



SCMC-AEI Ethics Review Committee

Study Protocol and Informed Consent Assessment Form

QR-ERC-002-04/02/10102025

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

INSTRUCTIONS

TO THE PRINCIPAL INVESTIGATOR: Please indicate in the space provided below whether or not the specified assessment point is addressed by your Study Protocol. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found.

TO THE REVIEWER: Kindly evaluate how the assessment points outlined below have been addressed by the Clinical Trial / Study Protocol and Informed Consent Form. Confirm the submitted information by putting your comments in the space provided under “Reviewer Comments”. Summarize your comments in the “Overall Criteria” and finalize your review by indicating your conclusions under “Recommended Action”. Sign and date the space provided for the reviewers.

REMINDER TO REVIEWER: DO NOT LEAVE ANY FIELD BLANK AND REFRAIN FROM WRITING “NO COMMENT” AS YOUR ASSESSMENT UNDER “REVIEWER COMMENT”

Study/Protocol No.:
Complete Study/Protocol Title:

Short Title (if applicable):

Principal Investigator:

Contract Research Organization: or N/A

Sponsor: or N/A

PART I: STUDY PROTOCOL	TO BE FILLED OUT BY THE PRINCIPAL INVESTIGATOR OR PROPONENT			Page and paragraph where it is found	TO BE FILLED OUT BY THE REVIEWER
	Indicate if the Protocol contains the specified point				
ASSESSMENT POINTS	YES	NO	N.A.		
1. SCIENTIFIC DESIGN					
1.1. Objectives Scientific soundness • Objectives should be SMART (Specific, Measurable, Achievable, Relevant and Time-Bound)					
Feasibility of the study • Analysis of how the study may be conducted and completed successfully					



SCMC-AEI Ethics Review Committee

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ASSESSMENT POINTS	YES	NO	N.A.	Reviewer Comments
1.2. Literature review <ul style="list-style-type: none"> Up-to-date review of literature relevant to the research topic including results of animal / human studies showing known risks and benefits of intervention, adverse drug effects in case of drug trials 				
Social relevance <i>Rationale / Significance of the study</i>				
1.3. Research design <i>Appropriateness of research methods in view of objectives including process flow chart</i>				
1.4. Sample size <i>Basis and computation of sample size</i>				
1.5. Inclusion criteria <i>Criteria both for scientific merit and safety concerns and of equitable selection</i>				
1.6. Exclusion criteria <i>Criteria both for scientific merit and safety concerns and of justified exclusion</i>				
1.7. Termination criteria <i>Withdrawal criteria for participants</i>				
1.8. Statistical / Data analysis <i>Appropriateness of statistical methods to be used and how participant data will be summarized and analyzed</i>				
2. CONDUCT OF STUDY				
2.1. Data Collection Plan <i>Appropriateness of data collection, including description of personal data to be collected.</i> <i>For studies involving use of database, database management and role of personal data collector, as well as authority of investigator to access database. (NEGHHR 2022)</i>				
2.2. Specimen Handling				



SCMC-AEI Ethics Review Committee

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ASSESSMENT POINTS	YES	NO	N.A.		
<i>Specimen storage, access, disposal, and terms of use, including appropriateness of biobank custodian and adherence to institutional guidelines for biobanking, including provision for sample and data removal and destruction for biobanked samples (NEGHHR 2022)</i>					
<p>2.3. Principal Investigator and Research Team Qualifications</p> <p><i>CV, GCP, or GRP (as appropriate) certifications from all members of the research team to ascertain capability to undertake the study and manage study related risks. Provide the job descriptions of all members of the research team</i></p>					
<p>2.4. Suitability of site</p> <p><i>Adequacy of research site and infrastructures</i></p>					
<p>2.5. Study Duration</p> <p><i>(The proposed study duration will support the collection of data, meeting the objective of the study)</i></p>					
3. ETHICAL CONSIDERATIONS: Provide a chapter or section to discuss the following:					
<p>3.1. Conflict of Interest</p> <p><i>Management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site (NEGHHR 2017)</i></p>					
<p>3.2. Privacy, confidentiality, and data protection plan</p> <p><i>Measures or guarantees to protect privacy and confidentiality of participant information and in compliance with the Data Privacy Act of 2012 as indicated by data collection methods including data protection plans including the steps to be taken so that all who have access to the data and the identities of the respondents can safeguard privacy and confidentiality (ex. providing adequate instructions to research assistants, transcribers, or translators) (NEGHHR 2022);</i></p>					



