STANDARD OPERATING PROCEDURES

DEFINITION OF TERMS

Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product or investigational device and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product or device, whether or not related to the medicinal (investigational) product or device. *(from ICH-GCP)*

Benefits

A positive value that may be directly or indirectly affecting the health or well-being of a study participant.

Case Report Form

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject. *(from ICH-GCP)*

Code of Federal Regulation (CFR)

Codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government of the United States. It is divided into 50 Titles. Related to clinical trial are the following sections: CFR Title 21 Food and Drugs Part 11 (Electronic Records, Electronic Signatures), Part 50 (Protection of Human Subject), Part 54 (Financial Disclosure by Clinical Investigators), Part 56 (Institutional Review Boards) and Part 312 (Investigational New Drug Application).

Confidentiality

Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity and health information. (from ICH-GCP)

Conflict of Interest (COI)

Anyone who holds interests with respect to the application being assessed that may corrupt the person's ability to give an object and unbiased decision. Conflict of interest may be categorized either Financial COI (anyone who has financial gain/interest in the application being reviewed) or Role associated COI (this person may be the investigator, delegated or has a role to play in the study).

Decision Letter

A formal letter released by the ethics committee detailing its assessment and final recommendation of an application, query or report.

Declaration of Helsinki

Statement of ethical principles for medical research related to human subjects developed by World Medical Association.

Good Clinical Practice

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected. *(from ICH-GCP)*

Independent Consultant

Any individual who is not a member of the ethics committee that has competence in special areas to assist in the review of complex issues, his or her expertise is required beyond or in addition to that available on the ERC.

Informed Consent

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form. *(from ICH-GCP)*

Investigator's Brochure

A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects. *(from ICH-GCP)*

Investigational Device

A new or trial device that is being tested or used for an unapproved indication or used to collect additional data regarding an approved use.

Investigational Product

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. *(from ICH-GCP)*

Ethics Review Committee

An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. *(from ICH-GCP)*

International Organization for Standardization (ISO)

Standard that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose.

Layperson

A member who is not a medical practitioner or researcher.

Material Transfer Agreement (MTA)

A contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.

Membership List

A document that details the name of the members of the ethics committee, their profession/role in the ethics committee, affiliation and membership effectivity.

Principal Investigator/Investigator

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator. *(from ICH-GCP)*

Protocol Amendment

Any changes made to the approved protocol by the ethics committee.

Reviewer

A member of the ethics committee assigned by the Chairperson to assess a study proposal.

Risk

Exposure of a potential or actual study patient to injury related to his/her study participation.

Scientific Member

A member who is an expert in the field of science.

Serious Adverse Event

Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect. *(from ICH-GCP)*

Sponsor

An individual, company, institution, or organization which takes responsibility for the initiation, management and/or financing of a clinical trial. *(from ICH-GCP)*

Study Protocol

A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. *(from ICH-GCP)*

Suspected Unexpected Serious Adverse Reaction

These are suspected adverse reaction that is both unexpected and serious.

1. INTRODUCTION

Asian Eye Institute, Inc. (AEI) recognizes the importance not only of biomedical research but also other fields of research; hence in line with the expansion of AEI, the AEI-ERC is also envisioned to grow and develop to be a more independent, diverse and well-rounded committee capable to standby its objective of protecting the rights, safety and welfare of not only study participants within the institution but also in the whole community.

In this regard, AEI has signed a partnership with an accredited third level referral hospital, St. Frances Cabrini Medical Center (SCMC), which specializes in cancer and organ transplant services. The partnership widens the clinical aspects of research for both institutions. AEI serves as the exclusive Ophthalmology Department of the SCMC. A community-oriented focus is common to both institutions and the partnership will see more public health and health operations research.

With these developments, a common ERC will provide the ethical needs of the partnership. This will be named St. Cabrini Medical Center – Asian Eye Institute Ethics Review Committee (SCMC-AEI ERC).

2. VISION AND MISSION OF SCMC-AEI ERC

Our Vision

The SCMC-AEI ERC envisions itself as one of the premiere, accredited, and recognized research ethics committees in the ethical review, approval, and monitoring of clinical, operational, and policy studies in the Philippines.

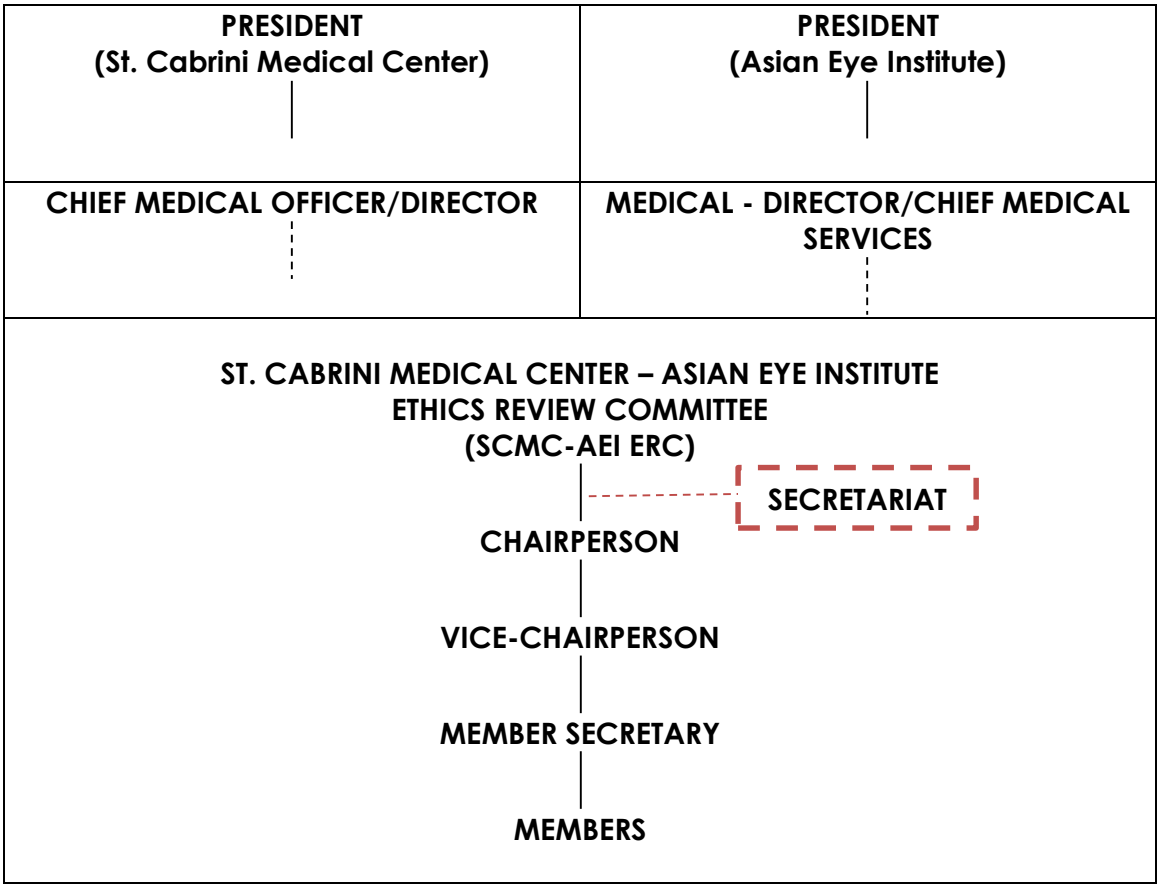
Our Mission

SCMC-AEI ERC aims:

1. To safeguard the dignity, rights, safety, and well-being of all actual or potential research participants;
2. To ensure quality and consistency in reviewing and approving all research study protocol involving humans;
3. To ensure that the site and investigator/s conduct the trials and other research according to protocol and applicable local and international guidelines; and
4. And to follow national and international ethical guidelines for biomedical and other research in human subjects.

3. ORGANIZATIONAL STRUCTURE

SCMC-AEI ERC shall operate as an independent committee according to the organization structure shown hereafter.



- SCMC-AEI ERC Implementing office:
  - Chairperson
  - Vice Chairperson
  - Member-Secretary
  - Members
    1. Medical, Affiliated Member
    2. Medical, Non-Affiliated Member
    3. Lay person, Affiliated Member
    4. Lay person, Non-Affiliated Member
- The SCMC-AEI ERC shall be composed of at least five (5) regular members.
- Its membership shall be multi-disciplinary and multi-sectoral.

- SCMC-AEI ERC shall include at least one (1) member whose primary concern is in the medical area and at least one (1) member whose primary concern is in the non-medical area, or who is a lay person.
- SCMC-AEI ERC shall include at least one (1) member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- The SCMC-AEI ERC shall have a majority of members at each meeting to comply with quorum requirements as set forth by the Philippine Health Research Ethics Board (PHREB).
- SCMC-AEI ERC may invite independent consultant with competence in special areas to assist in the review of complex issues, which require expertise beyond or in addition to that available on the ERC.

4. ESTABLISHMENT AND MANDATE OF SCMC-AEI ERC

The AEI-ERC, formerly known as AEI-IRB, was established in 2002 with the main objective of overseeing all studies being conducted at the AEI. Its purpose of protecting the rights and welfare of all potential and existing study participants has been its main thrust in continuing its service. Since its establishment, more than 100 studies have been submitted and reviewed by the committee.

In order to continue the delivery of quality service to its stakeholders, improvements have been in place to guide the SCMC-AEI ERC to serve the community better. SCMC-AEI ERC has been following both local and international guidelines, such as the Philippine National Ethical Guidelines for Health Research, Standard and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, International Conference of Harmonization Tripartite Guidelines for Good Clinical Practice, and World Health Organization (WHO) Operational Guidelines for Ethics Committees that review Biomedical Research and International Ethical Guidelines for Epidemiological Studies. SCMC-AEI ERC is also registered with PHREB since 2011. In 2014, the AEI-ERC was accredited Level two (2) by the PHREB.

Also in 2014, AEI formally partnered with SCMC taking on the responsibility of providing ophthalmological services, research and ethics review experience to the Hospital. SCMC with its centers of excellence in cardiac surgery, renal transplantation and oncology is no stranger to the ethical intricacies of procedures in these specialties and has an established ethics committee to address them. Both institutions share a vision of an ethics committee where members are constantly trained in ethical standards for present and future areas of research, ready to assess any ethical issue that may arise. The expertise of the various departments of SCMC provides a source of independent consultants in almost all fields of medicine.

5. PRINCIPLES/GUIDELINES GUIDING THE SCMC-AEI ERC

Basis for Ethical Framework

SCMC -AEI ERC will function and be guided by the ethical principles and procedures of the following local and international guidelines:

a. Declaration of Helsinki 2013
b. World Health Organization (WHO) Guidelines 2011
c. International Conference on the Harmonization of Good Clinical Practice (ICH-GCP E6, R2 2016)
d. Council for International Organizations of Medical Science (CIOMS) 2016
e. DOH AO 2019-049 (Single Joint Review)
f. DOH AO 2020-0010 (Conduct of Clinical Trials of Investigational Products)
g. Relevant Philippine Health Research Ethics Board (PHREB) resolutions and accreditation policies
h. National Ethical Guidelines for Health Research (NEGHHRR) 2017
i. Philippine Data Privacy Act of 2012 and its Implementing Rules and Regulations (IRR) of 2016
j. Appendix A – SJREB SOP
k. ISO 14155:2020 Clinical Investigation of Medical Device for Human Subjects
l. ASEAN Medical Device Directive

SCMC-AEI ERC recognizes that the protocols reviewed and approved by the committee may also be approved by the national/local ethics committee prior to its implementation.

SCMC-AEI ERC will also ensure that its members are well-informed of the diversity of laws, cultures, and practices governing health research in various countries around the world.

SCMC-AEI ERC may refer multi-site protocols that are funded by DOH, PCHRD, DOST, PHIC, PHREB, CHED and other local organizations, including industry organizations and other foreign entities to Single Joint Research Ethics Board (SJREB). In reviewing multi-sites or multi-center protocols, SCMC-AEI ERC shall be guided by the SJREB SOP.

1. OBJECTIVES

This Chapter describes the organizational structure, composition and functions of SCMC-AEI ERC.

2. SCOPE

This Chapter covers the organizational structure, its composition, selection, appointment, resignation, disqualification and replacement of Members. It outlines the specific duties, functions and responsibilities of the members and staff.

This Chapter covers also the procedures pertaining to training, management of conflict of interest, confidentiality issues and incentives for the members.

3. RESPONSIBILITY

3.1. The **SCMC and AEI Medical Directors** shall be responsible in appointing the officers of SCMC-AEI ERC after nomination among existing members.

3.2. The **Medical Directors and/or Chairperson** shall decide whether a member or potential member is capable of assuming the roles and functions of a member or officer of SCMC-AEI ERC.

3.3. **SCMC-AEI ERC** shall ensure that all members have the necessary training prior to assuming the responsibility by educating and training them regularly.

3.4. The **Chairperson** shall

3.4.1. be responsible in appointing the members of the SCMC-AEI ERC after consultation and agreement with the members of SCMC-AEI ERC;

3.4.2. budget and allocate funding for SCMC-AEI ERC activities including incentives to members and consultants;

3.4.3. ensure that Investigators, Sponsors and Researchers are well-informed on the different types of review processes, criteria for review, and timelines.

3.5. The **Secretariat** shall be responsible for providing administrative and clerical support in the management and operations of SCMC-AEI ERC by keeping track of all the documents and other requirements of the members and staff.

