 2018_KCKE] - Participant Information Sheet [English and Chinese Versions: Version 4 (dated 3-Sep-2018)_KCKE] - Informed Consent Form [English and Chinese Versions: Version 4 (dated 3-Sep-2018)_KCKE] - Decreasing the target number of subjects from 60 to 24
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.

Conditions (Cont'd)	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 January 2019 (use KCKE SOP001F9a)*. 7. Report study closure (use KCKE SOP001F9b)* by January 2020. 8. Report the study results and submit any relevant publications to REC(KC/KE).

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

Dr Roger NG
Panel Chairman of REC(Operation)
(Kowloon Central/Kowloon East)

cc. Honorary Chief of Service, 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

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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.: 2015.573

28 DEC '15

To: Prof. Mårten Erik BRELEN
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:** Subthreshold micropulse yellow (577 nm) laser versus half-dose photodynamic therapy for central serous chorioretinopathy : a randomized controlled pilot study
- **Investigator(s):** Mårten Erik BRELEN, Frank Hiu Ping LAI, Danny NG, Helena SIN and Mary HO

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:** 22 December 2015
- **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
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

28 DEC '15

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.: 2015.573

Schedule 1
Documents Reviewed

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

- Research Protocol, Version 3, dated 03 December 2015
- Participant Information Sheet and Informed Consent Form, English Version 3, dated 03 December 2015
- Participant Information Sheet and Informed Consent Form, Chinese Version 3, dated 03 December 2015

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 03 Nov 2015
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), FRCPCH(UK)	M		
Prof. Lijia CHEN	Assistant Professor, Department of Ophthalmology Visual Sciences, CUHK	Bachelor of Med (China), Master of Op (China), PhD (CUHK), FRCS (Edin), MRCS (Edin)	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. Bonnie Ching Ha KWAN	Associate Professor, Department of Medicine and Therapeutics, PWH, CUHK	MBBS(London), MHKCP, MRCP(UK), FHKCP, FHKAM	F	√	√
Prof. Brigette MA	Professor, Department of Clinical Oncology, CUHK	FRACP(Australia),F HKCP, 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 03 Nov 2015
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, Department of Medicine and Geriatrics, 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	√	
Mr. Bryan Ping Ho CHUNG	Physiotherapist I, Physiotherapy Department, TPH	BSc in Physiotherapy, MSc in Health Care (Physiotherapy)	M	√	√
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. Christopher LIU	Executive Director, Liu Chong Hing Investment Ltd.	Bachelor of Arts (Oxford), Master of Arts in Jurisprudence (Oxford)	M		
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		√

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8 OCT '19

CREC Ref. No.: 2015.573-T

To: Prof. Mårten Erik BRELEN
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 Controlled Clinical Trial Comparing Subthreshold Micropulse Yellow (577 nm) Laser versus Half-dose Photodynamic Therapy for Central Serous Chorioretinopathy
- **Investigator(s):** Mårten Erik BRELEN, Frank Hiu Ping LAI, Danny NG, Helena SIN and Mary HO

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:** 04 January 2019
- **Date of Amendment Approval:** 10 September 2019
- **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
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Tel : (852) 3505 3935 / 2144 5926 Fax : (852) 2646 6653 Website : http://www.crec.cuhk.edu.hk

8 OCT '19

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,

Envy Lee (Secretary)
for and on behalf of
The Joint CUHK-NTEC CREC

EL/ci

CREC Ref. No.: 2015.573-T

Schedule 1
Documents Reviewed

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

Amendment dated 03 September 2018

- Research Protocol, Version 5, dated 03 September 2018 - clean and track changes version
  - With revised study title
- Participant Information Sheet and Informed Consent Form, English Version 03 September 2018 - clean and track changes version
- Participant Information Sheet and Informed Consent Form, Chinese Version 03 September 2018 - clean and track changes version

