香港大學
University of Hong Kong

醫院管理局
HOSPITAL AUTHORITY

香港大學及醫管局港島西醫院聯網研究倫理委員會

Institutional Review Board of the University of Hong Kong/
Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB)

Address: Rm 901, 9/F, Administration Block, Queen Mary Hospital, 102 Pokfulam Road, Hong Kong Tel 2255 3923 2255 4086

Dr. KP Au

Surgery

Queen Mary Hospital

07-May-20

Dear Dr. Au,

IRB Reference Number: **UW 20-328**

The HKU/HA HKW IRB is authorized by a joint agreement of the University of Hong Kong and Hospital Authority Hong Kong West Cluster to review and monitor clinical research. It serves to ensure that research complies with the Declaration of Helsinki and acts in accordance to ICH GCP guidelines, local regulations and Hospital Authority and the University policies.

In accordance with our standard operating procedures, we have duly performed ethics and scientific review of your application/submission. We hereby write to inform you that your application/ submission has been approved, on the above date, by an expedited process with details shown below.

Protocol title	:	Initial Experience with Stereotactic Body Radiotherapy for Intrahepatic Hepatocellular Carcinoma Recurrence after Liver Transplantation
Study site(s)	:	Queen Mary Hospital
IRB reviewer	:	Dr. James Ho, Deputy Chairman of the HKU/HA HKW IRB
Document(s) approved	:	01. Clinical Research Ethics Review Application Form
	:	02. Study Protocol; Version 1.0 dated 30th March, 2020
Document(s) reviewed	:	03. Short CV of Principal Investigator
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 ("HKU/HA HKW IRB 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 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 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 SOP; and
- submitting a final report in accordance with the requirements in the IRB 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; and
- obtaining prior approval before commencing the study from the appropriate head(s) of the study site (e.g. Head / COS / Nurse Manager / Department Manager etc) with regards to the use of facilities and subject recruitment logistics/arrangement. It is advisable to print IRB's Reference Number on all recruitment materials for potential and actual study participants.
- **comply with the new reporting requirement of study results with effect from June 2015 as stated in the World Health Organization (WHO) Statement on Public Disclosure of Clinical Trial Results for any phases of clinical trials on: (1) the main findings within 12 months, or at most within 24 month, of study completion, and (2) the key outcomes within 12 months of study completion. These results must be posted in a free-to-access, public available, searchable clinical trial registry. The full text of the WHO Statement is available in http://www.who.int/ictrp/results/reporting/en/\.**

Yours sincerely,

Mr. Chris Yip
HKU/HA HKW IRB Secretary