4. IMPLEMENTING PROCEDURES

4.1. Appointment of Members

ACTIVITY	RESPONSIBILITY
Nominate *new members*	Members
Submits *Curriculum Vitae and Training Record Form (QR-ERC-001-01)*	Nominee
Receives Curriculum Vitae and Training Record Form (QR-ERC-001-01) for review of Chairperson	Secretariat

ACTIVITY	RESPONSIBILITY
Provide new members with new relevant documents to accomplish	Secretariat
Attend relevant trainings and submit updated CV	New member/s
File all documents in the membership file	Secretariat

4.1.1. Prospective members are selected and assessed using the *Nomination Form (QR-ERC-001-02)* by current members of the SCMC-AEI ERC.
4.1.2. A copy of the member's updated *Curriculum Vitae and Record Form (QR-ERC-001-01)* along with certificates of relevant trainings must be submitted to the Secretariat.
4.1.3. A member who has previous affiliation with industry partner or study sponsor which may present possible conflict of interest will not be accepted as a member. A minimum one (1) year disengagement period from affiliation with industry partner or study sponsor will be observed prior to membership acceptance.
4.1.4. The accepted member will be given the following documents at the start of his/her appointment:
  4.1.4.1. *Appointment Letter (QR-ERC-001-03)*
    4.1.4.1.1. The appointment letter shall reflect the following: type of membership (regular or alternate member), functions as a member of the SCMC-AEI ERC, period of appointment, scope of work, and membership requirement and conditions.
    4.1.4.1.2. All new members (regardless of membership classification see section 4.4.4.6) are given two (2) years term and are subject to reappointment (of same duration), unless they express pre-termination of appointment; or when their performance is not up to SCMC-AEI ERC standards as deemed by the Chairperson.
  4.1.4.2. *Acceptance Letter (QR-ERC-001-04)*
    4.1.4.2.1. To be accomplished and transmitted to the Secretariat to signify acceptance.
  4.1.4.3. *Confidentiality Agreement and Conflict of Interest Disclosure (QR-ERC-001-05)*
  4.1.4.4. Copy of SCMC-AEI ERC Standard Operating Procedures (SOP)
4.1.5. Refusal to sign any of the above-mentioned documents can be grounds for disqualification.
4.1.6. All members are required to attend at least one of the following trainings once a year: basic research ethics, GCP, SOP, continuing review procedures and updates of local and international regulations training.

Curriculum Vitae and Training Record Form (QR-ERC-001-01) should reflect the relevant trainings completed and submit the completed form every January.

4.1.7. All other documents relevant in SCMC-AEI ERC membership file.

4.1.8. The Secretariat shall maintain an updated *Committee Composition Form (QR-ERC-001-06)*.

4.2. Nomination and Appointment of Officers

ACTIVITY	RESPONSIBILITY
Nomination of *new officer/s*	Members
Approve appointment of the *new officer/s*	SCMC and AEI Medical Directors
Send the *Appointment Letter (QR-ERC-001-03)* and *Acceptance Letter (-QR-ERC-001-04)* to the selected new officer	Secretariat
Signs the *Acceptance Letter (QR-ERC-001-04)* and submit other necessary documents	Officer

4.2.1. At the end of the period of appointment of the Chairperson, Vice-Chairperson, and Member-Secretary and during the second to the last meeting of the year, the Members shall nominate among the existing members for the position of Chairperson, Vice-Chairperson, and Member-Secretary. Outgoing Chairperson, Vice-Chairperson, and Member-Secretary may also be nominated.

4.2.2. The nominee with the most number of votes shall be designated as the new Chairperson, Vice-Chairperson, and Member-Secretary. Whenever it shall appear that two (2) or more nominees have received an equal and highest number of votes, the Committee shall proceed to the drawing of lots of the nominees who have tied and shall proclaim as elected the nominee who may be favored by luck, and the nominee so proclaimed shall have the right to assume office in the same manner as if he/she had been elected by plurality of vote.

4.2.3. The name and qualification of the new officer shall be submitted to the SCMC and AEI Medical Directors for approval.

4.2.4. *Appointment Letter (QR-ERC-001-03)* and *Acceptance Letter (QR-ERC-001-04)* to be released to the incoming officers.

4.2.5. On the *Appointment Letter (QR-ERC-001-03)* provided to the officers, the following shall be indicated:

4.2.5.1. functions as an officer of the Committee;

4.2.5.2. period of appointment;

4.2.5.3. scope of work; and
4.2.5.4. membership requirement and conditions.

4.2.6. SCMC-AEI ERC shall ensure and strive for continuity, development and maintenance of expertise within the group, with mechanism of rotating its officers. The Chairperson, Vice-Chairperson, and Member-Secretary shall have a period of appointment of three (3) years, with possible reappointment upon the recommendation and approval of the SCMC and AEI Medical Directors. The Chairperson, Vice-Chairperson, and Member-Secretary shall have a period of appointment of three (3) years.

4.2.7. Incoming officer to sign the *Acceptance Letter (QR-ERC-001-04)* and submit necessary documents.

4.3. Nomination and Appointment of Independent Consultants

ACTIVITY	RESPONSIBILITY
Nominate an *Independent Consultant*	Chairperson or any Members
Review credentials and expertise for final listings	Members
Notify the Independent Consultant and ask to submit necessary documents	Secretariat
Accomplish and submit the necessary documents	Independent Consultants

4.3.1. Any member of the committee may nominate an independent consultants to help out in the review activity of the committee.

4.3.2. The nominator shall provide the names and expertise of the consultant whom they strongly believe can help the committee during the review process.

4.3.2.1. Independent consultant to submit signed and dated *Curriculum Vitae and Training Record Form (QR-ERC-001-01)* for review of credentials and expertise.

4.3.2.2. Among the list, Chairperson will inform the Directors of the institutions of the chosen independent consultants.

4.3.2.3. The Secretariat shall create and maintain a list of all independent consultants.

4.3.3. The Secretariat shall provide the Independent consultants the following:

4.3.3.1. *Appointment Letter (QR-ERC-001-03)*
4.3.3.2. *Acceptance Letter (QR-ERC-001-04)*
4.3.3.3. *Confidentiality Agreement and Conflict of Interest Disclosure Form (QR-ERC-001-05)*

4.3.4. Any member may request for an independent consultant to assist in the study protocol review based from the list.

4.4. Organizational Roles, Responsibilities and Authorities of Members

4.4.1. *Chairperson*

4.4.1.1. *Role:*

The Chairperson provides leadership, oversees and directs the whole operations and management of the SCMC-AEI ERC within applicable regulatory requirements and ensuring that all study protocols are in adherence to the highest ethical standards of research.

4.4.1.2. *Qualifications:*

4.4.1.2.1. The Chairperson must be a highly respected individual, from the SCMC and AEI, fully capable of managing the SCMC-AEI ERC and the matters brought before it with fairness and impartiality.

4.4.1.2.2. Must possess leadership qualities, fair and impartial.

4.4.1.2.3. Must be respectful of divergent views, able to encourage and help achieve consensus.

4.4.1.2.4. Shall be available to participate in SCMC-AEI ERC activities on a regular basis, including attendance at scheduled meeting.

4.4.1.3. *Knowledge Requirements:*

4.4.1.3.1. Should be familiar with the different methodologies and ethical considerations that apply to each type of proposed research they review.

4.4.1.3.2. Must be aware of the general ethical principles: respect for person or rights; beneficence; non-maleficence; and justice.

4.4.1.3.3. Must be able to ascertain the acceptability of proposed research in terms of institutional commitments and country regulations, applicable laws, and standards or professional conduct and practice.

4.4.1.3.4. Possesses professional competence necessary to review the specific research activities.

4.4.1.3.5. Must be sufficiently qualified through the experience and expertise, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subject.

4.4.1.3.6. Must have the ability to evaluate the risks or benefits to study participants, and to determine the ethical and medical merit of proposed research.

4.4.1.3.7. Must declare any conflict of interest (COI) and follow the procedures to manage any possible COI in the course of his/her decision making.

4.4.1.4. *Skills Requirements:*

4.4.1.4.1. Must have administrative, leadership, critical thinking and interpersonal skills.

4.4.1.4.2. Must have listening skills, patience, ethical decision making skills, and trustworthiness.

4.4.2. *Vice-Chairperson*

4.4.2.1. *Role:*

The Vice-Chairperson assists the Chairperson, provides leadership, oversees and directs the whole operations and management of the SCMC-AEI ERC within applicable regulatory requirements and ensuring that all study protocols are in adherence to the highest ethical standards of research.

4.4.2.2. *Qualifications:*

4.4.2.2.1. Must have the leadership and administrative skills necessary to preside meetings in the absence of the Chairperson and to exercise the authorities and responsibilities of their positions.

4.4.2.2.2. Must also be highly motivated to fulfill the duties of the Chairperson with the commitment of time/effort necessary for these essential functions.

4.4.2.2.3. Must have the knowledge, skills, and abilities necessary to carry out the functions of the SCMC-AEI ERC.

4.4.2.2.4. Takes responsibility of the Chairperson to provide leadership especially on his/her absence.

4.4.2.2.5. He/she assists the Chairperson in ensuring that the operations of the SCMC-AEI ERC is within all applicable regulatory requirements.

4.4.2.2.6. The Vice-Chairperson, in the absence of the Chairperson, is authorized to head the Committee and ensure that all research activities are conducted in adherence to the highest ethical standards of research.

4.4.2.3. *Knowledge Requirements:*

4.4.2.3.1. Should be familiar with the different methodologies and ethical considerations that apply to each type of study protocol they review.
4.4.2.3.2. Must be aware of the general ethical principles: respect for persons or rights; beneficence; non-maleficence; and justice.
4.4.2.3.3. Must be able to ascertain the acceptability of proposed research in terms of institutional commitment and country regulations, applicable law, and standards or professional conduct and practice.
4.4.2.3.4. Possesses professional competence necessary to review the specific research.
4.4.2.3.5. Must be sufficiently qualified through the experience and expertise, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
4.4.2.3.6. Must have the ability to evaluate the risks or benefits to study participants, and to determine the ethical and scientific merit of proposed research.
4.4.2.3.7. Must declare any conflict of interest (COI) and follow the procedures to manage any possible COI in the course of his/her decision making.

4.4.2.4. *Skills Requirements:*
4.4.2.4.1. Must have administrative, leadership, critical thinking and interpersonal skills.
4.4.2.4.2. Must have listening skills, patience, ethical decision-making skills, and trustworthiness.

4.4.3. *Member-Secretary*
4.4.3.1. *Role:*
4.4.3.1.1. The Member-Secretary coordinates the activities of the SCMC-AEI ERC among the members and the study protocol stakeholders. He/ She is likewise responsible for supervising the office operations through the Secretariat.
4.4.3.1.2. The Member-Secretary, in the absence of the Chairperson and Vice-Chairperson, is authorized to head the Committee and ensure that all study protocol related activities are conducted in adherence to the highest ethical standards of research.

4.4.3.2. *Qualifications:*

4.4.3.2.1. Must have appropriate skills relevant to the management of office operations.

4.4.3.2.2. Must have the leadership and administrative skills necessary to preside meetings in the absence of the Chairperson and Vice-Chairperson to exercise the authorities and responsibilities of their positions.

4.4.3.2.3. Must also be highly motivated to fulfill the duties of the Chairperson and Vice-Chairperson with the commitment of time/effort necessary for these essential functions.

4.4.3.2.4. Must have the knowledge, skills, and abilities necessary to carry out the functions of the SCMC-AEI ERC.

4.4.3.3. *Knowledge Requirements:*

4.4.3.3.1. Should be familiar with the different methodologies and ethical considerations that apply to each type of proposed research they review.

4.4.3.3.2. Must be aware of the general ethical principles: respect for persons or rights; beneficence; non-maleficence; and justice.

4.4.3.3.3. Must be able to ascertain the acceptability of proposed research in terms of institutional commitment and country regulations, applicable law, and standards or professional conduct and practice.

4.4.3.3.4. Possesses professional competence necessary to review the specific research.

4.4.3.3.5. Must be sufficiently qualified through the experience and expertise, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

4.4.3.3.6. Must have the ability to evaluate the risks or benefits to study participants, and to determine the ethical and scientific merit of proposed research.

4.4.3.4. *Skills Requirements:*

4.4.3.4.1. Must have administrative, leadership, critical thinking, and interpersonal skills.

4.4.3.4.2. Must have listening skills, patience, ethical decision-making skills, and trustworthiness.

4.4.3.4.3. Must have administrative skills in management of office operations.

4.4.4. *Members*

4.4.4.1. Required to review all assigned study protocols and ensure adherence to the highest ethical standards of research.
4.4.4.2. Serves as a voting member of the Committee.
4.4.4.3. May or may not affiliated with the Institution.
4.4.4.4. May or may not come from the medical profession.
4.4.4.5. At least one (1) lay person as member.
4.4.4.5.1. Primary background may not be in health research;
4.4.4.5.2. Share insights about the communities from participants are likely to be drawn;
4.4.4.5.3. May or may not be affiliated with the institution.

4.4.4.6. *Membership Classification (Regular and Alternate Member)*
4.4.4.6.1. A Regular Member is a member that is required to attend the monthly full-board meeting.
4.4.4.6.2. A member who is appointed as Chairman, Vice-Chairman and Member Secretary is automatically considered as a Regular Member.
4.4.4.6.3. An Alternate Member is a member that is called to replace an absent regular member to attend the full-board meeting.
4.4.4.6.4. Both the Regular and Alternate Members are eligible to become either a Primary or Secondary Reviewer.
4.4.4.6.5. Both the Regular and Alternate Members have the same appointment duration (see section 4.1.4.1.2).

4.4.5. *Independent Reviewer*

4.4.5.1. *Role:*
4.4.5.1.1. Review specific protocols that require his/her expertise.
4.4.5.1.2. Primarily ensures the medical and technical soundness of the study protocol.
4.4.5.1.3. Ascertains that the rights and welfare of study protocol participants are adequately protected.
4.4.5.1.4. May or may not be affiliated with the institution.
4.4.5.1.5. Does not participate in the approval voting process.

4.4.5.2. *Knowledge Requirements:*
4.4.5.2.1. Must possesses competence in special areas to assist in review of complex issues, which require expertise beyond or in addition to that available on the SCMC-AEI ERC.
4.4.5.2.2. Must have the ability to determine the medical merit of the study protocol and evaluate the risks and benefits to study protocol participants.

4.4.5.2.3. Must be sufficiently qualified to have the knowledge and expertise on the topic he/she is called upon to review.
4.4.5.2.4. Must be aware of the general ethical principles: respect for persons or rights; beneficence; non-maleficence; and justice.

4.4.5.3. *Duration of Service*
4.4.5.3.1. The services rendered by the independent consultant is per study protocol basis.
4.4.5.3.2. The independent consultant may wish not to continue to render his/her service on the succeeding study protocol by notifying the Chairperson.
4.4.5.3.3. The SCMC-AEI ERC may discontinue seeking the service of the independent consultant should he/she does not comply with the responsibility set forth in this SOP.