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ASSESSMENT POINTS	YES	NO	N.A.		
<i>Appropriateness of processing personal data, storage of data, access, disposal, and terms of use (NEGHHR 2022; Data Privacy Act of 2012)</i>					
<ul style="list-style-type: none"> Data Collection and Processing: Only the necessary personal data compatible with the purpose of the research should be collected 					
<p>3.3. Justification for the Involvement of Vulnerable Groups</p> <p><i>Vulnerable groups include the elderly, ethnic and racial minority groups, the homeless, prisoners, and people with incurable disease, people who are politically powerless or junior members of a hierarchical group. Vulnerable participants are those who are relatively or incapable of deciding for themselves whether or not to participate in a study for reasons such as physical and mental disabilities, poverty, asymmetric power relations, and marginalization, among others and who are at greater risk for some harms. Involvement of vulnerable groups must always be assessed in the context of the protocol and the participants (NEGHHR 2017)</i></p>					
<p>3.4. Justification for Involving Minors (less than 18 years old)</p> <p><i>Involvement of minors and impact on informed consent (see 3.8.). Research involving minors must always be assessed in the context of the protocol and the participants.</i></p>					
<p>3.5. Monitoring and Protection of Vulnerable Subjects</p> <p><i>This would include special protection and monitoring plan to ensure that vulnerable subjects are not subjected to undue harm and risk. (NEGHHR 2022)</i></p>					



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ASSESSMENT POINTS	YES	NO	N.A.	Reviewer Comments
<p>3.6. Recruitment process</p> <p><i>Enumerate in a detailed manner the recruitment, including the appropriateness of identified recruiting parties. Submit recruitment materials, such as posters, flyers, leaflets, online advertisements, and the like.</i></p>				
<p>3.7. Informed Consent Process</p> <p><i>Application of the principle of autonomy and respect for persons; who will administer the informed consent process; how, where, and when it will be done; who may give consent especially in cases of vulnerable groups. Inclusion of an impartial witness. Indicate whether the investigator is serving only as an investigator or as both investigator and the participant's attending physician. Note that the attending physician cannot obtain the consent from their own patients. (NEGHHR 2022)</i></p>				
<p>3.8. Consent for Continued Participation</p> <p><i>For research involving children and adolescents, review of process for obtaining consent if the participant reaches legal age during the research. (CIOMS 2016)</i></p>				
<p>3.9. Risks</p> <p><i>Level of risk and measures to mitigate these risks (physical, psychological, social, economic), including plans for adverse event management; Review of justification for allowable use of placebo as detailed in the Declaration of Helsinki (as applicable); Review of course of action in case of breach of data (as applicable)</i></p>				
<p>3.10. Benefits</p> <p><i>Potential direct and indirect benefit to the participants; the potential to yield generalizable knowledge about the participants' condition and/or problem; non-material benefits to participant (health education, contribution to scientific</i></p>				



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ASSESSMENT POINTS	YES	NO	N.A.	Reviewer Comments
<i>knowledge, etc.) where no clear, direct benefit from the project will be received by the participant.</i>				
3.11. Safety Monitoring Plan <i>Appropriateness of measures to assess risk and burdens to the participants and precautions taken to minimize negative impact of the study on the well-being of the participants (NEGHHR 2022)</i>				
3.12. Post-Trial Access <i>Provision of clinical trials for post-trial access</i>				
3.13. Incentives or compensation and reimbursement of expenses <i>Amount and method of compensation to cover for transportation, meals, loss of income, or reimbursement of study-related expenses, post-trial access to study drug or procedure.</i>				
3.14. Community considerations <i>Impact of the research on the community where the research will be implemented and/or to whom findings can be linked; including issues like stigma or draining of local capacity; sensitivity to cultural and indigenous traditions, involvement of the community and community leaders in decisions about the conduct of study.</i>				
3.15. Collaborative study terms of reference <i>Contracts and approval of relevant offices (MOA) if study is collaborative in nature; Material Transfer Agreement (MTA), Intellectual Property approval, Investigational Device Exemption (IDE), when relevant (NEGHHR 2022)</i>				
3.16. Dissemination / Data Sharing Plan/ Statement <i>Appropriateness in sharing research results which may have significant implications on the well-being</i>				



