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St. Luke's Medical Center

DOCUMENT REVIEW AND REVISION HISTORY

General Information		
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Review Order	Dates	Revision
1	April 2013	1
2	June 2015	2
3	January 2016	3
4	December 2018	4
5	September 2019	5
6	June 2022	6

Revision Details

1. The Institutional Ethics Review Committee Standard Operating Procedures (SOPs) has evolved into a written Manual as a result of the integration of the following SOPs:
   - SOP 1: SL-IERC STRUCTURE AND COMPOSITION
   - SOP 2: TYPES OF REVIEW
   - SOP 3: MANAGEMENT OF INITIAL SUBMISSIONS
   - SOP 4: CONTINUING REVIEW AND MONITORING OF PROTOCOLS
   - SOP 5: DOCUMENTATION AND ARCHIVING
   - SOP 6: PREPARATION OF STANDARD OPERATING PROCEDURES (SOPS) AND GUIDELINES FOR THE SL-IERC
2. Added the following based on the latest review:
   - SOP 2.6: Review of Clinical Trials Related to Pandemic Diseases or Disease Outbreaks
   - SOP 5.7: Electronic Submission, Review, and Documentation

Approved by:	Prepared by:	Reviewed by:	Recommended by:
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1. INTRODUCTION:

The challenges that face the ethical review process of medical research continue to escalate and demand dynamic strategies in order to respond to them. Aptly described in the Introduction to the 2016 edition of the Standard Operating Procedures are external conditions that steadily confront ethics review committees. These include constantly emerging technologies and scientific advancement, ever-changing complexity of disease entities, particularly an increasing number of new and resistant infectious organisms, and more recently the COVID-19 global pandemic which generated stringent regulations from government and regulatory agencies. National and global ethical guidelines are invariably updated to face this evolving landscape of medical research. Governments have enacted laws for human subject protection and rightly so, subjects are more aware of their rights and privileges. The stakeholders namely, the regulatory agencies, pharmaceutical companies, research organizations, investigators and ethics review committees, need to keep pace and strive to work harmoniously in order to obtain safe, efficacious and morally sound solutions to the medical problems.

The 2019 accreditation of St. Luke's Medical Center by the Joint Commission International (JCI) as an academic medical center has amplified the challenge that faces the St. Luke's Institutional Ethics Review Committee (SL-IERC). Apropos with the academic title is the recognition of medical research as a vital component of hospital operations. In this mandated environment of research, the SL-IERC is expected to remain vigilant and fortify its commitment in upholding the integrity and protection of human subjects.

Accredited initially in 2012 by the Philippine Health Research Ethics Board (PHREB) and recognized by the Forum for Ethics Review Committees in Asia and the Western Pacific (FERCAP), the St. Luke's IERC modified its initial set of Standard Operating Procedures (SOPs) based on the recommendations made during the survey. A repeat accreditation in 2015 by the same accrediting bodies resulted in a number of significant changes in the operations of the SL-IERC which resulted in another revision of the SOPs in 2016. In the year 2019 motivated by the judicious suggestions of PHREB, FERCAP and JCI, the SL-IERC presented another set of revisions in the SOPs, which modified the conduct of the full-board review, and described the conduct of site visits and monitoring, as well as the SL-IERC's additional role as a regulatory reviewer for the Philippine Food and Drug Administration (PFDA).This most recent edition of 2022 documents the current manner of ethics review by the SL-IERC. Primarily as a consequence of the global COVID-19 pandemic which drastically affected multiple aspects of all social interaction, there are two new chapters, which include the Review of Clinical Trials Related to Pandemic Diseases or Disease Outbreaks and the Electronic Submission, Review, and Documentation.

This 2022 edition was prepared in accordance with International, national and institutional guidelines, to wit:

- National Ethical Guidelines for Health and Health Related Research 2017
- Philippine National Health Research System Act of 2013
- Declaration of Helsinki, 2013
- CIOMS guidelines for ethics review, 2016
- WHO standards and operational guidance for ethics review of health-related research with human participants, 2011
- ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2), 2016
- Data Privacy Act of 2012

Henceforth, this new document shall guide the ethics research committee in managing the ethical review of research protocols. It is with firm confidence that the new standard operating procedures shall sustain and uphold

2. OBJECTIVES:

The purpose of this SL-IERC Standard Operating Procedure (SOP) manual is to provide the IERC members the standard procedures in reviewing the ethical aspects of human subject research protocols that are compliant with applicable laws, regulations, requirements, and standards of local and international regulatory and accrediting bodies related to research. This manual also provides guidelines to the Principal Investigators, Project Leaders, study team, Sponsors and Clinical Research Organizations on the requirements of the IERC for submitting clinical research protocols for initial review and the required reports after the protocols have been approved for implementation. The manual provides the IERC staff the procedures for managing all submissions, communications, minutes of meetings and agenda, and maintaining a database.

3. RESPONSIBILITIES:

The Head of Research and Biotechnology (R&B) Group is responsible for providing oversight of all research activities conducted in the Medical Center to ensure that the studies are compliant to applicable laws, regulations, requirements, and standards of local and international regulatory and accrediting bodies related to research.

The R&B Office of Research Integrity (ORI) is responsible for provision of support to the structure and operational requirements of the IERC, annual review of all research review processes, implementing education and training activities for the IERC members and staff and researchers in SLMC. It ensures that the IERC complies with the local applicable laws and regulations by maintaining its accreditation by the Philippine Health Research Ethics Board (PHREB) and recognition by the WHO SIDCER Forum for Ethics Review Committees in Asia and the Western Pacific (FERCAP).

The St. Luke's Institutional Ethics Review Committee (SL-IERC) is responsible for the review of the protocols of all sponsor-initiated clinical trials (SiT) and investigator-initiated research studies involving human subjects (IiT) to ensure that the studies adhere to the ethical standards of the International Conference of Harmonization Guidelines for Good Clinical Practice (ICH-GCP), the Philippine Health Research Ethics Board (PHREB), and other standards and guidelines on ethics in research (i.e. Declaration of Helsinki, Philippines National Ethical Guidelines for Health Research).

4. STANDARD OPERATING PROCEDURES:

SOP 1. SOPs on SL-IERC Structure and Composition

1.1.1. PURPOSE

The purpose of this SOP is to describe the organizational structure of the St. Luke's Institutional Ethics Review Committee and ensure that the standard process of selecting and replacing its Members, the criteria for membership, the duties and responsibilities of the Chair, Vice Chair, Member-Secretary and Members are met.

1.1.2. SCOPE

This SOP covers the organizational structure, composition, selection and replacement, duties and responsibilities of the SL-IERC in reviewing clinical research protocols or research studies involving human participants (i.e. clinical trials) submitted by the Medical Consultants, Residents, Fellows and Administrative Staff of SLMC Quezon City, Global City and St. Luke's Extension Clinic, faculty and students of SLMC College of Medicine-WHQM (SLMCCM-WHQM), and other non-SLMC researchers conducting research in the Medical Center such as Sponsors, Contract Research Organizations (CROs), and Academic Research Organizations (AROs).

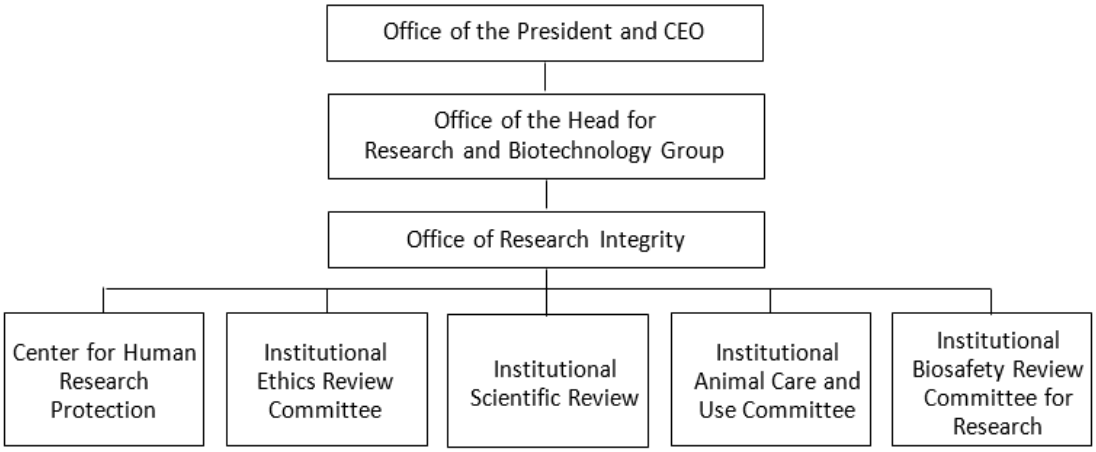
1.1.3. FLOW CHART

PROCESS	PERSON/S RESPONSIBLE
Recommendation for constitution of SL-IERC membership	Head of Research and Biotechnology (R&B) SL-IERC Chair
Appointment of SL-IERC Members	President and CEO
Selection and designation of SL-IERC Officers	Head of R&B President and CEO
Replacement of an SL-IERC Member	SL-IERC Chair, Head of R&B, President and CEO

1.1.4. PROCEDURES

1.1.4.1. Organizational Structure

1.1.4.1.1. The SL-IERC shall function under the Office of Research Integrity of the Research and Biotechnology of SLMC [*See related policy on Functional Group Policy (Research and Biotechnology Group)*] with the following organizational structure:



1.1.4.2. Membership

1.1.4.2.1. Method of Selection and Terms of Reference

1.1.4.2.1.1. The Head of Research and Biotechnology (R&B) shall recommend the membership of the SL-IERC and shall base his/her recommendation on the endorsement of the SL-IERC Chair in accordance with the guidelines set by the *Philippine Health Research Ethics Board* and the *WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants*. The primary mandate of the SL-IERC is to ensure safety, protect the rights and promote the welfare and well-being of research participants. Thus, membership of the SL-IERC, at least 9 members, shall be multidisciplinary and multi-sectoral with the following minimum composition:

- A physician from the institution with experience in medical research
- A lawyer, who represents concerns of the community
- A basic medical scientist , who is a Medical Doctor (MD) in one of the basic sciences, i.e. anatomy, physiology, biochemistry, molecular biology, pharmacology, microbiology, pathology
- A layperson independent from the institution and with no scientific expertise
- An individual independent from the institution with scientific expertise on behavioral or social sciences
- A clinician who is experienced in working with vulnerable participants (e.g. children and those persons incapable of giving consent)

1.1.4.2.1.2. The Head of the Center for Human Research Protection (CHRP) may sit as an *ex-officio* who is a non-voting member to ensure that the rights, well-being and safety of human subject participants are protected. [See

related policy on Functional Group Policy (Research and Biotechnology Group) for the function of the CHRP].

1.1.4.2.1.3. Alternate members shall be appointed to be a part of the SL-IERC. However, they shall only be called to attend a research ethics review meeting when a regular member will not be able to attend. They have the same responsibilities and rights as a regular member.

1.1.4.2.1.4. Subject experts or External/Independent Consultants may be invited to be the Primary Reviewer if no SL-IERC member is an expert on the clinical study/research to be reviewed. Their inputs will be maintained on record and be considered by the SL-IERC when making a decision. However, they have no voting rights.

1.1.4.2.1.5. Both male and female genders and old and young age groups shall be represented in the SL-IERC.

1.1.4.2.1.6. The President and CEO shall officially appoint members of the SL-IERC and may appoint additional members to the SL-IERC in conformity with ICH-GCP regulations. *(Refer to SL-IERC Template # 01 Letter of Appointment, Template # 03A and 03B Duties and Responsibilities of the SL-IERC Chair and the SL-IERC Members, Template # 02 SL-IERC Composition)*

1.1.4.2.2. Terms of Appointment

1.1.4.2.2.1. Members of the SL-IERC shall be appointed for a term of two (2) years. There shall be no limit as to the maximum number of terms a member is reappointed.

1.1.4.2.3. Conditions of Appointment

1.1.4.2.3.1. Prior to the appointment as an SL-IERC regular/alternate member, each member shall sign:

- a disclosure document which states that he/she has no conflict of interest (e.g. financial interests in a pharmaceutical company) (*Refer to SL-IERC Form # 01A)*
- a confidentiality agreement regarding meeting deliberations, applications, information on research participants, and related matters.

1.1.4.3. Independence of the SL-IERC

The SL-IERC Chair and Members have direct access to the President and CEO and can report directly any experience of undue influence or other concerns about the functions of the SL-IERC.

1.1.4.4. Roles and Responsibilities of the SL-IERC

1.1.4.4.1. The SL-IERC shall determine whether an activity involved in the protocol is research and whether the research involves human participants.

1.1.4.4.2. The SL-IERC shall act as a central review committee which can review onsite clinical research studies or research studies involving human participants. The SL-IERC shall review research studies (sponsor- and investigator-initiated) that involve human participants including research on identifiable human material or identifiable data.

1.1.4.4.3. The SL-IERC shall review essential documents of clinical research studies (i.e. all phases of clinical trials including investigator-initiated, observational, databank/registry and post marketing surveillance studies) submitted to SL-IERC to safeguard the rights, dignity and welfare of human participants.

1.1.4.4.4. The SL-IERC shall ensure that clinical research studies shall be conducted in accordance with Philippine laws and National Ethical Guidelines for Health and Health-Related Research (2017) by Philippine Health Research Ethics Board (PHREB), Declaration of Helsinki (2013 ed.), and International Conference on Harmonization (ICH) for Good Clinical Practice (GCP) E6(R2) (2016).

1.1.4.4.5. The SL-IERC shall recommend the approval of sponsor-initiated clinical trials and investigator-initiated research studies involving human participants based on any or all of the following conditions:

1.1.4.4.5.1. all ethical issues have been addressed.

1.1.4.4.5.2. the protocol is compliant with Good Clinical Practice guidelines.

1.1.4.4.5.3. the protocol has been revised in accordance with the Notice of Action issued by the SL-IERC Secretariat to the Principal Investigator/Project Leader and the SL-IERC has made a continuing review of the response. *(Please refer to SL-IERC SOP # 2.3 Review of Protocols that Require Revisions after Initial Review)*

1.1.4.4.6. The SL-IERC shall identify and recommend an External/Independent Consultant, a known expert, to provide additional information about a study when necessary.

1.1.4.4.7. The SL-IERC shall assemble for meetings on the following occasions:

1.1.4.4.7.1. Regularly every 2nd Wednesday of the month or on a date unanimously agreed upon by the SL-IERC members

1.1.4.4.7.2. Emergency meetings called by the SL-IERC chair

1.1.4.4.7.3. Special assignments designated by the Philippine Food and Drug Administration (PFDA), Philippine Health Ethics Review Board (PHREB), St. Luke's Medical Center President & CEO, and SLMC Medical Officers.

1.1.4.4.8. The SL-IERC shall issue the Ethical Clearance (EC) to indicate approval following review of the Protocol. *(Refer to SL-IERC Form # 13A)*

1.1.4.4.8.1. The Ethical Clearance shall indicate the dates of review, approval, validity and responsibilities of the Principal Investigator/Project Leader.

1.1.4.4.8.2. The Ethical Clearance shall be valid for a maximum of one (1) year. Validity may be shorter depending on the level of risk *(Refer to SL-IERC SOP # 4.1, Section 4.1.4.1.3).*

1.1.4.4.8.3. Extension of the validity of the Ethical Clearance shall be granted upon compliance with the following requirements:

- written request of the Principal Investigator/Project Leader
- submission of progress report *(using SL-IERC Form # 16)*
- favorable evaluation of the progress report
- payment of extension fee

1.1.4.4.9. The SL-IERC shall evaluate reports on adverse drug reactions (ADRs)/serious adverse events (SAEs)/suspected unexpected serious adverse reactions (SUSARs) and perform continuing review of each ongoing trial at intervals appropriate of the risk to human subjects or at least once a year *(based on the SL-IERC review approval date)* using the SL-IERC Continuing Review Report Form *(SL-IERC Form # 16)* issued by the SL-IERC Secretariat *(Refer to policy on Monitoring of Clinical Safety of Investigational Drugs and SOP on Continuing Review Procedures, Chapter 4, SOP # 4.2).*

1.1.4.4.10. The SL-IERC shall have authority to suspend or terminate approval of human research not being conducted in accordance with the SL-IERC's requirements or that has been associated with unexpected serious harm to subjects.

1.1.4.4.11. The SL-IERC may observe or authorize the CHRP to observe, in certain occasions *(e.g. numerous reports of protocol deviations/violations, onsite SAEs & SUSARs and complaints)* the consent process and the conduct of the human research.

1.1.4.4.12. The SL-IERC shall evaluate conflict of interest (COI) of investigators and research staff and have the final authority to decide whether the COI and management plan, if any, allow the human research to be approved.

1.1.4.5. Responsibilities of the SL-IERC Member

Each Member of the SL-IERC shall have the following responsibilities:

1.1.4.5.1. Reads the Minutes of the Meetings sent by email before the scheduled full board meeting

1.1.4.5.2. Attends SL-IERC meetings regularly and participates in the review and evaluation of clinical research protocols and other related requests as part of a full or expedited review

1.1.4.5.3. Participates in the evaluation of approved protocols through the continuing review process

1.1.4.5.4. Participates in the review of progress and final reports, amendments, ADR/SAE/SUSAR reports, and protocol deviation/violation reports presented during SL-IERC meetings

1.1.4.5.5. Makes himself familiar with the SOPs of the SL-IERC

1.1.4.5.6. Attends seminars, workshops and conferences in research ethics to enhance his competencies as member of the SL-IERC

1.1.4.5.7. Obtains Good Clinical Practice (GCP) certificate which shall remain valid for three (3) years.
1.1.4.5.8. Submits an updated Curriculum Vitae (CV) at the start of each new appointment
1.1.4.5.9. Declares any conflict of interest (COI) on any of the clinical research protocols submitted for review
1.1.4.5.10. Maintains confidentiality of the documents and deliberations of the SL-IERC meetings

1.1.4.6. Responsibilities of the SL-IERC Layperson

The SL-IERC Layperson shall have the following responsibilities:

1.1.4.6.1. Reviews informed consent to ensure participant protection
1.1.4.6.2. Evaluates the risks and benefits of research participants
1.1.4.6.3. Reviews informed consent to ensure that language and other aspects of the study are comprehensible by a layperson
1.1.4.6.4. Ensures his/her presence always in SL-IERC meetings to meet the quorum requirement *(50% plus one, but not less than five (5), including a lay member, a non-affiliated member and presence of both female and male members)*

1.1.4.7. Selection and Designation of the SL-IERC Officers

1.1.4.7.1. The Head of R&B shall recommend officers of the SL-IERC from the members of the SL-IERC. Recommendation shall be forwarded to the President and CEO of St. Luke's Medical Center (SLMC) at least two (2) months before the year ends.
1.1.4.7.2. The President and CEO of SLMC shall officially designate officers of the SL-IERC, i.e. Chair, Vice-Chair and the Member-Secretary from the appointed SL-IERC Members. Appointment of officers shall be done in December prior to the start of a new year.
1.1.4.7.3. The SL-IERC Chair's, Vice-Chair's and Member-Secretary's term of office shall be two (2) years with re-appointment.
1.1.4.7.4. The term of office shall start on the 1st day of January of the year following the appointment and end on the last day of December of the succeeding year.