4.4.6. <u>*Secretariat*</u>
4.4.6.1. *Role:*
4.4.6.1.1. Under the supervision of the Chairperson, Vice-Chairperson, and Member-Secretary, provides administrative support in the proper functioning of the SCMC-AEI ERC in its daily office operations and functions.
4.4.6.1.2. Organize and prepare necessary requirements and documentations for SCMC-AEI ERC meetings;
4.4.6.1.3. Prepare the *Meeting Agenda (QR-ERC-002-07)* and *Minutes of the Meeting (QR-ERC-002-08)*;
4.4.6.1.4. Receive and acknowledge all documents submitted in a timely manner;
4.4.6.1.5. Establish open communication with all members of the Committee, sponsors, investigators and study coordinators;
4.4.6.1.6. Ensure that the SCMC-AEI ERC database is up to date;
4.4.6.1.7. Ensure proper filing and record keeping of all documents;
4.4.6.1.8. File all study related communication in the SCMC-AEI ERC master file;
4.4.6.1.9. Ensure that the SCMC-AEI ERC master file, which contains all the activities, membership information, is updated and maintained accordingly;
4.4.6.1.10. Keep track all the expenses of the SCMC-AEI ERC and submit to the Chairperson for review;

4.4.6.1.11. Prepare required letters and forms;
4.4.6.1.12. Secure offices and files in accordance with existing policies and procedures; and
4.4.6.1.13. Submit weekly status update to Chairperson and Member-Secretary.

4.4.6.2. *Qualifications:*
4.4.6.2.1. Must be a college graduate.
4.4.6.2.2. Must be a regular AEI employee.
4.4.6.2.3. Must undergo relevant training prior to performing his/her tasks as Secretariat.

4.4.6.3. *Knowledge and Skills Requirements:*
4.4.6.3.1. Basic office skills including typing, filing, sorting, documenting, and archiving;
4.4.6.3.2. Good interpersonal skills; and
4.4.6.3.3. Good communication skills.

4.5. Renewal, Resignation, Disqualification and/or Replacement of a Member
4.5.1. Renewal:
4.5.1.1. An outgoing member or officer may be renewed for another term.
4.5.1.2. The member must meet the following criteria to be eligible for renewal:
4.5.1.2.1. Participated in more than sixty percent (60%) of the total meetings held during the time of his/her appointment; and
4.5.1.2.2. Completed required training during his/her appointment duration.
4.5.1.3. Proper conduct and behavior are expected in all members of the SCMC AEI ERC. Officers has the discretion to not renew a member if he/she has shown unprofessional or inappropriate manner during the course of his/her appointment.
4.5.1.4. Upon the approval of the Chairperson or SCMC and AEI Medical Directors, the member or officer shall be re-appointed.

4.5.2. Replacement:
4.5.2.1. Members and officers who have resigned or disqualified may be replaced through the same process of nomination/selection as stated above.
4.5.2.2. Existing members may nominate new members or officer. For members who will act as the replacement shall have a period of appointment limited to the remaining term of the member

he/she replaced. He/she can be reappointed for another three (3) years upon the approval of the Chairperson.

4.5.3. Resignation:
- 4.5.3.1. A member and officer may resign from their position at any point during his/her term.
- 4.5.3.2. For members, a letter of resignation indicating the reason for his/her resignation shall be submitted to the Secretariat and addressed to the Chairperson.
- 4.5.3.3. For Chairperson, a letter of resignation indicating the reason for his/her resignation shall be submitted to the Secretariat and addressed to the director of the institutions.

4.5.4. Disqualification:
- 4.5.4.1. A member or officer may be disqualified and removed if there is a legitimate cause or reason as determined by SCMC-AEI ERC (e.g. intentionally violating the rules and regulations of the SCMC-AEI ERC).
- 4.5.4.2. A deliberation among members will be made and majority vote of the SCMC-AEI ERC is necessary to determine disqualification of the member.
- 4.5.4.3. The decision will be recorded in the *Minutes of the Meeting (QR-ERC-002-08)* and all pertinent documents will be filed accordingly.

4.6. Training of Members

4.6.1. Initial training to new member and staff
- 4.6.1.1. The Chairperson/Secretariat shall provide initial training to new members and/or staff.
- 4.6.1.2. Initial training shall include ICH-GCP training, mentoring of SCMC-AEI ERC SOP, and observation during committee meeting.
- 4.6.1.3. The Chairperson or any designated personnel may conduct the initial training to the new members and/or staff.

4.6.2. Training records
- 4.6.2.1. All training records must be kept and filed by the Secretariat.
- 4.6.2.2. Training records include: in-house training attendance and certificates, if applicable.
- 4.6.2.3. A copy of the certificates obtained through external trainings must be submitted by the members to the Secretariat.
- 4.6.2.4. The Secretariat must keep track all the trainings participated by the members and also the trainings that is needed by the members in order to fulfill their duties.

4.6.3. Continuing education for members and staff

4.6.3.1. All members and Secretariat must undergo yearly training of at least one of the following: SOP training for member and staff (especially if there are changes in the SOP), Use of the Assessment Forms and Templated, Basic Research Ethics Training, Continuing Review Procedures (amendment, progress, final report, site visit, SAEs/SUSARs and deviations), Implementation of local regulations.

4.6.3.2. The Chairperson or Secretariat shall develop a yearly calendar of trainings that will be shared to the members at the start of the year.

4.6.3.3. Trainings shall be coordinated and arranged by the Secretariat.

4.7. Compensation of Members and Independent Consultants

4.7.1. Every 3rd or 4th quarter of the year, the Chairperson develops the SCMC-AEI ERC's budget plan for the following year. Budget plan shall include the meeting expenses such as food, honorarium, training expenses, and office supplies. The final budget is subject to approval of the institute.

4.7.2. Check request shall be requested by the Secretariat from the AEI Finance Department.

4.7.3. Processing and issuance of the final check to be done by AEI Finance Department.

4.7.4. An honorarium will only be given after a service has been rendered. The full amount shall be given by the Secretariat to the members and/or consultants at the end of the meeting or service.

4.7.5. The member/consultant shall acknowledge the honorarium in writing using the *Acknowledgement Receipt (QR-ERC-001-07)*. The documentation will be filed in the SCMC-AEI ERC master file and liquidation report will be submitted to AEI Finance Department.

4.8. Management of Conflict of Interest and Confidentiality Issues

Conflict of Interest as stated in the National Ethical Guidelines for Health and Health-Related Research (NEGHHRR) 2017 arises when member/s of the Ethics Committee holds interests with respect to specific applications for review that may jeopardize his/her ability to provide free and independent evaluation of the research focused on the protection of the research participants. Conflict of interests may arise when a member has financial, material, institutional, or social ties to the research. For example: serving as a member of the research team, receiving salary from the sponsor, having equity interest of and holding management position in the business entity, or holding patent right or receiving royalties from such rights whose value may affect the value of the research outcome.

4.8.1. *Financial Conflict*

A financial interest is defined as anything of monetary value related to the research, including, but not limited to:

4.8.1.1. Salary or other payments for services (e.g. consulting fees or honoraria);
4.8.1.2. Equity interests (e.g. stocks, stock options or other ownership interests, excluding any interest arising solely by reason of investment in a business by a mutual, pension, or other institutional investment fund over which the SCMC-AEI ERC member or his/her immediate family does not exercise control); and
4.8.1.3. Intellectual property rights (e.g. patents, copyrights, and royalties from such rights).

4.8.2. *Role Conflict*

This involves any situation where an SCMC-AEI ERC member has any significant personal interest. Examples of a conflicting interest would be if the SCMC-AEI ERC member is a:

4.8.2.1. Principal Investigator;
4.8.2.2. Co-Principal Investigator;
4.8.2.3. Investigator receiving funding from the study, as listed in the study budget;
4.8.2.4. In a supervisory role over the Primary Investigator of the study;
4.8.2.5. Anyone who is involved in the conduct of the research or a competing study;
4.8.2.6. Acts as a consultant/employee of the study sponsor; and
4.8.2.7. Family member or relative of the Primary Investigator.
4.8.2.8. Member who is previously affiliated with study sponsors or industry partner.

4.8.3. *Managing Conflict of Interest*

Possible conflict of interest will always exist, and it is the responsibility of SCMC-AEI ERC to manage and control any conflict of interest in order to maintain an objective and credible decision.

To ensure unbiased review of the study proposal, the SCMC-AEI ERC shall exercise the following:

4.8.3.1. All members to declare any conflict of interest (using the *Confidentiality Agreement and Conflict of Interest Disclosure Form (QR-ERC-001-05)* prior to acceptance of their appointment;
4.8.3.2. At the start of every meeting, all members shall disclose any conflict of interest regarding the study protocol which is scheduled to undergo review;
4.8.3.3. Any member having reported financial, or role conflict will be asked to leave the meeting; and

4.8.3.4. Any conflict of interest and the steps taken to manage the situation shall be recorded in the *Minutes of the Meeting (QR-ERC-002-08)*.

4.8.4. *Confidentiality*

4.8.4.1. All information (study protocol, consent forms, patient materials, results, etc.) submitted to the SCMC-AEI ERC are considered confidential information likewise deliberations during the meeting are also considered confidential information. It is expected by the investigator, researcher, sponsor and patients that all information shared will be kept confidential and will not be divulged to any third party or unauthorized individual.

4.8.4.2. In order to protect researcher, sponsor and study protocol participants' privacy and confidentiality SCMC-AEI ERC shall:

4.8.4.2.1. Require all members to sign *Confidentiality Agreement and Conflict of Interest Disclosure Form (QR-ERC-001-05)* prior to acceptance of their appointment; and

4.8.4.2.2. Require non-members (e.g. independent consultant) who will attend the meeting to sign the *Confidentiality Agreement Form for Non-Member (QR-ERC-002-10)* at the start of the meeting.

5. FORMS AND APPENDIX

5.1. QR-ERC-001-01 - Curriculum Vitae and Training Record Form
5.2. QR-ERC-001-02 - Nomination Form
5.3. QR-ERC-001-03 - Appointment Letter
5.4. QR-ERC-001-04 - Acceptance Letter
5.5. QR-ERC-001-05 - Confidentiality Agreement and Conflict of Interest Disclosure Form
5.6. QR-ERC-001-06 - Committee Composition Form
5.7. QR-ERC-001-07 - Acknowledgement Receipt
5.8. QR-ERC-002-07 – Meeting Agenda
5.9. QR-ERC-002-08 – Minutes of the Meeting
5.10. QR-ERC-002-10 – Confidentiality Agreement Form for Non-Member

6. REVISION HISTORY

Version No.	Date	Author/s	Main Change
00	01 April 2011	Mary Ann Catacutan	
01	20 March 2013	Mary Ann Catacutan	Added reports submission, confidentiality, conflict of interest, trainings and independent consultant

Version No.	Date	Author/s	Main Change
02	13 January 2014	Mary Ann Catacutan	Changed SOP format
03	10 September 2014	Mary Ann Catacutan	Added milestone and COI form
04	29 April 2015	Mary Ann Catacutan	Added process flows and related forms
05	25 November 2015	Mary Ann Catacutan /Carmina Villanueva	Changed process flow format
06	17 February 2016	Mary Ann Catacutan /Carmina Villanueva	Updated responsibilities of Chairperson and Member-Secretary
07	10 July 2017	Mary Ann Catacutan	Updated responsibilities of Member-Secretary
08	11 December 2018	Joe Vincent Aguila	Alternate Membership; Formation of *quorum*
09	14 September 2020	Joe Vincent Aguila / Rachelle A. Manzo / Noemi Luz Mojares	Updated the contents and related forms
10	20 September 2021	Mary Ann Catacutan-Catis	Updated the contents based on the PHREB and FERCAP assessment
11	02 April 2024	Mary Ann Catacutan-Catis/ Noemi Luz Mojares	Updated the Basis for Ethical Framework and clarification on the renewal, resignation and disqualification of member.

1. OBJECTIVES

This Chapter describes the management of initial review, resubmission, classification, assignment, review and approval and documentation processes of study protocols by the SCMC-AEI ERC.

Additionally, this will describe the conduct of study protocol review and scheduling of meetings processes.

2. SCOPE

This Chapter covers the following:

2.1. type of study protocols received and accepted;
2.2. submission of requirements for study protocol review;
2.3. management of study protocol classification, initial review, resubmission and release of decision;
2.4. assignment of study protocols reviewers;
2.5. conduct of reviews and meetings;
2.6. guidance in the conduct of study protocol reviews during initial submission, and resubmissions; and
2.7. guidance and timeliness in the review process, meeting preparations and decision-making.

3. IMPLEMENTING PROCEDURES

3.1. Jurisdiction of Study Protocol Review

SCMC-AEI ERC reviews study protocols conducted by residents, fellows and other trainees, consultants, and employees of SCMC and AEI. It also reviews study protocols conducted by non-SCMC and non-AEI Principal Investigators who plan to conduct their study protocols involving hospital patients, hospital employees, staff and trainees as subjects; the use of specimen, hospital facilities, records, databases; and, the use of the hospital as a research site.

The SCMC-AEI ERC, under special circumstances, may accept other study protocols outside of aforementioned jurisdiction. The SCMC-AEI ERC can accept protocols if it falls in one of the following conditions: (a.) The facility has no institutional REC (b.) No willing REC at the site of the study which the Principal Investigator needs to declare and clarify (c.) SCMC-AEI has the expertise to review the protocol and exercise oversight (d.) SCMC-AEI review is in accordance with relevant guidelines and regulations (PHREB, DOH, FDA, etc.).

