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

Chapters	Document Code
Chapter 1	SCMC-AEI Doc. 01-06-2016
Chapter 2	SCMC-AEI Doc. 02-05-2015
Chapter 3	SCMC-AEI Doc. 03-05-2016
Chapter 4	SCMC-AEI Doc. 04-04-2015
Chapter 5	SCMC-AEI Doc. 05-02-2016
Chapter 6	SCMC-AEI Doc. 06-01-2015
Chapter 7	SCMC-AEI Doc. 07-01-2015
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SCMC-AEI Ethics Review Committee
Standard Operating Procedures
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ABBREVIATION INDEX

AE	Adverse Event
AEI	Asian Eye Institute
AEI-ERC	Asian Eye Institute-Ethics Review Committee
AOR	Acknowledgement of Receipt
CFR	Code of Federal Regulation
CIOMS	Council for International Organizations of Medical Science
COI	Conflict of Interest
CRF	Case Report Form
CV	Curriculum Vitae
DOH	Department of Health
ERC	Ethics Review Committee
GCP	Good Clinical Practice
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH-GCP	International Conference on the Harmonization of Good Clinical Practice
IRB	Institutional Review Board
PCHRD	Philippine Council for Health Research and Development
PFDA	Philippine Food and Drug Administration
PHREB	Philippine Health Research Ethics Board
PI	Principal Investigator
SAE	Serious Adverse Event
SCMC	St. Cabrini Medical Center
SCMC-AEI ERC	St. Cabrini Medical Center-Asian Eye Institute Ethics Review Committee
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
WHO	World Health Organization

GLOSSARY

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 part of a profession and represents the rest of the community.

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.

Nuremberg Code

Code for ethical research

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

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)*

Protocol Amendment

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

Reviewer

A member of the ethics committee assigned by the chairman 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)*

Suspected Unexpected Serious Adverse Reaction

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

REFERENCES

1. Code of Federal Regulation Title 21 Food and Drugs
2. ICH-GCP Guidelines
3. National Ethical Guidelines for Health Research 2011
4. Operational Guidelines for Ethics Committees the Review Biomedical Research 2000 by the World Health Organization (WHO)
5. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011 by the World Health Organization (WHO)
6. Council for International Organizations of Medical Science (CIOMS) 2002 and 2008

INTRODUCTION

The Asian Eye Institute (AEI) recognizes the importance not only of biomedical research but also other fields of research hence in line with the expansion of the Institute, 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, the institute 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. Asian Eye will serve as the ophthalmology department of the hospital. 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).

VISION and MISSION of ERC

Our Vision

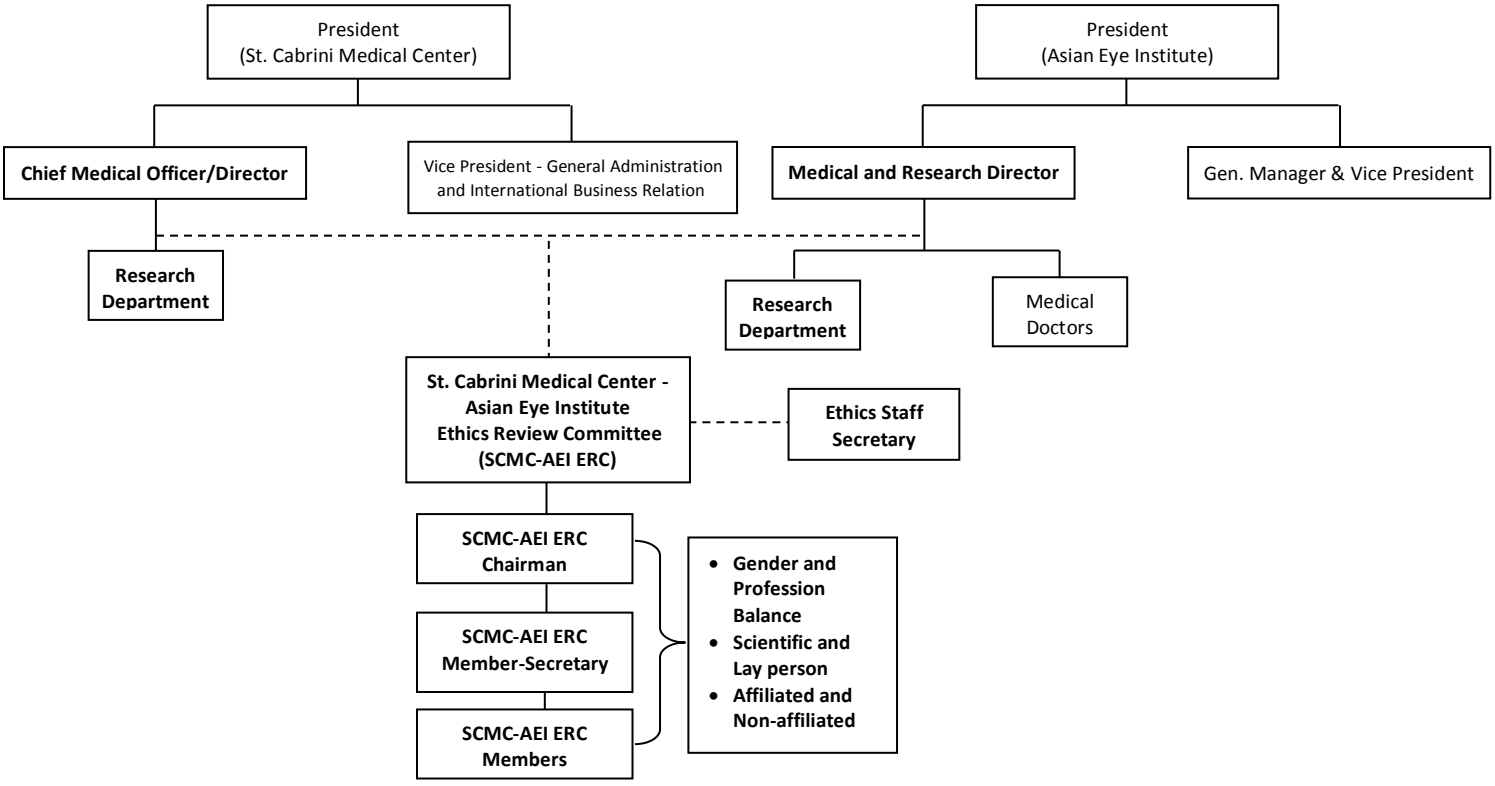
In the next five (5) years, SCMC-AEI ERC will be a reviewer of clinical, operational, and policy studies in the Philippines.

Our Mission

We deliver to all stakeholders a standard of ethical review that is based on national and international ethical standards and guidelines protecting the welfare of Filipino and regional patients.

Organizational Structure

The SCMC-AEI ERC shall operate as an independent committee according to the organization structure shown below:



- SCMC-AEI ERC Implementing office:
    - Chairman
    - Member-Secretary
    - Members
        1. Scientific, Affiliated Member
        2. Scientific, Non-Affiliated Member
        3. Layperson, Affiliated Member
        4. Layperson, Non-Affiliated Member
- The SCMC-AEI ERC shall be composed of at least 7 members.
- The members shall represent an appropriate balance of profession, gender, ethical, legal, cultural, educational, and community interest.
- SCMC-AEI ERC shall include at least one member whose primary concern is in the scientific areas and at least one member who is a layperson (non-scientific area).
- SCMC-AEI ERC shall include at least one 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 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.

Establishment of and Mandate of the 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 Asian Eye Institute. 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 delivery of quality service to the public, improvements have been in placed to guide the committee to serve its community better. AEI-ERC has been following both local and international guidelines such as 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 WHO Operational Guidelines for Ethics Committees that review Biomedical Research and International Ethical Guidelines for Epidemiological Studies. AEI-ERC is also registered with the Philippine Health Research Ethics Board (PHREB) since 2011. In 2014, the AEI-ERC was accredited Level 2 by the Philippine Health Research Ethics Board.

Also in 2014, Asian Eye Institute 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.

Principles/Guidelines guiding the ERC

Basis for Ethical Framework

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

a. National Ethical Guidelines for Health Research 2011 by the Philippine Health Research Ethics Board (PHREB)
b. Philippine Food and Drug Authority (PFDA) administrative orders and guidelines
c. Declaration of Helsinki (2008)

d. Operational Guidelines for Ethics Committees the Review Biomedical Research 2000 by the World Health Organization (WHO)
e. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011 by the World Health Organization (WHO)
f. International Conference on the Harmonization of Good Clinical Practice (ICH GCP)
g. Council for International Organizations of Medical Science (CIOMS) 2002 and 2008

The 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.

The 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.

Brief history of the making of SOP

The first formal operating manual used by the committee was officially registered with the institute's document controller under the quality assurance department in April 2011. Realizing that several improvements need to be made with the evolvement of the clinical research industry and the ethics committee members needing a more concrete guideline to follow, the institution sent 3 ethics members (Dr. Juan Maria Pablo Nañagas, Kristina Manalili and Criselda Panganiban) and 1 research officer (Mary Ann Catacutan) to participate in the SOP Training hosted by UP-NIH in July 2012. The operating manual underwent 2 revisions (March 2013 and January 2014) following the learning gained from the training and recommendation from PHREB. In May 2014, the final SOP was submitted along with other documents for accreditation to PHREB. By August 2014, PHREB gave several suggestions to further improve the SOP, hence 3rd revision was done to comply with the changes requested. Finally in September 2014, the final SOP Manual version was submitted and acknowledged by PHREB. As part of the committee's mission to adhere with the local and international guidelines, a workshop on SOP-Training shall be part of the 2015 initiatives of the ERC.

Policy Statement / Objectives

The SCMC-AEI ERC subscribes to internationally accepted standards and protocols in the conduct of research. As such, the SCMC-AEI ERC describes the structure of the SCMC-AEI ERC and its composition in compliance with the national and international guidelines in ethical research.

Furthermore, the SCMC-AEI ERC aims to detail the following procedures:

1. Composition and Membership of ERC
2. Appointment of Members
3. Consultation with Independent Consultant
4. Training of Members and Staff
5. Incentives for ERC Members and Consultant

Scope

The St. Cabrini Medical Center-Asian Eye Institute Ethics Review Committee is an independent committee arising from the partnership of SCMC and AEI to oversee and protect the safety and welfare of all study participants in the two (2) institutions.

