The University of Hong Kong – Gleneagles Hospital Hong Kong
Institutional Review Board
(HKU-GHK IRB)

HKU-GHK IRB Secretariat, Gleneagles Hospital Hong Kong, 1 Nam Fung Path, Wong Chuk Hang, Hong Kong
Tel: (852) 3153 9775

HKU-GHK-IRB is an independent committee established by The University of Hong Kong and Gleneagles Hospital Hong Kong 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: <Date of Notice>

IRB Ref. No.: <Ref. No.>

To: <PI Name>
<PI Title & Department>
<PI Affiliated Institution>

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

- Study Protocol Title: <Title>
- Study Protocol No.: <No.>
- Coordinating Investigator (if applicable): <CI Name, or put "N/A"> *(for multicentre study and if different from the principal investigator of the following study site)*
- Study Site: <Study Site>

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: <Date of meeting/expedited review>
- 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 and undertaking the ultimate responsibility for the conduct 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):

- supervising your study team and ensuring compliance with the study protocol and all applicable requirements;
- observing and complying with all applicable requirements under our standard operating procedure ("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 participants 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 participants 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 participant 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.

For the avoidance of doubt, this notice only serves to inform you of our decision from our ethics and scientific evaluation and applies only to the study at the specified study site. It does not release you from your obligation to comply with other applicable management, regulatory and ethics requirements including (but not limited to):

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

- 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;
- if required by applicable laws or regulations or relevant organizations or institutions, obtaining other necessary approval(s) or permission(s) (whether local, national or overseas, or of ethical, regulatory, legal or other natures) relevant to the conduct of the study.

Yours sincerely,
for and on behalf of
HKU-GHK-IRB

_____
Name of Chairman/Designee
Title

Schedule 1
Documents Reviewed

The documents reviewed by HKU-GHK-IRB with respect to the said application/submission include:

<List documents. Include version date/no. if applicable>

Schedule 2
List of Reviewers

The reviewers participated in reviewing the said application/submission and making the decision on behalf of HKU-GHK IRB include:

Name	**Occupation & Affiliated Organization**	**Gender** (M/F)	**Membership Category** (Mark "Y" as appropriate)		
			Scientific	**Non-scientific**	**Independent**