3.2. Study Protocol Review Workflow

<table>
<tr><td colspan="3">Principal Investigator
Submits a complete protocol package Application Form (QR-ERC-002-01)
↓ (Day 1 – business day)</td></tr>
<tr><td colspan="3">Secretariat
Receives the complete documentary requirements under the protocol package, ensures correctness and completeness based on the Application (QR-ERC-002-01)
↓ (Day 2-3 – business day)</td></tr>
<tr><td colspan="3">Chairperson and/or Member-Secretary
Determines the study protocol's EXEMPTION FROM REVIEW of the kind of review required – EXPEDITED REVIEW or Full Board Review – based on risks classifications and assigns the Reviewers
↓ (Day 3-4 – business day)</td></tr>
<tr><td colspan="3">Principal Investigator/Sponsor
Receives invoice and Settle payment
↓
(invoice released between Day 5-7 – business day, payment should be settled on or before due date)</td></tr>
<tr><td>EXEMPTED FROM REVIEW</td><td>EXPEDITED REVIEW</td><td>FULL BOARD REVIEW</td></tr>
<tr><td colspan="3">Secretariat
Distributes the e-copy of the complete protocol package to the Reviewers.
↓
Copies to be distributed by ERC Secretary within 1-2 days after payment confirmation</td></tr>
<tr><td>Chairperson
Reviews the application for exemption from ethical review and accomplishes Certification of Exemption from Ethical Review Form (QR-ERC-002-03) and submit findings and recommendations to the Secretariat and/or may recommend reclassification to either Expedited or Full Board Review.
↓</td><td>Reviewers
Review the study protocol, accomplish the Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04) and submit the findings and recommendations to the Secretariat, or recommend reclassification to a Full Board Review.
↓</td><td>Reviewers
Review the study protocol, accomplish the Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04), and prepare to present findings and recommendations in a Full Board Meeting.
↓</td></tr>
</table>

(Reviewer is given 7-10 working days to complete review)	*(Reviewer is given 7-10 working days to complete review)*	*(Reviewer is given 7-10 working days to complete review)*
Secretariat • Collates the comments and recommendations of the Chairperson. • Prepares the decision/approval letters. • Includes in the meeting agenda if study protocol requires reclassification to a Full Board Review. ↓ *(within 14 working days after receipt from Chairman)*	**Secretariat** • Collates the comments and recommendations of the Reviewers. • Prepares the decision/approval letters. • Includes in the meeting agenda if study protocol requires reclassification to a Full Board Review. ↓ *(within 14 working days after receipt from reviewer)*	**Secretariat** • Includes in the meeting agenda. ↓ *(1-2 business days after receipt from reviewer)*
Chairperson Reviews and signs the *Protocol Decision Form (QR-ERC-002-05).* ↓ *(within 7 working days after receipt from secretariat)*	**Chairperson** Reviews and signs the *Protocol Decision Form (QR-ERC-002-05).* ↓ *(within 7 working days after receipt from secretariat)*	**Reviewers** Presents the study protocol synopsis and their comments and recommendation in the Full Board Meeting. ↓ *(presented on the day of the full board meeting)*
Secretariat Releases the *Protocol Decision Form (QR-ERC-002-05)* and annexes in the meeting agenda. ↓ *(within 2-3 working days)*	**Secretariat** Releases the *Protocol Decision Form (QR-ERC-002-05)* and annexes in the meeting agenda. ↓ *(within 2-3 working days)*	**Members** Discuss, deliberate, and vote on the decision as minor, major modification, approved or disapproved. ↓ *(presented on the day of the full board meeting)*
Principal Investigator Receives and acts on the recommendations	**Principal Investigator** Receives and acts on the recommendations *(Submit response within 30 working days, failure to do so*	**Secretariat** Prepares the *Protocol Decision Form (QR-ERC-002-05).* ↓

	may warrant cancellation of the study protocol and resubmission of documents will be required)	*(within 14 working days after the full board meeting)*
		Chairperson Reviews and sign the *Protocol Decision Form (QR-ERC-002-05).* ↓ *(within 7 working days after receipt from secretariat)*
		Secretariat Releases the *Protocol Decision Form (QR-ERC-002-05).* ↓ *(within 2-3 working days after receipt from chairperson)*
		Principal Investigator Receives and acts on the recommendations *(Submit response within 30 working days, failure to do so may warrant cancellation of the study protocol and resubmission of documents will be required)*

3.3. Receipt and Management of Study Protocol Submission

The Principal Investigator submits the study protocol package for initial review which must be received together with duly signed and accomplished forms and documents (as applicable) as enumerated in *the Application Form (QR-ERC-002-01):*

3.3.1. Basic Documents (must submit)

3.3.1.1. *Application Form (QR-ERC-002-01);*

3.3.1.2. *Request Letter for Review (QR-ERC-002-02)* addressed to the Chairperson (Submission/Cover Letter)

(Name of the Chairperson)
SCMC-AEI Ethics Review Committee Chairperson
8th Floor Phinma Plaza
Rockwell Center, Makati City, Philippines

Include in the *Request Letter for Review (QR-ERC-002-02)* a statement if the protocol has been reviewed by other ERCs or regulatory authorities and specify all significant decision by other ERCs or regulatory authorities;

3.3.1.3. Investigator may request for review exemption. A statement should be included in the cover letter with reason;

3.3.1.4. *Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04);*
3.3.1.5. Study protocol (must include version and date);
3.3.1.6. One (1)-page study protocol summary, (including process flow chart, ethical considerations);
3.3.1.7. Updated Curriculum Vitae of Principal Investigator/Author(s) and Sub-Investigators with signature;
3.3.1.8. Good Clinical Practice (GCP) certificate of Principal Investigator/Author(s) and Sub-Investigator;
3.3.1.9. SCMC-AEI ERC will require a MOA with research sites (except St. Cabrini Medical Center and Asian Eye Institute), organization or institution funding and managing the study;
3.3.1.10. Copy of Clinical Trial Agreement (CTA) maybe requested as needed by the members;
3.3.1.11. Material Transfer Agreement (if applicable)
3.3.1.12. Proof of payment of initial review fee;

3.3.2. Study-Specific Documents (submit as needed):
3.3.2.1. Informed Consent Form in English and Tagalog or local language where the study will be conducted (MUST include a footer with the following format: Protocol Number or the word "Study Protocol" *[for studies with no assigned protocol number]*, version number or amendment number, version or amendment date, site number of site name);
3.3.2.2. Investigator's Brochure (must include version number and/or date);
3.3.2.3. Data Collection Forms (if applicable/available);
3.3.2.4. Recruitment advertisements (posters, videos, flyers, etc.); and
3.3.2.5. Other information or documents that will be provided to participants (such as questionnaires, diaries, etc).

3.3.3. The Principal Investigator/Sponsor is required to settle the review fee prior to start of review as determined by the SCMC-AEI ERC to cover the operating cost and honoraria of the reviewers.
3.3.4. The principal investigator or sponsor shall use the ERC Online Submission Portal to upload all documents for submission to ERC. SCMC-AEI ERC shall not accept or process any printed copies.
3.3.5. Soft copies in WORD or PDF format of the submission documents must be uploaded three (3) weeks prior to the set full board meeting date through the online submission portal. Please refer to a separate memo related to the schedule of submission of documents.
3.3.6. The Secretariat ensures correctness and completeness of submitted forms and documents.
3.3.7. Incomplete, incorrect or submission of documents not following the submission schedules will not be accepted and processed by the Secretariate.

3.3.8. The Secretariat receiving the study protocol assigns ERC number to the study protocol/document submitted. The ERC number is assigned as follows: **< YYYY- NNN >**

YYYY Represents the year submitted (i.e. 2014)

NNN Represents sequential number as issued the by Secretariat (i.e. 001)

3.3.9. The Secretariat shall acknowledge receipt of study protocol through email. The Secretariat shall inform the PI/ Site/ Sponsor/ CRO whether the documents submitted shall be accepted or missing documents shall be required to be uploaded.

3.3.10. In case of missing or incomplete submission, the PI/ Site/ Sponsor/ CRO shall re-upload the entire submission package in the ERC Online Submission Portal.

3.4. Classification of Submission

3.4.1. The Chairperson, or in the absence of the former, the Member-Secretary classifies the study protocol review as:

3.4.1.1. **Full Board Review**

If the study protocol carries more than minimal risks and based on the specificities. The following consideration may also be utilized as criteria:

- involves vulnerable populations.
- involves the collection of stigmatizing information.
- does not use anonymized data.
- Continuing review of clinical trials that involve further significant recruitment of participants.
- Continuing review of study protocols previously classified under full review.

3.4.1.2. **Expedited Review**

If the study protocol carries no more than minimal risks amendments that are administrative in nature and do not affect the study protocol considerably such as:

- chart review,
- survey of non-sensitive nature
- use of anonymous or anonymized laboratory/pathology samples or stored tissues or data

3.4.1.3. **Exempted from Review**

If the study protocol:

- does not involve human participants.
- does not involve identifiable human tissue, biological samples, and/or sensitive personal information (e.g., systematic reviews, meta-analysis, etc)
- involves publicly available data or information.
- does not involve more than minimal risk or harm:
  - Studies involving institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests; and
  - Studies involving survey procedures, interview procedures, or observation of public behavior which met the following:
    - no disclosure or human participants' responses outside the research that could place the participant at risk of criminal or civil liability or may be damaging to their financial standing, employability, or reputation; and,

- recording of information ensures that the identity of the human participant cannot readily be ascertained directly or through identifiers linked to the participants.

3.4.2. For initially classified expedited review, if the Reviewers deem it necessary for a Full Board Review, it may be reclassified as such.

3.4.3. For initially classified Full Board Review, the study protocol may be re-classified during the next resubmission as expedited if the decision is for minor modifications and upon the decision of the majority of the members.

3.5. Assignment of Reviewers

3.5.1. For Full Board Review, the Chairperson, or in the absence of the former, the Member-Secretary, assigns two (2) Reviewers consisting of one (1) medical or scientific reviewer and one (1) non-medical or non-scientific reviewer.

3.5.2. For expedited reviews, the Chairperson, or in the absence of the former, the Member-Secretary, assigns one Primary Reviewer for protocols not requiring informed consent. A non-medical member is added as a secondary reviewer for protocols requiring an informed consent.

3.5.3. Reviewers are selected on the basis of their expertise. The Reviewers are tasked to review scientific soundness, related ethical issues and the informed consent process.

3.5.4. The Secretariat prepares and sends the complete study protocol package and the *Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04)* to the assigned Reviewers.

3.5.5. All files submitted shall be stored in the Google Drive.

3.6. Study Protocol Review Process

3.6.1. Full Board Review

3.6.1.1. Study protocols classified for Full Board Review are distributed to the Reviewers within seven (7) working days.

3.6.1.2. Reviewers should refer to all the documents submitted by the investigator, sponsor or researcher when evaluating the study. The following documents should be reviewed entirely and thoroughly by the reviewer: Study Protocol, Informed Consent Form, Investigator's Brochure, Data Gathering Tool, etc. Reviewer to evaluate and make recommendations and accomplish the *Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04)* completely and comprehensively. All sections of the forms that requires Reviewer's comment should be completely filled out. Recommendations may be minor modifications, major modifications, approval, disapproval, and/or Pending.

3.6.1.3. The Secretariat prepares the *Minutes of Meeting (QR-ERC-002-08)* and includes the study protocol in the *Meeting Agenda (QR-ERC-002-07)*.

3.6.1.4. The Reviewers present the protocol synopsis, comments, and recommendations during the full board meeting.

3.6.1.5. The Members discuss, deliberate, and decides through a majority vote:

- Approved – the submitted study proposal is accepted by the committee and is given clearance to proceed.
- Disapproved – the submitted proposal does not merit approval from the Committee.
- Major Modifications – any required changes in the protocol or any study document that has a significant effect on the study. This may include but not limited to the following: changes in treatment arm, modification or addition of visits and procedures, study extension or decrease study duration, or modification in any part of the study protocol or document that will have safety impact, changes in the inclusion and exclusion criteria. Upon resubmission of protocol or document that was given a Major Modification decision by the committee will automatically be subjected to a full board review process
- Minor Modifications – any changes in the protocol or any study document that has little or no significant impact on the study. This may include but is not limited to the following: grammar modification, typo-graphical errors, administrative changes, or any changes initiated by REC. Upon resubmission of proposal or document that was given a Minor Modification decision by the committee will be subjected to an expedited review process
- Pending – further information from the sponsor or investigator is required to clarify certain issues in order to come up with a final decision.

3.6.1.6. The Secretariat collates the comments and recommendations, prepares the *Protocol Decision Form (QR-ERC-002-05)* within fourteen (14) working days, updates the electronic database, and include in the *Meeting Agenda (QR-ERC-002-07)*.

3.6.1.7. The Chairperson reviews and signs the *Protocol Decision Form (QR-ERC-002-05)* for issuance by the Secretariat to the Principal Investigator within seven (7) working days.

3.6.1.8. The Secretariat informs the Principal Investigator through electronic mail that the *Protocol Decision Form (QR-ERC-002-05)* is ready to be downloaded.

3.6.1.9. The Principal Investigator receives and acts on the recommendations. Failure to submit recommendations or correspond within thirty (30) working days will warrant cancellation of the study protocol and repeat submission of all documents.

3.6.1.10. In the event that a Principal Investigator decides not to continue the application for ethics review, the Principal Investigator must accomplish the *Letter for the Withdrawal of Protocol Application (QR-ERC-002-11)* from the SCMC-AEI ERC. All requests for withdrawal will be discussed during the Full Board Meetings regardless of initial review classification. Upon approval of request, study protocol will be archived.

3.6.2. *Expedited Review*

3.6.2.1. Study protocols classified for expedited review are distributed to the Reviewers within five (5) working days.

3.6.2.2. Reviewers evaluate and make recommendations, accomplish the *Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04)* completely and comprehensively, and submit all documents to the Secretariat within seven to ten (7-10) working days. Recommendations may be:

- Approved – the submitted study proposal is accepted by the committee and is given clearance to proceed.
- Disapproved – the submitted proposal does not merit approval from the Committee.
- Major Modifications – any required changes in the protocol or any study document that has a significant effect on the study. This may include but not limited to the following: changes in treatment arm, modification or addition of visits and procedures, study extension or decrease study duration, or modification in any part of the study protocol or document that will have safety impact, changes in the inclusion and exclusion criteria. Upon resubmission of protocol or document that was given a Major Modification decision by the committee will automatically be subjected to a full board review process
- Minor Modifications – any changes in the protocol or any study document that has little or no significant impact on the study. This may include but is not limited to the following: grammar modification, typo-graphical errors, administrative changes, or any changes initiated by REC. Upon resubmission of proposal or document that was given a Minor Modification decision by the committee will be subjected to an expedited review process

- Pending – further information from the sponsor or investigator is required to clarify certain issues in order to come up with a final decision.

3.6.2.3. Study protocols that are for major modifications or disapproved by any Reviewer are automatically referred for Full Board Review.

3.6.2.4. The Secretariat collates the comments and recommendations, prepares the *Protocol Decision Form (QR-ERC-002-05)* within fourteen (14) working days, records in the electronic database, and includes it in the *Meeting Agenda (QR-ERC-002-07)*.

3.6.2.5. The Chairperson reviews and signs the *Protocol Decision Form (QR-ERC-002-05)* for issuance by the Secretariat to the Principal Investigator within seven (7) working days.

3.6.2.6. The Secretariat informs the Principal Investigator through electronic mail that the *Protocol Decision Form (QR-ERC-002-05)* is ready for downloading.

3.6.2.7. The Principal Investigator receives and acts on the recommendations. Failure to submit recommendations or correspond within thirty (30) working days will warrant cancellation of the study protocol and repeat submission of all documents.

3.6.2.8. In the event that a Principal Investigator decides not to continue the application for ethics review, the Principal Investigator must accomplish the *Letter for the Withdrawal of Protocol Application (QR-ERC-002-11) from the* SCMC-AEI ERC. All requests for withdrawal will be discussed during the Full Board Meetings regardless of initial review classification. Upon approval of request, study protocol will be archived.

