



INSTITUTIONAL ETHICS AND REVIEW BOARD
12th Floor, Our Mother of Perpetual Succour Medical Specialty Center
Perpetual Succour Hospital
Gorordo Avenue, Cebu City
Tel No/Fax No: +63-32-342-0853

Certificate of Approval

PSH-IERB
Form 4C

Date

Principal Investigator's Name
Site Address

PSH-IERB CODE:
CLINICAL PROTOCOL NUMBER:
SPONSOR:
PROTOCOL TITLE:

Type of Review: Full Board Expedited

This is to inform you that your study has been reviewed and **APPROVED** by PSH-IERB for 1 year from (date approved) until (date of expiry).

LIST OF DOCUMENTS:

Investigator's Responsibility after Approval:

A. Two copies of the following documents should be submitted to Ethics committee within the study period with attached corresponding IERB forms.

1. Amendments for IERB Approval (Form 4B).
2. SAEs within 7days after the knowledge of the event (Form 4D).
3. Bi-annual off site Safety Reports.
4. Study Protocol Deviations (Form 4H).
5. Yearly Status Update Report to be submitted 1 month prior to study approval expiration date (Form 4A). Due Date _____.
6. Final Report (Form4L).

B. Comply with all relevant international and national guidelines and regulations.

C. Abide by the principles of good clinical practice and ethical research.

(Note: All subsequent communications will have to include the **PSH-IERB code** aside from the sponsor assigned protocol no.)

INSTITUTIONAL REVIEW BOARD MEMBERS WHO REVIEWED THE PROTOCOL:

Member	Position on EC	Qualification	Attendance
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The Perpetual Succour Hospital – Institutional Ethics and Review Board is organized and operates according to ICH-GCP and applicable laws and regulations.

PSH-IERB Chairperson