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 CHENG Kai Chi

Associate Consultant
Department of Surgery
Kwong Wah Hospital

25 May 2021

Ref: KC/KE-21-0103/ER-1

Dear Dr CHENG,

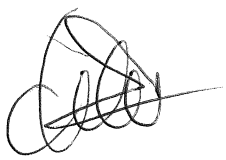
The REC(KC/KE) members are appointed by the Cluster Chief Executives to review and monitor clinical research independently according to the guidance of Declaration of Helsinki and ICH GCP Guidelines in order to safeguard the rights, safety and well-being of research subjects. It has the authority to 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 25 May 2021 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	Prognostic factors of survival and a new scoring system for liver resection of colorectal liver metastasis
Principal Investigator	Dr CHENG Kai Chi, Associate Consultant, Dept of Surgery, KWH
Co-investigator	Dr YIP Sze Man Ada, Resident, Dept of Surgery, KWH
Protocol title and version	Prognostic factors of survival and a new scoring system for liver resection of colorectal liver metastasis [Version 1 dated 7 May 2021]
Consent Form versions	N/A
Information Sheet versions	N/A
Certificate of indemnity/insurance	N/A
Other Documents	- Clinical Research Ethics Review Application Form - Data Collection Form [Version 1 dated 7 May 2021] - CV of Principal Investigator

Study site approved	Kwong Wah 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 (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 first study progress to REC by May 2022 (use KCKE SOP001F9a)*. 6. Report study closure (use KCKE SOP001F9b)* by June 2022. 7. Report the study results and submit any relevant publications to REC(KC/KE).

* *All post-approval activities such as protocol amendment, progress report, supplementary information and final report submissions should be made via HA CRER Portal.*



Dr CHAN Kam Tim
Deputy Panel Chairman of REC(Operation)
(Kowloon Central/Kowloon East)

cc. Chief of Service, Department of Surgery, KWH