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

Title and Name	Occupation	Qualification	Male / Female (M/F)	Study Reviewed by	Present in CREC meeting on 09 Oct 2018
Vice/Deputy Chairman: Dr. Gary C.P. CHAN	Associate Consultant Department of Medicine and Therapeutics, PWH	MBChB, MRCP (UK), FHKCP, FHKAM	M		
Prof. Alice P.S. KONG	Associate Professor, Department of Medicine and Therapeutics, PWH, CUHK	MBChB(CUHK), MD (CUHK), MRCP(UK), FHKCP, FHKAM(Medicine), FRCP(Glasgow, Edin)	F	√	
Prof. Alexander Yuk Lun LAU	Assistant Professor, Dept. of Medicine and Therapeutics, CUHK	SB, MBChB, MRCP, FHKCP, FHKAM (Medicine)	M		
Acting Chairman: Prof. Cheuk Chun SZETO	Professor, Department of Medicine and Therapeutics, PWH, CUHK	MBChB(Hons)(CUHK), MD(CUHK), FRCP(Edin & Lond), FHKCP, FHKAM	M	√	√
Dr. Brian Kai Ming AU	Senior Occupational Therapist, Occupational Therapy Department, TPH	PDOT(HKP), MSc(HKPU), PhD(HKPU)	M	√	√
Dr. Albert Kam Ming CHAN	Associate Consultant, Department of Amaesthesia & Intensive Care, PWH	MBBS, FHKCA, FHKAM, FANZCA	M	√	
Dr. Andrea O.Y. LUK	Resident Specialist, Department of Medicine and Therapeutics, PWH	FHKAM, FHKCP, MHJKCP	F	√	√
Dr. Bosco H.M. MA	Associate Consultant Department of Medicine and Therapeutic, PWH	MBChB (CUHK), MD (CUHK), FRCP (Glasg), FHKCP, FHKAM (Medicine)	M	√	√
Dr. Keary R. ZHOU	Lecturer, School of Pharmacy, CUHK	BS(UCLA), PharmD(USC)	F	√	√

Title and Name	Occupation	Qualification	Male / Female (M/F)	Study Reviewed by	Present in CREC meeting on 09 Oct 2018
Ms. Suzanne So Shan MAK	Nurse from Dept. of Clinical Oncology, PWH	RN, MN, FHKAN (Medicine-Oncology)	F	√	√
Ms. Sylvia Po Yi CHENG	Associate, Morrison & Foerster LLP	PCLL (HKU) BA Law and Business Studies (Warwick)	F		
Ms. Kristy K.Y. CHEUNG	CEO, The Hong Kong College of Anaestheiologists	BSc, MAEP	F	√	
Mr. Christopher K.S. LIU	Executive Director, Liu Chong Hing Investment Ltd.	Bachelor of Arts (Oxford), Master of Arts in Jurisprudence (Oxford)	M	√	√
Mr. Ping Hei TAO	Retired	MHRM(MQU), Dip Soc Sci(HKBU)	M		
Mr. Foster H.C. YIM	Barrister-at-Law	PCLL(CUHK), D(CUHK), Msc in Marketing (CUHK), MA in Philosophy (UK), BA (Hons) in Translation (LU)	M	√	√
Dr. Sylvia S.W. AU	Associate Consultant, Department of Anaesthesia and Intensive Care, PWH	MBChB (Hons), FANZCA, FHKCA, FHKAM (Anaesthesiology)	F	√	

KOWLOON WEST CLUSTER
九龍西醫院聯網

醫院管理局
HOSPITAL AUTHORITY

Dr LAI Hiu Ping, Frank,
Resident Specialist,
Department of Ophthalmology,
Caritas Medical Centre

21 April, 2017

Dear Dr LAI,

KWC-REC Reference: KW/EX-17-051(109-16)

Title: Subthreshold micropulse yellow (577 nm) laser versus half-dose photodynamic therapy for central serous chorioretinopathy : a randomized controlled pilot study