1.1.4.8. Vacancies for SL-IERC Officers

1.1.4.8.1. In the event that the SL-IERC Chair's position is vacated, the Vice-chair shall become the acting Chair until a new Chair is appointed.
1.1.4.8.2. Other vacated positions shall be filled upon appointment by the President and CEO of SLMC thru the recommendation of the Head of R&B.

1.1.4.9. Responsibilities of the SL-IERC Chair

The SL-IERC Chair shall have the following responsibilities:

1.1.4.9.1. Finalizes the agenda and presides in all SL-IERC meetings
1.1.4.9.2. Conducts a preliminary review of all clinical research protocols and decides on the nature of review

1.1.4.9.3. Assigns Primary Reviewer among SL-IERC Members for the review of the clinical research protocols
1.1.4.9.4. Assigns Members of the SL-IERC for expedited review
1.1.4.9.5. Ensures that a final decision on all clinical research protocols reviewed is made
1.1.4.9.6. Ensures that appropriate decisions/actions are made by the SL-IERC on issues that include but are not limited to research participants complaints, findings of non-compliance during an FDA audit, loss of records or study drugs, higher than expected occurrences of adverse events, unexpected adverse events that are at least possibly related to the study, drug accountability problems, unanticipated change in Principal Investigator/Project Leader, etc.
1.1.4.9.7. Signs the following communications: Notice of Meetings, Notice of Action to Principal Investigators/Project Leaders
1.1.4.9.8. Signs the Ethical Clearance Form in behalf of the SL-IERC
1.1.4.9.9. Communicates decisions of the SL-IERC to Principal Investigators/Project Leaders
1.1.4.9.10. Represents St. Luke's Medical Center in ethics-related symposia or meetings that require institutional participation upon proper authorization from the Head of R&B
1.1.4.9.11. Submits annual reports on the accomplishments of the SL-IERC to PHREB

1.1.4.10. Responsibilities of the SL-IERC Vice-Chair

The SL-IERC Vice-Chair shall have the following duties and responsibilities:

1.1.4.10.1. Performs all the duties of the SL-IERC Chair when the latter is unavailable or unable to perform them
1.1.4.10.2. Performs other tasks delegated by the SL-IERC Chair

1.1.4.11. Responsibilities of the SL-IERC Member-Secretary

The SL-IERC Member-Secretary shall have the following responsibilities:

1.1.4.11.1. Records and prepares the minutes of the meeting in real time
1.1.4.11.2. Performs other tasks delegated by the SL-IERC Chair

1.1.4.12. Resignation, Disqualification/Withdrawal of Appointment and Replacement of SL-IERC Members

1.1.4.12.1. An SL-IERC Member may resign from the SL-IERC at any time during his/her term by submitting a written letter addressed to the President and CEO through the SL-IERC Chair. A copy of the letter shall be furnished to the Head of R&B.
1.1.4.12.2. An SL-IERC Member may be recommended by the SL-IERC Chair for disqualification/withdrawal of Appointment for any of the following reasons:
1.1.4.12.2.1. Failure without justifiable reason to attend three (3) consecutive meetings of the SL-IERC without any valid reason or six (6) absences within a 12-month period
1.1.4.12.2.2. Failure to disclose Conflict of Interest as herein defined. (COI refers to circumstances where a primary interest, such as patient health, is compromised by a secondary interest such as financial profit)

1.1.4.12.2.3. Violation of the Confidentiality Rule

1.1.4.12.2.4. Other justifiable causes as determined by the SL-IERC

1.1.4.12.3. Replacement of the resigned SL-IERC Member shall be made by the President and CEO, upon recommendation of the SL-IERC Chair and Head of R&B *(SOP # 1.1, Sec. 1.1.4.1).*

1.1.5. REFERENCES

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—Nothing Follows—

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SOP Title: Organizational Structure, Composition, Duties and Responsibilities of the St. Luke's Institutional Ethics Review Committee	SL-IERC SOP No.: SOP # 1.1

DOCUMENT HISTORY

REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	07-2019		5	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

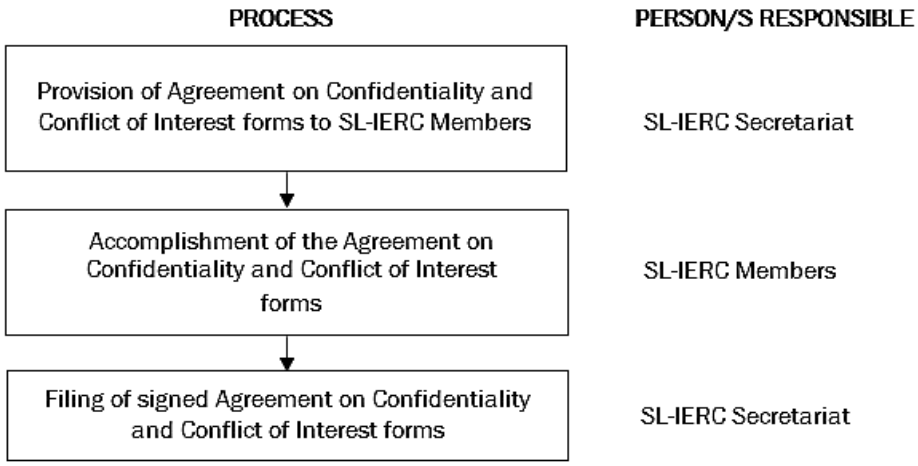
1.2.1. PURPOSE

The purpose of this SOP is to ensure that the Members of the SL-IERC read, understand, accept, sign and date an Agreement on Confidentiality and Conflict of Interest form upon appointment. This process ensures that the SL-IERC Members disclose conflict of interest and maintain confidentiality on the documents and issues taken up during SL-IERC meetings.

1.2.2. SCOPE

This SOP covers the signing of Agreement on Confidentiality and Conflict of Interest forms by the SL-IERC Members and the filing of the signed forms by the SL-IERC Secretariat.

1.2.3. FLOW CHART



1.2.4. PROCEDURE

1.2.4.1. The SL-IERC Secretariat shall provide the SL-IERC Members the Agreement on Confidentiality and Conflict of Interest form *(SL-IERC Form # 01A)* upon their appointment.

1.2.4.2. The SL-IERC Members shall sign and date the Agreement on Confidentiality and Conflict of Interest form.

1.2.4.2.1. The SL-IERC Members shall sign new Agreement on Confidentiality and Conflict of Interest form upon their re-appointment.

1.2.4.3. The SL-IERC Secretariat shall provide each SL-IERC Member a copy of the signed and dated Agreement on Confidentiality and Conflict of Interest form.

1.2.4.4. The SL-IERC Secretariat shall file the signed documents by the SL-IERC Members in the "Master Files of SL-IERC Members".

1.2.5. REFERENCES

1.2.5.1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

1.2.5.2. Philippine Health Research Ethics Board. (2017). National Ethical Guidelines for Health and Health Related Research. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

1.2.5.3. World Health Organization. (2000). Operational Guidelines For Ethics Committees That Review Biomedical Research. Geneva: World Health Organization.

1.2.5.4. World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.

—Nothing Follows—

DOCUMENT HISTORY

REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Training of SL-IERC Members and Secretariat	SL-IERC SOP No.: SOP # 1.3

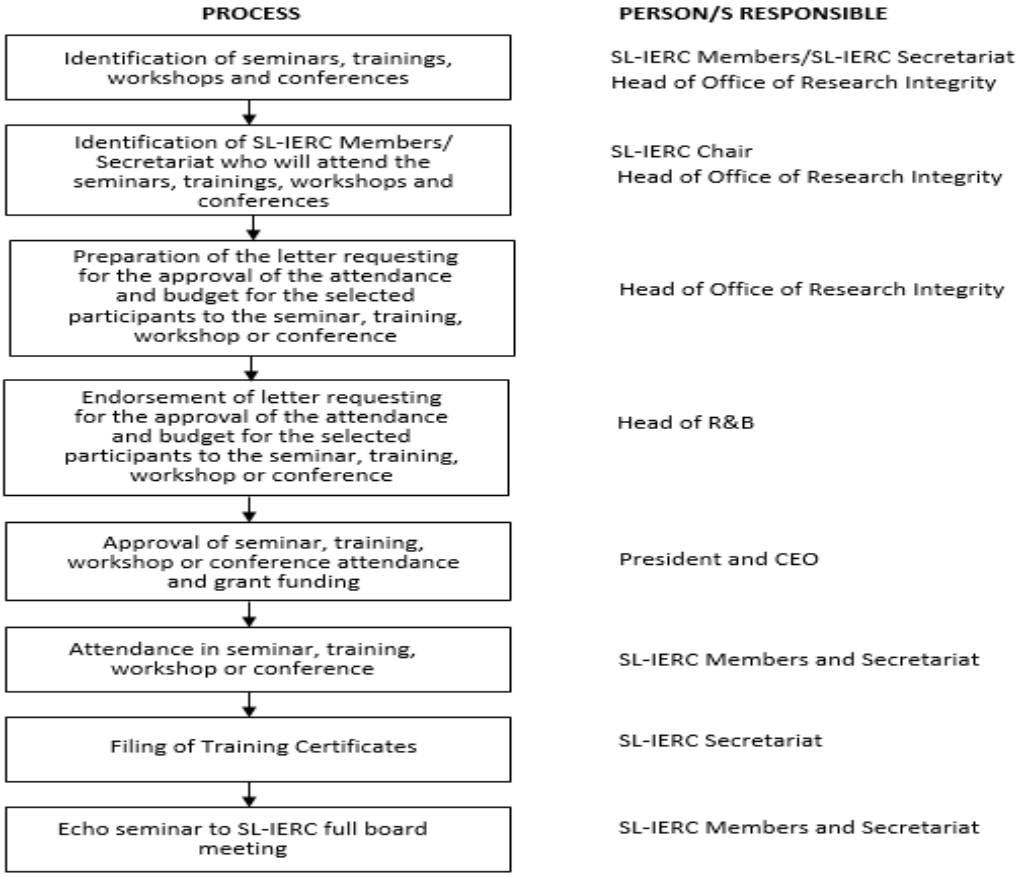
1.3.1. PURPOSE

The purpose of this SOP is to ensure that Members of the SL-IERC and SL-IERC Secretariat team regularly attend seminars, training, workshops, or conferences in order to maintain and enhance their competence and skills through an updated knowledge of research ethics and guidelines. Moreover, ICH-GCP requires regular training and updates of all SL-IERC Secretariat involved in human research every year. This SOP will also ensure that the SL-IERC Members maintain the validity of their GCP certification.

1.3.2. SCOPE

This SOP covers the process of identification of seminars, trainings, workshops and conferences, identification of SL-IERC Members and Secretariat who will attend the activity, requesting for funding, filing of certificates of attendance, and echoing the learnings during the SL-IERC full board meetings.

1.3.3. FLOW CHART



1.3.4. PROCEDURE

1.3.4.1. The SL-IERC Members, SL-IERC Secretariat, and Head of Office of Research Integrity (ORI) shall regularly obtain information on the availability and schedule of training courses, workshops, and conferences on research ethics such as advanced training on ethical issues and concerns, ethics review committees, and other related topics.

1.3.4.1.1. The SL-IERC Secretariat shall ensure that each SL-IERC Member and Secretariat have Good Clinical Practice training every three (3) years and annual trainings on research ethics and related topics.

1.3.4.2. The SL-IERC Chair and Head of ORI shall identify members of the SL-IERC and the SL-IERC Secretariat team who will attend seminars, trainings, workshops or conferences.

1.3.4.3. The Head of ORI shall prepare and submit to the Head of R&B the letter requesting for the approval of attendance and budget for the selected participants to the seminar, training, workshop or conference.

1.3.4.4. The Head of R&B shall endorse to the President and CEO the letter requesting for the approval of attendance and budget for the selected participants to the seminar, training, workshop or conference.

1.3.4.5. The SL-IERC Member and SL-IERC Secretariat who attend any seminar, training, workshop or conference shall submit their certificate or proof of attendance for filing by the SL-IERC Secretariat in the "Master Files of SL-IERC Members".

1.3.4.6. The SL-IERC Member who has attended external seminar, training, workshop or conference shall give an echo seminar to the SL-IERC Members during a full board meeting. This shall be considered part of the continuing training of the SL-IERC Members.

1.3.5. REFERENCES

1.3.5.1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

1.3.5.2. Philippine Health Research Ethics Board. (2017). National Ethical Guidelines for Health and Health Related Research. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

1.3.5.3. World Health Organization. (2000). Operational Guidelines for Ethics Committees that Review Biomedical Research. Geneva: World Health Organization.

1.3.5.4. World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.

—Nothings Follows—

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Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Training of SL-IERC Members and Secretariat	SL-IERC SOP No.: SOP # 1.3

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

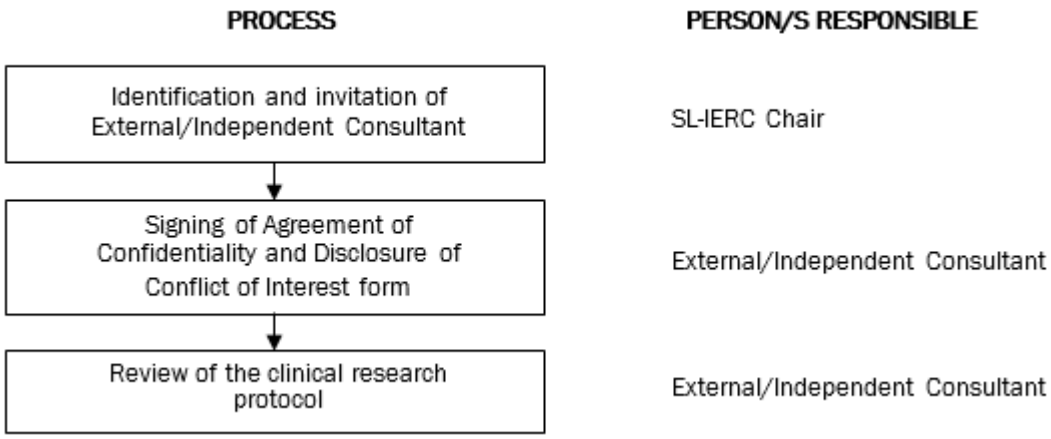
1.4.1. PURPOSE

The purposes of this SOP are to describe the process of obtaining the services of an expert to serve as External/ Independent Consultant on matters outside the expertise of members of the SL-IERC, and to guide the External/Independent Consultant in his/her responsibilities in the review of a clinical research protocol.

1.4.2. SCOPE

This SOP covers the process of determining the need, identification and appointment of External/Independent Consultants as well as the responsibilities of the External/Independent Consultants in the review of a clinical research protocol.

1.4.3. FLOW CHART



1.4.4. PROCEDURE

1.4.4.1. Selection of the External/Independent Consultant

1.1.4.1.1. When deemed necessary, the SL-IERC Chair may invite an expert to serve as External/Independent Consultant in the review of a clinical research protocol. The selection shall be based on his/her expertise.

1.1.4.1.2. The External/Independent Consultant shall sign an Agreement of Confidentiality and Disclosure of Conflict of Interest form upon his/her appointment *(SL-IERC Form # 01B)*.

1.1.4.1.2.1. The SL-IERC Secretariat shall file the signed Agreement of Confidentiality and Disclosure of Conflict of Interest form in the "Master files of External/Independent Consultants."

1.4.4.2. Responsibilities of the External/Independent Consultant

1.1.4.2.1. The External/Independent Consultant shall participate in the review of a specific protocol and give his/her inputs on specific issues related to his expertise. He/she shall perform the following:

- Sign the Disclosure of Conflict of Interest form *(SL-IERC Form # 01C)*
- Diligently reads the clinical research protocol details
- Conducts literature searches
- Fills up the Ethics Review Form for External/Independent Consultants *(SL-IERC Form #06)* with necessary and relevant comments regarding the protocol
- Attend the SL-IERC full board meeting and actively participate in the discussion of the clinical research.

1.1.4.2.2. The External/Independent Consultant shall not have any voting rights.

1.4.5. REFERENCES

1.4.5.1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

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1.4.5.3. World Health Organization. (2000). Operational Guidelines For Ethics Committees That Review Biomedical Research. Geneva: World Health Organization.

1.4.5.4. World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.

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Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Selection and Responsibilities of the External/Independent Consultant	SL-IERC SOP No.: SOP # 1.4

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
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6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

1.5.1 PURPOSE

The purpose of this SOP is to ensure that the SL-IERC Members, Secretariat and External/Independent Consultants are granted honoraria for their work in the committee.

1.5.2 SCOPE

This SOP covers the process of recommending, approving, and processing of the honoraria for the SL-IERC Members, Secretariat and External/Independent Consultants.

1.5.3 FLOW CHART

PROCESS	PERSON/S RESPONSIBLE
Recommendation for grant of honorarium of SL-IERC Members, Secretariat and External/Independent Consultants	Head of R&B
Approval/disapproval of honorarium	President and CEO
Request for preparation of honorarium checks	SL-IERC Secretariat
Preparation of request for honorarium checks	CCT Administrator
Approval of the request for honorarium checks	R&B Head
Submission of the request for honorarium checks to SLMC Accounting Department	CCT Administrator
Distribution of the honorarium checks to SL-IERC Members, Secretariat and External/Independent Consultants	CCT Administrator
Acknowledgment of the honorarium	SL-IERC Members, Secretariat, External/Independent Consultants
Filing of the vouchers of the honorarium checks	CCT Administrator

1.5.4 PROCEDURE

1.5.4.1 The Head of R&B shall recommend to the President and CEO the granting of honorarium to the SL-IERC Members and Secretariat for their work in the committee. The honorarium shall cover an amount for review of protocols, for attendance and participation in meetings and other SL-IERC activities and a year-end bonus.

1.5.4.1.1. The Head of R&B shall recommend an increase in the honorarium depending on the workload.

1.5.4.2 The SL-IERC Secretariat shall request from the R&B Center for Clinical Trials (CCT) Administrator for the payment of honorarium to the SL-IERC Members and External/Independent Consultants on a monthly basis.

1.5.4.3 The CCT Administrator shall prepare the request for honorarium checks.

1.5.4.4 The R&B Head shall approve and sign the request for honorarium checks.

1.5.4.5 The CCT Administrator shall forward the signed request for honorarium checks to the SLMC Accounting Department.

1.5.4.6 The CCT Administrator shall get the honorarium checks from the SLMC Accounting Department.

1.5.4.7 The CCT Administrator distributes the honorarium checks to the SL-IERC Members, Secretariat, and External/Independent Consultants.

1.5.4.8 The SL-IERC Members, Secretariat, and External/Independent Consultants shall sign a voucher to acknowledge receipt of the honorarium check.