The SCMC-AEI ERC shall organize an independent committee that will oversee all the clinical trials being conducted specially within the two (2) institutions. The committee shall be referred to as St. Cabrini Medical Center-Asian Eye Institute Ethics Review Committee (SCMC-AEI ERC).

All clinical trials which involve human subjects shall be initiated only after review and approval by, and remain subject to continuing review by SCMC-AEI ERC. It is the responsibility of the ERC to ensure that all studies submitted are reviewed according to the process set forth in this document.

Responsibility

The SCMC-AEI ERC aims:

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

1.1 Selection of Members SOP

1.1.1. Purpose

This section aims to illustrate the appointment procedure, qualification requirements and, roles and responsibilities of the members of the SCMC-AEI ERC.

1.1.2. Scope

The policy shall cover the nomination, appointment procedure and term of office of the members of the SCMC-AEI ERC.

1.1.3. Responsibility

The Chairman shall be responsible in appointing the members of the SCMC-AEI ERC after consultation and agreement with the members of ERC.

1.1.4. Workflow

ACTIVITY	RESPONSIBILITY
1.1.4.1 Nomination of *new members*	ERC member
1.1.4.2 Submission of CV for review of chairman	ERC staff secretary
1.1.4.3. Appointed member will be given relevant documents to accomplish	ERC staff secretary
1.1.4.4. All members to attend relevant training/refresher training and submit updated CV	ERC member
1.1.4.5. Filing of all relevant documents in the membership file	ERC staff secretary

1.1.4.1. Prospective members are selected and assessed through nomination (Related Form 1A) by current members of the ERC. Alternatively, individuals who are interested to be part of the SCMC-AEI ERC may do self-nomination.

1.1.4.2. A copy of the member's updated curriculum vitae along with certificates of relevant trainings should be submitted to the SCMC-AEI ERC staff secretary.

a. Member should have good moral character, ethical and/or scientific knowledge and expertise, as well as willing to volunteer their time and effort to fulfill their duties as member of the SCMC-AEI ERC.
b. Member should have or is willing to undergo trainings and refresher trainings related to his/her duties as a member of SCMC-AEI ERC, this would include but will not be limited to: ICH-GCP training, Basic Ethics training, SOP training on ethics committee member, etc.
c. Member should be willing to make public his/her full name, profession and affiliation as a member of SCMC-AEI ERC.
d. Member should be willing to take responsibility set forth in Section 1.3.

1.1.4.3. The accepted member will be given the following documents at the start of his/her appointment:

a. appointment letter (Related Form 1B)

i. The appointment letter shall reflect the following: functions as a member of the SCMC-AEI ERC, term of office, scope of work, and membership requirement and conditions

ii. All new members are given 2 year office term and are subject to reappointment (of same duration) unless they express termination of appointment or when their performance is not up to SCMC-AEI ERC standards or as deemed by the chairman.

b. acceptance letter (Related Form 1C)

c. confidentiality and non-disclosure agrement (Related Form 1D)

d. declaration of conflict of interest (Related Form 1E)

e. SCMC-AEI ERC SOP copy

Refusal to sign any of the above-mentioned documents can be grounds for disqualification.

1.1.4.4. All members are required to attend at least 1-2 relevant trainings during his/her membership term and submit updated curriculum vitae (signed and dated on the last page) once every 2 years.

1.1.4.5. All documents to be filed in the ERC membership file (see CHAPTER 6 – Documentation and Management of Files and Archiving)

1.2 Selection/Designation of Officers SOP

1.2.1. Purpose

This section aims to illustrate the appointment procedure, qualification requirements and, roles and responsibilities of the officers of the SCMC-AEI ERC.

1.2.2. Scope

The policy shall cover the nomination, appointment procedure and term of office of the officers of the SCMC-AEI ERC.

1.2.3. Responsibility

The medical director of the two (2) institutions shall be responsible in appointing the officers of the SCMC-AEI ERC after nomination among existing members of the ERC.

1.2.4. Workflow

ACTIVITY	RESPONSIBILITY
1.2.4.1. Nomination of *new officer/s*	ERC members
1.2.4.2. Medical Director of the 2 institutions to approve the new officer	Medical Director
1.2.4.3. Send letter of notification to the selected new officer	ERC staff secretary
1.2.4.4. New officer to sign the acceptance letter and submit necessary documents	ERC officer

1.2.4.1. At the end of the term of office of the Chairman and/or Member-Secretary and during the second to the last meeting of the year, the members of the committee shall nominate among the existing members for the position of Chairman and/or Member-Secretary. Outgoing Chairman/Member-Secretary may also be nominated.

i. The nominee should have the following qualifications:
   a. Good moral character, ethical and/or scientific knowledge and expertise, as well as willing to volunteer their time and effort to fulfill their duties as member of the SCMC-AEI ERC.
   b. Willing to undergo trainings and refresher trainings related to his/her duties as an officer of SCMC-AEI ERC, this would include but will not be limited to: ICH-GCP training, Basic Ethics training, SOP training on ethics committee, etc.
   c. Willing to make public his/her full name, profession and affiliation as an officer of SCMC-AEI ERC.
   d. Willing to take responsibility set forth in Section 1.3.

ii. The nominee with the most number of votes shall be designated as the new chairman/member-secretary.

1.2.4.2. The name and qualification of the new officer shall be submitted to the medical director of the two (2) institutions for approval.

1.2.4.3. Formal appointment letter and letter of acceptance to be released to the incoming officer (Chairman and/or Member-Secretary).

i. On the appointment letter (Related Form 1B) provided to each officer, the following shall be indicated: functions as an officer of the SCMC-AEI ERC, term of office, scope of work, and membership requirement and conditions.

ii. The ethics review committee shall ensure and strive for continuity, development and maintenance of expertise within the group, with mechanism of rotating its officers.

iii. The SCMC-AEI ERC Chairman shall have a term of office of 3 years, with possible reappointment upon the recommendation and approval of the medical director of the two (2) institutions.

iv. The SCMC-AEI ERC Member-Secretary shall have a term of office of 3 years.

1.2.4.4. Incoming officer to sign the acceptance letter and submit necessary documents.

1.3 Duties of ERC Officers and Members

The Chairman shall have full responsibility in all the activities being conducted by the committee. Below are the responsibilities of the different roles of the members of the ethics review committee:

	Responsibilities
A. Chairman:	i. Represents SCMC-AEI ERC in national and international fora ii. Presides over the meeting ensuring that all protocols reviewed by the committee adheres with the set SOP iii. Prepares annual budget allocation and expenses incurred for approval and review of the 2 institutions iv. Decide on type of review to be conducted (expedited or full board) and assigns reviewer v. Declare any conflict of interest vi. Participate in the continuing education programs vii. Comply with the established SOP viii. Maintain confidentiality at all times
B. Member-Secretary:	i. Support and assist the chairman in developing activities and initiatives for the committee ii. Support and assist the chairman in the implementation of the ethics' SOP iii. Performs other duties as designated by the chairman iv. Assist the ERC staff secretary during meetings v. Oversight on meeting documentation vi. Screen and assess submitted proposal; makes decision on the type of review and assign reviewers vii. Review protocols and other study documents in a timely manner viii. Review and assess adverse event, progress report and other reports submitted to the committee ix. Takes over in the absence of the chairman x. Declare any conflict of interest xi. Participate in the continuing education programs xii. Comply with the established SOP xiii. Maintain confidentiality at all times
C. Members:	i. Participate during meetings, review protocols and other study documents and reports in a timely manner ii. Perform other tasks as assigned by the committee iii. Declare any conflict of interest

	iv.	Participate in the continuing education programs
	v.	Comply with the established SOP
	vi.	Maintain confidentiality at all times

Note:

- *Accomplished assessment forms and review in sufficient details should be submitted by the assigned reviewer(s) a week before the set meeting date to the chairman/member-secretary through the ERC staff secretary.*
- *In the absence (due to emergency situations) of assigned reviewer(s) during the meeting, the chairman and the member-secretary shall present the review of the reviewer. Both should be aware of the review and ready to present the study.*

1.3.1. SCMC-AEI ERC Staff Secretary and Functions

1.3.1.1. The SCMC-AEI ERC shall have an office with complete work supplies and a dedicated support staff. The main office shall be located at the Asian Eye Institute 8F Phinma Plaza, Rockwell Center, Makati City and a satellite office at the St. Cabrini Medical Center Sto. Tomas, Batangas City. The ERC staff secretary shall manage both offices and will devote 80% of the work schedule at the main office and 20% at satellite office. A dedicated support staff (or additional staff) will be hired vis-à-vis volume of work and received proposals.

1.3.1.2. The SCMC-AEI ERC Staff Secretary is a non-member secretary that will act as a support staff assigned to assist all the members in performing the activities of the committee.

1.3.1.3. The SCMC-AEI ERC Staff Secretary shall be employed by the institute and shall perform the activities of the ethics review committee under the supervision of the chairman. Likewise with the members of the ethics review committee, the SCMC-AEI ERC staff secretary is required to undergo relevant training prior to performing his/her tasks as secretary.

1.3.1.4. The staff secretary shall have the following duties and responsibilities:

a. Organize and prepare ERC meetings
b. Prepare the meeting agenda and minutes of meetings
c. Receive and acknowledge all documents submitted in a timely manner
d. Establish open communication with all members of the committee, sponsors, investigators and study coordinators
e. Ensure that the ERC database (protocols, SUSAR/SAE reports) is up to date
f. Ensure proper filing and record keeping of all SCMC-AEI ERC documents
g. File all study related communication in the SCMC-AEI ERC master file
h. Ensure that the SCMC-AEI ERC master file, which contains all the activities, membership information, is updated and maintained accordingly
i. Keep track all the expenses of the committee and submit to the chairman for review
j. Prepare appointment letter, letter of acceptance, confidentiality and non-disclosure agreement form and conflict of interest form
k. Secure ERC offices and files

1.4 Designation of Independent Consultants SOP

1.4.1. Policy Statement

This section aims to describe the process for appointing SCMC-AEI ERC independent consultants. The SCMC-AEI ERC adheres to the principle of sourcing expertise regarding matters that are beyond the capabilities of the members of the ERC.

