CERTIFICATION OF APPROVAL

This certifies that the **University of the Philippines Diliman Research Ethics Board (UPD REB) <Review Panel #>** which is constituted and established, and functions following the requirements set by the University of the Philippines Diliman, the Philippine Health Research Ethics Board (PHREB); and in compliance with Council for International Organizations of Medical Sciences (CIOMS), the World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants (2011), World Medical Association Declaration of Helsinki and Declaration of Taipei, and the 2022 National Ethical Guidelines for Research Involving Human Participants (NEGRIHP), has approved the following study protocol and related documents:

STUDY PROTOCOL INFORMATION
Type of Submission: < Initial / Continuing Review / Study Protocol Amendment >
UPD REB Code:
Submission Date:
Study Protocol Title:
Principal Investigator:
Type of Review:
Sponsor/Funding Agency:

Approval Date:	<dd/mm/yyyy>
Expiry of Ethical Clearance*:	<dd/mm/yyyy>
Due Date of Application for Renewal of Ethical Clearance (30 Days before Expiry):	<dd/mm/yyyy> [Submit the application using the UPD REB FORM 3(A) 2024: Continuing Review Application]
Frequency of Continuing Review:	

Approved Site/s:
Date of Panel Meeting:
Quorum:
Conflict of Interest:
Members in Attendance: (Name1, position, expertise, sci/non-sci, institutional/non-institutional, male/female)

(Name2, position, expertise, sci/non-sci, institutional/non-institutional, male/female) (Name3, position, expertise, sci/non-sci, institutional/non-institutional, male/female) (Name4, position, expertise, sci/non-sci, institutional/non-institutional, male/female) (Name5, position, expertise, sci/non-sci, institutional/non-institutional, male/female)
ACTION TAKEN DURING PANEL MEETING: <APPROVAL/MAJOR MODIFICATIONS/MINOR MODIFICATIONS/DEFERRED> **(IF ACTION TAKEN IS MAJOR/MINOR/DEFERRED) FINAL APPROVAL WAS GRANTED THROUGH EXPEDITED REVIEW>**

DOCUMENTS APPROVED BY UPD REB:

1. Study Protocol <version #> <date of document>
2. Study Protocol file 1 <version #> <date of document>
3. Study Protocol file 2 <version #> <date of document>

TECHNICAL DOCUMENTS INCLUDED IN THE REVIEW:

1. Study Protocol file 3 <version #> <date of document>
2. Study Protocol file 4 <version #> <date of document>

ADDITIONAL DOCUMENTS APPROVED BY <NAME OF IRB/ERB/ERC> THROUGH <> REVIEW:

1. Study Protocol file 1 <version #> <date of document>
2. Study Protocol file 2 <version #> <date of document>

RESPONSIBILITIES OF PRINCIPAL RESEARCHER WHILE STUDY IS IN PROGRESS
(*Please note that forms may be downloaded from the UPD REB website: **https://bit.ly/updreb***)**:**

1. Progress report using the **UPD REB FORM 3(A) 2024: Continuing Review Application**, as indicated above, which includes the following: *(NOTE: In view of active ethical clearance, this report is mandatory even if the study has not started or is still awaiting the release of funds.)*
    a. The dates covered by the report
    b. Protocol summary and status report on the progress of the research
    c. Number of participants accrued
    d. Withdrawal or termination of participants
    e. Complaints about the research since the last UPD REB review
    f. Summary of relevant recent research literature, interim findings, and amendments since the last UPD REB review
    g. Any relevant multi-center research reports
    h. Any relevant information, especially about risks associated with the research

i. A copy of the informed consent document

2. Any amendment/s in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial, including personnel changes and revisions in the informed consent, must be submitted or reported using **UPD REB FORM 3(B) 2024: Study Protocol Amendment** Report of non-compliance (deviation/violation), whether minor or major, at the soonest possible time up to **six (6) months** after the event, using **UPD REB FORM 3(C) 2024: Non-Compliance (Deviation/Violation) Report**.

3. Reportable Negative Events (RNE) including from other study sites (national, international) using the **UPD REB FORM 3(F) 2024: Reportable Negative Events (RNE) Report**, guided by the list of Reportable Negative Events using the **UPD REB FORM 3(G) 2024: Queries and Notification Form** and **UPD REB FORM 3(H) 2024: Complaints**.

4. Notice of Early Termination of the study and reasons for such using **UPD REB FORM 3(D) 2024: Early Study Termination Report**, or notice of the time of completion of the study using **UPD REB FORM 3(E) 2024: Final Report**.

5. Any event which may have ethical significance, and/or any information which is needed by the UPD REB to do an ongoing review.

<NAME OF CHAIR>
Chair, UPD REB < Review Panel #>