1.5.4.9 The CCT Administrator shall file the signed vouchers of the honorarium checks.

1.5.5 REFERENCES

1.5.5.1. Philippine Health Research Ethics Board. (2017) National Ethical Guidelines for Health and Health Related Research. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

1.5.5.2. World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.

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Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Honorarium of SL-IERC Members, Secretariat and External / Independent Consultants	SL-IERC SOP No.: SOP # 1.5

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
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Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022
SOP Title: Duties and Responsibilities of the SL-IERC Secretariat	SL-IERC SOP No.: SOP # 1.6

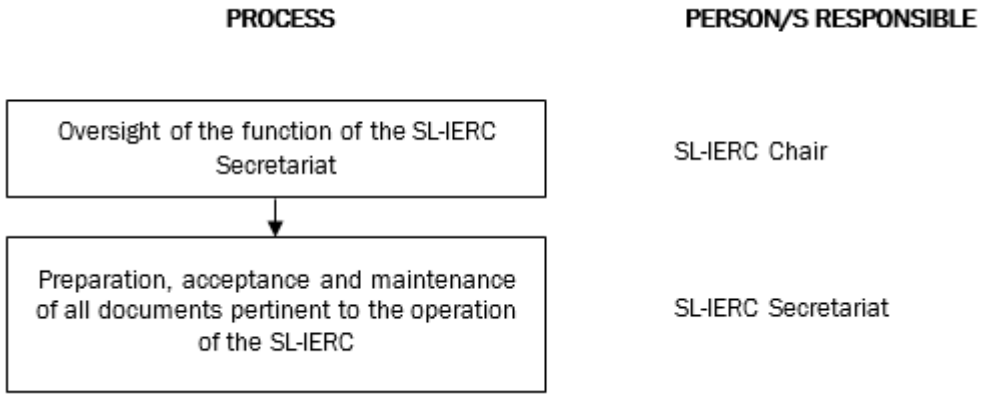
1.6.1. PURPOSE

The purpose of this SOP is to describe the duties and responsibilities of the SL-IERC Secretariat.

1.6.2. SCOPE

This SOP covers the duties and responsibilities of Secretariat in the providing administrative support to the SL-IERC.

1.6.3. FLOW CHART



1.6.4. PROCEDURE

1.6.4.1. The Secretariat shall be composed of the administrative staff of the SL-IERC and the SL-IERC Member-Secretary.
1.6.4.2. The SL-IERC Chair shall oversee the Secretariat.
1.6.4.3. The SL-IERC Secretariat shall be the administrative support staff of the SL-IERC.
1.6.4.4. The following shall be the responsibilities of the SL-IERC Secretariat:
1.6.4.4.1. Receives, documents, and records all applications for initial protocol review
1.6.4.4.2. Receives continuing review documents such as amendments, serious adverse event (SAE)/suspected unexpected serious adverse reaction (SUSAR) reports, protocol deviations, progress reports and other communication and transmits the same to the SL-IERC Chair or to the appropriate SL-IERC subcommittees.
1.6.4.4.3. Receives clinical trial documents from the Philippine Food and Drug Administration (PFDA) and arranges the schedule of review by the Chair and the designated committee
1.6.4.4.4. Prepares the tracking form and assigns a tracking number for all complete initial submission of protocols and related documents

1.6.4.4.5. Forwards the submitted protocol to SL-IERC Chair for initial review in order to determine type of review process

1.6.4.4.6. Forwards the submitted protocol and related documents and Assessment forms to the SL-IERC Members once it has been determined to undergo expedited review

1.6.4.4.7. Collates all essential documents for SL-IERC meetings and distributes these to SL-IERC Members at least two (2) weeks before the scheduled full board meeting

1.6.4.4.8. Prepares the agenda and Minutes of Meetings of SL-IERC and sends to all SL-IERC members at least two (2) days before a scheduled full board meeting via email

1.6.4.4.9. Prepares and distributes protocols, Assessment form, and communications to, and coordinates with, External/Independent Consultants the schedule of protocol presentation

1.6.4.4.10. Requests the use and assures the availability of the venue for SL-IERC meetings

1.6.4.4.11. Coordinates with Food and Nutrition, Transport Services and Center for Clinical Trials regarding SL-IERC requirements

1.6.4.4.12. Records via mp3 recorder and prepares Minutes of SL-IERC Meetings

1.6.4.4.13. Collects and collates all protocols and related documents and accomplished Assessment forms from the SL-IERC Reviewers

1.6.4.4.14. Prepares all communications to the Principal Investigators/Project Leaders

1.6.4.4.15. Maintains and updates the database for SL-IERC

1.6.4.4.16. Keeps and maintains archives of the following: protocol files of each reviewed clinical research studies, agenda, notice and minutes of meetings, file of SL-IERC Members, attendance sheets, files of External/Independent Consultants, communications with Principal Investigators/Project Leaders, and other relevant documents

1.6.4.4.17. Answers queries from Investigators on matters relevant to the functions/ activities/schedules, etc. of the SL-IERC

1.6.4.4.18. Maintains confidentiality of all documents of the SL-IERC

1.6.4.4.19. Prepares reports and other matters to be presented at SL-IERC meetings

1.6.4.4.20. Performs other functions as requested by the SL-IERC Members

1.6.4.4.21. Helps the Head of the Office of Research Integrity in preparing the annual budget for the SL-IERC operations

1.6.5. REFERENCES

1.6.5.1. National Ethics Committee Standard Operating Procedures, version 2 (2015). Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

1.6.5.2. World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.

—Nothing Follows—

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Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Duties and Responsibilities of the SL-IERC Secretariat	SL-IERC SOP No.: SOP # 1.6

DOCUMENT HISTORY

REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
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5	08-2019		5	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

SOP 2. SOPs on Types of Review

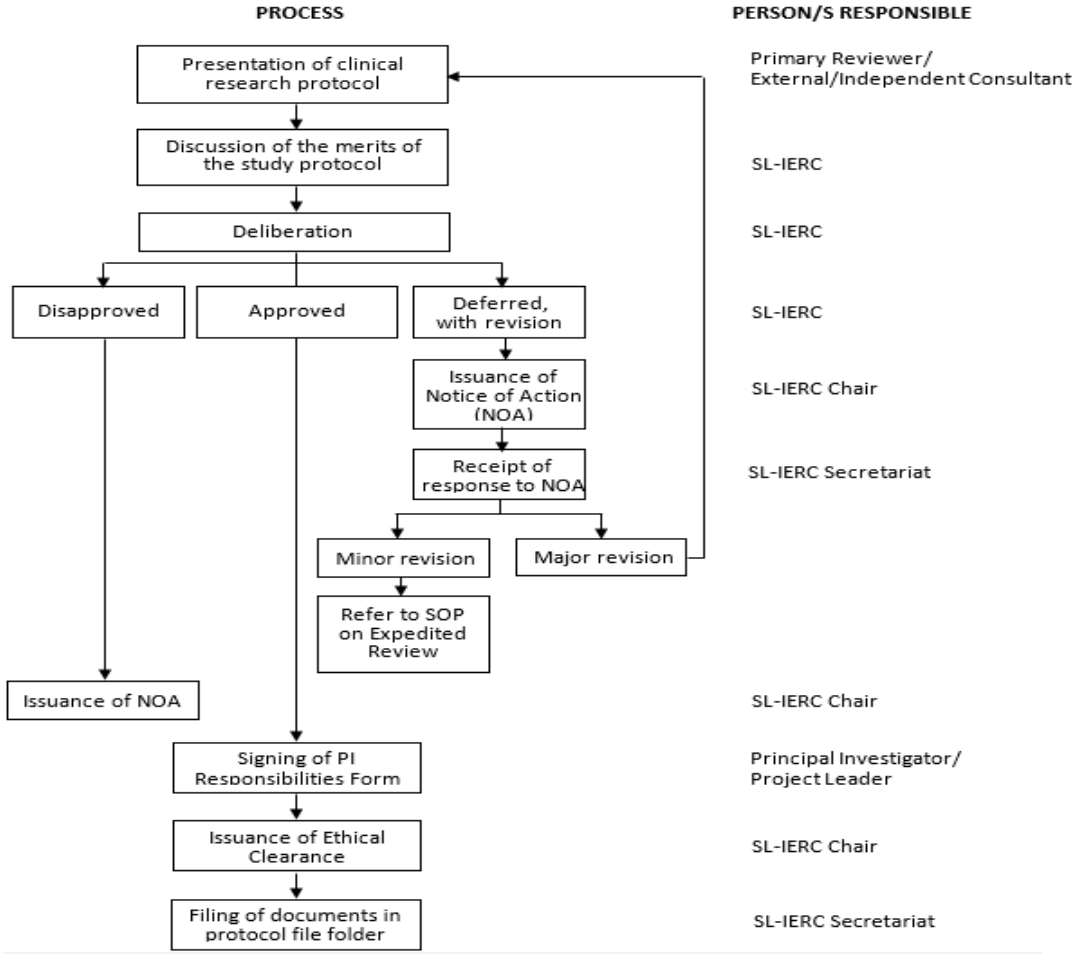
2.1.1. PURPOSE

The purpose of this SOP is to describe the procedure for full board review of submitted protocols and protocol-related documents of clinical trials and other clinical research studies that involve more than minimal risk to the human participants and to the community or involve vulnerable population.

2.1.2. SCOPE

This SOP covers the presentation of the clinical research protocol by the Primary Reviewer or External/Independent Consultant, discussion of merits of the protocol, deliberation, issuance of Notice of Action, and issuance of ethical clearance.

2.1.3. FLOWCHART



2.1.4. PROCEDURE

2.1.4.1. Presentation of Clinical Research Protocol

2.1.4.1.1. An SL-IERC Member shall be designated by the SL-IERC Chair to be the Primary Reviewer for the clinical research protocol based on his/her field of expertise. If none, then SL-IERC Chair shall appoint an External/Independent Consultant to be the Primary Reviewer. The Ethics Review Form for Protocol (*SL-IERC Form # 05A*) shall be provided by the SL-IERC Secretariat.

2.1.4.1.2. The SL-IERC Chair shall designate an SL-IERC Lay Person to review the Informed Consent Forms. The Ethics Review Form for Informed Consent (*SL-IERC Form # 05B*) shall be provided by the SL-IERC Secretariat.

2.1.4.1.3. The presentation of the Primary Reviewer or External/Independent Consultant shall include the following (*SL-IERC Template # 18 Elements for Presentation during Full Board Review of Clinical Research Protocols*):

- EC Reference Number and Protocol Title
- Principal Investigator/Project Leader
- Sponsor
- Conflict of interest of Principal Investigator/Project Leader
- Social and scientific value
- Scientific validity, study design
- Fair selection of subjects
- Inclusion/exclusion Criteria
- Justification for inclusion of vulnerable subjects
- Justifiable use of placebo, if applicable
- Standard of care
- Withdrawal criteria
- Risks-benefits assessment
- Recruitment process
- Informed Consent form
- Insurance
- Issues on the protocol

2.1.4.1.4. Discussion of the merits of the clinical research protocol by the SL-IERC shall be done after the presentation of the Primary Reviewer or External/Internal Consultant. The SL-IERC shall consider the comments and recommendations of the Institutional Scientific Review Committee (ISRC) on the scientific validity of the study in the discussion. The decision of the committee shall be reached by voting. The members shall be asked to raise their hands to signify their decision based as follows:

2.1.4.1.4.1. Risks:

- **High Risk** - if study can lead to an unexpected/unplanned loss of life, or permanent impairment of quality of life, or may lead to serious

legal action against Principal Investigator/Project Leader and/or institution.

The study risk is greater than a moderate risk study due to the increased probability for generating serious adverse events. There is a high probability of an event that is serious and prolonged or permanent occurring as a result of study participation.*

- **Moderate Risk** - Risks are recognized as being greater than minimal, but are not considered high. There is a medium to high probability of a moderate-severity event occurring as a result of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there is adequate surveillance and protections to identify adverse events promptly and to minimize their effects.
- **Minimal Risk** - if the consequences can be dealt with by routine operations the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102)

2.1.4.1.4.2. Protocol:

- **Approved** - clinical research protocol is approved when
  - Risks to subjects are minimal and reasonable in relation to anticipated benefits;
  - Selection of subjects is equitable;
  - Research plan makes adequate provisions for monitoring data collected to ensure safety of subjects and protect the privacy of subjects and confidentiality of data;
  - Additional safeguards have been included to protect welfare of vulnerable subjects.
- **Deferred**
  - **Minor Revision** - clinical research protocol is missing some minor but important issues that need to be attended to.
  - **Major Revision** - clinical research protocol is not scientifically or/and ethically adequate. Some questions on one or more of the following points or topics that the opinion of one or more member may compromised the patient safety or data integrity:
    - Inclusion criteria
    - Scientific prerequisite
    - Legal requirements
    - Sample size

- Insurance
- Information on treatment and examination
- Study objectives
- Information on methodology and statistics

- **Disapproved** - clinical research protocol is ethically unacceptable. However an appeal can be made by the Principal Investigator/Project Leader.

2.1.4.1.4.3. Informed Consent:

- **Approved** - when all the elements of an informed consent document are present as follows:
  - Description of clinical investigation
  - Risks and discomforts
  - Benefits
  - Alternative procedures or treatments
  - Confidentiality and data privacy
  - Compensation and medical treatments in event of injury
  - Contacts
  - Voluntary participation
  - Understandable language of the ICF
  - Additional elements of informed consent
    a. Unforeseeable risks
    b. Involuntary termination of subject's participation
    c. Additional costs to subject
    d. Consequences of subject's decision to withdraw
    e. Providing significant new findings to subjects
- **Deferred**
  - **Minor Revision** - grammatical corrections, inaccurate translation, no contact person
  - **Major revision** – one or more of the elements for a good informed consent document are not present (see elements mentioned above)

2.1.4.1.5. The SL-IERC Primary Reviewer and/or SL-IERC Chair shall review the response from Principal investigator/Project Leader for clinical research studies requiring minor revisions.

2.1.4.1.6. The SL-IERC shall decide full board review of response from Principal Investigator/Project Leader for clinical research studies requiring major revisions.

2.1.4.1.7. The SL-IERC Secretariat shall collect the Ethics Review Form for Protocol from Primary Reviewer or External/Independent Consultant and Ethics Review Form for Informed Consent Forms from Lay Person(s) immediately after the decision and verify

2.1.4.1.8. completeness. If the forms are incompletely accomplished, the SL-IERC Secretariat shall request the concerned SL-IERC Member to complete the form.

2.1.4.1.8.1. Other Members of the SL-IERC may accomplish the Ethical Review Forms when reviewing the protocol and ICF.

2.1.4.2. Notice of Action

2.1.4.2.1. The SL-IERC Secretariat shall prepare the Notice of Action (NOA) *(SL-IERC Template # 08 and Template 11A IERC Composition)* within 14 working days after the meeting stating the decision and recommendation of the committee for appropriate action by the Principal Investigator/Project Leader. The SL-IERC Secretariat shall submit the draft to the SL-IERC Chair for review.

2.1.4.2.2. The SL-IERC Secretariat shall prepare the final NOA report which is signed by the SL-IERC Chair

2.1.4.2.3. The SL-IERC Secretariat shall inform the Principal Investigator/Project Leader about the NOA via email, SMS message or telephone call.

2.1.4.2.4. The SL-IERC Secretariat shall issue the NOA once the Principal Investigator/Project Leader or study team member signs the Acknowledgment Receipt.

2.1.4.3. Ethical Clearance

2.1.4.3.1. Ethical Clearance shall be prepared when the Principal Investigator/Project Leader has addressed all the recommendations made by the SL-IERC and approved by the Committee.

2.1.4.3.2. The SL-IERC Secretariat shall inform the Principal Investigator/Project Leader about the Ethical Clearance via email, SMS message or telephone call.

2.1.4.3.3. The Ethical Clearance shall be issued once the Principal Investigator/Project Leader signs Conforme of the Principal Investigator's Responsibilities Form (*SL-IERC Template # 10*). A copy of the signed Principal Investigator's Responsibilities Form shall be returned to the SL-IERC Secretariat for filing.

2.1.4.4. Documents

2.1.4.4.1. All pertinent documents that has been approved by the SL-IERC and which will be used in the conduct of the study shall be stamped on the every page the words "IERC Approved" and the date of approval. The documents include research protocol, informed consent forms, case report forms or data collection forms, patient materials, and other study related documents.

2.1.4.4.2. The SL-IERC Secretariat shall keep the results and related documents in the clinical research protocol file.

2.1.5. REFERENCES:

2.1.5.1. Cash R, Wikler D, Saxena A, Capron A, eds. (2009). Casebook on Ethical Issues in International Research. Geneva: World Health Organization.

2.1.5.2. Office of Human Research Protections. (2016). *Code of Federal Regulations Title 45, Part 46, Section 46.102 Definitions for the Purposes of this Policy*. U.S. Department of Health & Human Services.

2.1.5.3. Philippine Health Research Ethics Board. (2017) National Ethical Guidelines for Health and Health Related Research. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

—Nothing Follows—

DOCUMENT HISTORY

REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

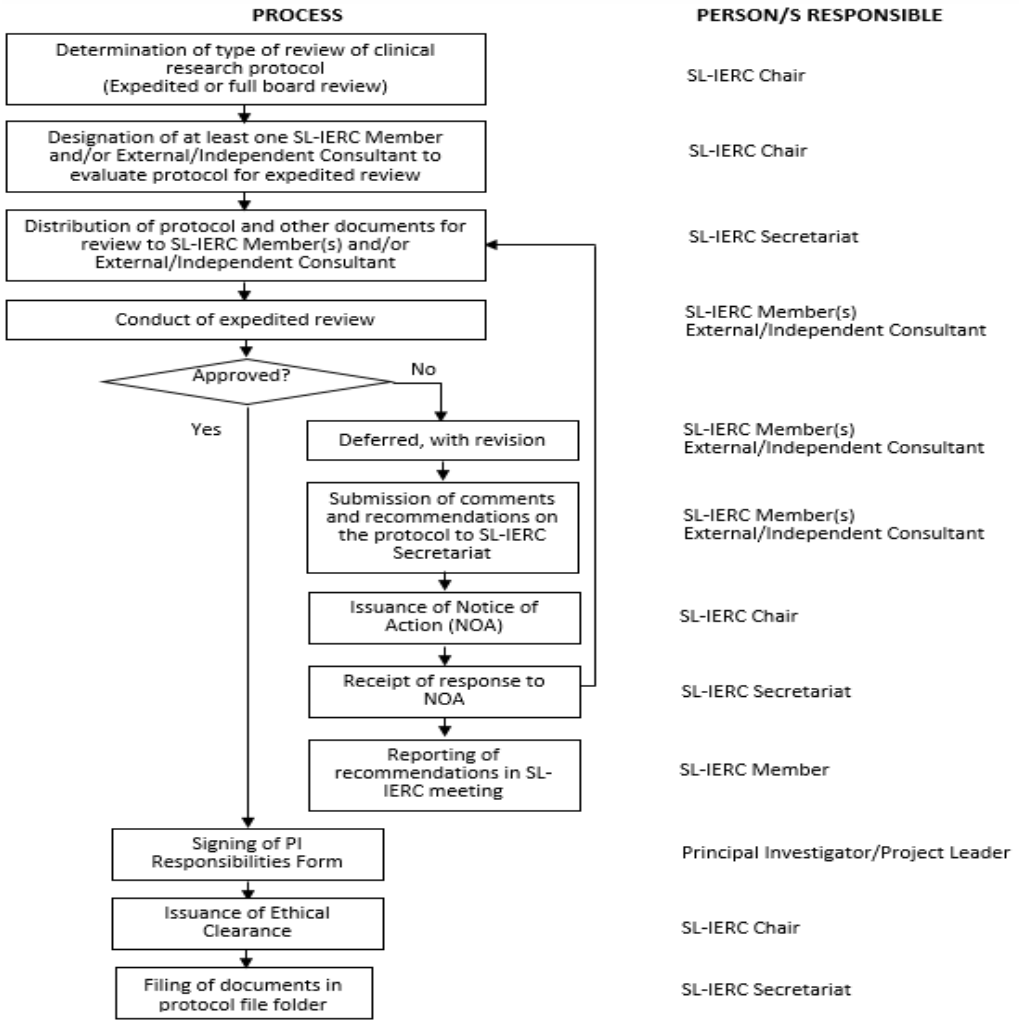
2.2.1. PURPOSE

The purpose of this SOP is to describe the criteria for classifying clinical research protocols for expedited review and describe the process of expedited review of protocols with minimal risk to human participants, does not involve vulnerable subjects, or retrospective in data collection.