1.4.2. Scope

The SCMC-AEI ERC may invite individuals 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. This policy shall cover the procedure for selecting and appointing an independent consultant.

1.4.3. Responsibilities

It is the responsibility of the members to nominate independent consultant to provide expert opinion on various topics for review.

1.4.4. Workflow

ACTIVITY	RESPONSIBILITY
1.4.4.1. Nomination of Independent consultant	ERC member
1.4.4.2. Credentials and expertise to be reviewed for final listing	ERC member
1.4.4.3. Independent consultant will be notified and ask to submit necessary documents	ERC staff secretary
1.4.4.4. Request for independent consultant	ERC member

Description of Activities:

1.4.4.1. The chairman or any member of the committee may nominate an independent consultant/s to help out in the review activity of the committee.

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

i. Independent consultant to submit signed and dated curriculum vitae for review of credentials and expertise

ii. Among the list of the consultants, the chairman will inform the directors of the institution of the chosen independent consultant.

iii. The SCMC-AEI ERC staff secretary shall create and maintain a list of all independent consultants.

1.4.4.3. Independent consultants shall receive and accomplish the following documents for filing in the SCMC-AEI ERC master file:
   i. Appointment letter with details of work responsibility and scope
   ii. Acceptance letter
   iii. Confidentiality and non-disclosure agreement form
   iv. Conflict of interest form

1.4.4.4. The chairman or any member of the committee may request for an independent consultant based on the list of consultants to assist in the study review.

1.4.5. Role of Independent Consultant

1.4.5.1. After completing all the required documentation, the committee secretary shall provide to the independent consultant the study protocol documents to be reviewed.

1.4.5.2. Along with the study protocol documents, copy of the review assessment form shall be given to the independent consultant to help him/her in evaluating the study. This must be completed and returned to the committee staff secretary not more than two weeks.

1.4.5.3. The independent consultant may attend the ethics review meeting to present his/her assessment of the study and participate during discussion and deliberation but is not allowed to vote.

1.4.5.4. After the review of the study, all study protocol documents given to the independent consultant shall be returned to the committee staff secretary.

1.4.5.5. All reports submitted and generated by the independent consultant shall be part of the final study report and filed in the SCMC-AEI ERC master file.

1.4.6. Duration of Service

1.4.6.1. The services rendered by the independent consultant are per project/protocol basis.

1.4.6.2. An independent consultant may wish not to continue to render his/her services on the succeeding project/protocol provided that he/she will notify the chairman.

1.4.6.3. SCMC-AEI ERC may discontinue seeking the service of the independent consultant should he/she not complied with the responsibility set forth on Section 1.4.5.

1.5 Renewal/Resignation/Disqualification/Replacement SOP

1.5.1 Policy Statement

The SCMC-AEI ERC shall employ its right to choose only qualified members to be part of the committee.

1.5.2 Scope

This section shall cover the renewal, resignation, disqualification and replacement process of all SCMC-AEI ERC members and officers.

1.5.3 Responsibility

It is the responsibility of the chairman and/or the medical director of the 2 institutions to decide whether a member or potential member is capable of assuming the roles and functions of a member or officer of the committee.

1.5.4 Workflow

A. RENEWAL	B. REPLACEMENT	C. RESIGNATION	D. DISQUALIFICATION
1.5.4.1. Outgoing member or officer to seek for term renewal	1.5.4.4. Resigned or disqualified member shall be replaced	1.5.4.7. Submitted letter of resignation addressed to the chairman or if officer, addressed to the medical director of the 2 institutions	1.5.4.10. Deliberation among members to determine disqualification
1.5.4.2. Must fulfill criteria to be eligible: participated in >60% of the total meeting; complete training	1.5.4.5. Existing members to nominate new member or officer	1.5.4.8. Existing members to nominate new members or officers	1.5.4.11. Members to vote for disqualification
1.5.4.3. Obtain approval from chairman or medical director	1.5.4.6. Term of the selected member shall be limited to term of the member replaced	1.5.4.9. Appointment letter with term duration will be given to the new member/officers	1.5.4.12. Decision will be recorded in the minutes of the meeting

A. Renewal:

1.5.4.1. An outgoing member or officer may seek for renewal of his/her term.
1.5.4.2. The member must meet the following criteria to be eligible for renewal:
- i. Participated in more than 60% of the total meetings held during the time of his/her appointment
- ii. Completed required training during his/her appointment duration

1.5.4.3. Upon the approval of the chairman or medical directors of the 2 institutions, the member or officer shall be re-appointed.

B. Replacement:

1.5.4.4. Members and officers who have resigned or disqualified may be replaced through the same process of nomination/selection as stated above.

1.5.4.5. Existing members may nominate new members/officer. For members who will act as the replacement shall have a term of office limited to the remaining term of the member he/she replaced. He/she can be reappointed for another two (2) years upon the approval of the chairman.

1.5.4.6. For chairman who will act as the replacement shall have a term of office limited to the remaining term of the chairman he/she replaced. He/she can be reappointed for another three (3) years upon the approval of the medical directors of two (2) institutions.

C. Resignation:

1.5.4.7. A member and officers may resign from their position at any point during his/her term.

1.5.4.8 For members, a letter of resignation indicating the reason for his/her resignation shall be submitted to the SCMC-AEI ERC staff secretary and addressed to the chairman.

1.5.4.9 For chairman, a letter of resignation indicating the reason for his/her resignation shall be submitted to the SCMC-AEI ERC staff secretary and addressed to the director of the institutions.

D. Disqualification:

1.5.4.10. A member or officer may be disqualified and removed in the committee if there is a legitimate cause/reason as determined by the committee (e.g. intentionally violating the rules and regulations of the ethics committee).

1.5.4.11. A deliberation among members will be made and majority vote of the committee is necessary to determine disqualification of the member.

1.5.4.12. The decision will be recorded in the minutes of the meeting and all pertinent documents will be filed accordingly.

1.6 Training

1.6.1. Policy Statement

It is of paramount importance that only competent and trained members are part of the SCMC-AEI ERC. This policy aims to describe the training requirement and continuing education available for the members and staff.

1.6.2. Scope

This policy shall cover the training requirements and continuing education programs for SCMC-AEI ERC members and staff.

1.6.3. Responsibility

It is the responsibility of the SCMC-AEI ERC to ensure that all members have the necessary training prior to assuming the responsibility. The SCMC-AEI ERC members and staff shall be responsible to educate and train themselves regularly. The ERC staff secretary shall keep track of all the training needs and requirements of the member and staff.

1.6.4. Activities

1.6.4.1. Initial training to new member and staff

1.6.4.1.1. The chairman/ERC staff secretary shall provide initial training to new members and/or staff.

1.6.4.1.2. Initial training shall include ICH-GCP training, mentoring of SCMC-AEI ERC SOP and observation during committee meeting.

1.6.4.1.3. The chairman or any designated personnel may conduct the initial training to the new members and/or staff.

1.6.4.1.4. Other trainings that may be included during the initial trainings are:

a. Declaration of Helsinki
b. National Ethical Guidelines
c. CIOMS
d. WHO Guidelines
e. Relevant local laws and regulations

1.6.4.2. Training records

1.6.4.2.1. All training records should be kept and filed by the ERC staff secretary.

1.6.4.2.2. Training records include: in-house training attendance and certificates if applicable.

1.6.4.2.3. A copy of the certificates obtained through external trainings should be submitted by the members to the ERC staff secretary.

1.6.4.2.4. The ERC staff secretary should 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.

1.6.4.3. Continuing education for members and staff

1.6.4.3.1. All members and ERC staff secretary should have ICH-GCP training, IRB SOPs training, Basic Ethics Training.

1.6.4.3.2. The chairman or ERC staff secretary shall look for trainings available and applicable to the members.

1.6.4.3.3. The ERC staff secretary to facilitate the scheduling and training payment.

1.7 Management of Conflict of Interest and Confidentiality issues

1.7.1. Conflict of Interest as stated in the National Ethical Guidelines for Health Research (NEGHR) 2011 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 an EC 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, holding patent right or receiving royalties from such rights whose value may affect the value of the research outcome.

1.7.1.1. Financial Conflict

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

a. Salary or other payments for services (e.g. consulting fees or honoraria)
b. 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 ERC member or his/her immediate family does not exercise control)
c. Intellectual property rights (e.g. patents, copyrights and royalties from such rights).

1.7.1.2 Role Conflict

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

a. Principal Investigator,
b. Co-Principal Investigator,
c. Investigator receiving funding from the study, as listed in the study budget,
d. In a supervisory role over the PI of the study,
e. Anyone who is involved in the conduct of the research or a competing study,
f. Acts as a consultant/employee of the study sponsor,
g. Family member or relative of PI.

1.7.1.3. 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 committee decision.

To ensure unbiased review of the study proposal, the committee shall exercise the following:

a. All members to declare any conflict of interest (Related Form 1E) prior to acceptance of their appointment (Section 1.1.4.3.)
b. At the start of every meeting, all members shall disclose any conflict of interest regarding a project which is scheduled to undergo ERC review
c. Any member having reported financial or role conflict will be asked to leave the meeting.
d. Any conflict of interest and the steps taken to manage the situation shall be recorded in the minutes of the meeting.

1.7.2. Confidentiality

All information (proposals, consent forms, patient materials, study results, etc.) submitted to the committee 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.

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

1.7.2.1. Require all members to sign confidentiality and non-disclosure form (Related Form 1D) prior to acceptance of their appointment.
1.7.2.2. Require non-members (e.g. independent consultant) who will attend the meeting to sign the confidentiality and nondisclosure form at the start of the meeting.

1.8 Compensation of ERC Members and Independent Consultants

1.8.1. Policy Statement

The SCMC-AEI ERC shall grant appropriate honorarium to the members of the committee and independent consultants for the time, expertise and services rendered.

1.8.2. Scope

This policy shall cover the procedure in obtaining incentives for the SCMC-AEI ERC members and independent consultants.

