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

Prof. Ian Wong

Pharmacology and Pharmacy

The University of Hong Kong

28-Oct-21

Dear Prof. Wong,

IRB Reference Number: **UW 20-556**

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	:	A Covid-19 Epidemiological Study on post-infection Outcomes (ACESO)
Study site(s)	:	Queen Mary Hospital
IRB reviewer	:	Dr. Desmond Yap, Deputy Chairman of the HKU/HA HKW IRB
Document(s) approved	:	01. Protocol Amendment Application Form dated 21 October 2021 (Addition of Co-Investigators' CV - Dr. Patrick IP and Ms. Eliza YT TAM)
	:	02. Study Protocol; Version 1.1 dated 15th September, 2021
Document(s) reviewed	:	03. Signed Short CV of Co-investigators
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,

[redacted]

Mr. Chris Yip
HKU/HA HKW IRB Secretary

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

Dr. Celine Chui
Pharmacology and Pharmacy
The University of Hong Kong
24-Mar-23

Dear Dr. Chui,

I write to acknowledge receipt of your submission to the HKU/HA HKW IRB as shown below, which has been dealt with via an expedited review. There was no comment raised by the Board on the submission.

IRB reviewer	:	Dr. Lui Sing Leung, Deputy Chairman of the HKU/HA HKW IRB
IRB ref. number	:	UW 21-149
Protocol title	:	COVID-19 vaccines Adverse events Response and Evaluation Programme (CARE Programme) -Part 3: To evaluate the safety of COVID-19 vaccines using electronic health records: record-linkage study
Item(s) submitted:		
		Research Progress Report Form dated 9 March 2023

Please be reminded to comply with the reporting timeframes of results, with effect from June 2015, 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 months, 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 the websites of HKU/HA HKW IRB and WHO (https://www.who.int/news/item/09-04-2015-japan-primary-registries-network#).

Yours sincerely,

Ms. Jenny Ng
HKU/HA HKW IRB Secretary

香港大學
University of Hong Kong

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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. Esther Chan
Pharmacology and Pharmacy
The University of Hong Kong
08-Mar-22

Dear Dr. Chan,

I write to acknowledge receipt of your submission to the HKU/HA HKW IRB as shown below, which has been dealt with via an expedited review. There was no comment raised by the Board on the submission.

IRB reviewer	:	Dr. Desmond Yap, Deputy Chairman of the HKU/HA HKW IRB
IRB ref. number	:	UW 21-138
Protocol title	:	Background rates of adverse events of special interest (AESI) for monitoring COVID-19 vaccines

Part 1

Item(s) submitted:

Research Progress Report Form dated 17 February 2022

Please be reminded to comply with the reporting timeframes of results, with effect from June 2015, 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 the websites of HKU/HA HKW IRB and WHO (https://www.who.int/news/item/09-04-2015-japan-primary-registries-network#).

Yours sincerely,

Mr. Chris Yip
HKU/HA HKW IRB Secretary

c.c. HKU CTC

By fax

MEMO

From:	AD(HA&P)	To:	AD(D)
Ref.:	(17) in L/M 21/2021 in DHHQ/1055/15/1/2	(Attn.:	Mr LAM Fung-shing, Edwin)
Tel.:	2961 8928	Your Ref.:	
Fax:	2573 7392	Date:	Fax: 2803 4962
Date:	25 February 2021	Total Pages:	1 + 1

LM 21/2021 COVID-19 vaccines Adverse events Response and Evaluation (DH Investigators: Mr LAM Fung-shing, Edwin/ Dr Terence CHEUNG)

I refer to the above application dated 29 January 2021.

2. I am pleased to inform you that approval has been given by the Department of Health and its Ethics Committee for you to conduct the above study. Approval has also been given to you for using departmental data as mentioned in the application while conducting the study in official capacity.

3. You are reminded to seek approval from SEO(Per)1 via Service Head under CSRs 521 & 524 if you wish to **publish** the study. Please note that there should be no presumption that approval to publish the study will be given even the approval has been given by the Ethics Committee of this Department.

4. You are also reminded to send a copy of the study report and related publications to the Headquarters Library for record purpose upon completion of the study.

(Janice YUE)
for AD(HA&P)

c.c. P/ file (Fax no.: 2803 5075)
Secretary of Ethics Committee [Attn: SMO(PM)] (Fax no.: 2761 3272)

We build a healthy Hong Kong and aspire to be an internationally renowned public health authority

Comments of the Ethics Committee on

L/M 21/2021
COVID-19 vaccines Adverse events Response and Evaluation

Ethics Committee requires the Investigator(s) to adhere to the following conditions:

1. Do not deviate from, or make changes to the study protocol without prior written approval from Ethics Committee, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues.

2. Report the followings to Ethics Committee:
   (i) study protocol or consent document change;
   (ii) study progress (use Form XIIa);
   (iii) final report (use Form XIIb);
   (iv) serious adverse event (use Form XIIc).

3. Report first study progress to Ethics Committee by **24 August 2021** and thereafter at six-monthly intervals until study closure.

From: hang_mei_lee@dh.gov.hk <hang_mei_lee@dh.gov.hk>
Sent: Thursday, September 8, 2022 10:07 AM
To: wongick <wongick@hku.hk>
Cc: anne_chee@dh.gov.hk; nanley_cheng@dh.gov.hk; Esther WY Chan <ewchan@hku.hk>; Carlos Wong <carlosho@hku.hk>; Vincent Yan <vcyan@connect.hku.hk>; pui_shan_chan@dh.gov.hk
Subject: RE: [Approval in Principle] ACESO project: application for use of CHP data (L/M 175/2022)

8 September 2022

Professor Ian Chi-kei WONG,
Department of Pharmacology and Pharmacy
The University of Hong Kong
Tel 3917 9024

Dear Professor WONG,

Application for Use of Information / Data of Department of Health
"A Covid-19 Epidemiological Study on post-infection Outcomes (ACESO)" (L/M 175/2022)

I refer to your captioned application dated 6 July 2022. I am pleased to inform you that, in principle, your application has been approved.

Enclosed is an "Undertaking on the Use of Information/Data of Department of Health" form (see SC 16-2006 Annex 6 (LM_175_2022)). Please complete it and return to us via email or at fax no. 2760 0563 for further processing.

Yours sincerely,
May LEE
(LEE Hang-mei)
for Director of Health

Tel: 2125 2182
Email: hang_mei_lee@dh.gov.hk

Encl.