2.2.2. SCOPE

This SOP covers the process of determining the type of review, designation of Primary Reviewer, conduct of expedited review, decision, issuance of Notice of Action and ethical clearance for clinical research protocols.

2.2.3. FLOWCHART



2.2.4. PROCEDURE

2.2.4.1. The following documents shall undergo expedited review:

2.2.4.1.1. Non-interventional clinical research protocols that entail only a minimal risk to the human participants and to the community

2.2.4.1.2. Human research participants do not belong to a vulnerable group

2.2.4.1.3. Clinical research protocols that are retrospective in data collection methodology

2.2.4.2. Evaluation and classification of clinical research protocols for expedited review

2.2.4.2.1. The SL-IERC Chair shall evaluate if a submitted clinical research protocol is qualified for expedited review.

2.2.4.2.2. The SL-IERC Chair may designate at least one (1) SL-IERC Member who will conduct the expedited review. The SL-IERC Chair may invite an External/Independent Consultant to review the protocol. If the protocol requires an informed consent, a lay person shall be included among the reviewers.

2.2.4.2.3. The SL-IERC Secretariat shall prepare and send the clinical trial or clinical research protocol to the designated SL-IERC Member(s) and/or External/Independent Consultant.

2.2.4.3. Conduct of Expedited Review

2.2.4.3.1. The SL-IERC Member(s) and/or External/Independent Consultant shall be given 14 working days to evaluate the clinical trial or clinical research protocol using the Ethics Review Form for Protocol (*SL-IERC Form # 05A*) and/or Ethics Review Form for Informed Consent (*SL-IERC Form # 05B*).

2.2.4.3.2. The recommendations of the SL-IERC reviewer(s) may be any of the following:

- Approved
- Deferred, with revisions

2.2.4.3.3. The SL-IERC Reviewer(s) shall submit to the SL-IERC Secretariat the results of the expedited review.

2.2.4.3.4. The SL-IERC Chair shall summarize the results of the expedited review and the comments and recommendations of the ISRC on the scientific validity of the study.

- If approved, Ethical Clearance shall be prepared by the SL-IERC Chair.
- If deferred with revisions, the SL-IERC Chair shall compose the Notice of Action.

2.2.4.4. Notice of Action

2.2.4.4.1. The SL-IERC Secretariat shall send a Notice of Action *(SL-IERC Template # 08 and Template 11A IERC Composition)*signed by the SL-IERC Chair to the Principal Investigator/Project Leader.

2.2.4.4.2. The SL-IERC Secretariat shall inform the Principal Investigator/Project Leader about the NOA via email, SMS message or telephone call.

2.2.4.4.3. The SL-IERC Secretariat shall issue the NOA once the Principal Investigator/Project Leader or study team member signs the Acknowledgment Receipt.

2.2.4.4.4. The SL-IERC Secretariat shall include the outcome of the expedited review in the agenda of the next SL-IERC regular meeting. Outcomes of the expedited reviews of clinical research protocols shall be reported by the SL-IERC Chair to inform the SL-IERC Members. A NOA to the Principal Investigator/Project Leader may precede the SL-IERC meeting.

2.2.4.5. Ethical Clearance

2.2.4.5.1. Ethical Clearance shall be prepared when the Principal Investigator/Project Leader has addressed all the recommendations made by the SL-IERC and approved by the reviewers.

2.2.4.5.2. The SL-IERC Secretariat shall inform the Principal Investigator/Project Leader about the Ethical Clearance via email, SMS message or telephone call.

2.2.4.5.3. The Ethical Clearance shall be issued once the Principal Investigator/Project Leader signs Conforme of the Principal Investigator's Responsibilities Form (*SL-IERC Template # 10*). A copy of the signed Conforme for the Principal Investigator's Responsibilities Form shall be returned to the SL-IERC Secretariat.

2.2.4.6. Documents

2.2.4.6.1. All pertinent documents that has been approved by the SL-IERC and which will be used in the conduct of the study shall be stamped on the every page the words "IERC Approved" and the date of approval. The documents include trial or clinical research protocol, informed consent forms, case report forms or data collection forms, patient materials, and other study related documents.

2.2.4.6.2. The SL-IERC Secretariat shall keep the results and related documents in the clinical trial or clinical research protocol file.

2.2.5. REFERENCES:

2.2.5.1. Cash R, Wikler D, Saxena A, Capron A, eds. (2009). Casebook on Ethical Issues in International Research. Geneva: World Health Organization.

2.2.5.2. Philippine Health Research Ethics Board. (2017) National Ethical Guidelines for Health and Health Related Research. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

—Nothing Follows—

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Expedited Review of Protocols	SL-IERC SOP No.: SOP # 2.2

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

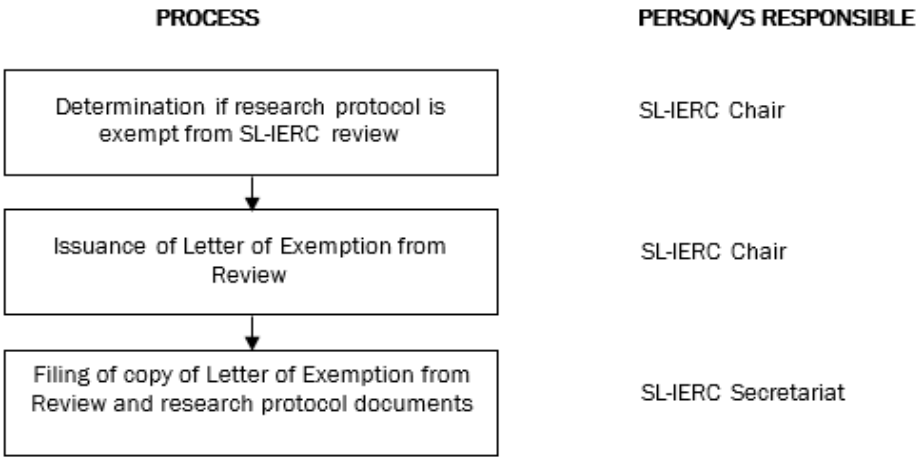
2.3.1. PURPOSE

The purpose of this SOP is to describe the criteria for exempting clinical research protocols from SL-IERC review and the process of exempting research protocols from review.

2.3.2. SCOPE

This SOP covers the process of determining the type of research protocol, criteria for exemption from review, issuance of Letter exempting the research from review, and filing of documents in the research protocol file binder.

2.3.3. FLOWCHART



2.3.4. PROCEDURES

2.3.4.1. The SL-IERC Chair shall determine if the submitted research protocol qualifies for exempt from review.

2.3.4.2. The SL-IERC Chair shall refer to the following criteria for exemptions from review based on the National Ethical Guidelines on Health and Health-Related Research (2017):

2.3.4.2.1. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., systematic and meta-analysis protocols)

2.3.4.2.2. Case studies or case reports that do not involve the use of articles (e.g., drugs, devices, biologics) that have not been approved for use in humans

2.3.4.2.3. Protocols that do not involve more than minimal risks or harms, such as those that are for:

a. institutional quality assurance purposes
b. evaluation of public service programs

c. public health surveillance
d. educational evaluation activities
e. consumer acceptability tests

2.3.4.2.4. Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:

a. There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation; and
b. The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers linked to the participant.

2.3.4.2.5. Protocols that involve the use of publicly available data or information.

2.3.4.2.6. Retrospective case report or study with no personal identifiers of the patient

2.3.4.2.7. Database will be used primarily for clinical care or hospital operations purposes

2.3.4.3. A Letter of Exemption from Review (*SL-IERC Template # 17*) shall be prepared and signed by the SL-IERC Chair.

2.3.4.4. The SL-IERC Secretariat shall inform the Principal Investigator/Project Leader about the Letter of Exemption from Review via email, SMS message or telephone call.

2.3.4.5. The Letter of Exemption from Review shall be issued once the Principal Investigator/Project Leader signs an Acknowledgement Receipt.

2.3.4.6. The SL-IERC Secretariat shall keep the copy of the Letter of Exemption from Review and related protocol documents in the research protocol file.

2.3.5. REFERENCE:

2.3.5.1. Philippine Health Research Ethics Board. (2017) National Ethical Guidelines for Health and Health Related Research. Manila: Department of Science and Technology – Philippine Council ffor Health Research and Development.

—Nothing Follows—

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
				New SOP as recommended by PHREB and FERCAP surveyors			
1	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Review of Protocols that Require Revisions after Initial Review	SL-IERC SOP No.: SOP # 2.4

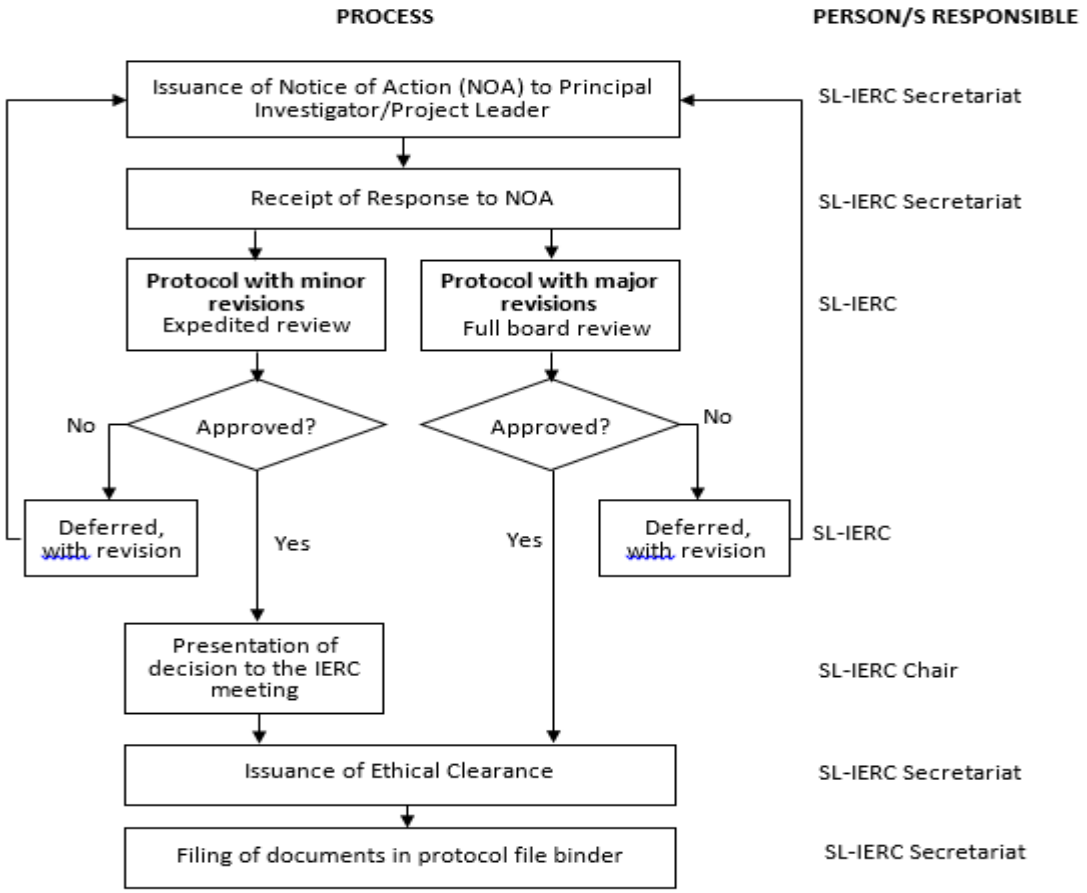
2.4.1 PURPOSE

The purpose of this SOP is to describe the management, review, and approval of the responses to Notice of Action of clinical research protocols that have been previously evaluated and assessed with minor or major revisions.

2.4.2 SCOPE

This SOP covers the process from issuance of Notice of Action (NOA) to receipt of response to NOA, review and approval of NOA, issuance of Ethical Clearance, and filing of documents in the clinical research protocol file binder.

2.4.3 FLOWCHART



2.4.4 PROCEDURE

2.4.4.1. Notice of Action and Response

2.4.4.1.1. The SL-IERC Secretariat shall prepare the Notice of Action *(SL-IERC Template # 08 and Template #11a IERC Composition)* and shall send it to the Principal Investigator/Project Leader.

2.4.4.1.2. The Principal Investigator/Project Leader shall acknowledge the Notice of Action by signing the Acknowledgment Receipt.

2.4.4.1.3. Principal Investigator/Project Leader shall be given a maximum of 90 calendar days to respond to the Notice of Action. Failure to respond within the time frame will be considered a withdrawal of the application. The submitted protocol files will be placed in the inactive file. Should the Principal Investigator/Project Leader decide to continue the clinical trial/research, a new application shall be filed. A new EC Reference number will be assigned to the new application.

2.4.4.2. Review of Response to Notice of Action

2.4.4.2.1. Protocol with minor revision(s) shall pass through expedited review *(Refer to SOP# 2.2 Expedited Review of Protocols).*

2.4.4.2.2. Protocol with major revision(s) shall pass through another full board review.

2.4.4.2.2.1. The designated SL-IERC Member/Primary Reviewer shall present the protocol and the pertinent major revisions.

2.4.4.2.2.2. The SL-IERC shall deliberate on the revision(s) and decide by voting:

- Approved
- Deferred
  - With minor revisions
  - With major revisions
- Disapproved

2.4.4.3. Decision/Notice of Action

2.4.4.3.1. The SL-IERC Secretariat shall inform the Principal Investigator/Project Leader about the NOA via email, SMS message or telephone call.

2.4.4.3.2. The SL-IERC Secretariat shall issue the NOA once the PI or study team member signs the Acknowledgment Receipt.

2.4.4.3.3. Depending on the status of the 2nd and succeeding NOA, the process follows the provision of 2.3.4.2 above.

2.4.4.4. Ethical Clearance

2.4.4.4.1. Ethical Clearance shall be prepared when the Principal Investigator/Project Leader has addressed all the recommendations made by the SL-IERC and approved by the committee.

2.4.4.4.2. The Ethical clearance shall be issued once the Principal Investigator/Project Leader signs Conforme of the Principal Investigator's Responsibilities Form (*SL-IERC Template #10*). A copy of the signed Principal Investigator's Responsibilities Form shall be returned to the SL-IERC Secretariat.

2.4.4.5. Documents

2.4.4.5.1. All pertinent documents that has been approved by the SL-IERC and which will be used in the conduct of the study shall be stamped on the every page the words "IERC Approved" and the date of approval. The documents include the clinical trial/research protocol, informed consent forms, case report forms, case report forms or data collection forms, patient materials, and other study related documents.

2.4.4.5.2. The SL-IERC Secretariat shall keep the results and related documents in the clinical research protocol file.

2.4.5 REFERENCES

2.4.5.1. Cash R, Wikler D, Saxena A, Capron A, eds. (2009). Casebook on Ethical Issues in International Research. Geneva: World Health Organization.

2.4.5.2. Philippine Health Research Ethics Board. (2017) National Ethical Guidelines for Health and Health Related Research. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

—Nothing Follows—

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Review of Protocols that Require Revisions after Initial Review	SL-IERC SOP No.: SOP # 2.4

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Change of SOP Number and improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Review of Protocols for Regulatory (PFDA) Approvals	SL-IERC SOP No.: SOP # 2.5

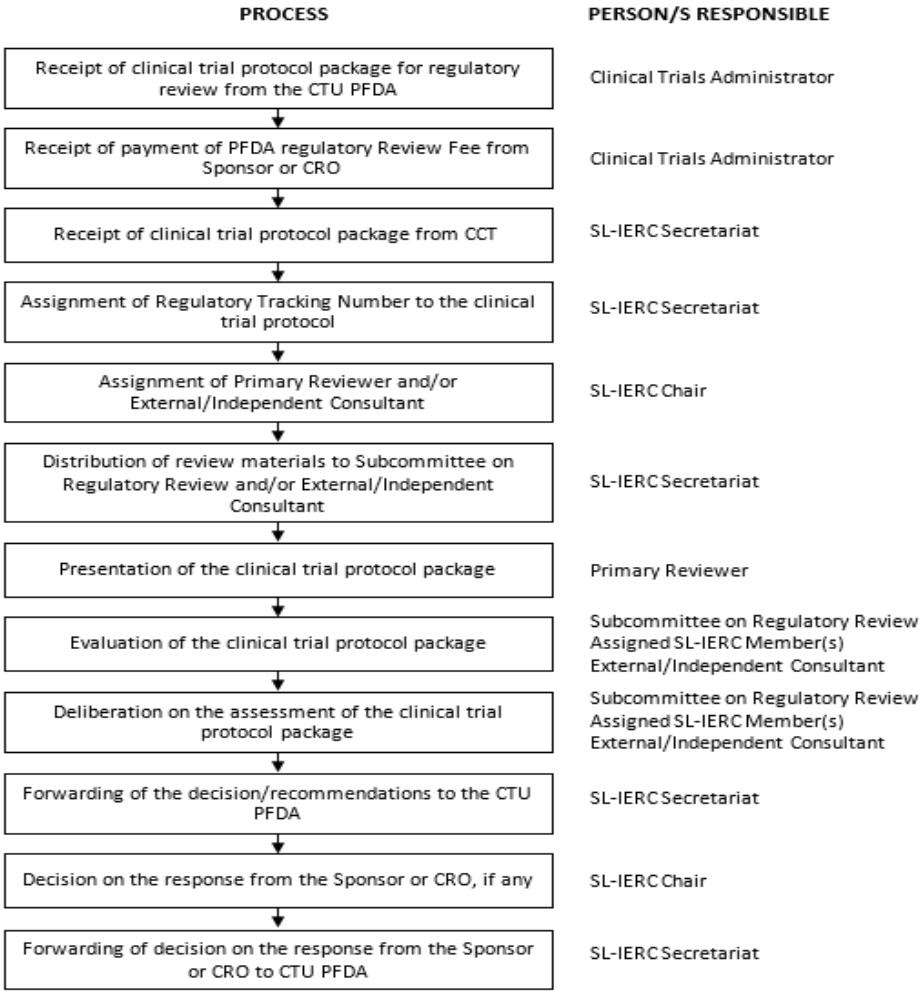
2.5.1. PURPOSE

To ensure a standard process of receiving and reviewing clinical trial protocols submitted to the Philippine Food and Drug Administration (PFDA) for regulatory approval

2.5.2. SCOPE

This SOP shall guide the SL-IERC Chair, Members, Secretariat, External/Independent Consultants and the Center for Clinical Trials (CCT) from receipt of clinical trial protocol package from the Clinical Trial Unit (CTU) of the PFDA, payment of regulatory review fee, conduct of review and forwarding of final recommendation to the PFDA.

2.5.3. FLOWCHART



2.5.4. PROCEDURE

2.5.4.1. The Center for Clinical Trials (CCT) Administrator shall receive six (6) sets of the clinical trial protocol package sent by the PFDA Clinical Trials Unit (CTU).

2.5.4.2. The CCT Administrator shall forward the complete clinical trial protocol package to SL-IERC Secretariat upon receipt of payment of the PFDA Regulatory Review Fee from the Sponsor or Contract Research Organization (CRO).

