PROTOCOL DECISION FORM

[Date dd/mmm/yyyy]

RE: [Protocol Title]

[Name of Principal Investigator]
[Address]

Dear [Name of Recipient]:

Peace and all good!

The SCMC-AEI ERC had an [type of review] review on the above-mentioned protocol and has approved the same.

For your guidance, the necessary *Certificate of Approval* is attached in this communication with the necessary details of the said approval.

This SCMC-AEI ERC is organized and operates in accordance with the requirements set by the Philippine Health Research Ethics Board (PHREB); and in compliance with the WHO Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants (2011), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (2016), and the National Ethical Guidelines for Health and Health-related Research (2017).

Yours sincerely,

[Name of Chairperson]
Chairperson
St. Cabrini Medical Center – Asian Eye Institute Ethics Review Committee

CERTIFICATION OF APPROVAL

This certifies that the *St. Cabrini Medical Center – Asian Eye Institute Ethics Review Committee* (SCMC-AEI ERC) which is constituted and established, and functions in accordance with the requirements set by the Philippine Health Research Ethics Board (PHREB); and in compliance with the WHO Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants (2011), the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (2016), and the National Ethical Guidelines for Health and Health-related Research (2017), has approved the following study protocol and related documents:

<table>
<tr><td colspan="2">Type of Submission:</td></tr>
<tr><td colspan="2">SCMC-AEI ERC Protocol Reference No.:</td></tr>
<tr><td colspan="2">Protocol No. and Title:</td></tr>
<tr><td colspan="2">Principal Investigator:</td></tr>
<tr><td colspan="2">Address:</td></tr>
<tr><td>Contract Research Organization:</td><td>Sponsor:</td></tr>
<tr><td colspan="2">Co-Investigator/s:</td></tr>
<tr><td colspan="2">Type of Review:</td></tr>
<tr><td>Initial Approval Date: [dd/mmm/yyyy]

Date of Progress Report Submission: [dd/mmm/yyy]</td><td>Validity of Re-approval certificate: [dd/mmmm/yyyy]

Study protocols are reclassified as Inactive after expiry of ethical clearance.</td></tr>
<tr><td>Due Date of Application for Renewal of Certificate of Approval (60 days before expiry): [dd/mmm/yyyy]
Submit application using the Continuing Review Application/Progress Report Form (QR-ERC-002-12).</td><td>Frequency of Continuing Review: [Yearly/Every six months/Quarterly/Monthly]</td></tr>
<tr><td colspan="2">Approved site/s:</td></tr>
<tr><td colspan="2">Date of ERC Meeting:</td></tr>
<tr><td colspan="2">Quorum:</td></tr>
<tr><td colspan="2">Conflict of interest:</td></tr>
<tr><td colspan="2">Members in Attendance:
1. _____
2. _____
3. _____
4. _____
5. _____</td></tr>
</table>

Documents Approved by SCMC-AEI ERC:

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>

Responsibilities of Principal Investigator while Study is in Progress:

1. Register research study in the Philippine Health Research Registry upon approval (http://registry.healthresearch.ph)
2. Progress report using the attached *Continuing Review Application/Progress Report Form* (QR-ERC-002-12), 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 release of funds.)
   - ✔ Date covered by the report
   - ✔ Protocol summary and status report on the progress of the research
   - ✔ Philippine Health Research Registry ID
   - ✔ Number of participants accrued
   - ✔ Withdrawal or termination of participants
   - ✔ Complaints on the research since the last SCMC-AEI ERC review
   - ✔ Summary of relevant recent research literature, interim findings and amendments since the last SCMC-AEI ERC review
   - ✔ Any relevant multi-center research reports
   - ✔ Any relevant information especially about risks associated with the research
   - ✔ A copy of the informed consent document
3. Any amendment/s in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, and revisions in the informed consent, must be submitted or reported using *Protocol Amendment Submission Form* (QR-ERC-002-06).
4. Report of non-compliance (deviation/violation), whether minor or major, at the soonest possible time up to six (6) months after the event, using *Protocol Deviation Report Form* (QR-ERC-002-15).
5. Reports of adverse events including from other study sites (national, international) using the *Serious Adverse Event/s (SAE) / Suspected Unexpected Serious Adverse Reaction/s (SUSAR) Report Form* (QR-ERC-002-14), with timelines for submission guided by the GL 02 Version 2.0: Guideline on Reporting Serious Adverse Events; or list of reportable negative events.
6. Notice of early termination of the study and reasons for such, or notice of time of completion of the study using *Final Report Form* (QR-ERC-002-13)
7. Any event which may have ethical significance, and/or any information which is needed by the SCMC-AEI ERC to do ongoing review.

SCMC-AEI ERC Chairperson	Signature:		Date: (dd/mmm/yyyy)
	Printed Name:		