1.8.3. Responsibility

It is the responsibility of the Chairman and/or Medical and Research Director to budget and allocate funding for SCMC-AEI ERC activities including incentives to members and consultants.

1.8.4. Workflow

ACTIVITY	RESPONSIBILITY
1.8.4.1. Drafting of budget plan for the following year	Chairman and medical director
1.8.4.2. Requisition of check	ERC staff secretary
1.8.4.3. Check processing and issuance by Finance Department	Finance Department
1.8.4.4. Dispensation of honorarium	ERC staff secretary
1.8.4.5. Acknowledgement of receipt	ERC member/ consultants

Description of Activities:

1.8.4.1. Every third or fourth quarter of the year, the chairman and/or the medical directors of the 2 institutions shall develop the committee's budget plan for the following year. Budget plan shall include the meeting expenses such as food, honorarium, etc., training expenses and office supplies. The final budget is subject for approval of the institute.

1.8.4.2. Check request shall be requested by the ERC staff secretary from the Finance Department.

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

1.8.4.4 Honorarium will only be given after a service has been rendered. The full amount shall be given by the ERC staff secretary to the member/consultant at the end of the meeting or service.

1.8.4.5. The member/consultant shall acknowledge the honorarium in writing (Related Form 1F). The documentation will be filed in the SCMC-AEI ERC master file and liquidation report will be submitted to the accounting department of the institute.

1.9 History of SOP

Version No.	Date	Author/s	Main Change
00	01 April 2011	MTC	
01	20 March 2013	MTC	Added reports submission, confidentiality, conflict of interest, trainings and independent consultant
02	13 January 2014	MTC	Changed SOP format
03	10 September 2014	MTC	Added milestone and COI form
04	29 April 2015	MTC	Added process flows and related forms
05	25 November 2015	MTC/CPV	Changed process flow format
06	17 February 2016	MTC/CPV	Updated responsibilities of Chairman and Member-Secretary

Policy Statement / Objectives

It is the policy of SCMC-AEI ERC that all studies conducted in the institute undergoes review process following current local and international guidelines. When so qualified, the SCMC-AEI ERC, being an independent body, can also review studies from other institutions on the following instances: (a) when such institution has no existing ERC of its own, or (b) it has an existing ERC but there is a Memorandum of Agreement between SCMC-AEI ERC whereby SCMC-AEI ERC undertakes to review studies from such institution, or (c) the ERC of the Institution concerned has given its written consent to such review, or (d) its own ERC is not qualified to review such study. The purpose of this policy is to document the types and procedures of review by which the SCMC-AEI ERC carry out the review process of all study protocols submitted to the committee and the preparation and activities prior, during and after every meeting.

Scope

The policy shall cover the different types of review process being conducted as well as the criteria and timelines for each type.

Responsibility

It shall be the responsibility of the SCMC-AEI ERC to ensure that investigators and sponsors are well informed of the different types of review process, criteria for review and timelines. The SCMC-AEI ERC chairman and/or an assigned member of the ERC will evaluate any application to ensure that the protocol submission is reviewed appropriately and in a timely manner.

2.1 Expedited Review

In an Expedited Review procedure, the review shall be carried out by the chairman or by one or more experienced reviewers designated by the chairman from among the members of the SCMC-AEI ERC.

In reviewing the study, the reviewer may exercise all of the authorized functions of the ERC except that the reviewers may not disapprove the study. If there are major changes needed or the study needs to be disapproved, the investigator can modify and update the submitted documents and re-submit for review. Once re-submitted, the document will be subject to full board review. After the review, the committee shall inform the investigator in writing of the decision made by the reviewer. Details of the expedited review shall also be included in the agenda of the next meeting.

A proposal may be qualified for expedited review procedure if it meets either or both of the criteria listed below:

a. Some or all of the research appearing on the list (OHRP – Categories of Research That May be Reviewed by the IRB through Expedited Review) and found by the reviewer/s to involve no more than minimal risk. (see Appendix A)
b. Minor changes in previously approved research that does not cause any direct or indirect safety concern to potential and/or ongoing subjects.

Workflow:

ACTIVITY	RESPONSIBILITY
2.1.1. Proposal received and reviewed for completeness by ERC staff secretary/chairman	ERC staff secretary
2.1.2. To approve if qualified for expedited review procedure	Chairman/Member-Secretary
2.1.3. Investigator/researcher will be notified if approved for expedited review	ERC staff secretary
2.1.4. To assign reviewer/s	Chairman/Member-Secretary

2.1.1 Upon receipt of the request for expedited review, the ERC staff secretary/chairman shall review all the documents received for completeness.

2.1.2 Once all documents submitted are deemed complete, the chairman/member-secretary shall decide whether the proposal is eligible for expedited review based on the criteria listed above.

2.1.3 The investigator/researcher will be notified whether the submitted proposal is qualified or not for this type of review. In the event the proposal will not be eligible for expedited review, the proposal will be automatically marked for 'full board review' and included in the next scheduled meeting.

2.1.4 If eligible for expedited review, the chairman/member-secretary shall assign reviewer/s. The ERC Staff secretary shall immediately forward all the necessary documents to the assigned reviewer/s. The reviewer/s shall be given 1-2 weeks to complete his/her assessment. Once completed, the reviewer/s shall forward all the documents including the accomplished review assessment forms to the ERC staff secretary.

i. A decision letter shall be released after the final review of the accomplished assessment forms by the chairman.
ii. The decision shall be communicated to all members during the next scheduled meeting

2.2 Full Board Review

Unless stated otherwise, all study proposal submitted for review shall automatically be assessed through 'full board review'. In a full board review, members are asked to assess the protocol and give their recommendation at the end of the deliberation. Proposal that has one or more of the conditions listed below are required to undergo full board review:

a. Presents more than minimal risk to patients
b. Involvement of vulnerable population (e.g. children, pregnant women, women, cognitively impaired patients, prisoners, etc.)
c. Study involving sensitive social topics

A full board review will not proceed unless **all** of the following quorum requirement is met:

i. More than half of the members are present
ii. Equal representation of the committee (represented by both male and female gender, one member who's scientific, one member whose primary concern is in non-scientific area, affiliated and non-affiliated members).

In cases wherein the above quorum requirement is not met, the meeting shall be postponed and move to another date.

Workflow:

ACTIVITY	RESPONSIBILITY
2.2.1. Proposal received for full board review	ERC staff secretary
2.2.2. Assignment of primary and secondary reviewer	Chairman/Member secretary
2.2.3. Quorum established	Chairman
2.2.4. Reviewer to present the study	Primary and Secondary reviewer
2.2.5. Member to deliberate accordingly	ERC members

2.2.1 Upon receipt of the study proposal, the ERC staff secretary shall review all the documents received for completeness.

2.2.2 As soon as all documents submitted are deemed complete, the chairman/member secretary shall assign two (2) reviewers. A primary reviewer who has scientific background and a secondary reviewer preferably a layperson or non-technical.

2.2.3 Once quorum has been established by the chairman, the committee may proceed to assess the proposal.

2.2.4 The primary and secondary reviewer shall be asked to present and discuss pertinent points about the proposal.

2.2.5 The presentation shall be followed by a brief deliberation among members. If available, the investigator maybe asked to answer questions raised during the deliberation. Chairman to announce the decision at the end of each study review.

2.3 History of SOP

Version No.	Date	Author/s	Main Change
00	01 April 2011	MTC	
01	20 March 2013	MTC	Added reports submission, confidentiality, conflict of interest, trainings and independent consultant
02	13 January 2014	MTC	Changed SOP format
03	10 September 2014	MTC	Revised related forms
04	29 April 2015	MTC	Revised chapter title and content
05	25 November 2015	MTC/CPV	Changed process flow format

APPENDIX A
Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure[1]

Applicability

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
B. The categories in this list apply regardless of the age of subjects, except as noted.
C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
D. The expedited review procedure may not be used for classified research involving human subjects.
E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
   Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i)

mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b. where no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Policy Statement / Objectives

To warrant absolute and timely review of all new protocols, all documents submitted will be examined for completeness and appropriateness prior to initial review process.

Scope

This procedure shall cover all documents submitted (protocols and other relevant supporting documents), how these documents are being handled until the release of the decision letter, the use of the assessment forms during review and review of medical devices.

Responsibility

The ERC staff secretary/chairman is responsible in managing all the protocols submitted for review on the other hand it is the responsibility of the investigator/researcher to make sure that a complete submission be made to aide SCMC-AEI ERC members in delivering timely review of the study proposal.

3.1 Management of Protocol Submission

The SCMC-AEI ERC staff secretary shall inform the study coordinator, Investigator and/or sponsor of the ERC requirements prior to the meeting. The following document/s are required to be submitted for appropriate and timely review of the initial study proposal:

3.1.1 Protocol (include version and date)
3.1.2 Informed consent (English/Filipino) See Appendix B
3.1.3 Investigator's Brochure (include version) or product information (if applicable)
3.1.4 Questionnaires, advertising or recruitment materials, reading cards, diaries or any other documents that will be provided to patients if applicable
3.1.5 Material Transfer Agreement (if applicable)
3.1.6 Updated curriculum vitae and *GCP certificate of the Principal Investigator and Sub-investigator/s with signature and date on the last page of the CV
3.1.7 One page summary of the study for review (for all clinical trials)
3.1.8 2 copies of Submission letter/Cover letter addressed to: (See Related Form 3A)

(Name of the ERC Chairperson)
SCMC-AEI ERC Chairperson
8th Floor Phinma Plaza
Rockwell Center, Makati Philippines

Include in the submission letter 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.