2.5.4.3. The SL-IERC Secretariat shall assign a Regulatory Tracking number to the clinical trial protocol. Regulatory tracking number is composed of the year received and a 3-digit running number e.g. 016 – 001 (2016 is the year protocol was received, 001 first protocol received from PFDA for that year).

2.5.4.4. Regulatory review is scheduled every last Wednesday of the month. However, additional review dates may be appointed depending on the number of protocols received from the PFDA.

2.5.4.5. SL-IERC Secretariat shall inform the SL-IERC Chair about the clinical trial protocol.

2.5.4.6. The SL-IERC Chair will appoint SL-IERC Members as reviewers in addition to the Members of the Subcommittee on Regulatory Review based on the Members' expertise. An External/Independent Consultant may be invited if needed.

2.5.4.7. The Subcommittee on Regulatory Review shall be composed of the following:

a. SL-IERC Chair
b. SL-IERC Member who is an expert in Pharmacology or Pharmacy
c. SL-IERC Member who is an expert in the disease (e.g. Pediatrician, Infectious Disease Specialist, Oncologist, etc.)
d. External/Independent Consultant, if necessary
e. Biostatistician/Epidemiologist

2.5.4.8. The SL-IERC Secretariat shall distribute the clinical trial protocol documents and PFDA Regulatory Review Assessment Form to the Members of the Subcommittee on Regulatory Review and the additional SL-IERC Member and/or External/Independent Consultant.

2.5.4.9. The SL-IERC Chair shall assign a Primary Reviewer among the Members of the Subcommittee on Regulatory Review. If needed, the SL-IERC Chair shall assign other Members of the SL-IERC to be the Primary Reviewer based on their expertise. If no Member of the Subcommittee on Regulatory Review or the other regular Members of the SL-IERC is an expert on the subject disease, an External/Independent Consultant may be assigned as the Primary Reviewer.

2.5.4.10. The Primary Reviewer shall present to the Subcommittee on Regulatory Review his/her assessment of the clinical trial protocol.

2.5.4.11. The Subcommittee on Regulatory Review Members will discuss and deliberate on the clinical trial protocol based on the assessment of the Primary Reviewer.

2.5.4.12. The decision of the Subcommittee on Regulatory Review shall be forwarded to the CTU of the PFDA within 60 calendar days upon receipt of the clinical trial protocol package.

2.5.4.13. If the CTU of PFDA submits a response from the Sponsor or CRO, the SL-IERC Chair may decide and answer the response. The SL-IERC Chair may also obtain the comments and opinion of the designated SL-IERC Members and External/Independent Consultant who reviewed the clinical trial protocol.

2.5.4.14. The decision of the SL-IERC Chair shall then be sent back to the CTU of the PFDA.

2.5.5. REFERENCES

2.5.5.1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

2.5.5.2. Food and Drug Administration. (2012). FDA Circular No. 2012-007 Recognition of Ethical review Board/Committee (ERB/ERC) for Purposes of the Conduct of Clinical Trials on Investigational Medicinal Products in the Philippines and Other Purposes. City of Muntinlupa: Department of Health Food and Drug Administration.

—Nothing Follows—

DOCUMENT HISTORY

REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	04-2016		1	Compliance with suggestions of PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2016
2	07-2018		2	Process improvement	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
3	08-2019		3	Compliance with suggestions of PHREB and FERCAP surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
4	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

2.6.1. PURPOSE

The purpose of this SOP is to describe the procedure for the rapid review of submitted protocols and protocol-related documents of clinical trials that involve pandemic diseases or disease outbreaks. Due to the urgency of finding efficacious treatments and vaccines to address health emergencies, the SL-IERC must be prepared, flexible, and organized to conduct a thorough, rapid, and efficient review of the clinical trial protocols.

2.6.2. SCOPE

This SOP covers the process from receipt of protocol, protocol-related documents, and other required documents, to determination of type of review, designation of reviewers, scheduling of virtual meetings, issuance of Notice of Action or Approval, issuance of Ethical Clearance, and management of clinical trial and related documents.

2.6.3. PROCEDURE

2.6.3.1. Receipt of clinical trial protocol related to pandemic diseases of disease outbreaks

2.6.3.1.1. The SL-IERC Secretariat receives the soft copy of the clinical trial protocol dossier from the Center for Clinical Trials.

2.6.3.1.2. Upon receipt of the clinical trial protocol dossier, the SL-IERC Secretariat logs the protocol submission using the Clinical Research Tracking Form. (*Refer to SOP# 3.1 Initial Protocol Submission)*

2.6.3.1.3. The SL-IERC Secretariat assigns an EC Reference Number to the protocol even if there are no valid GCP Certificates submitted. (*Refer to SOP# 3.1.4.2.2 for the EC Reference Number*).

2.6.3.1.4. The GCP certificates may be submitted to the SL-IERC Secretariat on or before the issuance of Ethical Clearance.

2.6.3.1.5. The SL-IERC Secretariat shall send the soft copy of the protocol dossier to the SL-IERC Chair within one to two (1-2) working days from receipt of the submission.

2.6.3.2. Classification of type of review

2.6.3.2.1. The clinical trial protocol shall undergo full board review.

2.6.3.2.2. The SL-IERC Chair may decide to have an expedited review of a clinical trial protocol if it is multi-center and has been submitted to the Department of Health's Single Joint Review Ethics Board (SJREB) for review and approval.

2.6.3.3. Designation of Reviewers

2.6.3.3.1. The SL-IERC Chair shall designate the following upon determining the type of review:

2.6.4.1.4.1. an SL-IERC Member to be the Primary Reviewer for the clinical research protocol. If there is none, the SL-IERC Chair shall appoint an External/Independent Consultant to be the Primary Reviewer. The Primary

2.6.4.1.4.2. Reviewer must have knowledge of the ethical aspects of research in emergency situations.

2.6.4.1.4.3. an SL-IERC Lay Person to review the Informed Consent Forms.

2.6.3.3.2. The designated Primary Reviewer, Lay Person and/or External/Independent Consultant must be available to carry out a rapid and thorough review of the protocol and the informed consent form(s), respectively.

2.6.3.3.3. The SL-IERC Secretariat shall send the soft copies of the clinical trial protocol dossier and Evaluation Forms (SL-IERC Forms # 05A and 05B) to the designated Reviewers within one to two (1-2) working days upon knowledge of the assignments.

2.6.3.4. Rapid review of clinical trial protocols

2.6.3.4.1. For expedited reviews:

2.6.4.4.1.1. The designated Reviewers shall conduct expedited review following SOP# 2.2 Expedited Review of Protocols.

2.6.4.4.1.2. A designated Reviewer shall attend the SJREB meeting physically or virtually to relay the comments and recommendations of the Reviewers.

2.6.4.4.1.2.1. In the event that the SL-IERC full board meeting and the SJREB meetings are scheduled on the same date and time, the SL-IERC shall send a copy of the comments and recommendations to the SJREB before the meeting.

2.6.4.4.1.3. All comments and recommendations of the designated Reviewers must be submitted electronically to the SL-IERC Secretariat within three to seven (3-7) working days upon receipt of the protocol submission.

2.6.4.4.1.4. The SL-IERC may accept the SJREB's decision as its own institutional IERC decision.

2.6.3.4.2. For full board reviews:

2.6.4.4.2.1. Schedule of full board meetings shall be determined by the SL-IERC Chair.

2.6.4.4.2.1.1. The full board meeting may be scheduled during the regular scheduled meetings of the SL-IERC, which is every second Wednesday of the month.

2.6.4.4.2.1.2. In the event that the review must be done within ten (10) days from submission as mandated by the sub-Technical Working Group for Vaccine Development of the Department of Science and Technology, the SL-IERC Chair shall schedule the meeting within five to seven (5-7) calendar days from receipt of submission.

2.6.4.4.1.1. Full board reviews shall be conducted according to SOP# 2.1 Full Board Review of Protocols.

2.6.4.4.1.1.1. Full board reviews may be conducted virtually to ensure the safety of the SL-IERC Members and Secretariat.

2.6.4.4.1.1.2. Virtual meeting shall be conducted using the platform approved by SLMC.

2.6.4.4.1.1.3. A quorum shall consist of one third of all SL-IERC members, including the designated Primary Reviewer and Lay Person.

2.6.4.4.1.1.4. If a designated Reviewer submits his/her review but is unable to join the meeting, he/she will be considered as part of the quorum requirement.

2.6.3.5. Notice of Action or Approval

2.6.3.5.1. Issuance of Notice of Action or Approval shall be in accordance with the following SOPs:
SOP 2.1 Full Board Review of Protocols
SOP 2.2 Expedited Review of Protocols
SOP 2.4 Review of Protocols that Require Revisions after Initial Review

2.6.3.6. Continuing reviews

2.6.3.6.1. The SL-IERC shall be responsible for site monitoring and review of progress reports, SAEs, SUSARs, protocol deviations and violations, and final report of onsite clinical trials. (*Refer to SOP # 4.1, 4.2, 4.3, and 4.5*)

2.6.3.7. Documentation

2.6.3.7.1. Upon approval of the clinical research protocol, the PI must submit soft copies of all pertinent documents that have been approved by the SL-IERC, including the GCP Certificates, CVs, and COIs.

2.6.3.7.2. The SL-IERC Secretariat shall stamp on the every page the words "IERC Approved" and the date of approval to the following documents: research protocol, informed consent forms, case report forms or data collection forms, patient materials, and other study related documents.

2.6.3.7.3. The SL-IERC Secretariat shall keep the soft copies of the documents in the clinical research protocol file.

2.6.3.7.4. The SL-IERC Secretariat shall keep all soft copies of the clinical research protocol dossier, GCP Certificates, CVs, COIs, communications, minutes of meetings, accomplished evaluations forms and other related documents in the clinical research protocol folder in the Google Drive cloud.

2.6.4. REFERENCES:

2.6.4.1. Philippine Health Research Ethics Board. (2020) PHREB Resolution on the Review of Research Proposals on COVID-19. PHREB Resolution No. 20-001, Series of 2020, April 13, 2020.

2.6.4.2. Philippine Health Research Ethics Board. (2020) PHREB Resolution on the Timelines of Approval for COVID-19 Clinical Trial Proposal. PHREB Resolution No. 20-002, Series of 2020, October 15, 2020.

2.6.4.3. World Health Organization. (2020) Guidance for Research Ethics Committees for Rapid Review of COVID-19 Research. World Health Organization.

2.6.4.4. Pan American Health Organization. (2020) Template and operational guidance for the ethics review and oversight of COVID-19-related research, April 15, 2020.

2.6.4.5. World Health Organization. (2016) Guidance for Managing Ethical Issues in Infectious Disease Outbreaks.

—Nothing Follows—

DOCUMENT HISTORY

REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
				New SOP as recommended by PHREB			
1	06-2022		1	Replaced hard copies to soft copies of documents	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

SOP 3. SOPs on Management of Initial Submissions

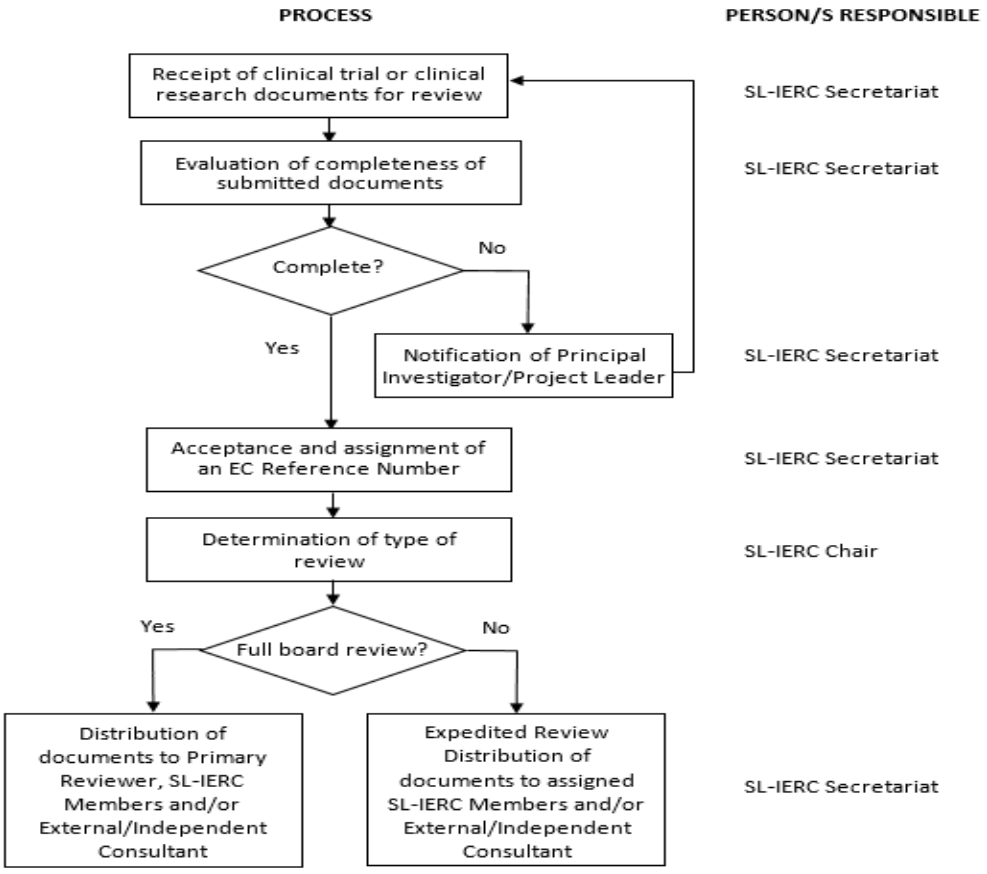
3.1.1 PURPOSE

The purpose of this SOP is to ensure a standard process in managing submissions of clinical research protocols for review and approval of the SL-IERC.

3.1.2 SCOPE

This SOP covers the process from receipt of the clinical research protocol documents to evaluation of completeness of submitted documents, assignment of EC Reference Number, determination of type of review, and distribution of the protocol documents to SL-IERC Members designated to review the documents.

3.1.3 FLOW CHART



3.1.4 PROCEDURE

3.1.4.1. Receipt of documents for review

3.1.4.1.1. The SL-IERC Secretariat shall receive the complete protocol dossier at the SL-IERC Office from the Center for Clinical Trials (CCT) for sponsor-initiated clinical trials and clinical research studies and from the Institutional Scientific Review Committee (ISRC) for investigator-initiated clinical research studies. The protocol dossier includes the following:

3.1.4.1.1.1. **For investigator-initiated research studies (IiT) or Administrative or Operational Research studies:**

- Endorsement from the Institutional Scientific Review Committee (ISRC)
- Letter of Intent addressed to the SL-IERC Chair
- Initial Submission Form for Clinical Research *(SL-IERC Form # 02)*
- Soft copy of the Protocol which include the following attachments (if applicable):
  - Informed Consent Forms (English and Filipino and/or pertinent Philippine language, e.g. Cebuano, Ilonggo, Chabacano, Ilocano, etc.)
  - Data collection forms
  - Questionnaires (English and Filipino and/or pertinent Philippine language, e.g. Cebuano, Ilonggo, Chabacano, Ilocano, etc.)
  - Other related study materials (e.g. Advertisement)
- Curriculum Vitae (CV) of the proponent and study team members
- Valid GCP certificates of the proponent and study team members, preferably taken locally in a face-to-face training course
- Signed Conflict of Interest Disclosure Form by all the Study Team members *(SL-IERC Form # 01C)*

3.1.4.1.1.2. **For sponsor-initiated clinical research studies (SiT):**

- Letter of intent addressed to SL-IERC Chair
- Initial Submission Form for Clinical Research (*SL-IERC Form # 02*)
- Soft copy of the Protocol with the following attachments (if applicable):
  - Informed Consent Forms (English and Filipino and/or pertinent Philippine language, e.g. Cebuano, Ilonggo, Chabacano, Ilocano, etc.)
  - Case Report Forms
  - Investigator's Brochure
  - Subject Worksheets/Patient Diary/Alert Cards (English and Filipino and/or pertinent Philippine language, e.g. Cebuano, Ilonggo, Chabacano, Ilocano, etc.)

- Questionnaires (English and Filipino and/or pertinent Philippine language, e.g. Cebuano, Ilonggo, Chabacano, Ilocano, etc.)
- Philippine Food and Drug Administration Approval
- Certificate of Product Registration in the Philippines for Post Marketing Surveillance Studies (PMSS)
- Insurance Policy
- Other related study materials (e.g. Advertisement)
- List of the Study team members and their duties and responsibilities
- Curriculum Vitae (CV) of Investigators and study team members
- GCP Certificates of Investigators and study team members, preferably taken locally in a face-to-face training course
- Signed Conflict of Interest Disclosure Form by all the Study Team members *(SL-IERC Form # 01C)*
- Sponsor or CRO License to Operate

3.1.4.1.2. The SL-IERC Secretariat logs the protocol submission using the Clinical Research Tracking Form. *(SL-IERC Form # 04)*

3.1.4.2. Evaluation of completeness of the dossier based on the Initial Protocol Review Acknowledgement Form from ISRC and CCT *(SL-IERC Form # 03).*

3.1.4.2.1. If the dossier is incomplete, the SL-IERC Secretariat shall not accept the submission.

- For protocols only awaiting approval from the PFDA, the SL-IERC can conduct a parallel review; however, the issuance of Ethical Clearance shall be withheld until completion of said requirement.

3.1.4.2.2. If the dossier is complete, the SL-IERC Secretariat assigns an EC Reference Number to the protocol. EC Reference Number is composed of the letters, **S L**, last 2 digits of the year; running number starting with 1 (e.g. **SL 11 001**) **SL** is for St. Luke's, **11** is for 2011; **001** is first protocol received for the year.

3.1.4.3. Determination if in the submitted protocol is research and if it involves human participants

3.1.4.3.1. The SL-IERC Secretariat shall inform the SL-IERC Chair of the receipt of a new protocol.

3.1.4.3.2. The SL-IERC Chair shall determine whether the activity in the submitted protocol involves research. The activity is research if any of the following criteria is met:

3.1.4.3.2.1. the activity in the submitted protocol is a systematic investigation (including research development, testing and evaluation) *[DHHS Definition of Research]*

3.1.4.3.2.2. the activity in the submitted protocol is designed to develop or contribute to generalizable knowledge *[DHHS Definition of Research]*

3.1.4.3.2.3. the activity in the submitted protocol is an experiment that involves a test article and one or more human subjects that requires prior submission or

for which the results are intended to be submitted later to or held for inspection by the FDA as part of an application for a research or marketing permit. *[FDA Definition of Clinical Investigation]*

3.1.4.3.3. If the activity in the submitted protocol is research, the SL-IERC Chair shall determine whether the research involves human participants. The research involves human participants if any of the following criteria is met:

3.1.4.3.3.1. data being obtained is about one or more living individuals *[DHHS Definition of Human Subject]*

3.1.4.3.3.2. data collected is through an intervention (physical procedures by which data are gathered or manipulations of the subject or the subject's environment that are performed for research purposes) or interaction (communication or interpersonal contact between investigator and subject) with the individual [DHHS Definition of Human Subject]

3.1.4.3.3.3. identifiable private information is being obtained. Private identifiable information includes behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public, e.g. medical record. [DHHS Definition of Human Subject]

Note: Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

3.1.4.3.3.4. the project involves an individual (either a healthy human or a patient) who is or becomes a participant in research, either as a recipient of the test article or as a control [*FDA Definition of Human Subject*]

3.1.4.3.3.5. the project involves an individual (in normal health or with a medical condition or disease) who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control [*DHHS Definition of Human Subject]*

3.1.4.4. Classification of type of review

3.1.4.4.1. After it has been determined that the research involves human participants, the SL-IERC Chair shall determine if the protocol is for full board review or for expedited review. All research protocols involving human participation will go full board review unless they qualify for an expedited review. Expedited review shall be done if *(Refer to SOP 2.2 Section 2.2.4.1.; SOP 3.3 Section 3.3.4.2.4.3.)*

3.1.4.4.1.1. the research entails only a minimal risk to the human participants and to the community

3.1.4.4.1.2. study participants do not belong to a vulnerable group

3.1.4.4.1.3. the research is retrospective in data collection methodology.