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 21 April, 2017 by an 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 13 April, 2017) II. Research Protocol Version 3 dated 10 April, 2017 III. Participant Information Sheet and Consent Form - English Version 3 dated 3 April, 2017 IV. Participant Information Sheet and Consent Form - Chinese Version 4 dated 13 April, 2017
Document(s) reviewed	I. Approval Letter issued by Joint CUHK-NTEC CREC dated 23 December, 2015 II. Approval Letter issued by REC(KC/KE) dated 12 January, 2016 III. CV of Principal Investigator
Conditions	1. Observe and comply with all applicable requirements under our Standard Operating Procedures (SOP), the Declaration of Helsinki and the ICH-GCP (if applicable). 2. Do not implement 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. 3. Submit safety reports to the KWC-REC on all Serious Adverse Events (SAEs) observed from any subject recruited at your study site or Suspected Unexpected Serious Adverse Reactions (SUSARs) reported from outside your study site in accordance with the requirements set out in Appendix 8 of our SOP by using the REC's specified form. 4. Report the followings to KWC-REC* : (i) changes in study protocol, consent document or source of funding, (ii) protocol deviation or breach of privacy, (iii) new information that may be relevant to a subject's willingness to continue participation in the study. 5. Submit Research Final Report Form to KWC-REC by **31 May, 2018**#. 6. Apply a clinical trial certificate from Department of Health if applicable. 7. Report any adverse events to hospital management through Advanced Incidents Reporting System (AIRS) in a timely manner if applicable and state the AIRS number on the SAE form to KWC-REC. 8. As this is a study with funding support / pending for funding approval, an Alternative Source of Income (ASOI) approval shall be obtained before the start of the research. Principal Investigator should approach the Hospital Finance for details. [*Forms are available from KWC-REC intranet webpage.] [#Failure to comply with point 5 may result in non-acceptance of any future research application as Principal Investigator or Co-investigator.]

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

(AY)

KOWLOON WEST CLUSTER
九龍西醫院聯網

醫院管理局
HOSPITAL AUTHORITY

Please quote the REC Reference **KW/EX-17-051(109-16)** 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(OPH), CMC
KWCFS SFM(FP&M)/(CMC)

Secretariat of
Research Ethics Committee,
Kowloon West Cluster

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新界瑪嘉烈醫院道2-10號
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(AY)

與民攜手 Helping People Stay Healthy
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KOWLOON WEST CLUSTER
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醫院管理局
HOSPITAL AUTHORITY

Dr LAI Hiu Ping, Frank,
Associate Consultant,
Department of Ophthalmology,
Caritas Medical Centre

30 January 2019

Dear Dr LAI,

KWC-REC Reference: KW/EX-17-051(109-16)(2)

Title: A Randomized Controlled Clinical Trial Comparing Subthreshold Micropulse Yellow (577 nm) Laser versus Half-dose Photodynamic Therapy for Central Serous Chorioretinopathy

Thank you for submitting the protocol amendment application to the Research Ethics Committee of the Kowloon West Cluster (KWC-REC). I am pleased to inform you that the following amendment item(s) and document(s) have been reviewed and approved by the KWC-REC through an expedited process on 30 January 2019.

No.	Document / Amendment Type
1.	Protocol Amendment Application Form dated 22 November 2018 Changed study title from "Subthreshold micropulse yellow (577 nm) laser versus half-dose photodynamic therapy for central serous chorioretinopathy : a randomized controlled pilot study" to "A Randomized Controlled Clinical Trial Comparing Subthreshold Micropulse Yellow (577 nm) Laser versus Half-dose Photodynamic Therapy for Central Serous Chorioretinopathy"
2.	Updated CV of Co-investigators
3.	Research Protocol (Version 5 dated 12 Nov 2018_KWC)
4.	Participant Information Sheet and Informed Consent Form (English Version 5 dated 12 Nov 2018_KWC)
5.	Participant Information Sheet and Informed Consent Form (Chinese Version 6 dated 12 Nov 2018_KWC)

Please note that all conditions pertaining to the previous approval of your research study as stated in the letter of 21 April 2017 are still in force.

Yours sincerely,

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

Secretariat of
Research Ethics Committee,
Kowloon West Cluster

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

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

131 / (AY)

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