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	YES	NO	N.A.		
<i>of the participants and the community and in relation to achieving social value. (NEGHR 2022)</i>					
3.17. Other issues <i>Review of issues not subsumed in the issues covered above.</i>					

PART II: INFORMED CONSENT FORMS	TO BE FILLED UP BY THE PRINCIPAL INVESTIGATOR OR PROPONENT			TO BE FILLED UP BY THE REVIEWER	
Both the oral informed consent discussion and the written ICF to be provided to subjects should include explanations of the following in layman's terms:	Indicate if the ICF contains the specified point			Page and paragraph where it is found	Reviewer Comments
	YES	NO	N.A.		
1. The ICF is written in both English and in a language appropriate to the level of understanding of the research participants <i>(NEGHR 2022)</i>					
2. That the subject is being invited to participate in the research stating the researcher's name and from which institution <i>(NEGHR 2022)</i>					
3. The reasons for considering the individual suitable for the study and that participation is voluntary <i>(NEGHR 2022)</i>					
4. That the subject is free to refuse to participate or withdraw in the research without penalty or loss of benefits to which he or she is entitled					



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	Indicate if the ICF contains the specified point				
Both the oral informed consent discussion and the written ICF to be provided to subjects should include explanations of the following in layman's terms:	YES	NO	N.A.		
(NEGHHR 2022)					
5. The purpose of the research is stated. (NEGHHR 2022)					
6. The expected duration of the subject's participation (including number of visits, duration of each visit in the research facility) and the possibility of early termination of the study or study visit extension (NEGHHR 2022)					
7. Approximate number of subjects involved in the trial. (NEGHHR 2022)					
8. For clinical trials involving randomization or masking, the participant is told what these involves and what chances they have of getting which group/treatment (NEGHHR 2022)					
9. Justification for the use of <i>placebo</i> in the study. The ICF should clearly states that receiving placebo treatment means no treatment will be given. (NEGHHR 2022)					
10. Available alternative procedure/s or course/s of treatment that may be available to the subject and their					



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Both the oral informed consent discussion and the written ICF to be provided to subjects should include explanations of the following in layman's terms:	YES	NO	N.A.		Reviewer Comments
important potential benefits and risks. <i>(ICH-GCP E6, R3 2025)</i>					
11. In both control and experimental group: Any foreseeable risks, pain or discomfort, or inconvenience to the subject (when applicable to an embryo, fetus, or nursing infant) associated with participation in the research, including risks to the health or well-being of the individual's spouse or partner <i>(NEGHHR 2022 and ICH-GCP E6, R3 2025)</i>					
12. Reasonably expected benefits (maybe benefit directly to the subject, to the community/society or contribution to scientific knowledge). When there is no intended clinical benefit to the subject, the subject should be made aware of this. <i>(NEGHHR 2022 and ICH-GCP E6, R3 2025)</i>					
13. Compensation whether money or other forms of material goods that will be provided in return for the subject's participation and, if so, the kind and amount <i>(NEGHHR 2022)</i>					
14. Anticipated expenses, if any, to the subject for participating in the trial <i>(ICH-GCP E6, R3 2025)</i>					



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Both the oral informed consent discussion and the written ICF to be provided to subjects should include explanations of the following in layman's terms:	YES	NO	N.A.		Reviewer Comments
15. Compensation and/or treatment available to the subject in the event of trial-related injury <i>(ICH-GCP E6, R3 2025)</i>					
16. Foreseeable circumstances and/or reasons under which the subject's participation will be terminated <i>(ICH-GCP E6, R3 2025)</i>					
17. Statement that the subject or subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue study participation <i>(ICH-GCP E6, R3 2025)</i>					
18. Responsibilities of the participants, investigator and sponsor are stated <i>(NEGHHR 2022 and ICH-GCP E6, R3 2025)</i>					
19. Whether when and how any intervention proven by the research to be safe and beneficial will be made available to the individuals after the have completed their participation in the research, and whether they will be expected to pay for them <i>(NEGHHR 2022)</i>					
20. Statement that the monitor/s, auditor/s, ERC and regulatory authority/ies will be granted direct					