3.1.5 REFERENCES

3.1.5.1 Office of Human Research Protections. (2016). Code of Federal Regulations Title 45, Part 46, Section 46.102 Definitions for the Purposes of this Policy. U.S. Department of Health & Human Services.

3.1.5.2 US Food and Drug Administration (FDA). (2018). Code of Federal Regulations Title 21, Part 56, Section 56.102 Definitions. U.S. Food and Drug Administration.

—Nothing Follows—

DOCUMENT HISTORY

REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

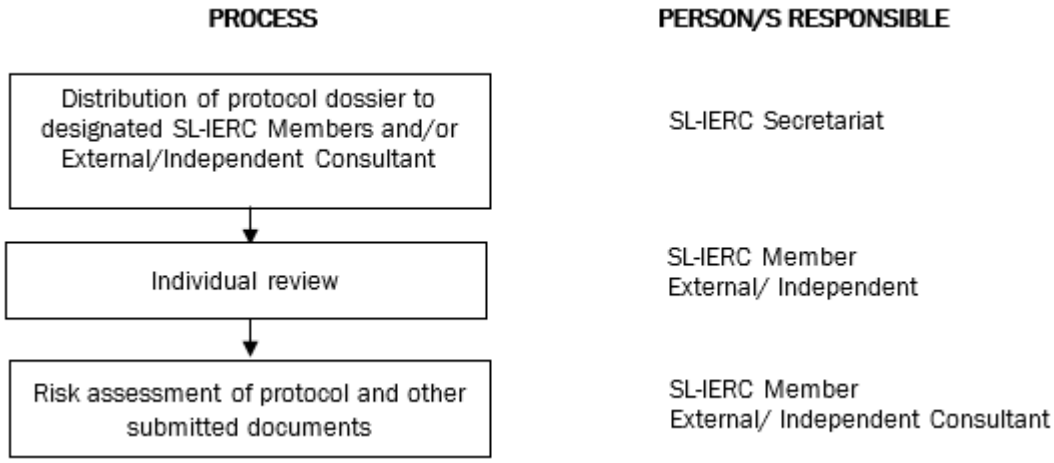
3.2.1. PURPOSE

The purpose of this SOP is to establish a documented procedure for the preliminary ethical review of clinical research protocols by designated SL-IERC Members and/or External/Independent Consultant prior to their presentation to a full board SL-IERC meeting.

3.2.2. SCOPE

This SOP covers the process from distribution of protocol dossier to each designated SL-IERC Member and/or External/Independent Consultant to risk assessment of the protocol.

3.2.3. FLOW CHART



3.2.4. PROCEDURE

3.2.4.1. The SL-IERC Secretariat shall provide designated SL-IERC Members, two (2) weeks prior to the scheduled regular or special meeting, a copy of all clinical research protocols for review.

3.2.4.2. Each designated SL-IERC Member shall make his/her own individual review by using the Ethics Review Forms *(SL-IERC Forms # 05A, 05B).* The External/Independent Consultant shall evaluate the protocol using Ethics Review Form for External/Independent Consultant (*SL-IERC Form # 06*).

3.2.4.3. In the review of the clinical research protocols, the designated SL-IERC Member and/or External/Independent Consultant shall

3.2.4.3.1. Evaluate and give comments on the technical aspects of the protocol

3.2.4.3.2. Evaluate the Informed Consent Form (ICF)

3.2.4.3.3. Comment on the Assent Form if the protocol includes children as participants

3.2.4.3.4. Make a risk assessment by checking the appropriate box as follows:

3.2.4.3.4.1. **High Risk** - if study can lead to an unexpected/unplanned loss of life, or permanent impairment of quality of life, or may lead to serious legal action against Principal Investigators and/or institution.
The study risk is greater than a moderate risk study due to the increased probability for generating serious adverse events. There is a high probability of an event that is serious and prolonged or permanent occurring as a result of study participation.

3.2.4.3.4.2. **Moderate Risk -** Risks are recognized as being greater than minimal, but are not considered high. There is a medium to high probability of a moderate-severity event occurring as a result of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there is adequate surveillance and protections to identify adverse events promptly and to minimize their effects.

3.2.4.3.4.3. **Minimal risk -** if the consequences can be dealt with by routine operations; the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102)

3.2.4.3.5. Give his/her final recommendations on the protocol and ICF.

3.2.5. REFERENCES

3.2.5.1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

3.2.5.2. Office of Human Research Protections. (2016). Code of Federal Regulations Title 45, Part 46, Section 46.102 Definitions for the Purposes of this Policy. U.S. Department of Health & Human Services.

3.2.5.3. Philippine Health Research Ethics Board. (2017). National Ethical Guidelines for Health and Health Related Research. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

—Nothings Follows—

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Preliminary Review by SL-IERC Members Prior to Protocol Presentation	SL-IERC SOP No.: SOP # 3.2

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
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4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
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6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022
SOP Title: Continuing Review (Progress/Final/Termination Report)	SL-IERC SOP No.: SOP # 4.1

SOP 4. SOPs on Continuing Review and Monitoring of Protocols

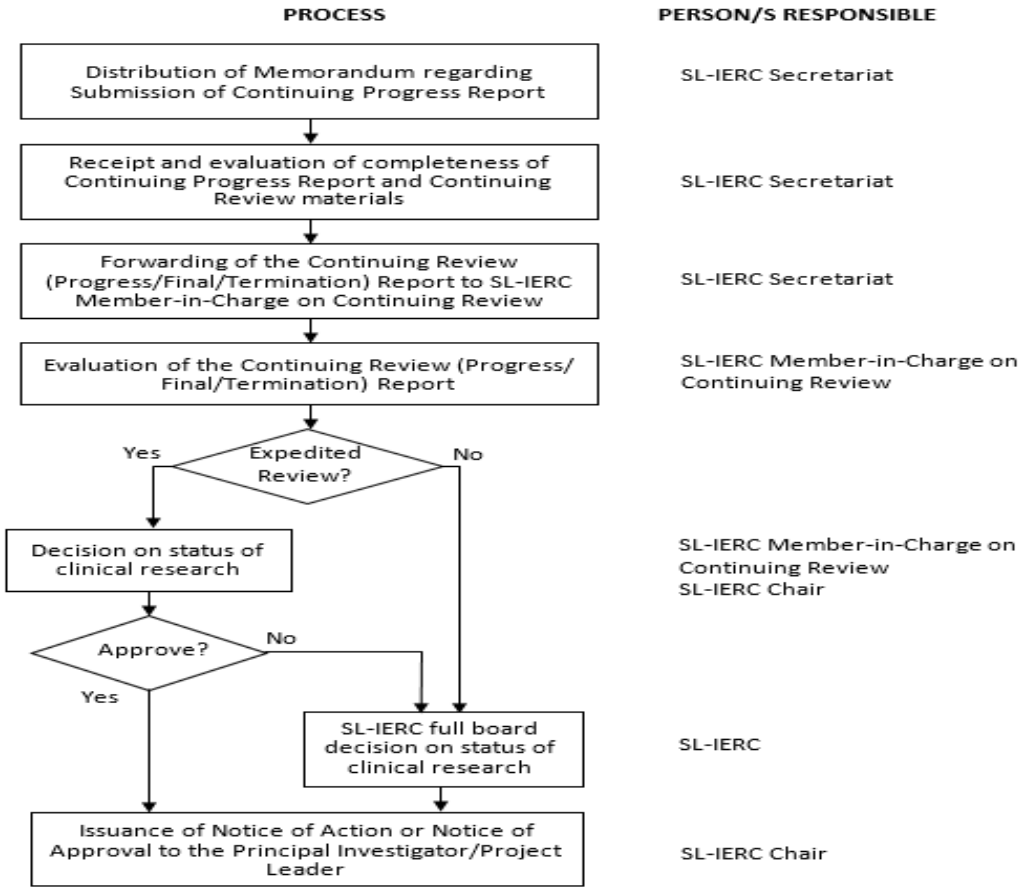
4.1.1. PURPOSE

The purpose of this SOP is to promote and ensure the continued ethical acceptability of an approved clinical research. This SOP describes the process of regular continuing review of Progress Report, Final Report, and Termination Report of previously approved clinical research protocol for assessing possible change in risk-benefit ratio.

4.1.2. SCOPE

This SOP covers the process from distribution of Memorandum regarding submission of Continuing Progress Report to receipt of submitted report, evaluation of the report, and issuance of Notice of Action or Approval to the Principal Investigator/Project Leader.

4.1.3. FLOWCHART



4.1.4. PROCEDURE

4.1.4.1. The following terms shall be defined and used in this SOP

4.1.4.1.1. Continuing Review is a process wherein the SL-IERC shall monitor and continuously review a protocol that it has approved during the life of the trial or research. This is to ensure the continued ethical acceptability of the trial. The Committee has the authority to determine the level of risks of a trial and frequency of reporting based on the level of risks.

4.1.4.1.2. Level of Risks:

- **High Risk** - if the study can lead to an unexpected/unplanned loss of life, or permanent impairment of quality of life, or may lead to serious legal action against Principal Investigator/Project Leader s and/or institution
  The study risk is greater than moderate due to the increased probability for generating serious adverse events. There is a high probability with occurrence of an event that is serious and prolonged or permanent occurring as a result of study participation
- **Moderate Risk** - Risks are recognized as being greater than minimal, but are not considered high. There is a medium to high probability of a moderate-severity event occurring as a result of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there is adequate surveillance and protections to identify adverse events promptly and to minimize their effects.
- **Minimal risk** - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102)

4.1.4.1.3. Frequency of reporting based on the Level of Risks.

- **Low/Minimal Risk – Annually. Counting from the approval date.** Reporting date is 12 months from the approval date.
- **Moderate/Medium Risk – Semi-annually. Counting from the approval date.** Reporting date is six (6) months from approval date.
- **High Risk – Quarterly. Counting from the approval date/Number of Subjects enrolled.** Reporting date is three (3) months from approval date or when a recommended number of subjects have been enrolled.
  e.g. At the *time of initial review and approval of a high-risk trial, the SL-IERC may require the PI to submit a progress report after* three (3) *months or after enrolling a certain number of subjects whichever comes first.*

4.1.4.2. Preparation of Memorandum to the Principal Investigator/Project Leader.

4.1.4.2.1. The SL-IERC Secretariat shall prepare and send a memorandum to the Principal Investigator/Project Leader reminding him to submit a progress report of his on-going clinical research for the purpose of a continuing review. *(SL-IERC Template # 15)*

4.1.4.2.2. The SL-IERC Secretariat shall send the memorandum to the Principal Investigator/Project Leader two (2) months prior to the designated reporting date. The Principal Investigator/Project Leader shall submit the progress report a month before the designated reporting date.

4.1.4.2.3. The designation of the date for the initial continuing review shall be based on the initial date when the SL-IERC issued the Ethical Clearance.

4.1.4.2.3.1. Protocols approved by full board review

a) When the SL-IERC approves a clinical research without requiring changes to protocol or informed consent the effective date of the initial approval is the date of that full board meeting.

b) When the SL-IERC requires revisions, clarifications in the protocol or informed consent, or submission of additional documents, the SL-IERC Chair or Member-in-Charge on Continuing Review is directed to accept, review and approve the submitted materials. If found satisfactory, the initial approval date is the date when the Chair or designated member approved the submitted materials.

4.1.4.2.3.2. Protocols approved by expedited review shall be designated to have an initial continuing review date one year after the SL-IERC Chair and designated IERC Reviewers had approved the clinical research protocol.

4.1.4.2.3.3. The schedule of subsequent Continuing Review dates shall depend on the assessment of the immediate previous progress report.

a) If the immediate progress report is found satisfactory in terms of conduct and safety, the subsequent effective review date shall be one (1) year after the SL-IERC issued the Ethical Clearance.

b) If the immediate progress report is found with unwarranted violations, undue risks and/or unresolved safety problems, the SL-IERC may declare an earlier continuing review date and more frequent progress reports.

c) In a full board review of a progress report, the date of the convened SL-IERC meeting which conducted a continuing review and approved the continuation of the study (with or without conditions) determines the latest permissible date of the next continuing review.

d) In an expedited review of a progress report, the date when the SL-IERC Chair and/or Member-in-Charge on Continuing Review approved the continuation of the study shall be the permissible date of the next continuing review.

4.1.4.3. Receipt and Evaluation for Completeness of Continuing Review Materials

4.1.4.3.1. The SL-IERC Secretariat shall receive the Continuing Review/Progress Report materials and evaluate it for completeness before forwarding all materials to SL-IERC Member-in-Charge of Continuing Review and/or SL-IERC Chair.

4.1.4.3.2. The Continuing Review/Progress Report materials are the following:

4.1.4.3.2.1. Progress report that includes the following: *(refer to SL-IERC Form # 16)*

a) List of the study team including the Principal Investigator/Project Leader with their corresponding responsibilities

b) Details of the Study
- Title of Study
- EC Reference Number
- Date of Ethical Clearance
- Sponsor/CRO

c) Commencement and Termination Dates
- What was the expected start date? Did it start on time?
- Is the study finished? If not, what is the expected completion date?
- If you do not expect the study to be completed per schedule, give reasons.

d) Participants
- Number of subjects accrued as proposed in original application. (If multi-center also report number accrued study-wide).
- Number of participants who completed the trial
- Number of withdrawals from trial to date, due to
  i. Withdrawal of consent
  ii. Loss to follow-up
  iii. Death
- Number of treatment failures to date due to
  i. Adverse events
  ii. Lack of efficacy

e) Statement if there have been any serious difficulties in recruiting participants. If yes, give details. Indicate if there are plans to increase number of recruitment into the study.

4.1.4.3.2.2. Safety Reports - A summary of any unexpected serious adverse events, any unanticipated problems and available information regarding adverse events. (Indicate if the adverse events that have occurred are of the expected frequency and level of severity as indicated in the

research protocol, the informed consent document and the Investigators Brochure.)

4.1.4.3.2.3. Amendments - A brief summary of the amendments to the research protocol and informed consent approved by the SL-IERC since the initial review or the last continuing review.

4.1.4.3.2.4. New Information - Any new and relevant information, published or unpublished since the last SL-IERC review.

4.1.4.3.2.5. Violations/Deviations - Any violations/deviations of the protocol and breaches of Good Clinical Practice during the past year.

4.1.4.3.2.6. The latest version of the SL-IERC-approved protocol and Informed Consent documents

4.1.4.3.2.7. Proposed modifications to the informed consent document or protocol

4.1.4.3.2.8. Current Investigator Brochure, if available including any modifications

4.1.4.4. Evaluation and Report of the SL-IERC Member-in-Charge on Continuing Review

4.1.4.4.1. The SL-IERC Member-in-Charge on Continuing Review or SL-IERC Chair shall evaluate all the submitted documents and compose a summary of its findings. It can decide to approve the progress report through an expedited process or submit its findings and recommendation for full board review. *(Refer to Sec. 4.1.4.6 and 4.1.4.7)*

4.1.4.4.2. The Summary of the continuing review findings should include:

4.1.4.4.2.1. Any critical issues for consideration by the SL-IERC

4.1.4.4.2.2. Any key changes being proposed by the Investigator

4.1.4.4.2.3. The rate of subject enrolment as expected or otherwise

4.1.4.4.2.4. Adverse events their type and frequency, whether expected or otherwise

4.1.4.4.2.5. Complaints of subjects about the conduct of research, if any, which resulted in withdrawal of subject.

4.1.4.4.2.6. Whether the clinical research has satisfied the criteria required for approval under 45 CFR 46.111.

a) Risks to subject are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever, appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

b) Risks to subject are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result.

c) Selection of subject is equitable.

d) Informed consent are sought from each subject or the subject's legally authorized representative, and appropriately documented.

e) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
f) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
g) Appropriate safeguards are included to protect subjects likely to be vulnerable to coercion or undue influence.

4.1.4.5. Expedited Review

4.1.4.5.1. Only clinical research studies initially approved thru expedited review may be reviewed under the Expedited Continuing Review.

4.1.4.5.2. An expedited review procedure may be used for the continuing review of clinical research previously approved by the SL-IERC at a full board meeting on the following conditions:

4.1.4.5.2.1. The clinical research previously approved by full board progresses to the stage where all of the remaining human subjects research activities involve no more than minimal risk to the subjects and fall within the scope mentioned in the Expedited Review SOP

4.1.4.5.2.2. Where the clinical research is (i) permanently closed to the enrolment 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

4.1.4.5.2.3. Where no subjects have been enrolled and no additional risks have been identified

4.1.4.5.2.4. Where the remaining clinical research activities are limited to data analysis.

* "Long-term follow-up" includes:

a) Research interactions that involve no more than minimal risk to subjects (e.g. quality of life surveys)
b) Collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol.

4.1.4.5.3. The SL-IERC Member-in-Charge or SL-IERC Chair shall report to the convened SL-IERC all actions taken on the clinical research and its progress report that have been reviewed under the expedited procedure.

4.1.4.6. Full Board Review

4.1.4.6.1. The Continuing review of a clinical research initially reviewed during a full board SL-IERC meeting shall also be reviewed by the SL-IERC as such.

4.1.4.6.2. The SL-IERC Member-in-Charge on Continuing Review shall present to the full board, progress report of the research, summary of the findings and recommendations of the sub-committee.

4.1.4.6.3. The full board SL-IERC shall deliberate and vote on the actions to be taken based on the findings and recommendations of the sub-committee, i.e.:

- Approval
- Suspension
- Termination

4.1.4.7. Notice of Action/Renewal of Ethical Clearance

4.1.4.7.1. The SL-IERC Secretariat shall prepare and send a Notice of Action (*SL-IERC Template # 08*) if there are queries or Renewal of Ethical Clearance (*SL-IERC Template # 13B*) if approved signed by the SL-IERC Chair to the concerned Principal Investigator/Project Leader.

4.1.4.7.2. The SL-IERC Secretariat shall include in the minutes of the SL-IERC meeting details on the deliberations and actions of the Committee.

4.1.4.8. Final Report/Termination Report

4.1.4.8.1. Upon termination of a clinical research, the Principal Investigator/Project Leader shall submit a final report within one (1) year of the clinical research termination (*SL-IERC Form # 17*). The final report shall include:

- information on whether the study achieved its objectives
- the main findings
- arrangement of publication or dissemination of the clinical research including any feedback to clinical research participants

4.1.4.8.2. The SL-IERC Member-Secretary shall review the final/termination report submitted by the Principal Investigator/Project Leader within two (2) weeks of receipt for compliance with approved protocol.

4.1.5. REFERENCES:

4.1.5.1. Cash R, Wikler D, Saxena A, Capron A, eds. (2009). Casebook on Ethical Issues in International Research. Geneva: World Health Organization.