3.6.3. *Exempted from Review*

3.6.3.1. The Secretariat notifies the Chairperson about the application for exemption from review.

3.6.3.2. The Chairperson reviews and evaluates the application for study protocol review exemption using the *Certification of Exemption from Ethical Review Form (QR-ERC-002-03)* completely and comprehensively and submits the documents to the Secretariat within seven (7) working days. Recommendations may be:

- For Full Board Review;
- For Expedited Review; or
- Exempted from Review

3.6.3.3. The Secretariat collates the comments and recommendations, prepares the *Protocol Decision Form (QR-ERC-002-05)* within fourteen (14) working days, records in the electronic database, and include in the Meeting Agenda.

3.6.3.4. The Chairperson reviews and signs the *Protocol Decision Form (QR-ERC-002-05) and Certification of Exemption from Ethical Review (QR-ERC-002-03)* whichever is applicable for issuance by the Secretariat to the Principal Investigator within seven (7) working days.

3.6.3.5. The Secretariat informs the Principal Investigator through electronic mail that the *Protocol Decision Form (QR-ERC-002-05)* is ready to be downloaded.

3.7. Full Board Review Meeting Workflow

ACTIVITY	RESPONSIBILITY
Schedule meeting and prepare *Meeting Agenda (QR-ERC-002-07)*	Chairperson and Secretariat
Distribute meeting agenda	Secretariat
Prepare meeting materials	Secretariat
Signs the *Attendance Sheet (QR-ERC-002-09)* ↓	Members
Determine and confirm quorum ↓	Member-Secretary
Call the meeting to order ↓	Chairperson
Declare Conflict of Interest (COI) ↓	Chairperson
Read, correct, and approve the minutes of the previous meeting ↓	Members
Discuss the matters arising from minutes of the previous meeting ↓	Members
Present the agenda of the current meeting for approval ↓	Chairperson
Approve the agenda of the meeting ↓	Members
Present protocol summary, comments, and recommendations of initial submissions and	Reviewers

ACTIVITY	RESPONSIBILITY
resubmissions (resubmissions classified under major modification) ↓	
Discuss, deliberate and vote on presented protocol ↓	Members
Review post-approval submissions (Refer to Chapter 3 for post-approval process) ↓	Members
Review annexed report of results of expedited review (including resubmissions classified under minor modification) ↓	Members
Discuss other matters included in the agenda ↓	Members
Adjourns meeting ↓	Chairperson
Collects, stores, or disposes meeting materials	Secretariat

3.7.1. *Regular Meeting Schedule*

3.7.1.1. The SCMC-AEI ERC meets every 1st Wednesday or Friday of the month except during holidays. Special meetings may be held upon the discretion of the Board.

3.7.1.2. The Chairperson calls the meeting.

3.7.1.3. The Secretariat confirms venue reservation for the scheduled meeting date and time one (1) week before the meeting.

3.7.1.4. The Secretariat ensures that the venue, equipment, and facilities are made available and in good working condition prior to the meeting day to allow ample time for the equipment replacement or purchase of necessary supplies.

3.7.2. *Distribution of the Meeting Agenda*

3.7.2.1. The Secretariat distributes the *Meeting Agenda (QR-ERC-002-07)* to attendees (members, invited PIs, Independent Reviewers, and others) at least five (5) working days before the meeting through written, SMS, verbal notice of meeting.

3.7.2.2. SCMC-AEI ERC members should confirm their attendance within seven (7) days before the meeting.

3.7.2.3. In case of anticipated lack of quorum, the Chairman and/or Member Secretary will search for a suitable corresponding alternate from the list of Alternate Members.

3.7.2.4. The Secretariat sends meeting reminders to all people who will be in attendance through electronic mail, SMS, or phone call the day before the meeting. Non-members who will be attending only specific portions of the meeting should be informed accordingly, through a written notice, phone calls, SMS, or email.

3.7.3. *Preparation of the Agenda, Study Protocols, Study Protocol-Related Documents Scheduled for Review, and Other Meeting Materials*

3.7.3.1. The Secretariat emails the approved previous *Minutes of the Meeting (QR-ERC-002-08)* to all Members three (3) days before the meeting.

The Secretariat will flash on the screen the approved previous *Minutes of the Meeting* during the actual meeting.

3.7.4. *Determination of Quorum*

3.7.4.1. Meeting will not commence unless a quorum has been met. Only those who are invited shall be inside the room during the meeting.

3.7.4.2. Fixed minimum number of eligible SCMC-AEI ERC members who must be physically present at any meeting before any official business may be transacted or a decision taken therein becomes legally binding. For this purpose, a quorum shall consist of one half (1/2) or fifty percent (50%) plus one (1) SCMC-AEI ERC member. When a member and his or her alternate both attend a meeting, only one member may vote.

3.7.4.3. *Loss of Quorum.* If the required quorum is achieved at the beginning of the meeting, and enough members withdraw (leave) from the meeting to leave less than a quorum, actions may continue to be taken so long as they are approved by at least a majority of the members required to constitute a quorum. Otherwise, no action may continue to proceed without the maximum quorum requirement.

3.7.4.4. At any point after the opening of the meeting, any member of the Board may call attention to the lack of quorum. The meeting shall then terminate.

3.7.4.5. An *Attendance Sheet (QR-ERC-002-09)* is issued for all present members to affix their signatures.

3.7.5. *Calling the meeting to order and completion of required procedures prior to review proper.*

3.7.5.1. The Chairperson formally confirms quorum by citing the attendance requirements.

3.7.5.2. The Chairperson calls the meeting to order upon confirmation of quorum.

3.7.5.3. The Chairperson calls for declaration of Conflict of Interest (COI) in respect of any study protocol or submission scheduled for review. Members declaring COI are documented by the Secretariat. The Chairperson instructs the members who declared COI to excuse themselves from the deliberation of the respective study protocol for which the COI declaration was made.

3.7.5.4. The Secretariat documents the proceedings of the meeting under the supervision of the Member-Secretary, as soon as the meeting is called to order by the Chairperson, noting the time. The Secretariat documents the development of the agenda, specifically all members' opinions and actions with respective reason, for inclusion in the meeting minutes, and subsequent communication with the Principal Investigator.

3.7.5.5. The Chairperson presides over the review of the *Minutes of the Meeting (QR-ERC-002-008)*. Any member can declare a motion for approval, which any member can second. The Chairperson then declares approval of the minutes of the previous meeting.

3.7.5.6. The Chairperson proceeds to facilitate discussion of matters arising from the minutes, the results of which are noted by the Secretariat for inclusion in the minutes of the current meeting.

3.7.5.7. The Members also allow, at the discretion of the Chairperson, guests (such as auditors or surveyors) or observers (such as students or trainees) to observe SCMC-AEI ERC meetings. They are required to sign a *Confidentiality Agreement Form for Non-member (QR-ERC-002-10)*

3.7.6. <u>*Discussion of Initial Study Protocol Submissions and Resubmissions*</u>

3.7.6.1. Full review of study protocol and study protocol-related submissions typically includes review of the following in sequence:

- Initial Study Protocol Submissions Presentation
- Resubmission/Study Protocols for Modification
- *Protocol Amendment Submission Form (QR-ERC-002-06)*
- *Letter for the Withdrawal of Protocol Application (QR-ERC-002-11)*
- *Continuing Review Application/Progress Report Form (QR-ERC-002-12)*
- *Final Report Form (QR-ERC-002-13)*

- *Serious Adverse Event/s (SAE) / Suspected Unexpected Serious Adverse Reaction/s (SUSAR) Report Form (QR-ERC-002-14)*
- *Study Protocol Deviation Reports (QR-ERC-002-15)*
- *Early Study Termination Application (QR-ERC-002-16)*
- *Site Visit Report Form (QR-ERC-005-01)*

3.7.6.2. The Chairperson may allow some modifications of the sequence of review in exigent circumstances.

3.7.6.3. The Chairperson instructs the member who had previously declared conflict of interest (COI) to excuse himself/herself from ensuing study protocol deliberation by leaving the room just before the respective study protocol is presented for deliberation. In some instances, such members may be called in by the Committee to answer questions to assist the Committee in arriving at a Committee action, but under no circumstances participate in the decision.

3.7.6.4. The Primary Reviewer is instructed to focus presentation of findings on scientific, social value and technical soundness and its impact on human subject population, while the Secondary Reviewer is instructed to focus presentation of findings on the informed consent process and Informed Consent Form (ICF) and its compliance with the requirements of international and national ethical guidelines, as well as national and international policies.

3.7.6.5. The members deliberate on the overall criteria for approval which includes scientific soundness, social value, technical soundness, ethical considerations and ICF.

3.7.6.6. For review of resubmissions, the following criteria shall be followed: Minor Modifications will undergo expedited review and Major Modifications will automatically fall under full board meeting review. The Chairperson calls the Primary Reviewers to present findings on the response of the PI to the previous recommendations *(classified as Major Modification)* of the Committee summarized in the *Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04)*.

3.7.6.7. In case of unavailability of the Reviewers to attend the meeting, said members are required to forward the completed *Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04)* to the Secretariat at least three (3) days before the meeting. The findings summarized therein will be presented by the Chairperson when the study protocol is deliberated on. If the Chairperson feels that the present committee composition does

not have the expertise to proceed with the review, the discussion of the study protocol may be deferred till the next meeting.

3.7.6.8. If in case the Reviewer is absent and has not submitted his/her review, discussion of study protocol may still proceed at the discretion of the Chairperson. If the Chairperson feels that the present committee composition does not have the expertise to proceed with the review, the discussion of the research/clinical trial may be deferred till the next meeting. Also, the Committee may request comments from the Principal Investigator.

3.7.6.9. The Board allows Principal Investigators and other resource persons (such as an Independent Reviewer commissioned by the SCMC-AEI ERC or the technical reviewer who endorsed the study protocol) of highly specialized areas to attend the part of the meeting related to specific studies for purposes of clarifying issues related to the study protocol only (and not to present the study protocol to the Board).

3.7.6.10. For decision on both initial study protocol submission and resubmission, the Chairperson calls for any of the following actions:

- Approval;
- Disapproval;
- Major Modification;
- Minor Modification; or
- Pending

3.7.7. *Review of Annexed Results of Expedited Review*

3.7.7.1. The Chairperson reports all the study protocols and related submissions that were processed under expedited review as annexed in the Meeting Agenda. Generally, study protocols reviewed under the expedited process are not discussed under a full board meeting except when ethical issues are raised by SCMC-AEI ERC members.

3.7.7.2. For expedited reviews that have been reclassified for Full Board Review will follow the process of Full Board Review.

3.7.8. *Discussion Matter*

3.7.8.1. The Chairperson calls for any non-study protocol matters that need attention or action, as the need arises.

3.7.9. *Adjournment of the Meeting*

3.7.9.1. With no further matters for discussion, the Chairperson formally adjourns the meeting, with the time noted by the Secretariat.

3.7.10. *Management of Study Protocols and Collection, Storage and Disposal of Meeting Materials*

3.7.10.1. Study Protocol and Informed Consent Form/s (and all other approved documents) shall be saved and tagged as approved in the google drive. SCMC-AEI ERC will no longer stamp or sign the final approved Informed Consent Form/s. Kindly refer to the Decision Letter for the list of documents that were approved by the committee.

3.7.10.2. If the Study is not yet approved, the Secretariat saves the files under "pending" and will be re-classified once a response to the Decision Letter has been received/reviewed.

3.7.10.3. Whenever a physical copy is used, the Secretariat will collect the, *Minutes of the Meeting (QR-ERC-002-08), Attendance Sheet (QR-ERC-002-09) and Meeting Agenda (QR-ERC-002-07)* mindful that these materials are confidential and must be handled in accordance with the standard operating procedures and filed in the *Agenda & Minutes Folder*.

3.7.10.4. Whenever a physical copy is used, the Secretariat shall shred all other non-relevant documents.

3.7.11. *Conduct of Special Meeting*

Special meetings are conducted following the same sequence as a full board meeting and are called by the Chairperson or by request of the proponent based on the following criteria:

3.7.11.1. Urgent issues (if delay will affect or have impact on the public benefit, national economy, etc.)

3.7.11.2. Occurrence of unexpected serious adverse events

3.7.11.3. Other similar situations

3.7.12. *Referral to Single Joint Research Ethics Board (SJREB)*

Multi-site protocols that are funded by DOH, PCHRD, DOST, PHIC, PHREB, CHED and other local organizations, including industry organizations and other foreign entities to Single Joint Research Ethics Board (SJREB; SJREB SOP Appendix A).

Classification of Protocols Submitted for SJREB's Initial Review

3.7.12.1. For Exemption from Ethics Review

- *Research about public behavior (voting trends, opinion surveys, etc)*
- *Evaluation of public programs by the agency itself*
- *Quality control studies by the agency itself*
- *Standard educational tests and curriculum development*
- *Surveillance functions of DOH*

- *Historical and cultural events*
- *Research involving large statistical data without identifiers*
- *Research not involving humans*

3.7.12.2. For Expedited Review

- *Topic that should not result in causing social stigma*
- *Does not involve vulnerable populations*
- *Retrospective studies using anonymized data from medical records*
- *Studies using simple questionnaires without identifiers*
- *Laboratory research that uses anonymized human tissue/specimen*

3.7.12.3. For Full-Board Review

- *more than minimal risk protocols*

4. FORMS AND APPENDIX

4.1. QR-ERC-002-01 Application Form
4.2. QR-ERC-002-02 Request Letter for Review
4.3. QR-ERC-002-03 Certification of Exemption from Ethical Review Form
4.4. QR-ERC-002-04 Study Protocol and Informed Consent Assessment Form
4.5. QR-ERC-002-05 Protocol Decision Form
4.6. QR-ERC-002-06 Protocol Amendment Submission Form
4.7. QR-ERC-002-07 Meeting Agenda
4.8. QR-ERC-002-08 Minutes of the Meeting
4.9. QR-ERC-002-09 Attendance Sheet
4.10. QR-ERC-002-10 Confidentiality Agreement for Non-member Form
4.11. QR-ERC-002-11 Letter for the Withdrawal of Protocol Application
4.12. QR-ERC-002-12 Continuing Review Application / Progress Report Form
4.13. QR-ERC-002-13 Final Report Form
4.14. QR-ERC-002-14 Serious Adverse Event/S (SAE) / Suspected Unexpected Serious Adverse Reaction/S (SUSAR) Report Form
4.15. QR-ERC-002-15 Protocol Deviation Report Form
4.16. QR-ERC-002-16 Early Study Termination Application Form
4.17. Appendix A – SJREB SOP

5. REVISION HISTORY

Version No.	Date	Author/s	Main Change
00	01 April 2011	Mary Ann Catacutan	
01	20 March 2013	Mary Ann Catacutan	Added reports submission, confidentiality, conflict of

Version No.	Date	Author/s	Main Change
			interest, trainings and independent consultant
02	13 January 2014	Mary Ann Catacutan	Changed SOP format
03	10 September 2014	Mary Ann Catacutan	Revised related forms
04	29 April 2015	Mary Ann Catacutan	Revised chapter title and content
05	25 November 2015	Mary Ann Catacutan /Carmina Villanueva	Changed process flow format
06	17 February 2016	Mary Ann Catacutan	Update SOP Scope
07	10 July 2017	Mary Ann Catacutan	Clearly define who is responsible for reviewing initial submission Updated expedited and Full Board Review process
08	11 December 2017	Pacifico Calderon/ Mary Ann Catacutan	Clearly define the process of communicating decision letter to investigator/researcher
09	14 September 2020	Joe Vincent Aguila / Rachelle A. Manzo / Noemi Luz Mojares	Updated the contents and related forms
10	20 September 2021	Mary Ann Catacutan-Catis	Updated the contents based on the PHREB and FERCAP assessment; Added SJREB SOP Appendix A
11	02 April 2022	Mary Ann Catacutan-Catis/ Noemi Luz Mojares	Updated contents related to the processing of submission

1. OBJECTIVES

This chapter describes the following:

1.1. how the Board processes post-approval submissions by the Investigators, Sponsors or Researchers, and

1.2. how to submit procedures, required forms, review procedure, documentation of committee action, communication of committee action and filing of results.

