HONG KONG EAST CLUSTER
港 島 東 醫 院 聯 網

Hong Kong East Cluster Research Ethics Committee (HKEC REC)

3 Lok Man Road, Chai Wan, Hong Kong
Tel: +852 2595 6111 Fax: +852 2505 9021

HKEC REC is an independent committee established by Hong Kong East 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.

Date: 13 May 2016 REC Ref. No.: HKEC-2015-098

To: Dr. PANG Yin Chun Skyi
Associate Consultant,
Surgery, PYNEH

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

- Study Protocol Title: Paclitaxel-eluting balloon Versus plain angioplasty balloon for dysfunctional dialysis access: a prospective double-blinded randomized controlled trial
- Study Protocol No.: N/A
- Lead Principal Investigator (if applicable): N/A *(for multicentre study and if different from the principal investigator of the following study site)*
- Study Site: PYNEH

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:
- Mode of Review: ☑ Full review ☐ Expedited review
- Date of Review/Decision: 13 May 2016
- 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 approved
  - ☐ Receipt of submission acknowledged without comment
  - ☐ Application disapproved (see opinion(s) below)
  - ☐ Others (see opinion(s) below)

• Opinion(s) (if applicable):	N/A
• 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. Please refer to Section 10.2.6 for the consequences of failure to submit progress report(s);
- 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;
- maintaining the validity of the insurance policy applied for this study until study closure, if applicable;
- 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. Please refer to Section 10.7.4 for the consequences of failure to submit final report. Application dossiers and all related documents will be discarded by REC after 3 years upon study completion or termination of the study.

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
HKEC REC

(Lydia HUNG)
Secretariat, REC, HKEC
(for Chairperson of REC, HKEC)

cc. COS(Surgery), PYNEH; COS(Radiology), PYNEH; COS(Medicine), PYNEH

Schedule 1
Documents Reviewed

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

- Application Form dated 23 December 2015.
- Research Protocol, Version 1.0, Date: 4 January 2016.
- Informed Consent Form, English Version, Version 1.1; Date: 25th April 2016.
- Informed Consent Form, Chinese Version, Version 1.1; Date: 25th April 2016.
- Urgent Contact Card, English Version, Version 1.1; Date: 18th April 2016.
- Urgent Contact Card, Chinese Version, Version 1.1; Date: 18th April 2016.
- Data Collection Form, Version 1.0; Date: 4 January 2016.

Schedule 2
List of Reviewers

The reviewers participated in reviewing the said application/submission and making the decision on behalf of HKEC REC include:

Name	Occupation & Affiliated Organization	Gender (M/F)	Membership Category (Mark "Y" where appropriate)		
			Scientific	Non-scientific	Independent
Dr. Loletta SO	Chairperson of REC, HKEC / Consultant, Dept. of Medicine, PYNEH	F	Y		
Dr. Edwin CHAN	Consultant, Dept. of Ophthalmology, PYNEH	M	Y		
Ms. Janet YUNG	Advanced Practice Nurse, Dept. of Ear, Nose and Throat, PYNEH	F	Y		
Mrs. Amy YAM	Representative of Hospital Volunteer Services Group	F		Y	
Rev. SUNG Po King	Hospital Chaplain, PYNEH	F		Y	
Mr. Philip MAK	Director, APEX Insurance (Holding) Ltd.	M		Y	Y
Dr. Angel LEE	College Senior Lecturer, HKU SPACE Community College	F			Y