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Both the oral informed consent discussion and the written ICF to be provided to subjects should include explanations of the following in layman's terms:	YES	NO	N.A.		
access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject of the subject's legally acceptable representative is authorizing such access <i>(ICH-GCP E6, R3 2025)</i>					
21. Statement that records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential. <i>(ICH-GCP E6, R3 2025)</i>					
22. The possible research uses, direct or secondary, of the subject's medical or health records, and the possible future use and final disposition of biological specimen (if applicable) <i>(NEGHHR 2022)</i>					
23. If the specimens collected will not be destroyed, then where, how and for how long will they store the specimen (if applicable)					



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	Indicate if the ICF contains the specified point					Reviewer Comments									
Both the oral informed consent discussion and the written ICF to be provided to subjects should include explanations of the following in layman's terms:	YES	NO	N.A.												
(NEGHHR 2022)															
24. Statement that the subject has the right to decide on the future use, continued storage, or destruction of collected specimens and/or personal information (NEGHHR 2022)															
25. Plans to develop commercial products may be developed from biological specimens, and whether the research participant shall receive monetary or other benefits from the development of such products (NEGHHR 2022)															
26. For research involving children and adolescent, separate consent is required per age brackets:															
<table border="1"> <tr> <td>Under 7 years old</td> <td>Parental Consent</td> </tr> <tr> <td>7 years old to under 12 years old</td> <td>Parental Consent + Verbal Assent Script</td> </tr> <tr> <td>12 years old to under 15 years old</td> <td>Parental Consent + Simplified Assent Form</td> </tr> <tr> <td>15 years old to under 18 years old</td> <td>Co-sign ICF to be signed by Participant and Parent</td> </tr> <tr> <td>18 years old and above</td> <td>Informed Consent Form for Adults</td> </tr> </table>	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					
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														
27. For research involving elderly subjects: statement in which conditions the subject is not capable															



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	Indicate if the ICF contains the specified point				
Both the oral informed consent discussion and the written ICF to be provided to subjects should include explanations of the following in layman's terms:	YES	NO	N.A.		
of giving consent and the need to obtain subject's assent and consent of a legally authorized representative (LAR) in accordance with applicable laws. <i>(NEGHHR 2022)</i>					
28. For research involving children and adolescents, statement that consent will be obtained if the participant reaches legal age in the duration of the study					
29. For research involving female of childbearing potential, proposed birth control methods should be listed and a written consent from the partner/husband should be sought. <i>(Declaration of Helsinki)</i>					
30. If the subject becomes pregnant, statement on the status of the subject's participation and monitoring plan (participation will be continued or will be withdrawn from the study)					
31. Person/ to inform in the study team including their contact numbers for further information regarding the study and whom to inform In the event of study-related injury <i>(NEGHHR 2022)</i>					



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<p>32. Statement that SCMC-AEI ERC has approved the study, and may be reached through the following contact for information regarding rights of study participants, including grievances and complaints:</p> <p><i>Name of SCMC-AEI ERC Chairperson</i> <i>Address: 8th Floor PHINMA Plaza, Rockwell Center, Makati City, Philippines</i> <i>E-mail Address: ethics@asianeyeinstitute.com</i> <i>Telephone Number: +63-8898-2020 loc. 865</i> <i>(NEGHR 2022)</i></p>					
<p>33. A statement that study participant or legally acceptable representative shall receive a copy of the signed and dated written consent form, prior to study participation.</p>					
<p>34. Statement describing extent of participant's right to access his/her records (or lack thereof vis à vis pending request for approval of non or partial disclosure) <i>(Data Privacy Act 2012)</i></p>					
<p>35. Statement whether the Investigator is serving only as an Investigator or as both Investigator and the participant's attending physician.</p>					



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Both the oral informed consent discussion and the written ICF to be provided to subjects should include explanations of the following in layman's terms:	YES	NO	N.A.		Reviewer Comments
Clear indication which activities form part of research and which form part of healthcare. <i>(Data Privacy Act 2012)</i>					
36. Other issues not subsumed in the issues covered above.					