2. SCOPE

This Chapter covers all study protocol-related submissions after approval has been issued. This includes request for amendments, continuing review applications, final reports, progress reports, deviation or violation reports, early study termination, serious adverse event reports (SAEs), and suspected unexpected serious drug reactions (SUSARs).

3. IMPLEMENTING PROCEDURES

<table>
<tr><td colspan="2">Investigator
Submits a complete post-approval package
↓</td></tr>
<tr><td colspan="2">Secretariat
Receives the post approval package, ensures correctness and completeness, encodes in the ERC Database
↓</td></tr>
<tr><td colspan="2">Secretary
Classifies the post-approval package either as Expedited or Full Board Review based from the initial review classification unless otherwise indicated by the specificities of the submitted information and assigns to the original Reviewers.
↓</td></tr>
<tr><td>EXPITED REVIEW</td><td>FULL BOARD REVIEW</td></tr>
<tr><td colspan="2">Secretariat
Distributes the post approval package to the Reviewers
↓</td></tr>
<tr><td>Secretary
Includes in the meeting agenda as Annex
↓</td><td>Secretary
Includes in the meeting agenda
↓</td></tr>
<tr><td>Reviewers
Review and submit comments, recommendations and decision to the Secretariat using the following:</td><td>Reviewers
Review and present comments, and recommendations.
↓</td></tr>
</table>

↓	**Members** Discusses, deliberates and votes for decision based on the following: ↓
1. **For Amendments:** Approved, Minor modification, Major modification, Disapproved Pending	1. **For Amendments:** Approved, Minor modification, Major modification, Disapproved Pending
2. **For Continuing Review, Progress and Final Reports:** Approved Request information Recommend further action Pending	2. **For Continuing Review, Progress and Final Reports:** Approved Request information Recommend further action Pending
3. **SAE and SUSAR Reports:** No further action Request information Recommend further action Pending	3. **SAE and SUSAR Reports:** No further action Request information Recommend further action Pending
4. **Protocol Deviation:** No further action Request information Recommend further action Pending	4. **Protocol Deviation:** No further action Request information Recommend further action Pending
5. **Early Study Termination:** Approved Request information Recommend further action Pending ↓	5. **Early Study Termination:** Approved Request information Recommend further action Pending ↓
Secretariat Prepares the decision/approval letters ↓	
Chairperson Reviews and signs the decision/approval letters ↓	
Secretariat Releases the decision/approval and annexes in the meeting agenda ↓	

Secretariat Communicates results to the Investigators/Sponsor through electronic mail ↓
Investigator / Sponsor Receives and acts on the recommendations (if applicable) ↓
Secretariat Files all relevant documents in the ERC database and or Study Protocol Folder

3.1. *Post-Approval Documents*

3.1.1. *Amendments*

3.1.1.1. Any changes or updates related to the previously approved version of document/s (e.g. protocol, consent form, questionnaire, any patient related materials or recruitment materials, etc.) should be resubmitted to SCMC-AEI ERC for review and approval prior to implementation.

3.1.1.2. The document for review can be classified either under Minor Amendment or Major Amendment.

3.1.1.2.1. Minor Amendment: Changes in the previously approved documents that have little to no significant impact on the study or do not pose harm or risk to study participants.

3.1.1.2.2. Major Amendment: Changes in the previously approved document that have significant effect on the study conduct or can possibly cause harm or risk to study participants.

3.1.1.3. A document that will be classified under Minor Amendment will be reviewed through expedited process while a document that will be classified under Major Amendment will be reviewed under full board process with recommendation from the primary reviewer.

3.1.1.4. The Reviewer shall use the Protocol Amendment Submission Form (QR-ERC-002-06) to document evaluation of the study protocol amendments.

3.1.1.5. Results of the review shall be included in the next SCMC-AEI ERC meeting.

3.1.2. *Progress Report and Final Report*

3.1.2.1. Progress Report

3.1.2.1.1. All Investigators, Sponsors or Researchers that have received approval to conduct their study shall follow the prescribed frequency of progress reporting using

the *Continuing Review Application/Progress Report Form (QR-ERC-002-12)*.

3.1.2.1.2. If the approval letter received did not specifically state the frequency of progress report submission, all investigators, sponsors, or researchers are required to submit progress report following these schedules:

- Initial approvals dated January to June are required to submit progress report not later than November 1st of the same year
- Initial approvals dated July to December are required to submit progress report not later than May 1st the following year
- For studies determined by the committee to be of greater risk than usual, a more frequent progress report submission will be required, and the schedule stated above shall not be applied.

An email reminder to the Investigator, Sponsor or Researcher to submit the progress report shall be sent out by the Secretariat 60 days prior to deadline.

3.1.2.1.3. The Continuing Review Application/Progress Report Form shall be uploaded in the ERC Online Submission Portal together with a cover letter.

3.1.2.1.4. An acknowledgement email shall be received after a successful upload of documents. Documents received shall be reviewed by the Member-Secretary by forwarding them through electronic mail.

3.1.2.1.5. Upon receipt of instructions via electronic mail or personal advice from the Member-Secretary, the Secretariat shall forward and acknowledge *Continuing Review Application/Progress Report Form (QR-ERC-002-12)* to the Board.

3.1.2.1.6. Progress report review shall follow the initial review classification (whether expedited or full board review). Progress report shall be forwarded to the primary review for evaluation and recommendation. For Progress Report under Full Board Review, the Secretariat shall include this in the meeting agenda.

3.1.2.1.7. During the SCMC-AEI ERC meeting, members shall review the study based on the progress report submitted and provide the appropriate action regarding the status of the study.

3.1.2.1.8. The Chairperson shall recapitulate the final status of the study reviewed and give instructions to Secretariat

regarding release of the *Protocol Decision Letter (QR-ERC-002-05)* and file the documents accordingly.

3.1.2.1.9. For studies that failed to submit progress report for 2 consecutive years despite repeated reminder by SCMC-AEI ERC would be taken up in the full board meeting to discuss and decide its disposition.

3.1.2.2. Final Report

3.1.2.2.1. At the end of conduct of study, the investigator, sponsor or researcher is required to submit the final status of the study using the Final Report Form (QR-ERC-002-13).

3.1.2.2.2. The final report is to be submitted as soon as all the required data in the Final Report Form (QR-ERC-002-13) are available.

3.1.2.2.3. The Final Report Form shall be uploaded in the ERC Online Submission Portal together with a cover letter.

3.1.2.2.4. An acknowledgement email shall be received after a successful upload of documents. Documents received shall be reviewed by the Member-Secretary by forwarding them through electronic mail.

3.1.2.2.5. Upon receipt of instructions via electronic mail or personal advice from the Member-Secretary, the Secretariat shall forward and acknowledge *Final Report Form (QR-ERC-002-13)* to the Primary Reviewer.

3.1.2.2.6. All final reports received shall be included in the SCMC-AEI ERC Full Board Meeting agenda for review/evaluation of the members.

3.1.2.2.7. During the SCMC-AEI ERC meeting, the Primary Reviewer shall make recommendations whether to accept or approve the final report or additional information is required.

3.1.2.2.8. The Chairperson shall make the final review of the report and give instructions to Secretariat whether to request for additional information such as requiring the Investigator, Sponsor or Researcher to re-submit the *Final Report Form (QR-ERC-002-13)*, accepted and approved.

3.1.2.2.9. Failure of Investigator, Sponsor or Researcher to submit a Final Report may affect the status of their subsequent new protocol submissions.

3.1.3. *Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reaction (SUSARs)*

3.1.3.1. The principal investigator is required to report all the SAE and SUSARs to the SCMC-AEI ERC.

3.1.3.2. SAEs should be reported within 24-48 hours upon notification of the event while SUSARs should be reported as soon as received from the sponsor.

3.1.3.3. The Secretariat upon receipt of the report shall update the ERC database. All onsite SAEs shall go through full board review and offsite SAEs shall go through expedited review.

3.1.3.4. The Secretariat shall notify both Member-Secretary and Chairperson of the report received. A copy of the document shall be forwarded to Member-Secretary and Chairperson through electronic mail.

3.1.3.5. The Chairperson and/or Member-Secretary shall assign member to review and recommend appropriate action. Assigned member shall follow the criteria below in reviewing the report:

3.1.3.5.1. Assessment of events that is unlikely or not related to the investigational product or device: the assigned reviewer shall provide his/her recommendation to the Chairperson/Member-Secretary. The final recommendation shall be reported during the next Full Board meeting.

3.1.3.5.2. Assessment of events that is expected or most likely determined related to the investigational product or device: the assigned reviewer shall refer to the investigator's brochure and study protocol for the list of expected SAEs prior to giving his/her recommendation to the Chairperson/Member-Secretary. The final recommendation shall be discussed during the next Full Board meeting.

3.1.3.5.3. Assessment of events that is unexpected but suspected to be possibly related to the investigational product or device: the assigned reviewer may refer to previously submitted reports and look for trends. Informed consent maybe recommended to be updated so new information can be immediately shared to existing study participants. The final recommendation shall be discussed during the next full board meeting.

3.1.3.6. During the Full Board Meeting, the Chairperson or Member-Secretary shall request for a consensus to either:

3.1.3.6.1. Request for additional information or follow up reports which is applicable only for onsite SAE reports; or

3.1.3.6.2. Request amendment of informed consent form; or

3.1.3.6.3. No additional action necessary

3.1.4. *Protocol Deviation*

3.1.4.1. Secretariat receives *Protocol Deviation Report Form (QR-ERC-002-15)* and forward through electronic mail to Member-Secretary for review before sending to Reviewers.

3.1.4.2. Upon confirmation from Member-Secretary, the Secretariat shall forward the document to primary reviewer who will assess the report and make appropriate recommendation to the Chairperson/Member-Secretary.

3.1.4.3. The report shall be consolidated and included in the next Meeting. Protocol deviation can be classified into:

3.1.4.3.1. Minor violation – these are deviations that does not affect participants' safety and scientific integrity.

3.1.4.3.2. Major violation – these are deviations that affect the participants' safety and scientific integrity.

3.1.4.4. SCMC-AEI ERC's decision shall be consolidated by the Secretariat and conveyed to the investigator. Recommended action will be as follow:

3.1.4.4.1. No action required which is deemed very minor and will not impact patient and study integrity (corrective action is sufficient and will address the violation).

3.1.4.4.2. Written warning requesting for further explanation and clarification (for repeated minor violations with same corrective action).

3.1.4.4.3. Site visit (if the explanation and clarification is not sufficient)

3.1.4.4.4. Temporary study approval withdrawal

3.1.4.4.5. Permanent study approval withdrawal

3.1.5. *Review of Early Study Termination*

3.1.5.1. Early study termination may be initiated by the following: Study Sponsor, SCMC-AEI ERC or Regulatory Agency. The SCMC-AEI ERC and Regulatory Agency may recommend terminating a study if it is found that the study poses higher risk to participants than what is expected without concrete action by sponsors or the study site have committed multiple major protocol deviations causing or potentially causing harm to participants.

3.1.5.2. For Sponsor Initiated Study Termination: Secretariat receives notification either from the investigator or sponsor regarding the early termination of a study. The letter must include details on:

3.1.5.2.1. Reason for early termination;

3.1.5.2.2. Current status of the study on-site; and

3.1.5.2.3. After-care for all study participants who have not completed the study.

3.1.5.2.4. Secretariat shall acknowledge the receipt of the letter, update database, and forward the document through electronic mail to the Member-Secretary for review and further instructions.

3.1.5.3. Member-Secretary to assess the document and include in the agenda for next Full board meeting. During the meeting, the committee may ask for additional information related to the study termination or require the investigator to give post-follow up care to the study participants. Member-Secretary to consolidate the committee's decision and communicate its decision to the principal investigator.

3.1.6. *Continuing Review*

3.1.6.1. The Investigator shall be granted a period of not more than one (1) year upon approval of the initial review.

3.1.6.2. It is the responsibility of the sponsor, investigator or researcher to submit Continuing Review Application/Progress Report Form on or before the due date stated in the Protocol Decision Form (QR-ERC-002-05)

3.1.6.3. The *Continuing Review Application/Progress Report Form (QR-ERC-002-12)* shall be evaluated depending on the type of review it initially underwent. Full board reviewed protocols will undergo full board review and expedited reviewed protocols will undergo expedited review process. The assigned Primary Reviewer will provide recommendation whether the application will be granted another year of approval. The recommendation of the Primary Reviewer will be forwarded to the Chairman and/or Member-Secretary for final evaluation. For protocols under full board review, it will be included in the agenda of the next full board meeting; for protocol under expedited review, recommendations will be collated and forward to the Chairman and/or Member-Secretary for final evaluation.

3.1.6.4. In evaluating the *Continuing Review Application/Progress Report Form*, the SCMC-AEI ERC members shall put into consideration the benefit-risk ratio. Risk can either be arising from the following: physical risk (may cause death, disability, or infection), psychological risk (possible depression or anxiety), economic risk (loss of job or income) or social risk (possible discrimination or stigma).

