Gleneagles Hospital
HONG KONG
港怡醫院

Notice for HKU-GHK IRB's Decisions

University of Hong Kong - Gleneagles Hospital Hong Kong Institutional Review board (HKU-GHK IRB)

1 Nam Fung Path, Wong Chuk Hang, Hong Kong
Tel: +852 3153 9547 Fax: +852 3903 3409

HKU-GHK IRB is an independent authority established by 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> HKU-GHK IRB Ref. No.: <Ref. No.>

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

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

- Study Protocol Title: <Title>
- Study Protocol No.: <No.>
- Lead Principal Investigator: <Lead PI 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 scientificreview 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: <List document(s), or put "See Schedule 1">
- Reviewer(s): <List reviewer(s), or put "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): <State opinion(s), or put "N/A" if not applicable>
- Regular Progress Report(s) Required: Every <No.> months from the date of initial approval and during the period of the study

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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):

- observing and complying with all applicable requirements under our standard operating procedure ("HKU-GHK 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 HKU-GHK 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 HKU-GHK 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 HKU-GHK IRB SOP; and
- submitting a final report in accordance with the requirements in the HKU-GHK 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.

Yours sincerely,
for and on behalf of
University of Hong Kong - Gleneagles Hospital Hong Kong Institutional Review Board

_____
<Name of Chairman/designee>
<Title>

Attachments:

1. Schedule 1: Documents reviewed with respect to the said application/submission
2. Schedule 2: List of reviewers (including membership category) participated in reviewing the said application/submission and making the decision.

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:

<List reviewers. Include membership category>