4.1.5.2. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

4.1.5.3. Office of Human Research Protections. (2016). Code of Federal Regulations Title 45, Part 46, Section 46.102 Definitions for the Purposes of this Policy. U.S. Department of Health & Human Services.

4.1.5.4. Office of Human Research Protections. (2016). Code of Federal Regulations Title 45, Part 46, Section 46.111 Criteria for Approval of Research. U.S. Department of Health & Human Services.

4.1.5.5. Philippine Health Research Ethics Board. (2017) National Ethical Guidelines for Health and Health Related Research. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

4.1.5.6. World Health Organization. (2000). Operational Guidelines for Ethics Committees that Review Biomedical Research. Geneva: World Health Organization.

4.1.5.7. World Health Organization International Agency for Research. (2017). IARC Ethics Committee (IEC) Standard Operating Procedures (SOPs). Lyon: World Health Organization International Agency for Research.

—Nothing Follows—

DOCUMENT HISTORY

REVIEW NO.	REVIEW DATE	REVISION NONE	REVISION NO.	REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

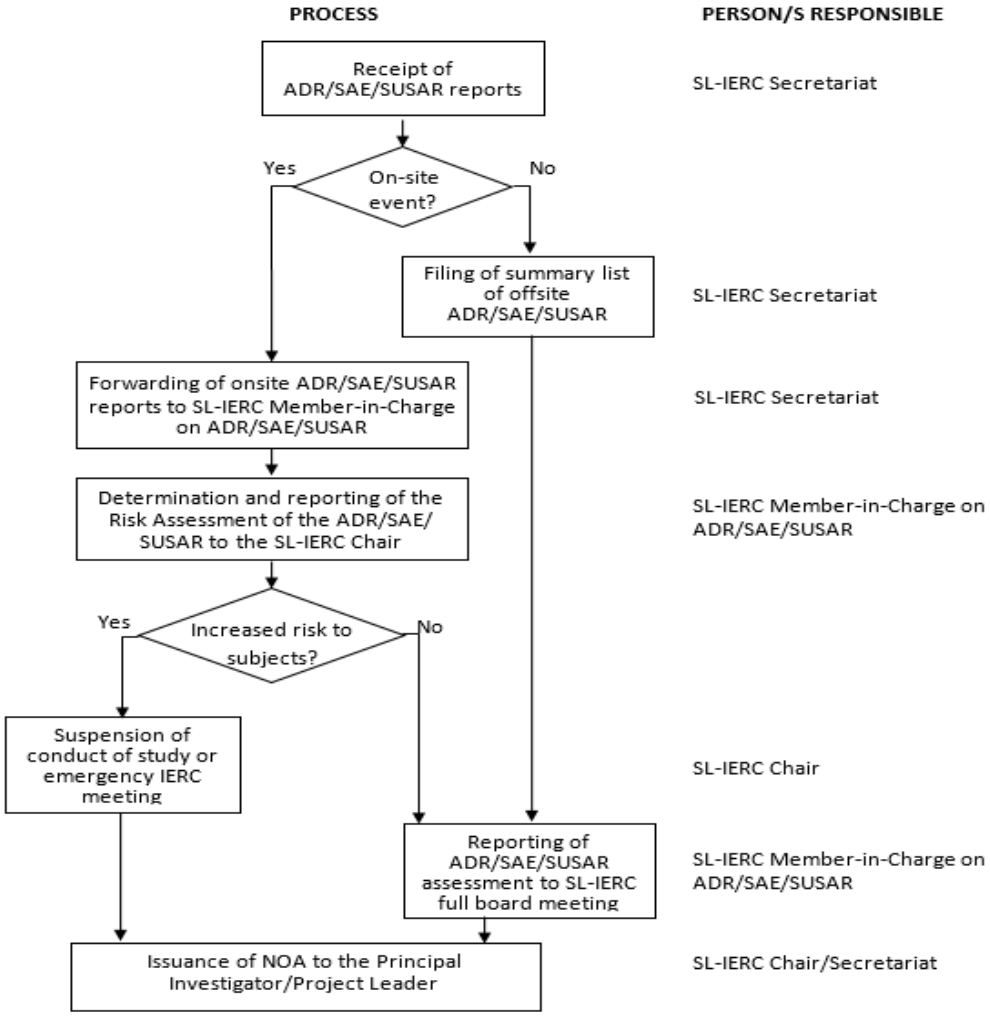
4.2.1. PURPOSE

The purpose of this SOP is to describe the process handling and monitoring safety reports which include adverse drug reactions (ADRs), serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARS) that affect the health, welfare and safety of human participants.

4.2.2. SCOPE

This SOP covers the process from receipt of safety reports of ADRs, SAEs and SUSARS to handling and assessment of reports until issuance of Notice of Action to Principal Investigator/Project Leader.

4.2.3. FLOWCHART



4.2.4. PROCEDURE

4.2.4.1. The following terms shall be defined and used in this SOP:

4.2.4.1.1. **Adverse Events (AE)**

- Any untoward or unfavorable medical occurrence in a human subject including any abnormal sign (e.g. abnormal physical exam or laboratory finding) symptom or disease, temporarily associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 ICH-GCP E-6)
- Encompass both physical and psychological harms occurring commonly in biomedical research but occasionally can occur in social and behavioral research.

4.2.4.1.1.1. Types of adverse events reported in an institution

a) Internal adverse events – adverse events experienced by subjects enrolled in a particular clinical trial in this institution (St. Luke's Medical Center Quezon City or Global City)
b) External adverse events – adverse events experienced by subjects in other institutions/medical centers enrolled in same clinical trial as conducted in this institution

4.2.4.1.2. **SAE (Serious Adverse Event/Serious Drug Experiences)** as defined under 21 CFR 312.32

4.2.4.1.2.1. An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

a) Death
b) Life-threatening drug experience
c) In-patient hospitalization or prolongation of existing hospitalization
d) Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
e) Congenital anomaly/birth defect

4.2.4.1.2.2. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

4.2.4.1.3. **SUSAR (Suspected Unexpected Serious Adverse Reaction):** Any adverse drug experience the specificity or severity of which is not consistent with the current Investigator Brochure or with the risk information described in the general investigational plan or elsewhere in the current application. "Unexpected" as used in this definition refers to an

adverse drug experience that has not been previously observed or from the perspective of the pharmacological properties of the test product is not anticipated.

4.2.4.1.4. **Adverse Drug Reaction (ADR)** can be considered unexpected or unanticipated based on the following criteria:

a) Unexpected since nature of event, severity, or frequency is not consistent with either:
   - Known or foreseeable risks of adverse events described in the SL-IERC approved protocol and informed-consent document, Investigator Brochure and other relevant sources of information such as product labelling and package inserts.
   - Expected natural progression of any underlying disease, disorder or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

b) Definitely related or possibly related to participation in the research. Possibly related means there is a reasonable probability that the incident, experience or outcome may have been caused by the procedures involved in the research.

c) Incident or outcome of the research places subjects or others at a greater risk of harm (i.e. physical, psychological, economic or social harm that was previously known or recognized

4.2.4.2. Submission of Internal or Onsite ADR/SAE/SUSAR using ADR/SAE/SUSAR Report Form *(SL-IERC Form # 14)*

4.2.4.2.1. Principal Investigators/Project Leaders shall follow guidelines on submission of ADR/SAE/SUSAR reports in accordance with R&B Policy on Monitoring of Clinical Safety of Investigational Drugs.

4.2.4.2.1.1. Reports of the Principal Investigators/Project Leaders should include the following:

a) Appropriate identifying information for the clinical trial/research protocol, such as the title, Principal Investigator's/Project Leader's name and EC Reference Number (**ST-** followed by last two digits of the year followed by 3 digits sequential number)

b) Detailed description of the adverse event, incident, experience or outcome

c) Explanation of the basis for determining that the adverse event, incident, experience or outcome represents an unexpected problem.

d) Description of any changes to the protocol or other corrective actions that have been taken or proposed in response to the unanticipated problem.

4.2.4.2.1.2. Time frame in reporting adverse events to the SL-IERC

a) Unexpected problems that are serious adverse events should be reported to the SL-IERC within one (1) week (7 calendar days) of the PI becoming aware of the event

b) Any other unexpected problem should be reported to the SL-IERC with two (2) weeks (15 calendar days) of the Principal Investigator/Project Leader becoming aware of the problem.

4.2.4.2.2. The SL-IERC Secretariat shall receive, acknowledge and date the ADR/SAE/SUSAR report.

4.2.4.2.2.1. The SL-IERC Secretariat shall log the ADR/SAE/SUSAR report in a Logbook for SAEs and file the SAE report in each study binder.

4.2.4.2.2.2. The SAE report shall indicate if the event is:

a) Unrelated to Study

b) Unlikely related to Study

c) Possibly related to Study

d) Definitely related to Study

4.2.4.2.3. Upon receipt of an ADR/SAE/SUSAR report, the SL-IERC Secretariat shall forward a copy of the report to the SL-IERC Member-in-Charge on ADR/SAE/SUSAR for immediate action, to the SLMC Pharmacy Therapeutics Committee (PTC), and to the SLMC Head of Medical Practice Group within 24 hours or next working day upon receipt of the report. A line listing or summary of the reports of ADRs, SAEs and SUSARs shall be submitted to the Quality and Patient Safety Group on a quarterly basis.

4.2.4.2.4. The SL-IERC shall keep all records of the ADRs/SAEs/SUSARs on file.

4.2.4.3. Submission of External or Offsite SAE/SUSAR (quarterly submission)

4.2.4.3.1. The Principal Investigator/Project Leader shall submit external or offsite ADRs/SAEs/SUSARs quarterly.

4.2.4.3.2. The SL-IERC Secretariat shall file a summary list of the ADRs/SAEs/SUSARs.

4.2.4.3.3. The SL-IERC Member-in-Charge on ADR/SAE/SUSAR shall report every quarter a summary list of the ADRs/SAEs/SUSARs received to the SL-IERC full board meeting.

4.2.4.3.4. The SL-I.ERC shall make a decision by voting to adopt measures as mentioned in Section 4.2.4.2.3.1.

4.2.4.4. Evaluation and Report of the SL-IERC Member-in-Charge on ADR/SAE/SUSAR

4.2.4.4.1. The SL-IERC Member-in-Charge on ADR/SAE/SUSAR shall evaluate submitted ADRs/SAEs/SUSARs in terms of risk to the human subject participant.

4.2.4.4.1.1. If ADR/SAE/SUSAR received needs immediate action as it exposes the human subject participant to risk of further harm, the SL-IERC Member-in-Charge on ADR/SAE/SUSAR will report to the SL-IERC Chair. The SL-IERC Chair may temporarily suspend the clinical research or call for an emergency meeting of the full board SL-IERC if there is an urgent need to

make a decision. The following are other measures that can be undertaken to prevent further harm to subjects:

a) Changes to the research protocol as initiated by the Principal Investigator/Project Leader prior to submission of report to the SL-IERC to eliminate apparent immediate hazards to subjects.
b) Modification of inclusion or exclusion criteria to mitigate the newly identified risks
c) Implementation of additional procedures for monitoring subjects.
d) Suspension of enrolment of new subjects
e) Suspension of research procedures in currently enrolled subjects
f) Modification of informed consent documents to include a description of newly recognized risks
g) Provision of additional information about newly recognized risks to previously enrolled subjects

4.2.4.4.1.2. If the SL-IERC Member-in-Charge on ADR/SAE/SUSAR deems that no immediate action is required, he/she shall discuss the report with the SL-IERC Chair for expedited review and inform the Committee of the recommendations during full board meeting.

4.2.4.5. Notification of SL-IERC Action

4.2.4.5.1. If the decision of the SL-IERC is any of the measures mentioned in Section 4.2.4.2.3.2, the SL-IERC Secretariat shall prepare a Notice of Action (*SL-IERC Template # 08)* to the Principal Investigator/Project Leader.
4.2.4.5.2. The Secretariat shall ask the SL-IERC Chair to sign the NOA.
4.2.4.5.3. The SL-IERC Secretariat inform the Principal Investigator/Project Leader of the NOA.
4.2.4.5.4. The Principal Investigator/Project Leader shall acknowledge receipt of the NOA.
4.2.4.5.5. The SL-IERC Secretariat shall file the report and copy of the NOA in the appropriate clinical research binder and SAE binder.

4.2.5. REFERENCES:

4.2.5.1. Association for the Accreditation of Human Research Protection Programs, Inc. (2018). Evaluation Instrument for Accreditation. Washington, DC: Association for the Accreditation of Human Research Protection Programs, Inc.

4.2.5.2. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

4.2.5.3. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (1994). ICH Harmonised Tripartite Guideline Clinical Safety Data Management: Definitions and Standards for Expedited Reporting E2a. Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

4.2.5.4. Office of Human Research Protections. (2018). Code of Federal Regulations Title 21, Part 312, Section 312.32. U.S. Department of Health & Human Services.

4.2.5.5. Philippine Health Research Ethics Board. (2017) National Ethical Guidelines for Health and Health Related Research. Manila: Department of Science and Technology – Philippine Council for Health Research and Development.

4.2.5.6. World Medical Association. (2013). Declaration of Helsinki – Ethical Principles For Medical Research Involving Human Subjects. Journal of the American Medical Association (Special Communication).

—Nothing Follows—

DOCUMENT HISTORY

REVIEW NO.	REVIEW DATE	REVISION NONE	REVISION NO.	REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
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5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Reporting and Handling of Protocol Deviations and Violations	SL-IERC SOP No.: SOP # 4.3

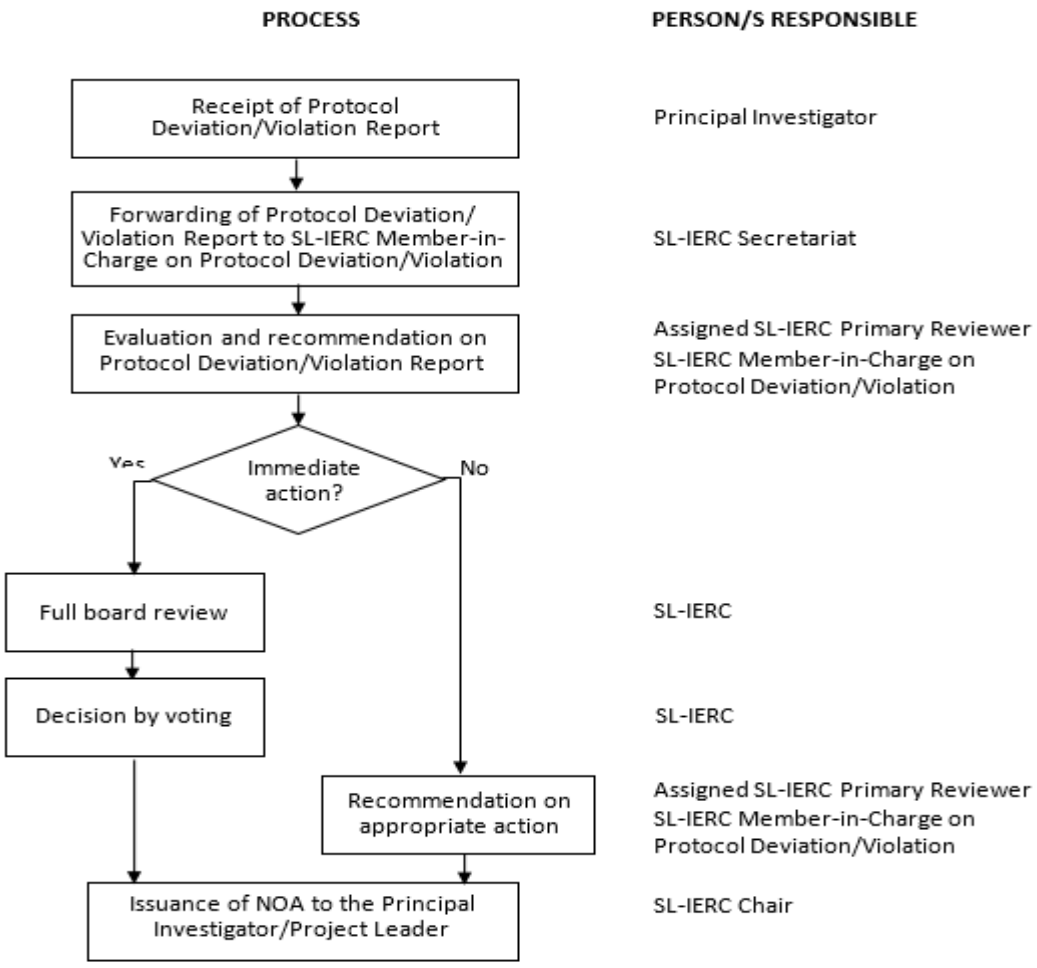
4.3.1. PURPOSE

The purpose of this SOP is to describe the process for handling reports of protocol deviations or violations to the SL-IERC and the appropriate actions to be taken by the Committee to minimize risks to human research participants.

4.3.2. SCOPE

This SOP covers the process from receipt of reports of protocol deviation or violation to evaluation of the reports and issuance of Notice of Action.

4.3.3. FLOWCHART



4.3.4. PROCEDURE

4.3.4.1. The following terms shall be defined and use in this SOP:

4.3.4.1.1. **Protocol Deviation**: means a minor or administrative departure from the SL-IERC approved protocol procedures (e.g. the protocol, informed consent document, recruitment process or study materials) that was made without prior SL-IERC approval. It is an **accidental or unintentional change to, or non-compliance with the clinical research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data**. A deviation may be due to the human subject participant's non-adherence, or an unintentional change to or non-compliance with the clinical research protocol on the part of the Principal Investigator/Project Leader or the study team.

Examples of a deviation include:

a) A rescheduled study visit
b) Failure to collect an ancillary self-report questionnaire
c) Subject's refusal to complete scheduled research activities

4.3.4.1.2. **Protocol Violation:** means an accidental or unintentional change to, or non-compliance with the SL-IERC approved procedures (e.g. the protocol, informed consent document, recruitment process or study materials) without prior SL-IERC approval**. Protocol violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the research data.**

Examples of protocol violations:

a) Failure to obtain valid informed consent (e.g., obtained informed consent on a non-date stamped form)
b) Loss of laptop computer that contained identifiable, private information about subjects
c) Accidental distribution of incorrect study medication or dose
d) Not following inclusion/exclusion criteria

4.3.4.1.3. **Protocol Exception:** means a temporary protocol deviation that is pre-approved by the sponsor of funding agency. It is generally for a single subject (e.g. the patient/subject is allergic to one of the medications provided as supportive care) or occasionally, a small group of subjects. The protocol exception is usually evaluated by both the sponsor or funding agency and the SL-IERC in order to determine that it does not increase the risk to the subject(s), or jeopardize the integrity of the research data. Documentation of the sponsor's pre-approval and SL-IERC approval of the exception shall be maintained in the Investigator's research file.

4.3.4.2. Receipt of Protocol Deviation/Violation Report

4.3.4.2.1. The SL-IERC Secretariat shall receive the report on protocol deviations and/or violations from the Principal Investigator/Project Leader or any of the following who become aware of their occurrences:

a) Study team
b) Clinical research participants

4.3.4.2.2. Protocol violations/deviations shall be reported by the Principal Investigator/ Project Leader to the SL-IERC using Protocol Deviation/Violation Form *(SL-IERC Form # 15)*.