3.1.6.5. Once approved, the Secretariat shall issue Protocol Decision Form (QR-ERC-002-05) to the Investigator.

4. FORMS AND APPENDIX

4.1. QR-ERC-002-05 Protocol Decision Form

4.2. QR-ERC-002-06 Protocol Amendment Submission Form
4.3. QR-ERC-002-07 Meeting Agenda
4.4. QR-ERC-002-12 Continuing Review Application/Progress Report Form
4.5. QR-ERC-002-13 Final Report Form
4.6. QR-ERC-002-14 Serious Adverse Event/S (SAE) / Suspected Unexpected Serious Adverse Reaction/S (SUSAR) Report Form
4.7. QR-ERC-002-15 Protocol Deviation Report Form
4.8. QR-ERC-002-16 Early Study Termination Application Form

5. REVISION HISTORY

Version No.	Date	Author/s	Main Change
00	01 April 2011	Mary Ann Catacutan	
01	20 March 2013	Mary Ann Catacutan	Added reports submission, confidentiality, conflict of interest, trainings and independent consultant
02	13 January 2014	Mary Ann Catacutan	Changed SOP format
03	29 April 2015	Mary Ann Catacutan	Changed chapter title and content
04	25 November 2015	Mary Ann Catacutan /Carmina Villanueva	Changed process flow format
05	20 March 2017	Mary Ann Catacutan	Update process flow
06	10 July 2017	Mary Ann Catacutan	Update all process flow details
07	11 December 2017	Pacific Calderon	Clearly define the roles of the Chairperson, Member-Secretary, and ERC Secretariat in the process on continuing review
08	14 September 2020	Joe Vincent Aguila / Rachelle A. Manzo / Noemi Luz Mojares	Updated the contents and related forms
09	20 September 2021	Mary Ann Catacutan-Catis	Updated the contents based on the PHREB and FERCAP assessment

Version No.	Date	Author/s	Main Change
10	02 April 2024	Mary Ann Catacutan-Catis/ Noemi Luz Mojares	Updated the contents

1. OBJECTIVES:

This Chapter describes the process on documentation and archiving of study protocol related documents. This includes the active study protocols, archived files and administrative documents.

This chapter will also describe the proper handling, storage, and safekeeping of confidential documents including proper disposal.

2. SCOPE:

This chapter is applicable to full board and expedited study protocols, active and archived files, files involving post-approval processes, minutes of the meeting, administrative and membership files and reference materials.

3. IMPLEMENTING PROCEDURE

3.1. Minutes of the Meeting Workflow

ACTIVITY	RESPONSIBILITY
Prepares *Minutes of the Meeting (QR-ERC-002-08)*	Secretariat
Prepares draft of *Minutes of the Meeting (QR-ERC-002-08)*	Member-Secretary and Secretariat
Approves the *Minutes of the Meeting (QR-ERC-002-08)*	Members
Prepares *Protocol Decision Form (QR-ERC-002-05)*	Secretariat
Store the approved *Minutes of the Meeting (QR-ERC-002-08)*	Secretariat
Release *Protocol Decision Form (QR-ERC-002-05)* to the Investigators	Secretariat

3.2. Preparation of the Templates of the Minutes of the Meeting

3.2.1. The Secretariat under the supervision of Member-Secretary uses the *Minutes of the Meeting (QR-ERC-002-08)* to organize the minutes ahead of the meeting date.

3.2.2. In case of special meeting, the *Minutes of the Meeting (QR-ERC-002-08)* will be adjusted to actual content requirements of the meeting of this type of panel.

3.2.3. All the relevant identifying information should be filled out such as standard text in the regular sections and relevant study protocol information.

3.2.4. The draft of the minutes of the meeting is generated as the meeting progress. The Secretariat with the guidance of the Member-Secretary takes care of the documentation notes of all Board opinions and actions in all specific sections of the agenda, as the agenda is developed and

discussed, with respective reasons in the case of study protocol-related actions.

3.2.5. The development of the minutes during the meeting is displayed in a multimedia screen to allow members to make immediate corrections and approval in real time.

3.3. Preparation of the Draft of the Minutes

3.3.1. The Secretariat submits a complete draft of the minutes to the Member-Secretary within one (1) week after the meeting for form and content corrections and finalization. The finalized draft is sent to the Chairperson immediately for approval and signature.

3.3.2. The following information must be indicated in the minutes:

3.3.2.1. Date and venue of meeting;
3.3.2.2. Members attendance (members present and absent);
3.3.2.3. Guest's and observer's attendance;
3.3.2.4. Time when the meeting was called to order and adjourned;
3.3.2.5. Items discussed per Meeting Agenda;
3.3.2.6. Name and signature of person who prepared the Minutes;
3.3.2.7. Name and signature of the Member-Secretary to indicate that the contents have been verified and corrected; and
3.3.2.8. Name and signature of the Chairperson to indicate the approval, and date of approval.

3.4. Approval of the Minutes

3.4.1. In the succeeding meeting, a review and approval of the previous minutes of the meeting is done to check on the technical correctness and to discuss matters arising from the previous minutes of the meeting.

3.4.2. The following shall affix their signature in the printed final copy of the minutes of the previous meeting to attest to its correctness:

- Chairperson;
- Member-Secretary; and
- Secretariat.

3.4.3. Upon the approval of the draft of the minutes, the Secretariat transfers contents of the Comments, Recommendations and Actions taken in the corresponding sections (per study protocol discussed) into the forms as applicable for issuance to the Investigator and shall be forwarded within one to two (1-2) weeks after the meeting.

3.5. Storage of the Meeting Minutes

3.5.1. The Secretariat files the original copy of the *Meeting Agenda & MOM Files*.

3.5.2. The approved draft of the minutes will be re-presented in the next full board meeting for Board's approval on its technical correctness.

3.6. Study Protocol Communication Record Flow

3.6.1. Secretariat sorts all communications received and issued by the SCMC-AEI ERC and records them in appropriate forms and logbooks. Communications can come in the form of letters, official memoranda, or electronic mail.

3.6.2. Logbooks are updated as each submission is received and issued. The logbook should contain, but is not limited to, the following:

- ERC No.
- Study Protocol Code
- Study Protocol Title
- Principal Investigator/Sponsor
- Date Received/Released
- Type of Submission
- Content of Submission
- Decision

3.6.3. Upon completion of the *Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04)* and *Logbook*, the Secretariat saves and renames all files accordingly into the google drive.

3.6.4. The Secretariat updates the *Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04)* as each communication record is filed.

3.7. Compilation of Administrative Records

3.7.1. The Secretariat maintains administrative documents not related to specific study protocols, but used in daily operations of the ERC such as:

- Documents and recordings used during every meeting (Minutes of the Meeting, Meeting Agenda, voice records, etc.)
- Reference materials and guidelines both local and international
- Standard Operating Procedure
- Communication issued to and received from persons other than Principal Investigators, on matters that are not related to any study protocols.
- SCMC-AEI ERC members and staff files Appointment letters, Signed *Confidentiality Agreement and Conflict of Interest Disclosure Form (QR-ERC-001-05), Curriculum Vitae* and *Training Record Form (QR-ERC-001-01)*, certificates of training.
- SCMC-AEI ERC Forms

3.7.2. These documents are maintained separately from study protocol-related documents.

3.8. Sorting and Storage of Documents

3.8.1. The Secretariat updates, labels and files administrative documents sequentially in appropriate folders. These are incoming and outgoing communications, members/staff records, signed *Confidentiality Agreement and Conflict of Interest Disclosure Form (QR-ERC-001-05)* and Training Records.

3.8.2. SOP Manual, guidelines and references are filed chronologically.
3.8.3. Starting June 1, 2024, SCMC-AEI ERC shall use the ERC Online Submission Portal for receiving all documents. A separate database shall be maintained to track the progress of each study/submission.

3.9. Disposal of Unnecessary Copies
3.9.1. All printed copies of the archived files beyond three (3) years are shredded but remain stored in the electronic files.
3.9.2. Disposal of unused and excess documents must be done one (1) week after the *Minutes of the Meeting (QR-ERC-002-08)* has been finalized, read, and approved by the Chairperson.

3.10. Active Files
3.10.1. Creation of Coding System for Active Study Folders
3.10.1.1. Active files are study protocols that have been received by the Secretariat and are either undergoing review (full board or expedited) or approved by ERC.
3.10.1.2. The Secretariat receiving the study protocol assigns an ERC Number to the protocol/document submitted. The Protocol Reference Number is assigned as follows: **< YYYY-NNN >**

YYYY	Represents the year submitted (i.e. 2014)
NNN	Represents sequential number as issued by Secretariat (e.g. 001)

3.10.1.3. The study protocols are generally classified into Active and Archived files and categorized into various groups. These are as follows:
3.10.1.3.1. ACTIVE FILES
- New Study Protocols:
  - newly (initial) submitted study protocols; and
  - ongoing review process
- Active Protocols/Documents:
  - approved and conduct of study is still ongoing
- Administrative files:
  - issued and received within a five (5) year period e.g. contract

3.10.1.3.2. ARCHIVED (Inactive) FILES
- Archived Protocols:
  - Approved and completed studies. Electronic files shall be maintained for an indefinite period of time.
- Archived Documents:
  - Administrative files (old membership files, incoming and outgoing communications, decision/approval

letters, outdated ethical guidelines) that are beyond the five (5) year office retention period. A letter of request for document disposal addressed to the Medical Directors of the AEI and SCMC and noted by the Chairperson shall be prepared by the Secretariat documenting the actual number and type of records to be disposed. Archived documents shall be disposed upon approval. The scanned copies shall be saved in an external hard drive at the ERC Office.

- On-going Approved:
  - Study Protocols previously reviewed and approved but no study-related activities for one (1) year or more.
- Pending Approval Protocols:
  - Study Protocols with pending approvals but no study-related activities for one (1) year or more.
- Disapproved Protocols
  - Deemed not technically, scientifically, and ethically sound.
- Cancelled Protocols:
  - Reviewed protocols with corresponding revisions but investigators failed to respond after thirty (30) working days, hence cancelled by Committee.
- Suspended Protocols:
  - Withdrawal of previously approved study protocols due to ethical violations.
- Terminated, Early Terminated, Withdrawn protocols:
  - Ended or discontinued before its scheduled completion when the safety or benefit of the study participants is doubtful or at risk or initiated by the investigator for a cause or inability to locate or follow up subject or by the sponsor.

3.10.1.4. The ERC No and date of archive shall appear prominently on the side of the study protocol folder.

3.10.2. Organizational of Contents of Active Study Folders

3.10.2.1. Relevant data are encoded into the *Application Form (QR-ERC-002-01),* which contains the following information:

- ERC No.
- Category of Study/Investigator
- Study Protocol Code
- Study Protocol Title
- Principal Investigator/s
- Reviewers

- Sponsors/CRO
- Type of Initial Review: Expedited or Full Board Review
- Initial Submission Date: Protocol Version 1 Date, Protocol Version 1 Date 2, Protocol Version 1 Date 3, Protocol Version 1 Date 4
- Review Dates: 1st Review, 2nd Review, 3rd Review, 4th Review
- Initial Approval Date
- Validity Date of Initial Approval
- Amendment Submission Date
- Final Report Submission Date Final Report Approval Date
- Final Report Archiving Date
- Date (refers to date received, minutes of meeting when the protocol was reviewed, dates of Protocol Decision, dates where the ERC Forms were accomplished by the Reviewers e.g. Protocol and Informed Consent Assessment)
- Document Particulars
- Issued By
- Received By
- Status

3.10.2.2. The Secretariat puts study protocol files in study protocol folders upon processing of the submission of the study protocol, ensuring that one (1) folder contains documents for one (1) study protocol, labeled and coded accordingly.

3.10.2.3. Folders are then kept in secure cabinets labeled as "Active Files".

3.10.2.4. Cabinets labeled as "Active Files" should only contain study protocol folders classified as ongoing or active.

3.10.2.5. A Study Protocol Folder contains the following documents, as applicable:

3.10.2.5.1. Application Form (QR-ERC-002-01)

3.10.2.5.2. Basic Documents:

- Letter of request (cover letter) addressed to the Chairperson
- *Request Letter for Review (QR-ERC-002-02)*
- *Study Protocol and Informed Consent Assessment Form (QR-ERC-002-04)*
- Study Protocol
- Updated *Curriculum Vitae* of Principal Investigator and co-investigator
- Updated GCP

3.10.2.5.3. Study specific documents:

- Informed Consent Form (ICF)
- Assent Form and Script
- Investigator's Brochure or Basic 'Product Information Document

- Data Collection Form
- Questionnaires/Survey Forms
- Recruitment Advertisements
- List of other Sites and assigned Principal Investigators
- Memorandum of Agreement or Terms of Agreement

3.10.2.5.4. *Protocol Decision Form (QR-ERC-002-05)*
3.10.2.5.5. *Protocol Amendment Submission Report (QR-ERC-002-06)* with cover letter addressed to the Chairperson
3.10.2.5.6. *Continuing Review Applications/Progress Report Form (QR-ERC-002-12)* with cover letter addressed to the Chairperson
3.10.2.5.7. *Final Report Form (QR-ERC-002-13)* with cover letter addressed to the Chairperson
3.10.2.5.8. *Serious Adverse Event/S (SAE) / Suspected Unexpected Serious Adverse Reaction/S (SUSAR) Report Form (QR-ERC-002-14)* with cover letter addressed to the Chairperson
3.10.2.5.9. *Protocol Deviation Report Form (QR-ERC-002-15)* with cover letter addressed to the Chairperson
3.10.2.5.10. *Feedback Form (QR-ERC-006-01)* with cover letter addressed to the Chairperson
3.10.2.5.11. Site Visit Reports (QR-ERC-005-01)
3.10.2.5.12. Notification letters
3.10.2.5.13. Miscellaneous Communications

3.11. Maintenance of Active Study Protocol File

3.11.1. The Secretariat files all the aforementioned documents in the study protocol folder as they come.
3.11.2. The Secretariat tag all documents before putting them in the folders.

