SCMC-AEI Ethics Review Committee

Application Form (Initial Submission)

QR-ERC-002-01/03/10102025

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

APPLICATION FORM *(for INITIAL SUBMISSION ONLY)*

PLEASE READ:
Instructions: Fill out this form and sign the attached *Certificate of Agreement and Compliance*; thereafter attach the accomplished and completed *QR-ERC-002-01 Application From* to the initial submission package. Incomplete documents will not be accepted. Review of study protocol is based on a first-come-first-served basis.

ERC Protocol No. (to be filled out by ERC Secretariat):

To be filled out by the Investigator
Study or Protocol No.:
Study Title:

Principal Investigator:

Address:

Contract Research Organization:	**Sponsor:**

Co-Investigator/s: *(please use additional page for a complete list of co-investigators if necessary)*

☐ Investigator Initiated Research	☐ Sponsor Initiated Research

Category of Investigator	☐ affiliated	☐ non-affiliated	☐ others: *(please specify)*

Type of Research	☐ **Clinical Trial**	☐ Phase I	☐ Phase II	☐ Phase III	☐ Phase IV
	☐ **Experimental Studies**	☐ **Observational**	☐ **Chart Review**	☐ **Case Report**	☐ others: *(please specify)*
Use of Special Population	☐ Minors	☐ Elderly	☐ PWD	☐ Military	☐ PLHIV/AIDS
☐ not applicable	☐ Patients in Emergency Care	☐ Indigenous People	☐ Homeless Persons	☐ Pregnant Women	☐ others: *(please specify)*

Target No. of Subjects (for this site):

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Study Site: *(please specify exact location)*	**Study Duration:**

☐ ***Mark this if Principal Investigator is affiliated with Asian Eye Institute or St. Cabrini Medica Center Skip the questions below and sign the bottom page.***

For Principal Investigators that is not affiliated with Asian Eye Institute or St. Cabrini Medical Center, kindly complete below information. Please tick whichever is applicable and provide supporting documents if required.	
	Affiliated facility of Principal Investigator does not have an institutional REC
	No willing REC to receive and review at the site of the study (PI needs to provide documentation and state the reason/s)
	SCMS-AEI has the expertise to review the protocol and exercise oversight (PI needs to provide documentation and state the reason/s)

CERTIFIED CORRECT:			
Principal Investigator	Signature:		Date: (dd/mmm/yyyy)
	Printed Name:		

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CERTIFICATE OF AGREEMENT AND COMPLIANCE

This certifies that the undersigned agrees to comply with the following local and international ethical guidelines for research ethics and to adhere to the SCMC-AEI ERC-approved research protocol:

- Declaration of Helsinki 2024
- World Health Organization (WHO) Guidelines 2024
- International Conference on the Harmonization of Good Clinical Practice (ICH-GCP E6, R3 2025)
- Council for International Organizations of Medical Science (CIOMS) 2016
- Philippine Health Research Ethics Board (PHREB) National Ethical Guidelines for Health Research (NEGHHRR) 2022
- Philippine Food and Drug Administration (FDA) administrative orders and guidelines
- Philippine Data Privacy Act (DPA) of 2012 and its Implementing Rules and Regulations (IRR) of 2016

Principal Investigator:

_____
Print Name

_____ _____
Signature Date (dd/mmm/yyyy)

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

REQUIREMENTS CHECKLIST

(ERC secretariat to check if required documents were included in the submission package)

Put ✓ or ✗ or NA	BASIC DOCUMENTS	MUST SUBMIT
☐	1. Request Letter for Review (QR-ERC-002-02) or Cover letter with details of all the documents that are for review.	Request letter for review addressed to the SCMC-AEI ERC Chairperson signed by ALL Principal Investigators.
☐	2. Application Form (QR-ERC-002-01)	Relevant data and information about the Principal Investigators, study team, and sponsors signed by ALL Principal Investigators.
☐	3. Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04)	Completely filled-up, including page and paragraph number.
☐	4. Clinical Trial Protocol / Research Protocol	Provide the following: • Protocol abstract/project summary; • Process flow chart of the protocol (not applicable for case report/series); and • Ethical considerations in the study as a separate section in the protocol.
☐	5. Principal Investigator and Site Staff Information Sheet (QR-ERC-000-00)	Complete this form together with necessary supporting documents
☐	6. Good Clinical Practice (GCP) Training Certificate (as appropriate)	Updated GCP of Principal Investigator and research team (valid for three [3] years).

Put ✓ or ✗ or NA	STUDY-SPECIFIC DOCUMENTS	SUBMIT AS NEEDED
☐	1. Endorsement Letter	For Trainees: Certification that the protocol has been technically reviewed, approved, and endorsed by the affiliated institution.
☐	2. Informed Consent Form	Written in English or Filipino or dialect spoken and understood by research participants. Refer to the guidelines set by Philippine Health Research Ethics Board (PHREB) National Ethical Guidelines for Health Research (NEGHHRR) 2017.

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Put ✓ or ✗ or NA	STUDY-SPECIFIC DOCUMENTS	SUBMIT AS NEEDED
☐	3. Consent Form	For pediatric research participants: **Under 7 years old** — Parental Consent **7 years old to under 12 years old** — Parental Consent + Verbal Assent Script **12 years old to under 15 years old** — Parental Consent + Simplified Assent Form **15 years old to under 18 years old** — Co-sign ICF to be signed by Participant and Parent **18 years old and above** — Informed Consent Form for Adults
☐	4. A. Investigator's Brochure B. Basic Product Information document; Published literature / medical device information	A. For Phase I, II, III studies (for pharmaceutically sponsored clinical trials) B. For Phase IV studies
☐	5. Case Report Form or Data Collection Forms	Only the specified data as required by the objectives of the clinical study should be taken. Data collection should not be excessive in relation to the objectives of the clinical study.
☐	6. Questionnaires, Survey Forms or any document that will be provided to the study patient	Research tools that will be used in the study.
☐	7. Recruitment Materials	Information documents for participants (such as posters, diaries, identification cards, videos, online advertisements, etc.).
☐	8. Memorandum of Agreement for collaborative studies, Material Transfer Agreement or Good Laboratory Practice	
☐	9. Other documents deemed required: a. MOA between SCMC-AEI ERC and research sites b. MOA between SCMC-AEI ERC and institution or organization	

SCMC-AEI ERC no longer accept printed copies. All submission should be done via the ONLINE SUBMISSION portal. For inquires please email ethics@asianeyeinstitute.com