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



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OVERALL CRITERIA FOR APPROVAL	TO BE FILED-UP BY THE REVIEWER
	Reviewer Comments
<p>1. Scientific Soundness, Research Relevance, Social Value</p> <p><i>Objectives are scientifically sound. There is genuine uncertainty of results. Results will contribute to the solution of the problem. Results will provide benefits for the participants or the society as a whole.</i></p>	
<p>2. Technical Soundness</p> <p><i>Study uses accepted scientific principles and research methodologies: sample size, statistical techniques to produce reliable and valid data, blinding methodology, if applicable, proper data collection, etc.</i></p>	
<p>3. Ethical Soundness</p> <p>3.1. Minimization of Risks</p> <p><i>Both physical & non-physical risks to human subjects should be minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. Whenever appropriate, studies should use standard procedures already being performed on the subjects for diagnostic or treatment purposes.</i></p>	
<p>3.2. Equitable Selection of Subjects</p> <p><i>Consider the principle of justice in the application of fair selection and recruitment of research participants such as balanced inclusion of males and females, age distribution, socioeconomic, physical, mental, ethnic, and educational status.</i></p>	
<p>3.3. Adequate Safety Monitoring & Provisions for Privacy and Confidentiality</p> <p><i>Research plans make adequate provisions for proper data collection and safety monitoring to protect the privacy of participants and to maintain the confidentiality of individually-identifiable data.</i></p>	
<p>3.4. Protection of Vulnerable Subjects</p> <p><i>Adequate safeguards have been included in each study to protect the rights and welfare of vulnerable subjects. No undue influence, coercion, or manipulation to participate in the study.</i></p>	
<p>3.5. Conflict of Interest</p> <p><i>Ensure the reporting of conflicts by requiring Principal Investigators disclose, signed statements within their application, all potential financial conflicts of interest on the part of investigators they have a financial obligation or interest that may pose a conflict of interest which competes with the obligation to protect the rights and welfare of human subjects. ERC should ensure that steps are adequate to evaluate, manage, reduce or eliminate potential or real conflicts of interest.</i></p>	



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	Reviewer Comments
<p>3.6. Investigator's Educational Requirements and Certification</p> <p><i>PI and the members of his or her study team (all personnel engaged in the study) have met current educational requirements for protection of human research participants; and are qualified through education, training, and experience to conduct the study. All members of the team should have a valid GRP/GCP certification, whichever is applicable.</i></p>	
<p>3.7. Quality of Informed Consent Forms</p> <p><i>ICF should be age-appropriate, easy to comprehend and contain all required elements, conform to regulations and ethical standards, be complete, accurate, and comprehensible and provide potential participant with clear descriptions of the risks or discomforts & anticipated benefits. It should be in English and a language understood by the research participant. Ensure that only information or requirements that are applicable to site are included in the consent form any other information or requirement that are not applicable to the Philippines or site should be deleted.</i></p>	

TO BE FILED-UP BY THE REVIEWER

ADDITIONAL COMMENTS: *(If the space provided below is insufficient, please attach a separate sheet and indicate it in the space below.)*

RECOMMENDED ACTION:	<input type="checkbox"/> APPROVED
	<input type="checkbox"/> MINOR MODIFICATION/S (modification is required in 1 or more documents)
	<input type="checkbox"/> MAJOR MODIFICATION/S (modification is required in 1 or more documents)
	<input type="checkbox"/> PENDING (request for further information/clarification)



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	<input type="checkbox"/> DISAPPROVED State the reasons for the disapproval:
--	---

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



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		Protocol Number:	

DOCUMENT DECISION FORM

Study/Protocol No.:			
Study/Protocol Title:			
Principal Investigator:			
Contract Research Organization:		Sponsor:	
Document/s submitted:			
Date of Submission: (dd/mm/yyyy)		Meeting Date: (dd/mm/yyyy)	

RECOMMENDED ACTION: (Please sign on the corresponding box)

COMMENT/S AND RECOMMENDATION/S OR REASON/S FOR DISAPPROVAL				

APPROVED	MINOR MODIFICATION (write on comments)	MAJOR MODIFICATION (write on comments)	DISAPPROVED (write under reason for disapproval)	PENDING (write on comments)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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