Documents	Process	Responsibility
Request Letter for Review (QR-ERC-002-02)	Tag as received	Chairperson or Secretariat
SAE/SUSAR, Protocol Deviation, Non-compliance Reports, etc.	Tag as received	Chairperson
Notification Letters (insurance, study close out, early termination	Tag as received	Chairperson or Secretariat
Continuing Review Application/Progress Report (QR-ERC-002-12) and Final Report (QR-ERC-002-13)	Tag as received	Chairperson or Secretariat

3.11.3. All the above documents must be printed in two (2) copies. One (1) copy shall serve as the receiving copy and the other shall be filed in the Study Protocol Folder.
3.11.4. Active Files folders are maintained in the "Active Files" cabinet until the *Final Report Form (QR-ERC-002-13)* is approved by the SCMC-AEI ERC.
3.11.5. Starting June 1, 2024, SCMC-AEI ERC will no longer "stamp" the documents as received. Through the ERC Online Portal, the PI/Site/ Sponsor/CRO shall receive an acknowledge email for every successful upload/submission of documents.

3.12. Management of Archived Study Folders
3.12.1. Upon receipt of the *Final Report Form (QR-ERC-002-13)*, the Board reviews it in accordance with SOP Final Reports.
3.12.2. Upon approval of the *Final Report Form (QR-ERC-002-13)*, the Secretariat removes the entire study protocol file from the active study filing area and verifies that all documents are present in an organized manner.
3.12.3. An archived number is assigned to the document by adding the month and year of archiving at the end of the original code of the Study Folder.

FROM	TO
YYYY- NNN	**YYYY-NNN- YYYY-MM**

3.12.4. Correspondingly, the data about study and the year when archived should be entered on the *ERC Database*.

3.13. Sorting of Archived Administrative Documents
3.13.1. The Secretariat shall perform inventories of miscellaneous administrative documents yearly.
3.13.2. Administrative documents that are related to any fund are required to be archived in a manner that allows easy retrieval for audit purposes. These include documents that specify issuance of honorarium, financial reports, etc. One (1) set of such documents are stored in the appropriate storage container/cabinet for archived administrative files.
3.13.3. Unnecessary copies are disposed of accordingly by shredding.

3.14. Maintaining Confidentiality of Study Protocol Folders and Documents
3.14.1. All confidential and proprietary information disclosed by the Investigator and/or Sponsor related to the study protocol shall only be used by the SCMC-AEI ERC during review and assessment.
3.14.2. Non-members can access specific documents upon formal request and completion/signing of *Confidentiality Agreement for Non-Member Form (QR-ERC-002-10)* to be approved by the Chairperson.
3.14.3. The Chairperson and/or Member-Secretary will assess the request letter and may act within any of the following recommendations:

- Approved access to all requested documents
- Approved access to selected requested documents
- Disapproved

3.14.4. Additionally, the Chairperson and/or Member-Secretary will determine whether the document may be reproduced or not. It is ensured that documents are accessed and photocopied within the ERC office only, and that it is documented in the *Outgoing Logbook*.

3.14.5. Only the Secretariat can retrieve the documents either from Active Study, Protocol Folders or Archived once the letter is approved.

3.14.6. The Secretariat makes only the exact number of copies requested and as approved by the Chairperson and/or Member-Secretary.

3.14.7. The recipient signs in the *Outgoing Logbook* upon the receipt of said copies.

3.14.8. The Secretariat ensures the diligent recording of all copies of the issued documents.

3.15. Digital or electronic files shall be maintained by the Secretariat for an indefinite period. When needed, shall align with the institutional policy of Asian Eye.

4. FORMS AND APPENDIX

4.1.	QR-ERC-001-01	Curriculum Vitae and Training Record Form
4.2.	QR-ERC-001-05	Confidentiality Agreement and Conflict of Interest Disclosure Form
4.3.	QR-ERC-002-01	Application Form
4.4.	QR-ERC-002-02	Request Letter for Review
4.5.	QR-ERC-002-04	Study Protocol and Informed Consent Assessment Form
4.6.	QR-ERC-002-05	Protocol Decision Form
4.7.	QR-ERC-002-08	Minutes of the Meeting
4.8.	QR-ERC-002-10	Confidentiality Agreement for Non-Member Form
4.9.	QR-ERC-002-12	Continuing Review Application/Progress Report Form
4.10.	QR-ERC-002-13	Final Report Form
4.11.	QR-ERC-002-14	Serious Adverse Event/S (SAE) / Suspected Unexpected Serious Adverse Reaction/S (SUSAR) Report Form
4.12.	QR-ERC-002-15	Protocol Deviation Report
4.13.	QR-ERC-005-01	Site Visit Report Form
4.14.	QR-ERC-006-01	Feedback Form

5. REVISION HISTORY

Version No.	Date	Author/s	Main Change
00	29 April 2015	Mary Ann Catacutan	
01	25 November 2015	Mary Ann Catacutan /Carmina Villanueva	Changed process flow format
02	10 July 2017	Mary Ann Catacutan	Added details regarding preparation of meeting minutes; communication ERC decision and incoming communication
03	11 December 2017	Pacifico Calderon	Clearly define the role of the Member-Secretary in documentation
04	14 September 2020	Joe Vincent Aguila / Rachelle A. Manzo / Noemi Luz Mojares	Updated the contents and related forms
05	02 April 2024	Mary Ann Catacutan-Catis/Noemi Luz Mojares	Updated the contents

1. OBJECTIVES:

This Chapter describes the process of visiting sites conducting study protocol related activities.

2. SCOPE

This Chapter covers all the study protocols approved by the SCMC-AEI ERC to check adherence to GCP and SCMC-AEI ERC approved SOP.

3. IMPLEMENTING PROCEDURE

ACTIVITY	RESPONSIBILITY
Select study site/investigator to be visited	Members
Collect all relevant information about the site/investigator based on the SCMC-AEI ERC documents	Members
Inspect onsite documents and conduct interview	Members
Write the report and communicate the findings to all members	Members
Informs Study Protocol investigator of SCMC-AEI ERC's decision	Chairperson/ Secretariat

3.1. SCMC-AEI ERC Members shall review periodically the ERC Database of all the studies reviewed and approved by the committee. Members may select site for visit based on the following:
  3.1.1. Significant number of remarkable SAE report;
  3.1.2. Significant number of remarkable protocol deviation report;
  3.1.3. Significant study population in type and size; and/or
  3.1.4. Non-compliance to the SCMC-AEI ERCs recommendation and suggested action.

3.2. Prior to site visit, the SCMC-AEI ERC member/representative shall collect all relevant pieces of information about the site/investigator based on the SCMC-AEI ERC documents and inform the investigator of the purpose, scope, and duration of the visit.

3.3. During on-site visit, the SCMC-AEI ERC member/representative shall use the *Site Visit Report Form (QR-ERC-005-01)* for checking of the documents and machine at site to assess for accuracy and consistency. Investigator and/or study staff will be interviewed by the SCMC-AEI ERC member/representative for clarification and query resolution.

3.4. The SCMC-AEI ERC member/representative who conducted the visit shall write a report and forward the report to the Secretariat for inclusion in the next full

board meeting. During the full board meeting, the findings during site visit shall be presented to the members and the SCMC-AEI ERC committee shall decide for an appropriate action.

3.5. The Chairperson through the Secretariat shall communicate the decision of the SCMC-AEI ERC.

4. FORMS AND APPENDIX

4.1. QR-ERC-005-01 Site Visit Report Form

5. REVISION HISTORY

Version No.	Date	Author/s	Main Change
00	29 April 2015	Mary Ann Catacutan	
01	25 November 2015	Mary Ann Catacutan /Carmina Villanueva	Changed process flow format
02	14 September 2020	Joe Vincent Aguila / Rachelle A. Manzo / Noemi Luz Mojares	Updated the contents and related forms

1. OBJECTIVES

This Chapter describes the process of managing queries and complaints from study participants.

2. SCOPE

The Chapter covers all types of queries and complaints related to the rights and welfare arising from study participation.

3. IMPLEMENTING PROCEDURES

ACTIVITY	RESPONSIBILITY
Receives query or complaint from a patient	Member/ Secretariat
Assesses the complaint and refer to appropriate person	Member-Secretary
Responds to complaint or query	Member
Report to the full board and take appropriate action	All members
Documents and files all relevant correspondences	Secretariat

3.1 Receiving queries and complaints from study participants or any concern individual through various means of communication.

3.2 The query/complaint shall be assessed for its nature and validity.

3.3 The designated member shall respond to the query/complaint if within his/her authority and may refer to other members of the committee or escalate to the Chairperson for appropriate action. After thorough investigation, record all the query/complaint and the recommended action in the *Feedback Form (QR-ERC-006-01)*. This must be signed and dated by the member who conducted the investigation and recommended plan of action.

3.4 The *Feedback Form (QR-ERC-006-01)* shall then be forwarded to the Secretariat for inclusion in the next Full Board meeting agenda. The SCMC-AEI ERC shall communicate the decision to the person who raised the query/complaint.

3.5 SCMC-AEI ERC Secretariat to document and file all the correspondence related the event.

4 FORMS AND APPENDIX

4.1 QR-ERC-006-01 Feedback Form

5 REVISION HISTORY

Version No.	Date	Author/s	Main Change
00	29 April 2015	Mary Ann Catacutan	

01	25 November 2015	Mary Ann Catacutan /Carmina Villanueva	Changed process flow format
02	14 September 2020	Joe Vincent Aguila / Rachelle A. Manzo / Noemi Luz Mojares	Updated the contents and related forms

1. OBJECTIVE

This Chapter describes the process on writing, reviewing, distributing, amending, approving and storing the SCMC-AEI-ERC Standard Operating Procedure (SOP).

2. SCOPE

This Chapter covers any SOP and their amended versions as published and distributed by the SCMC-AEI ERC.

3. IMPLEMENTING PROCEDURE

3.1. Preparation and Approval of SOP Workflow

ACTIVITIES	RESPONSIBILITY
Design SOP Format, coding, and layout	Ad Hoc Group
Revise existing SOP	Ad Hoc Group
Present revised SOP to the SCMC-AEI ERC Members	Ad Hoc Group
Approve the revised SOP	Members
Affix appropriate signatures in the revised documents	Chairperson & Member-Secretary
Approve and sign the revised SOP	Medical Directors
Distribute and store revised SOP	Secretariat
Archive superseded SOP	Secretariat

3.2. Design of the Format, Document Coding, and Layout

3.2.1. An SOP follows the format:

3.2.1.1. Document Code, Revision No, and Effective Date
3.2.1.2. Document Title, which is descriptive of contents
3.2.1.3. Objectives, which defines the purpose and intended outcome
3.2.1.4. Scope, which defines the extent of coverage of the SOP and its limitations
3.2.1.5. Responsibilities, which delineates tasking ad accountabilities for SOP implementation
3.2.1.6. Workflow when necessary, which provides a graphic representation of the essential steps to implement the SOP
3.2.1.7. Detailed instructions, which elaborates the steps outline in workflow

3.2.1.8. Forms, which are documents to be filled out or accomplished by different parties as required by the SOP, with a list of Forms
3.2.1.9. Appendices, which provide elaborations or clarifications of specific sections including glossary and list of abbreviations
3.2.1.10. References, which lists the instruments use to draft the Guidelines such as other SOP, guidelines, or policies

3.2.2. Minor changes refer to the editorial, grammatical, or administrative changes that have no substantial effect on procedures, definitions, requirements, and similar considerations.

3.2.3. The layout of a typical SOP template uses a header and footer with the following elements:
3.2.3.1. Institutional seal or logo
3.2.3.2. Name of institution
3.2.3.3. Name of Manual
3.2.3.4. Document Title
3.2.3.5. Document Code
3.2.3.6. Issue No. and Revision No.
3.2.3.7. Effective Date
3.2.3.8. Page number

3.3. Review and Amendment of SOP

3.3.1. SOP is issued by the SCMC-AEI ERC in order to facilitate transparent, clear, and systematic implementation of its functions.
3.3.2. Any member can propose an amendment to the SOP.
3.3.3. The Chairperson shall include this request in the agenda of meeting, for deliberation approval of members.

3.4. Decision, Approval and Preparation of New/Revised SOP

3.4.1. Upon favorable action by the members and the Medical Directors.
3.4.2. The Secretariat prepares the approved documents for signature of the Chairperson, Member-Secretary, and Medical Directors.
3.4.3. The effective date of the document is reckoned as the date when the Medical Directors signs the documents. However, on the interest of the continuity of SCMC-AEI ERC work, SOP documents may be regarded as functionally approved as of the date of favorable action by the Committee.
3.4.4. The Secretariat shall file one (1) copy of the approved SOP with original signatures.

3.5. Distribution and Storage of New/Revised SOP

3.5.1. The Secretariat shall furnish a copy of the approved SOP to the members and include in the current SOP Manual.
3.5.2. In case of amended or revised SOP documents, the old version will undergo archiving procedures by the Secretariat. The word

"SUPERSEDED" is stamped on all pages of one complete set of the old version, after which it is stored separately from the current version.

3.5.3. Superseded versions are indicated in the History of the SOP of the new version by Secretariat prior to storage.

4. FORMS AND APPENDIX

None

5. REVISION HISTORY

Version No.	Date	Author/s	Main Change
00	29 April 2015	Mary Ann Catacutan	
01	25 November 2015	Mary Ann Catacutan /Carmina Villanueva	Changed process flow format
02	14 September 2020	Joe Vincent Aguila / Rachelle A. Manzo / Noemi Luz Mojares	Updated the contents and related forms

6. RECOGNITION AND CITATION

SCMC-AEI ERC expresses its sincerest gratitude and recognition to the University of Santo Tomas Hospital Institutional Review Board (USTH-IRB) and the University of the Philippines Manila Research Ethics Board (UPMREB). The recent revisions of this SOP are greatly influenced by the SOPs of both esteemed institutions.

ST. CABRINI MEDICAL CENTER - ASIAN EYE INSTITUTE (SCMC-AEI) ETHICS REVIEW COMMITTEE

STANDARD OPERATING PROCEDURE

Chapters	Document Code
Front Matter	PR-ERC-001-00
SOP I	PR-ERC-001-01
SOP II	PR-ERC-001-02
SOP III	PR-ERC-001-03
SOP IV	PR-ERC-001-04
SOP V	PR-ERC-001-05
SOP VI	PR-ERC-001-06
SOP VII	PR-ERC-001-07
SOP VIII	PR-ERC-001-08

Date: Apr. 2, 2024

Author/s:	Approved by:
Emerson M. Cruz, M.D. SCMC-AEI ERC Member Secretary	***Antonio D. Ligsay, M.D.*** SCMC-AEI ERC Chairperson
Noemi Luz P. Mojares SCMC-AEI ERC Member	***Juan Ma. Pablo R. Nañagas, M.D.*** AEI, Medical and Research Director
	Malen Gellido, M.D. SCMC, Chief Medical Director

Signature on File