*GCP certificate is mandatory for all medical doctors performing clinical trial

Note:

- *Number of printed copies to be determined (2 copies only for expedited review, 12 copies for full board review, ERC staff secretary may request for additional copies if needed)*
- *Soft copies in WORD or PDF format of the submission documents must be emailed to the ERC secretary 3 weeks prior to the set meeting date. (send all electronic copies to: email address - ROMedina@asianeyeinstitute.com)*

3.2 Initial Review Workflow

ACTIVITY	RESPONSIBILITY
3.2.1. Submission of study proposal	Investigator / Sponsor
3.2.2. Receive initial study proposal and check the completeness together with 2 copies of cover/submission letter	ERC Staff Secretary
3.2.3. Assign permanent code for reference to the initial package and log the protocol in the ERC database	ERC Staff Secretary
3.2.4. Two (2) copies will be stamped as received; one copy forwarded to the submitter and one (1) copy retained for ERC file	ERC Staff Secretary
3.2.5. Assign protocol reviewer	Chairman/Member-Secretary
3.2.6. Distribute the protocol and review assessment forms to the reviewers / members	ERC Staff Secretary
3.2.7. After the meeting/review, file the documents in the ERC active files cabinet. Retrieve all copies from the members for proper disposition.	ERC Staff Secretary

3.2.1. Investigator, researcher and/or Sponsor must submit his/her initial study proposal for review at least 3 weeks prior to the date of the review meeting.

3.2.2. The ERC staff secretary shall check if the submission dossier is complete or if there are additional documents that need to be submitted.

3.2.3. The study protocol will be assigned a permanent number code for reference and logged in the ERC database. Each study proposal shall be identified by an ERC number code. For writing the ERC #, the following format shall be used: ERC # yyyy-xxx (i.e. ERC # 2016-001), where yyyy is the year proposal is received and xxx is the number starting in 001 and so on.

3.2.4. Once marked as a complete submission, the ERC staff secretary shall stamp as received the 2 copies of the submission/cover letter. One copy will be given back to the submitter and the other copy will serve as ERC's copy.

3.2.5. Taking into consideration the type of the study protocol submitted, the chairman and/or member-secretary shall assign 2 reviewers among the members who will lead the review process. The 2 reviewers must be a combination of a scientific and a layperson specially when reviewing clinical trials. If needed, an independent consultant will be invited.

3.2.6. The ERC staff secretary shall notify the reviewers of their assignment and all study documents and review assessment forms shall be forwarded to them via email or courier at least 2 weeks prior to the meeting date. All documents shall be formatted for confidentiality and non-reproducibility.

3.2.7. All relevant documents will be filed accordingly by the ERC staff secretary. All study protocols previously sent to the members will be retrieved after the meeting for proper disposition.

3.3 Use of Assessment Forms – Workflow

ACTIVITY	RESPONSIBILITY
3.3.1. A copy of the Review Assessment Tool (RAT) will be given to the assigned protocol reviewer	ERC staff secretary
3.3.2. Primary and Secondary reviewer to complete the Review Assessment Tool prior to the meeting	ERC member
3.3.3. Primary reviewer and Secondary shall use the RAT in discussing the protocol and consent form during the meeting	ERC member
3.3.4. Final decision regarding the study	ERC member
3.3.5. Summarize the decision at the end of each study reviewed	ERC chairman/member-secretary

3.3.1. The assigned primary and secondary reviewer shall be given a checklist called Review Assessment Tool (Related Form 3B) together with the study for review. This checklist shall be used to evaluate the protocol and informed consent form. The Review Assessment Tool (RAT) form shall contain set of guide questions to help the members review the study appropriately. The members may add questions during the course of review if he/she feels that the checklist is insufficient to arrive at a valid decision.

3.3.2. The primary and secondary reviewer shall complete in advance the review assessment tool. The SCMC-AEI ERC shall determine that the following requirements are satisfied to come up with a decision:

i. Risk to subject is minimized

ii. Risks to subjects are reasonable in relation to anticipated benefits. These benefits mean anything related to health, psychosocial or other value to the individual research

subject, or something that will contribute to the acquisition of generalized knowledge. Money or other compensation for participation in research is not considered benefit but rather compensation for research related inconveniences.

iii. Selection of subjects is equitable

iv. In order to approve research in which some or all of the subjects are children, the ERC must determine that all research is in compliance with ICH-GCP and 21 CFR part 50 (50.50 – 50.56), subpart D

3.3.3. The RAT form shall be used by the primary and secondary reviewer to facilitate discussion of the protocol and consent form. Documents like questionnaires, patient cards, recruitment materials, etc., shall be discussed during the meeting and the Document Decision Form (Related Form 3C) shall be used to document the result/recommended action for these. After review and deliberation of the research study, the members shall come up with a consensus decision.

3.3.4. The decision of the committee shall be as follows: **Approved -** the submitted study proposal is accepted by the committee and is given clearance to proceed; **Minor Modification** - any changes in the protocol or any study document that has no significant impact on the study. This may include but not limited to the following: grammar modification, typographical errors, administrative changes or any changes initiated by the ERC. A proposal or document that was given a "Minor Modification" decision by the committee will be subjected to an expedited review process; **Major Modification** - any changes in the protocol or any study document that has 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 decreasing study duration, or modification in any part of the study protocol or document. A proposal or document that was given a "Major Modification" decision by the committee will automatically be subjected to a full board review process; and **Disapproved** - the submitted study proposal does not merit approval from the committee. For recommended actions with minor, major modification and disapproval, list of items to be amended and reason for disapproval should be clearly stated in the RAT form.

3.3.5. At the end of each study reviewed, the chairman or member-secretary shall summarize the recommendations for the study (if for modification) and announce the final decision before moving on to the next agenda.

3.4 Review of Medical Device Study

3.4.1. In reviewing a medical device study, the SCMC-AEI ERC shall follow the guidelines set forth by the following:

a. Department of Health - Bureau of Health Devices and Technology (DOH – BHDT)
b. Protocol should follow the standard set by: ISO 14155 – Clinical Investigation of Medical Devices for Human Subjects

c. Good Manufacturing Practice 21 CFR Part 820
d. National Ethical Guidelines for Health Research 2011 by the Philippine Health Research Ethics Board (PHREB)
e. Philippine Food and Drug Authority administrative orders and guidelines
f. Declaration of Helsinki (2008)
g. Operational Guidelines for Ethics Committees the Review Biomedical Research 2000 by the World Health Organization (WHO)
h. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011 by the World Health Organization (WHO)
i. International Conference on the Harmonization of Good Clinical Practice (ICH GCP)
j. Council for International Organizations of Medical Science (CIOMS) 2002 and 2008

3.4.2. The process in reviewing a medical device is the same as the process being implemented for initial review of the study protocols (stated in 3.2).

3.4.3. Special considerations when reviewing a medical device study:

i. Proposed investigational plan
ii. Description of the device
iii. Reports of prior use of the investigational device
iv. Choice of comparator (if applicable)
v. Risk and Benefit assessment
vi. List of additional procedures or medication

3.5. History of SOP

Version No.	Date	Author/s	Main Change
00	01 April 2011	MTC	
01	20 March 2013	MTC	Added reports submission, confidentiality, conflict of interest, trainings and independent consultant
02	13 January 2014	MTC	Changed SOP format
03	29 April 2015	MTC	Changed chapter title and content
04	25 November 2015	MTC/CPV	Changed process flow format
05	14 March 2016	MTC/CPV	Add operational definition of decision points for minor and major modification

APPENDIX B

Informed Consent Process

(Lifted from WHO Operational Guidelines for Ethics Committees That Review Biomedical Research)

1. Informed consent form and its process should be adequate, complete and understandable both in writing and when given verbally to the research participants, and when appropriate to their legally acceptable representative(s);
2. Informed consent form should contain the following information: name of the investigator, contact information, emergency number, name of the ethics committee/chairman, contact information of the ethics committee, version and date when the informed consent was created;
3. There should be a defined process for obtaining consent form, including identification of those responsible for obtaining consent;
4. Clear justification for the intention to include research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals;
5. Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation

Policy Statement/Objective

The SCMC-AEI ERC shall periodically review post review documents and reports according to local and international guidelines. The purpose of this policy is to detail the subsequent documents and reports submitted to SCMC-AEI ERC and describe how these documents are received and managed.

Scope

The policy shall cover all types of documents that are to be submitted to SCMC-AEI ERC during and after the conduct of a study and how all these documents are being processed and given due action by the committee. These documents shall include progress/final reports, amended documents, SAE reports, protocol deviation report and early termination report.

Responsibility

The investigator shall be accountable to ensure that the SCMC-AEI ERC is timely informed of important events and information related to the conduct of his/her study. The SCMC-AEI ERC staff secretary/chairman shall be responsible in receiving all documents accordingly and process them as set forth in this policy. It shall be the responsibility of the ERC members to review the documents submitted and provide appropriate action to any undue report specially related to subject's safety and welfare.

4.1 Review of Progress/Final Reports

The SCMC-AEI ERC shall conduct continuing review of studies at intervals appropriate to the degree of risk, but not less than once per year. This will ensure the continued protection of the rights and welfare of study subjects.

The factors considered in setting the frequency of review may include: nature of the study, degree of risk involved; and the vulnerability of the subject population. Otherwise specified, investigator is asked to submit a progress report on a yearly basis from the time it was initially approved.

Workflow

ACTIVITY	RESPONSIBILITY
4.1.1.Submission of Progress Report or Final Report	Investigator/Sponsor
4.1.2. Acknowledgement of the report and log in the database	ERC Staff Secretary
4.1.3. Include progress report/final report in the agenda of the next meeting	ERC Staff Secretary
4.1.4. Upon review of the progress report, committee to provide appropriate action regarding the status of the study	ERC member
4.1.5. Release of re-approval letter and file document in the appropriate binder	ERC staff secretary

4.1.1 All investigators shall follow the prescribed frequency of progress reporting as stated in the initial approval letter received. The investigator may follow the format outlined in (Related Form 4A) preparing a progress report. The investigator shall submit 2 copies of the progress report/final report to the ERC secretary.

4.1.2 The ERC staff secretary shall acknowledge receipt of the report and log in the database.

4.1.3 ERC staff secretary shall include the report in the next ERC meeting agenda for committee review.

4.1.4 During the meeting, the members shall review the study base on the progress report submitted and provide the appropriate action regarding the status of the study.

4.1.5 ERC to release re-approval letter and file the documents accordingly.

4.2 Review of Amendments

Any changes or updates related to the previously approved version of documents should be re-submitted to SCMC-AEI ERC for review.

