



SCMC-AEI Ethics Review Committee

Certification of Exemption from Ethical Review Form

QR-002-03/02/10222025

Document Date (dd/mmm/yyyy)		ERC Number:	
		Protocol Number:	

The St. Cabrini Medical Center – Asian Eye Institute Ethics Review Committee (SCMC-AEI ERC) has processed your application, and your study is being **EXEMPTION FROM ETHICAL REVIEW**. All conditions and considerations are stated below:

Protocol Title:	
Submission Date:	
Principal Investigator:	
Address:	
Contract Research Organization:	Sponsor:
Date of Review:	
Justification for this Certification:	
<ol style="list-style-type: none"> [FOR RESTROSPECTIVE CASE REPORTS / SERIES: Case reports and case series involve a small number of human participants, but are not considered research subjects, based on the premise that they do not involve research objectives and a corresponding protocol, for SCMC-AEI ERC consideration. There being no research protocol, case reports and case series are outside the scope of review conducted by SCMC-AEI ERC.] [FOR RESEARCHES THAT QUALIFIED WITH THE CRITERIA: The study protocol qualified with the criteria for exemption as stipulated on pages 48-49 in the National Ethical Guidelines for Health and Health-related Research 2022, since the study {indicate the criteria for exemption}] [FOR RESEARCHES WITH NO STUDY PROTOCOL AND DOES NOT CONSTITUTE HUMAN HEALTH RESEARCH: This activity does not constitute human health research and will not involve collection of individual identifiable data. Furthermore, the National Ethical Guidelines for Health and Health-related Research 2022 states that research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior, “if the information obtained is recorded by the investigator in such a manner that the identity of the participant cannot be ascertained”, is considered exempt from ethical review.] 	
Document/s included in the review on which this certification was based:	
<ol style="list-style-type: none"> _____ _____ _____ _____ 	



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Composition of Team on Record:

1. [Name of Principal Investigator]
2. [Names of Co-Investigators]
3. [Names of Co-Investigators]
4. [Names of Co-Investigators]
5. [Names of Co-Investigators]

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR WHILE STUDY IS IN PROGRESS:

1. Continuing compliance with the exemption criteria of the National Ethical Guidelines for Health and Health-Related Research 2017 in the duration of the study;
2. Nonetheless, such human participants in case reports / case series / non-health research are entitled to compliance of researchers with universal ethical principles of respect for persons, beneficence, and justice, as well as applicable local regulations including the Data Privacy Act of 2012 (Republic Act 10173). Thus, it is the responsibility of the author and investigator/s to ensure satisfactory compliance with the aforementioned principles and all applicable regulations, and to obtain informed consent from the human subjects involved, if personally identifiable information will be used in any way.
3. No substantial changes in research design, methodology, and subject population from the protocol submitted for exemption. Modifications that significantly affect previous risk-benefit assessment for qualification for exemption may be submitted as new protocol for initial review.

Protocols that qualify for **EXEMPTION** are automatically archived and classified as **INACTIVE**, and protocol records will be made available by SCMC-AEI ERC for three (3) years from date of action. Study protocols granted for exemption are exempt from further review including continuing review. All further queries regarding this request may be forwarded to the undersigned through ethics@asianeyeinstitute.com or telephone number +63 2 88982020 local 865.

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