Workflow

ACTIVITY	RESPONSIBILITY
4.2.1. Submission of amended document	Investigator/Sponsor
4.2.2. ERC Staff Secretary and/or Member-Secretary to check complete submission	ERC Staff Secretary/Member-Secretary
4.2.3. Chairman and/or member-secretary to determine whether amendment of the study protocol is applicable for expedited or full board review	Chairman / Member-Secretary
4.2.4. Amended documents will be assigned to the original/initial reviewers; ERC Staff secretary to forward the documents and review assessment form to the reviewers	ERC Staff Secretary
4.2.5. Communicate to the members the result of the amendment review	Member
4.2.6. Communicate to the investigator the review result	Chairman
4.2.7. File relevant documents to the appropriate ERC active file folder	ERC Staff Secretary

4.2.1. All amended documents (protocol, consent forms, patient related materials, etc.) should be submitted to the ERC for review and approval prior to use/implementation. The investigator shall submit the amendment documents as soon as these are available.

4.2.2. The ERC Staff Secretary/Member-Secretary shall check the completeness of the submission and properly acknowledge the documents. ERC staff secretary to log in submission.

4.2.3. Chairman shall determine whether the amended document is applicable for expedited or full board review (base on the criteria listed in Chapter 2: Types of Review).

4.2.4. Amended documents will be assigned to the initial reviewer for assessment. ERC Staff Secretary to forward to the reviewers and members the documents (including the assessment form for amendment - Related Form 3D).

4.2.5. For expedited review, the reviewer to communicate to the members during the next scheduled meeting the result of the amendment review. For full board review, the reviewer to present the summary of changes and other important changes in the document.

4.2.6. Chairman to prepare and sign the approval letter and communicate the result to the investigator.

4.2.7. All relevant documents will be filed accordingly by the ERC Staff Secretary.

4.3 Review of SAEs and SUSARs

A Serious Adverse Events (SAE) is defined as any untoward, undesirable medical event resulting to hospitalization or prolonged hospitalization, death, congenital abnormality, disability or incapacitation or any medically important event (including pregnancy if contraindicated in the study).

The SCMC-AEI ERC formed a mechanism to receive all SAE and SUSAR (Suspected Unexpected Serious Adverse Reaction) from the investigator of study that it has approved. It is the responsibility of the committee to ensure that all SAE and SUSAR reports received are properly received and reviewed. The SCMC-AEI ERC has the authority to suspend or terminate the approval of study at its site if it has been proven that the safety of its participants is at risk. If the committee decides to suspend or terminate a study, the decision shall be immediately communicated to the investigator and/or sponsor for immediate action.

Workflow

ACTIVITY	RESPONSIBILITY
4.3.1. Submission of SAEs and SUSARs	Investigator/Researcher
4.3.2. ERC Staff secretary to receive the report and log the details in the database	ERC Staff Secretary
4.3.3. Notify chairman of the report	ERC staff secretary
4.3.4. Chairman or any assigned member to review the SAE report to make the necessary recommendation	Chairman/Member
4.3.5. Reports to be presented during the meeting	ERC Staff Secretary/Chairman/Member
4.3.6. Notify Principal investigator of the decision. File all related documents in the appropriate binder.	ERC staff secretary

4.3.1. The principal investigator is required to report all the SAE and SUSARs to the SCMC-AEI ERC. The investigator may follow the format outlined in Related Form 4C.

4.3.2. The ERC Staff Secretary shall be responsible in receiving the report and updating of the database.

4.3.3. ERC staff secretary shall notify the chairman of the report received.

4.3.4. The chairman or the assigned member shall recommend an appropriate action as necessary and follow the criteria below:

a. Assessment of events that is unlikely or not related to the investigational product or device: the report will be forwarded to the chairman to assess whether this report should be included for review by the full board in the next meeting.

b. Assessment of events that is most likely or determined related to the investigational product or device: the report will be forwarded to the chairman and recommends being included for full board assessment in the next meeting.

c. Assessment of events that is unexpected, suspected and is possibly or certainly related to the investigational product or device: the report will be forwarded to the

chairman and recommends being included for full board assessment in the next meeting.

4.3.5. All SAE and SUSAR which are assessed to be included in the full board review shall be discussed during full board meeting. After deliberation, the chairman or member may request for a consensus to either:

i. Request for additional information or follow up reports
ii. Request amendment of protocol or informed consent
iii. No additional action necessary

4.3.6. The chairman shall notify the investigator of the recommended action by the committee in writing. ERC staff secretary to file all related documents in the appropriate binder.

4.4 Review of Protocol Violations/Deviations

All investigators are expected to follow and adhere to the protocol, procedure manual and consent form. All violation, deviation and non-compliance to the study protocol should be reported to the ERC. The report should include a brief explanation of the deviation and if applicable, action taken by the study team.

Workflow

ACTIVITY	RESPONSIBILITY
4.4.1. Receive protocol deviation report	ERC Staff Secretary
4.4.2. Include in the full board meeting and assess for appropriate action	ERC Members
4.4.3. Notify the investigator of the decision	Chairman/ERC Staff Secretary
4.4.4. Record and file all documents	ERC Staff Secretary

4.4.1. The SCMC-AEI ERC receives the protocol deviation report (Related Form 4D) from the investigator associated with any non-compliance to the previously approved protocol and other related documents.

4.4.2. The report shall be consolidated and included in the next full board meeting. Assessment of protocol deviation:

i. General impact to the study performance and outcome
ii. Impact to patient safety and well being

4.4.3. The investigator will be notified of the decision of the committee: The study approval may be temporarily or permanently withdrawn.

a. Repeated deviation which compromises the safety and well-being of study participants
b. Implementation of a protocol or related documents with major amendments without approval from the committee
c. No action required for protocol deviation which is deemed minor and will not impact the study performance and outcome and will not compromise patient safety.

4.4.4. ERC Staff secretary to record and store all relevant documents.

4.5 Review of Early Study Termination

Premature termination of a study shall be reported by the investigator to ERC as soon as notified by the Sponsor. The notification letter should include a statement of reason for termination and status of subjects enrolled/treated if applicable.

Workflow

ACTIVITY	RESPONSIBILITY
4.5.1. Submit early termination notification	Investigator/Sponsor
4.5.2. ERC staff secretary to acknowledge receipt of the letter and log in the database	ERC Staff Secretary
4.5.3. Include and discuss in the next full board meeting	Members
4.5.4 Record and file all relevant documents	ERC Staff Secretary

4.5.1. The SCMC-AEI ERC receives notification either from the investigator or sponsor regarding the early termination of a study. The letter should include details on:
   a. Reason for early termination
   b. Current status of the study on-site
   c. After-care for all study participants who have not completed the study

4.5.2. The ERC Staff Secretary shall acknowledge the receipt of the letter and forward to the chairman or duly designated member for review. ERC staff secretary to update the database.

4.5.3. The report shall be included for discussion in the 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. Committee's decision shall be communicated to the principal investigator.

4.5.4. All relevant records shall be filed appropriately by the ERC staff Secretary.

4.6 History of SOP

Version No.	Date	Author/s	Main Change
00	01 April 2011	MTC	
01	20 March 2013	MTC	Added reports submission, confidentiality, conflict of interest, trainings and independent consultant
02	13 January 2014	MTC	Changed SOP format
03	29 April 2015	MTC	Changed chapter title and content
04	25 November 2015	MTC/CPV	Changed process flow format

Policy Statement/Objective

To describe the procedures being followed by SCMC-AEI ERC in conducting its meeting.

Scope

This section covers the preparation and conduct of the full board meetings by SCMC-AEI ERC including special meetings.

Responsibility

The conduct of meetings is a shared responsibility by the whole SCMC-AEI ERC members and staff secretary. The preparation prior and post meeting shall be the responsibility of the ERC Staff secretary, the chairman is responsible in presiding the meeting and the assigned reviewers are tasked to present during the meeting.

5.1 Preparation for a Meeting and Agenda

Full board meetings are held monthly and are arranged at the start of the year. Meeting will be held once every quarter at St. Cabrini Medical Center, Sto. Tomas, Batangas. Meeting dates may change depending on the availability of the members.

Workflow

ACTIVITY	RESPONSIBILITY
5.1.1. Set the final date for the meeting	ERC Staff secretary
5.1.2. Inform members of the meeting date and meeting agenda	ERC Staff secretary
5.1.3. Finalization of meeting agenda	Chairman/member-secretary/ERC staff secretary
5.1.4. Preparation and sending of documents to the members (protocol and other related documents and review assessment form); draft meeting agenda: to include topics and important matters for discussion	ERC Staff Secretary
5.1.5. Logistics during the meeting	ERC Staff secretary

5.1.1. Based on the agreed meeting schedule, the ERC staff secretary shall finalize the meeting date.

5.1.2. The SCMC-AEI ERC staff secretary shall notify the members regarding the meeting date and agenda of the meeting. A quorum of more than half of the members (including one member whose primary concern are in non-scientific area and not affiliated with the institution) is needed to review a study. In case there is no quorum, the meeting shall be re-scheduled and the members, sponsor and investigator shall be notified of the re-scheduled date of the meeting. The meeting shall not push through and will be rescheduled until a quorum has been made.

5.1.3. The ERC staff secretary shall draft the meeting agenda (Related Form 5A) and present this to the chairman or member-secretary for review and final approval. The agenda shall include:

a. All new studies for review
b. Amended documents
c. Other reports: progress/final reports; SAE/SUSARS, protocol deviation report and early study termination report

5.1.4. ERC staff secretary shall prepare all the documents for sending to the members. All documents for review and approval will be sent to all members 2 weeks prior to the meeting. All documents shall be formatted for confidentiality and non-reproducibility.

5.1.5. The SCMC-AEI ERC staff secretary shall complete the following:

a. Check requisition form for request of meeting budget
b. Reservation of conference room and laptop
c. Prepare Statement of Account (SOA) for review fee addressed to the Sponsor. SOA shall be signed by the ERC secretary, ERC chairman and Finance Head.

5.2 Conduct of Meetings

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

Workflow

ACTIVITY	RESPONSIBILITY
5.2.1. Commencement of the meeting – start with review of the minutes of the previous meeting; discuss agenda; disclosure of COI	Chairman
5.2.2. Updates of all studies: reports on study progress; SAE/SUSARS, protocol deviation; early study termination, amendment – discussion and recommended action	ERC Staff Secretary and Members
5.2.3. Present study for initial review	Assigned reviewer/s
5.2.4. Discussion and deliberation	Members
5.2.5. Final decision on the study	Members

5.2.1. At the start of every meeting, minutes of the previous meeting shall be discussed and approved and administrative matters will be tackled by the chairman. The ERC chairman will discuss agenda of the meeting and disclosure by the members of any conflict of interest that may arise during the meeting. The ERC staff secretary shall ensure that all pertinent discussion and suggestions are recorded using a voice recorder, aside from actually writing down comments/discussions during the meeting, and recorded in the minutes of the meeting.

5.2.2. The ERC staff secretary, chairman or assigned member will give an update on the status of all ongoing studies including but not limited to amended documents, SAE reports, protocol deviation, progress/final report, early study termination and other documents that were received by ERC from the time of the last meeting. The members shall discuss if there are any notable report that requires necessary action.

5.2.3. The assigned reviewer/s shall be asked to present the key points about the study.

5.2.4. The assigned reviewer and other ERC members are encouraged to voice their comments, suggestions or raise specific questions about the study. The investigator may be called upon during the meeting to answer concerns and questions regarding the study.

5.2.5. Once all questions have been answered, the investigator is asked to step out of the meeting room for the final deliberation and decision of the members.

5.3. Special Meetings

Special Meetings may be called for by the chairman or any member of the committee whenever there are urgent matters that the committee should discuss and cannot be carried out during the full board meeting.

Workflow

ACTIVITY	RESPONSIBILITY
5.3.1. Request for special meeting by chairman or member	Chairman or Member
5.3.2. To set date of the meeting and finalize the meeting agenda	Chairman and ERC Staff Secretary
5.3.3. Conduct of the meeting	Chairman or Member
5.3.4. Record and file all important documents	ERC Staff secretary

5.3.1. Received request from the chairman or any member of the committee for a special meeting.

5.3.2. ERC Staff secretary to set a date for the meeting and chairman to draft the meeting agenda.

5.3.3. Conduct of the meeting. All important discussion shall be included in the minutes of the meeting.

5.3.4. After the meeting, all records shall be kept and filed by the ERC Staff secretary.

5.4. History of SOP

Version No.	Date	Author/s	Main Change
00	29 April 2015	MTC	
01	25 November 2015	MTC/CPV	Changed process flow format
02	17 February 2016	MTC/CPV	Added meeting venue at SCMC Batangas

Policy Statement/Objective

The SCMC-AEI ERC adheres to a policy of strict confidentiality in all studies. The purpose of this policy is to ensure that all relevant and confidential records and documents related to the activities of the ERC are filed and kept in a secure place.

Scope

The policy shall cover all types of records and documents used by ERC and all documents submitted to and produced by the committee.

Responsibility

It is the responsibility of the SCMC-AEI ERC to identify a secure place within the institute where all pertinent ERC documents and records will be kept. The SCMC-AEI ERC staff secretary shall be the custodian of all the documents and access to these documents by non-ERC members will be subject to approval of the SCMC-AEI ERC chairman.

6.1 Preparation of Meeting Minutes

Minutes of the meeting shall all be based on the presentation and discussion that transpired during every meeting. It is the responsibility of the ERC Staff secretary to prepare and record the minutes of the meeting making sure that all relevant information is properly documented.

6.1.1. ERC staff secretary should use the minutes of the meeting template (Related Form 6A) to record all relevant discussion and information during the meeting.

6.1.2. The ERC secretary shall ensure that all pertinent discussion and suggestions are recorded using a voice recorder, aside from actually writing down of comments/discussions during the meeting, and recorded in the minutes of the meeting.

6.1.3. After the meeting, the ERC Staff secretary shall finalized the minutes of the meeting and submit to the chairman for review.

6.1.4. All documents shall be kept and filed accordingly.

6.2 Communicating ERC Decisions

All of the decisions made by the SCMC-AEI ERC shall be communicated to all members in a timely manner.

6.2.1. After a study has been reviewed (both initial review and amendments) and a decision has been reached, the ERC chairman shall prepare the decision/approval letter (Related Forms 6B/6C). The decision/approval letter shall be forwarded to the investigator within 1-2 weeks after the meeting.

6.2.2. For decisions related to actions required base on the reports received and reviewed such as SAE/SUSAR report, deviation report and early study termination report, the chairman shall prepare the decision letter and forward to the investigator not less than 1 week.

6.2.3. All correspondences/ letters shall be prepared in 2 copies. One copy for the investigator and one copy for the ERC.
6.2.4. Correspondences/letters sent to the investigator shall be received by the investigator or duly assigned study personnel. It should be logged as received in the ERC log book with signature and date of receipt.
6.2.5. All correspondences/letters shall be kept and filed accordingly by the ERC staff secretary.

6.3 Incoming / Outgoing Communications

Communications both inbound and outbound should be recorded appropriately and reported to the whole committee. To effectively track all communications, the ERC staff secretary shall record and file all correspondences.

Incoming Communication

Documents	Receiving Process	Signed by
1. Initial submission letter 2. Submission letter for amended documents	Stamped as received	Staff Secretary and/or Chairman
1. IB submission	Stamped as received	Staff Secretary and/or Chairman
1. SAE/SUSAR reports 2. Deviation/Non-compliance Report	Acknowledgment of Receipt letter	Chairman
1. Notification Letter (insurance, study close out, study early termination, etc.)	Stamped as received	Chairman
1. Progress Reports/ Final Study Report	Stamped as received	Staff Secretary and/or Chairman

6.3.1. All above documents should be printed in 2 copies. One copy will serve as the receiving copy and the other will serve as ERC's copy.
6.3.2. All initial submission letter, submission letters related to amended documents, IB submission and progress/final study report shall be stamped as received and signed by either the chairman or staff secretary.
6.3.3. For notification letter such as insurance certificate, study close out report and early termination report, all these reports shall be stamped as received and signed by the chairman.
6.3.4. For SAE/SUSAR reports and deviation or non-compliance report, a formal letter of acknowledgement shall be prepared by the chairman.
6.3.5. In case of electronic correspondences, all communication shall be printed out and filed in the ERC active binder by the ERC staff secretary.
6.3.6. All documents received by the committee shall be filed and kept by the ERC staff secretary.

Outgoing Communication

6.3.7. All letters (decision letters, acknowledgement of receipt, etc.) that are sent to sponsor, investigator and partners shall be recorded in a log book.

6.3.8. The ERC staff secretary shall ensure the receiver of the letter sign and date the log book to indicate that the letter has been duly received.

6.4 Active Files

The SCMC-AEI ERC shall prepare and maintain adequate documentation of its activities which includes:

a. Copies of all research proposals and consent form submitted and reviewed
b. Progress reports and final reports
c. Serious adverse event reports
d. Investigator's brochure
e. Recruitment materials (if applicable) and other documents submitted by the investigators
f. CVs of investigators
g. Meeting attendance and minutes of the meeting
h. All documents and forms used during the meeting
i. Copies of all correspondences between SCMC-AEI ERC, investigators and sponsor
j. Correspondences among ERC members and secretary (both written and electronic)
k. Membership list
l. Standard Operating Procedure of SCMC-AEI ERC
m. Relevant guidelines and administrative orders both local and international
n. CVs of the ERC members and training certificates
o. Confidentiality and Non-disclosure Forms
p. Declaration of Conflict of Interest Forms

6.4.1. All studies received and reviewed by the committee are given a unique study code which serves as a basis for tracking the study. All files that are considered active and ongoing shall be filed and kept in a binder. All active binders are stored in a locked cabinet where all other active files are located.

6.4.2. All study files are considered active as long as progress reports are continuously submitted base on the frequency set by the committee as indicated in the approval letter and a final study report has not been received.

6.5 Archiving of Terminated, Inactive and Completed Files

Files are categorized either terminated, inactive or completed.

6.5.1. Terminated files pertain to files of a study that have been approved by the committee but for certain reasons terminated pre-maturely hence the study will no longer start or continue.

6.5.2. Upon receipt of the notification of study termination, all the study files shall be placed in a separate cabinet/location and will be stored in the ERC office at least one year prior to archiving.

6.5.3. All inactive files (files are inactive when no communications are received from the study or final site closure/completion notice has been received), shall be kept in the ERC office in a separate binder/cabinet for minimum of 3 years after the submission of the final site closure notice or after trial completion at site. After the said duration, all inactive records shall be archived in the accredited archiving facility of the institution.

6.5.4. Files from a study that have completed the whole study cycle are considered 'completed files'. All completed files shall be filed and stored in a separate binder and stored in the ERC office for 2 years prior to archiving.

6.6 Maintenance of Confidentiality of Study Files

6.6.1. Confidentiality

All confidential and proprietary information disclosed by the sponsor and/or investigator related to the study shall only be used by the members during review and assessment of a research study. All members are obliged to sign a confidentiality agreement at the start of their term and shall be renewed every year.

6.6.2. Records Management

6.6.2.1. All records deemed confidential shall be kept in a secure place and in the custody of the ERC staff secretary.

6.6.2.2. All correspondences of the committee with investigator, sponsor and other relevant agencies shall be kept both in hard and electronic copy.

6.6.2.3. The ERC shall maintain an updated membership list (Related Form 6D); CV of the members, recent training certificate related to their function as ERC member, correspondences with regulatory agencies, moreover, keep all study submission documents and correspondences.

6.6.2.4. Guidelines, policies and procedures of the committee shall be maintained and reviewed on a periodic basis.

6.6.2.5. Meeting attendance (Related Form 6E), minutes of the meeting and audio recordings of the meetings shall be kept and filed accordingly.

6.6.2.6. Research study documents shall be organized and kept per study protocol. All correspondences and submission for the said protocol shall be kept in one binder for easy reference and retrieval.

6.6.2.7. After every ERC meeting, all unused and excess study documents submitted shall be retrieved, shredded and disposed by the ERC staff secretary to maintain confidentiality.

6.6.2.8. Disposal of the excess/unused documents shall be done weeks after the minutes of the last meeting has been finalized, read and approved by the chairman.

6.6.2.9. Only the ERC staff secretary and chairman shall have access to all confidential documents. Access maybe granted upon the receipt of written request.

6.6.2.10. The ERC staff secretary shall maintain a log of all the personnel who requested access to these documents. The log shall have following information: Name of the requestor, date of request, study code, document requested, and purpose.

Archiving of Documents:

6.6.2.11. The SCMC-AEI ERC shall identify a secure archiving facility where all documents will be temporarily stored.

6.6.2.12. All documents that have been archived for 5 years or more shall be disposed. A letter of request for document disposal addressed to the Medical Director of the 2 institutes and noted by the current ERC chairman shall be prepared by the ERC staff secretary documenting the actual number and type of records to be disposed.

6.6.2.13. Upon receipt of the approval from the institution, the archived documents shall be disposed.

Request for study documents:

6.6.6.14. All document request and retrieval shall be coursed through the ERC staff secretary.

6.6.6.15. A formal letter of request addressed to the ERC chairman, stating the documents being requested, purpose, number of copies and duration shall be submitted to the secretary.

6.6.6.16. The ERC staff secretary shall maintain a log book for all document request with the following information: study code, date borrowed, borrower's name, document copied, number of copies and signature of the borrower.

6.6.6.17. The ERC staff secretary shall notify the requesting party of its approval and schedule of pick up.

6.7 History of SOP

Version No.	Date	Author/s	Main Change
00	29 April 2015	MTC	
01	25 November 2015	MTC/CPV	Changed process flow format

Policy Statement/Objective

To describe the process of visiting sites conducting study activities.

Scope

The site visit procedure shall apply to all studies approved by the committee to check adherence to GCP and ERC approved protocol.

Responsibility

It is the responsibility of the SCMC-AEI ERC to conduct or designate its member or qualified representative to conduct on its behalf site visit of the study that it has approved. The ERC member in consultation with the chairman may initiate site visit activity for any reason or for routine purposes.

Workflow

ACTIVITY	RESPONSIBILITY
7.1. Select study site/investigator to be visited	Members
7.2. Collect all relevant information about the site/investigator based on the ERC documents	Members
7.3. Inspect onsite documents and conduct interview	Members
7.4. Writing of the report and communicate findings to all members	Members
7.5. Inform investigator of ERC's decision	Chairman/ERC staff secretary

7.1. ERC members to review periodically the database file of all the studies reviewed and approved by the committee. Members may select site for visit based on the following:

a. Significant number of remarkable SAE report
b. Significant number of remarkable protocol deviation report
c. Significant study population in type and size
d. Non-compliance to the ERCs recommendation and suggested action

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

7.3. During on-site visit, the SCMC-AEI ERC member/representative shall use the site visit form (Related Form 7A) 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.

7.4. The SCMC-AEI ERC member/representative who conducted the visit shall write a report and forward the report to the ERC staff secretary 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 ERC committee shall decide for an appropriate action.

7.5. The chairman through the ERC staff secretary shall communicate the decision of the committee.

7.6 History of SOP

Version No.	Date	Author/s	Main Change
00	29 April 2015	MTC	
01	25 November 2015	MTC/CPV	Changed process flow format

Policy Statement/Objective

This procedure aims to describe the process related to managing queries and complaints from study participants.

Scope

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

Responsibility

The SCMC-AEI ERC shall designate a member who will be responsible to receive and respond to all queries and complaints from study participants, report all relevant questions and concerns to the committee for ERC to take appropriate action.

Work Flow

ACTIVITY	RESPONSIBILITY
8.1. Receive query or complaint from a patient	Member/ ERC staff secretary
8.2. Assess the complaint and refer to appropriate person	Member-Secretary
8.3. Responding to complaint or query	Member
8.4. Report to the full board and take appropriate action	All members
8.5. Document and file all relevant correspondences	ERC staff secretary

8.1. Receiving of queries and complaints from study participants or any concern individual through various means of communication (email, phone call, fax, letter or personal appearance).
8.2. The query/complaint shall be assessed for its nature and validity.
8.3. 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 chairman for appropriate action. After thorough investigation, record all the query/complaint and the recommended action in the feedback form (Related Form 8A). The feedback from must be signed and dated by the member who conducted the investigation and recommend plan of action.
8.4. Forward the feedback form to the ERC staff secretary for inclusion in the next full board meeting agenda. The member shall communicate the decision to the person who raised the query/complaint.
8.5. ERC staff secretary to document and file all the correspondences related the event.

8.6. History of SOP

Version No.	Date	Author/s	Main Change
00	29 April 2015	MTC	
01	25 November 2015	MTC/CPV	Changed process flow format

Policy Statement/Objective

It is the policy of the SCMC-AEI ERC to update and align its standard operating procedures with the current changes in local and international research policies and guidelines.

Scope

The policy shall cover the writing, approval, distribution and revision of the SCMC-AEI ERC Standard Operating Procedures.

Responsibility

It is the responsibility of the chairman to appoint personnel who will form a team that will draft or revise the SOP of the SCMC-AEI ERC, initiates the approval of the final version of the SOP and submits this to the medical directors of the 2 institution for the final approval.

The Team who will be responsible in writing and revising the SOP is an ad hoc group composed of current members of the SCMC-AEI ERC and invited resource persons. The Team shall be responsible in drafting and formulating new SOPs and when necessary amend the existing SOPs. The Team shall follow the format set by PHREB and the institutions SOP format (e.g. ISO format) when formulating the SOPs. The Team shall submit the SOP to the chairman for final review and initial approval.

The chairman and/or ERC staff secretary is responsible in maintaining all the current SOP version, coordinating the writing and revising of SOP and making sure that all members are aware of any changes and have access to the SOP.

9.1. Writing of SOPs

Workflow

ACTIVITY	RESPONSIBILITY
9.1.1. Create team responsible in writing and revising SOPs	Chairman
9.1.2. Design, layout and drafting of SOP	Team
9.1.3. Review and initial approval of SOP	Chairman
9.1.4. Final approval and signing/implementation of SOP	Medical Director
9.1.5. Communicate approved SOP to members and file all SOP accordingly	ERC staff secretary

9.1.1. The Chairman shall create an ad hoc group to spearhead the writing of the SCMC-AEI ERC SOP. The Team whose primary responsibility is to formulate and revise SOPs shall be composed of current members of the ERC and non-members who will serve as resource person.

9.1.2. The Team shall be in charge of the design and layout of the SOPs and shall strictly follow the recommended format by PHREB.

a. Document code: Document Number, Version Number, Date
(Each SOPs shall be identified by a Document Code. A document code shall bear the document number, version number and effective date. For writing the document code the following format shall be used: SCMC-AEI Doc. AA-BB-CCCC, where AA is the 2 digit number of the chapter or section in the manual, BB is the 2 digit number for the revision number and CCCC is the 4 digit year when the document was written/revised.)
b. Logo of the Institutions, SOP Title
c. Policy Statement or Policy Objective
d. Scope of the SOP
e. Responsibility
f. Illustration of the step by step process when necessary
g. Detailed description of the process
h. Related forms if applicable
i. References if applicable

9.1.3. The Team shall draft the SOP base on the above format and submits the final version to the chairman for review. The chairman shall communicate this to the members for comments and other suggestions. Once completed, the final version will be submitted to the medical directors of the 2 institution for final approval.

9.1.4. Upon approval of the final version by the medical directors, the ERC staff secretary disseminates a copy of the SOP to all members and uploads the SOP to the Institution's website.

9.1.5. ERC staff secretary to file one copy of the SOP with original signatures.

9.2. Revising of SOPs

ACTIVITY	RESPONSIBILITY
9.2.1. Recommend amendment of SOP	Members
9.2.2. Revise and submit new SOP	Team
9.2.3. Review and final approve new SOP version	Members/Chairman
9.2.4. Include the new version in the current SOP manual	ERC staff secretary
9.2.5. Archive superseded SOP	ERC staff secretary

9.2.1. Revision maybe necessary whenever an SOP or a section of the SOP is unclear or not sufficient to cover what it should. Revision may be categorized to either minor or major revision. A minor revision may consist of editorial, grammatical or administrative change that does not pose any effect on any of the procedures/processes. A major revision is those that will affect the conduct of a procedure/process, it may be an additional requirement, change in definition or other similar substantial change.

9.2.2. Any member of the committee may proposed amendment of the SOP and discusses this during a full board meeting. The members to suggest changes and these will be consolidated by the ERC staff secretary and forward to the Team for revision/inclusion the SOP. Upon revision of SOP, the document code and other relevant selection will also be updated reflecting the changes made to the SOP.

9.2.3. Chairman to review and approve the final amended version and forward this to the medical directors for final approval.

9.2.4. Once approved, the ERC staff secretary shall furnish a copy of the revised SOP to the members and include this in the current SOP Manual.

9.2.5. Old SOP shall be marked as 'superseded' and placed in a separate binder and archived.

9.3. History of SOP

Version No.	Date	Author/s	Main Change
00	29 April 2015	MTC	
01	25 November 2015	MTC/CPV	Changed process flow format

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

Chapters	Document Code
Chapter 1	SCMC-AEI Doc. 01-06-2016
Chapter 2	SCMC-AEI Doc. 02-05-2015
Chapter 3	SCMC-AEI Doc. 03-05-2016
Chapter 4	SCMC-AEI Doc. 04-04-2015
Chapter 5	SCMC-AEI Doc. 05-02-2016
Chapter 6	SCMC-AEI Doc. 06-01-2015
Chapter 7	SCMC-AEI Doc. 07-01-2015
Chapter 8	SCMC-AEI Doc. 08-01-2015
Chapter 9	SCMC-AEI Doc. 09-01-2015

Date: March 14, 2016

Author/s:	**Approved by:**
Mary Ann T. Catacutan, O.D. Clinical Research Officer	***Emerson M. Cruz, M.D.*** SCMC-AEI ERC Chairman
Atty. Carmina Agnes P. Villanueva SCMC-AEI ERC Member	***Juan Ma. Pablo R. Nañagas, M.D.*** AEI, Medical and Research Director ***Eduardo E. Uycoque, M.D.*** SCMC, Chief Medical Officer

Signature on File

SIGNATURE PAGE