4.3.4.2.2.1. All protocol violations that pose risks or potential risks to the clinical research participants or others or which can negatively impact the integrity of the data should be reported as soon as possible but no longer than five (5) working days after the Principal Investigator/Project Leader becomes aware of the event.

4.3.4.2.2.2. Protocol deviations which do not pose any risk to the clinical research participants or others or do not negatively impact the integrity of the data do not have to be reported to the SL-IERC. However, when five (5) or more deviations of the same nature occurs, these must be reported to the SL-IERC after the 5th deviation. Reporting to the SL-IERC must be done within 10 working days after the Principal Investigator/Project Leader has been notified of the 5th deviation. All deviations not previously reported must be submitted to the SL-IERC for consideration.

4.3.4.2.2.3. Protocol deviations that occur in the course of the clinical trial/research, which in the opinion of the Principal Investigator/ Project Leader pose no risks to the participants and are below five (4 or less) are reported to the SL-IERC at the time of the scheduled Continuing Progress Report. The report shall include the following:

- Summary of the non-risk related deviations that have occurred since the last SL-IERC review
- Justification why the Principal Investigator/Project Leader decided these events did not involve increased risks to participants or others or negatively impacted the integrity of the data
- An explanation whether there is a systemic problem with the approved procedures, processes, data collection methods, etc. that creates the number of deviations that have occurred, and therefore, warrants a revision to the protocol to minimize or eliminate such deviations

4.3.4.2.3. The SL-IERC Secretariat shall forward the report on protocol deviations and/or violations to the SL-IERC Primary Reviewer (assigned Reviewer during the initial review of the clinical research) and SL-IERC Member-in-Charge on Protocol Deviations/Violations or SL-IERC Chair.

4.3.4.3. Evaluation of the Reports on Protocol Deviations/Violations

4.3.4.3.1. The SL-IERC Primary Reviewer, Member-in-Charge on Protocol Deviations/Violations, and/or Chair shall evaluate all protocol violations/deviations reported by the Principal Investigator/Project Leader upon receipt of the report.

4.3.4.3.2. If, in the opinion of the SL-IERC Primary Reviewer, Member-in-Charge on Protocol Deviations/Violations, risks outweigh potential benefits, other participants may be at risk or risks have not been appropriately minimized, he/she will notify the SL-IERC Chair immediately and recommend and/or request any of the following courses of action:

a) additional information
b) corrective action plan before taking further action or making a final decision
c) a copy of any correspondence sent to or received from a sponsor, regulatory body, CRO or other agency regarding this deviation
d) full SL-IERC review of the deviation
e) any action necessary to protect human participants
f) suspension of enrollment or implementation of the study until the full board SL-IERC has had the opportunity to review the deviation.

4.3.4.3.3. In the absence of any need for immediate action, SL-IERC the Member-in-Charge on Protocol Deviations/Violations shall include the deviations/violations report and recommendations in the next monthly SL-IERC full board meeting.

4.3.4.3.4. During the SL-IERC full board meeting, the SL-IERC Member-in-Charge on Protocol Deviations/Violations shall have the authority to recommend any one or more of the following actions:

4.3.4.3.4.1. Seek additional information from the Principal Investigator/Project Leader and require revisions to the currently approved protocol
4.3.4.3.4.2. Place restrictions on the Principal Investigator/Project Leader, Coordinator or any study team personnel that may have been responsible for the deviation/violation
4.3.4.3.4.3. Audit Principal Investigator/Project Leader's site by an SL-IERC Member or by a CHRP Staff
4.3.4.3.4.4. Increase the frequency of the continuing review period for the study
4.3.4.3.4.5. Suspend or terminate the study or any portion of that study which may increase risk to participants or others.
4.3.4.3.4.6. Require changes in procedures to eliminate or reduce deviations that are occurring consistently and with risk to the participant

4.3.4.4. Notice of Action

4.3.4.4.1. The SL-IERC Secretariat shall send a Notice of Action to the Principal Investigator/Project Leader.
4.3.4.4.2. The Principal Investigator/Project Leader shall respond to the requests/recommendation of the SL-IERC. The SL-IERC Secretariat shall receive the response and communicate it to the SL-IERC Member-in-Charge on Protocol Deviation/Violation. The SL-IERC Member-in-Charge on Protocol Deviation/Violation shall evaluate and submit a recommendation according to Section 4.3.4.3.
4.3.4.4.3. The SL-IERC Secretariat shall keep a copy of all correspondence/reports in the SL-IERC files of the study.

4.3.5. REFERENCES

4.3.5.1. Goldfarb, Norman. (2005). Bringing Method to the Madness: Protocol Deviation and Violation Codes. Journal of Clinical Research Best Practices. Vol.1 (11).

4.3.5.2. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

4.3.5.3. Maine Medical Center Research Institute. (2018). MMC HRPP Standard Operating Procedures. Maine: Maine Medical Center Research Institute.

—Nothing Follows—

DOCUMENT HISTORY

REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Review of Protocol Amendments	SL-IERC SOP No.: SOP # 4.4

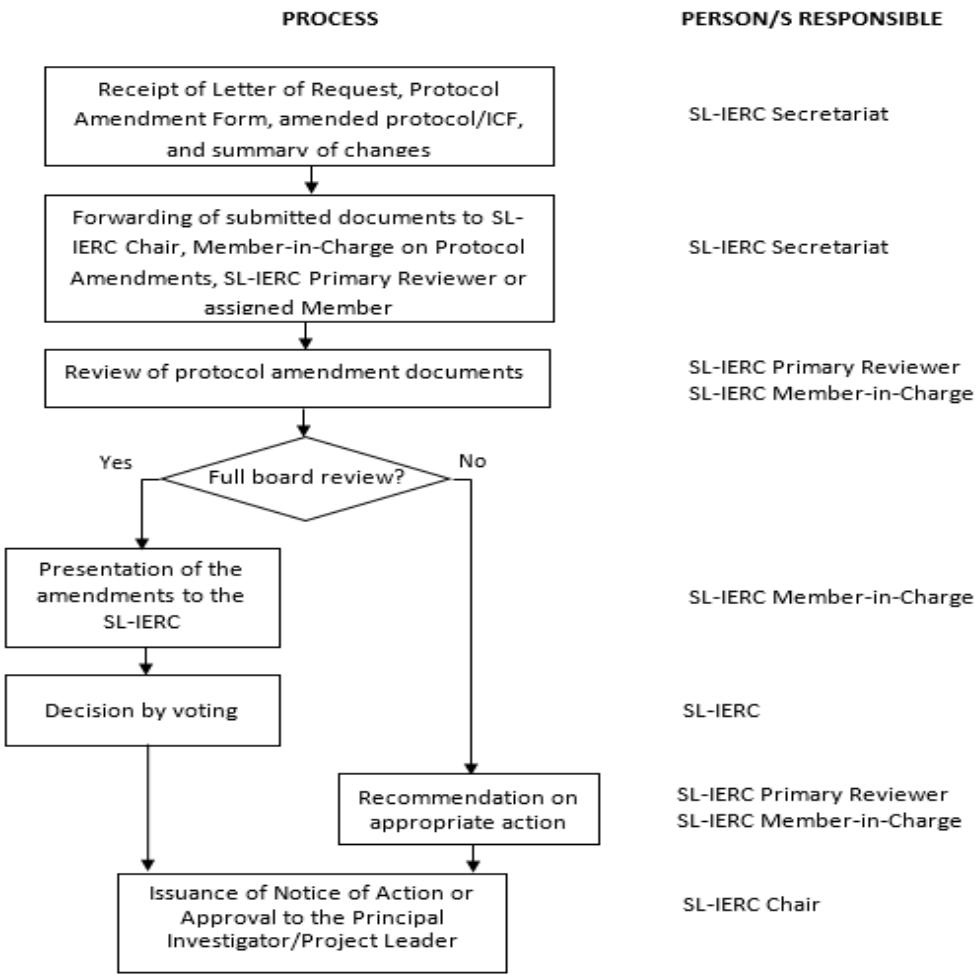
4.4.1. PURPOSE

The purpose of this SOP is to describe the process for handling amendments to study protocols to ensure regulatory and ICH-GCP compliance. This encompasses changes or modifications in SL-IERC approved protocol, Informed Consent form, Investigator's Brochure, addition of new investigators/proponents, study team and/or sites.

4.4.2. SCOPE

This SOP covers the process from receipt of request for amendment and amended clinical research protocol documents to review of amendments and issuance of Notice of Action or Approval for the amendments.

4.4.3. FLOWCHART



4.4.4. PROCEDURE

4.4.4.1. Receipt of Protocol Amendment Documents

4.4.4.1.1. Principal Investigator/Project Leader shall submit filled-up Protocol Amendment Form *(SL-IERC Form # 07)* together with soft copies (one with track changes and one clean copy) of the following:

- amended protocol or
- amended Informed Consent Form
- summary of protocol/ICF changes or
- names of new investigators/proponents or study team member or
- name of new sites

4.4.4.1.2. The SL-IERC Secretariat shall initially review the submitted documents and ensure the accurateness and completeness of the documents such as:

- version number of documents same as the one mentioned in the summary of changes and letter of the Principal Investigator/Project Leader
- added/new text is shown in bold letters
- deleted text is shown with strikethrough

4.4.4.1.3. The SL-IERC Secretariat shall forward the submitted amended protocol/ICF to the SL-IERC Primary Reviewer who did initial review of the protocol and to the SL-IERC Member-in-Charge on Protocol Amendments. If there was no Primary Reviewer, the SL-IERC Chair shall assign an SL-IERC Member to review the submitted documents.

4.4.4.2. Evaluation by the SL-IERC Primary Reviewer and Member-in-Charge on Protocol Amendments

4.4.4.2.1. The SL-IERC Primary Reviewer and Member-in-Charge on Protocol Amendments shall review and approve amendments or changes in the protocol/ICF. The decision shall be based on the following:

4.4.4.2.1.1. Major Modification – any change to a previously approved protocol that materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. Examples of major amendments (modifications/changes) to a protocol may include but not limited to:

a) Addition of a new subject population (e.g. control group, additional cohort, etc.), changes in number of subjects or age range of subjects;
b) Addition of research procedures that involve greater than minimal risk to subjects (e.g. addition of new drug to a treatment regimen, addition of invasive procedures, change in route or frequency of drug administration, change of comparator drug, duration of exposure to the drug, etc.);

c) Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation;
d) Addition of blood/tissue/cell banking or genetic testing;
e) Deletion of follow-up visits that appear necessary for monitoring subject safety and welfare;
f) Broadening the range of the inclusion criteria;
g) Narrowing the range of the exclusion criteria;
h) Appointment of new Principal Investigator/Project Leader or new investigators/proponents;
i) Changes in the investigational drug (e.g. addition of stability data/change of expiry date, change of formulation, additional toxicology data, change to route of synthesis);
j) Addition of new significant risks or serious unexpected adverse events to the informed consent document;
k) Changes which, in the opinion of the SL-IERC Reviewer and Member-in-Charge, do not meet the criteria or intent of a minor modification.

4.4.4.2.1.2. Minor Modification – any change to previously approved protocol, i.e. changes in clinical trial/research related activities that does not materially affect the assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study. Examples of minor amendments (modifications/changes) include, but are not limited to:

a) Minor increases or decreases in the number of participants;
b) Changes in remuneration;
c) Changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statements;
d) Narrowing the range of inclusion criteria;
e) Broadening the range of exclusion criteria;
f) Alterations in the dosage form (e.g. tablet to capsule or oral liquid) of an administered drug, provided the dose and route of administration remain constant);
g) Decreasing the number or volume of biological sample collections, provided that such change does not affect the collection of information related to safety evaluations;
h) An increase in the length of confinement or number of study visits for the purposes of increased safety monitoring;

i) A decrease in the length of confinement or study visits, provided that such a decrease does not affect the collection of information related to safety evaluations.

4.4.4.3. Approval of the Protocol Amendments

4.4.4.3.1. Approval by the SL-IERC full board of a protocol amendment shall be done if:

- Requested by the Principal Investigator/Project Leader
- SL-IERC Member-in-Charge on Protocol Amendments decides that it should be presented to SL-IERC Members
- If previously approved full board
- With major protocol amendment

4.4.4.3.2. SL-IERC Member-in-Charge on Protocol Amendments shall present to the full board SL-IERC his/her recommendations for protocols with minor amendments.

4.4.4.4. Notice of Action or Approval

4.4.4.4.1. The SL-IERC Secretariat shall send a Notice of Action (*SL-IERC Template # 08*) or Notice of Approval (*SL-IERC Template # 09 Notice of Approval, Template # 11B SL-IERC Composition*) to the Principal Investigator/Project Leader within 30 working days.

4.4.4.4.2. The Principal Investigator/Project Leader shall respond to the requests/recommendation of the SL-IERC. The SL-IERC Secretariat shall receive the response and communicate it to the SL-IERC Member-in-Charge on Protocol Amendments or SL-IERC Chair. The SL-IERC Member-in-Charge on Protocol Amendments or SL-IERC Chair shall evaluate and submit a recommendation according to Section 4.4.4.2.

4.4.4.4.3. The SL-IERC Secretariat shall keep a copy of all correspondence/reports in the SL-IERC files of the study.

4.4.5. REFERENCES

4.4.5.1. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

4.4.5.1. Directive 2001/20/EC of the European Parliament and of the Council

4.4.5.2. Office of Human Research Protections. (2018). Code of Federal Regulations Title 21, Part 312, Section 312.30. U.S. Department of Health & Human Services.

—Nothing Follows—

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Review of Protocol Amendments	SL-IERC SOP No.: SOP # 4.4

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
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5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

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Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022
SOP Title: Site Monitoring Visit	SL-IERC SOP No.: SOP # 4.5

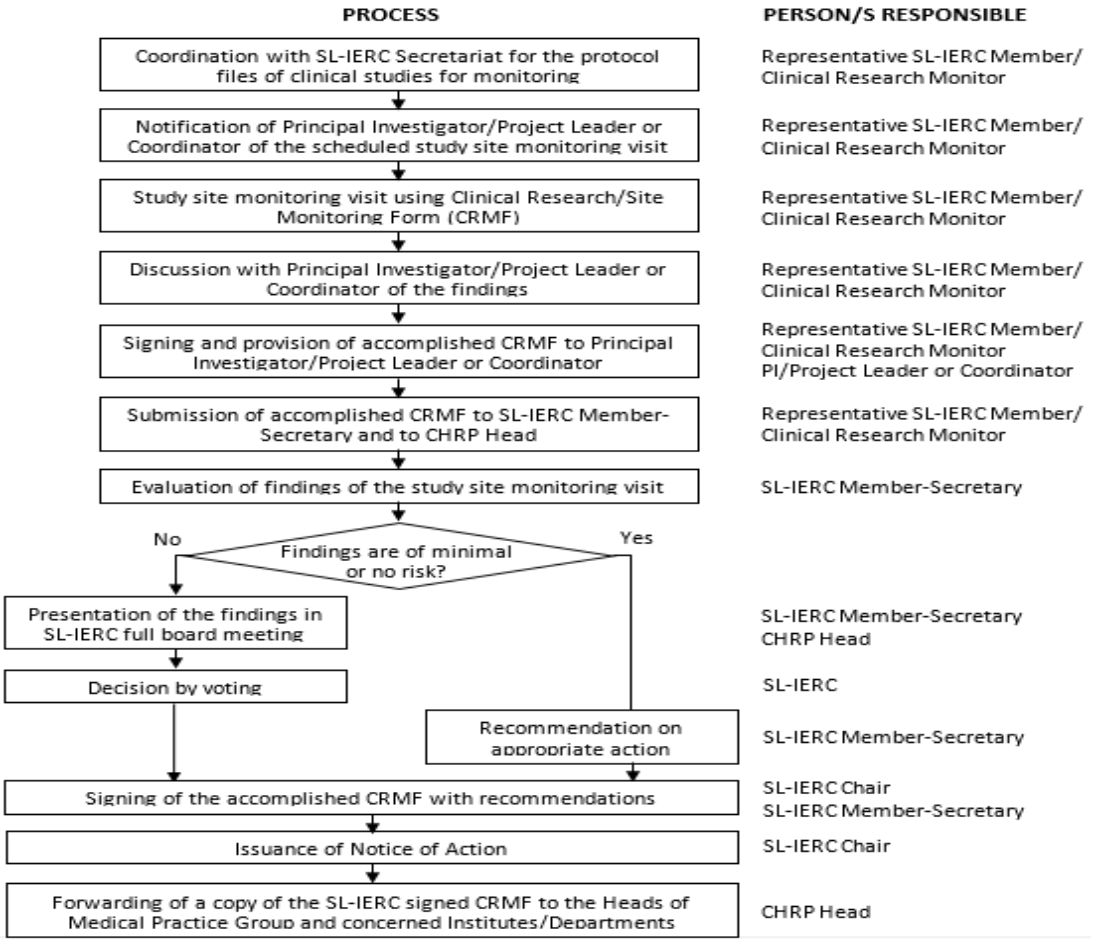
4.5.1. PURPOSE

The purpose of this SOP is to describe the process of when and how a study site, internal (SLMC QC and GC) or off-sites shall be visited and monitored for its performance or compliance to ICH-GCP guidelines.

4.5.2. SCOPE

This SOP covers the process from identifying clinical research studies for monitoring to notification of Principal Investigators/Project Leaders of scheduled monitoring visit, conduct of site monitoring visit, discussion with Principal Investigators/Project Leaders of the findings, submission of accomplished Clinical Research Monitoring Form to SL-IERC Member-Secretary, evaluation of the findings, issuance of Notice of Action, and submission of the SL-IERC report to the Heads of Medical Practice Group and Institutes/Departments and Principal Investigator/Project Leader.

4.5.3. FLOWCHART



4.5.4. PROCEDURE

4.5.4.1. Routine Monitoring of Study Site

4.5.4.1.1. Internal (Sites within St. Luke's Medical Center Quezon City and Global)

4.5.4.1.1.1. Routine monitoring of conduct of clinical studies, whether Sponsor-initiated or Investigator-initiated, shall be conducted by the designated SL-IERC Representative or CHRP Clinical Research Monitor (CRM).

4.5.4.1.1.2. Study sites or Principal Investigators/Project Leaders of all moderate to high risk and ten percent (10%) of randomly selected minimal risk clinical research studies in St. Luke's Medical Center Quezon City and Global shall be visited and monitored.

4.5.4.1.1.3. Monitoring of a study site shall be based on the anniversary of the Ethical Clearance. However, Continuing Review Report shall be submitted by the Principal Investigator/Project Leader based on the risks as stated in the Ethical Clearance:

- Low/Minimal Risk – Annually (counting from the approval date)
- Moderate/ Medium Risk – Semi-annually (counting from the approval date)
- High risk – Quarterly (counting from the approval date)

4.5.4.1.2. External or Off-Site Study

4.5.4.1.2.1. Monitoring of external or off-site shall also be done based on the anniversary of the Ethical Clearance.

4.5.4.2. "For-Cause Monitoring" of Study Site

4.5.4.2.1. "For-cause monitoring" shall be done at any site, internal or external, upon recommendation of any SL-IERC Member and approval of the SL-IERC Chair. "For-cause monitoring" shall be based on the following reasons/criteria:

- New study sites
- High number of protocol violations
- Large number of studies carried out at the study site or by the Principal Investigator/Project Leader
- Reports of remarkable serious adverse events (SAE)/suspected unexpected serious adverse reaction (SUSAR)
- High recruitment rate
- Complaints received from clinical research participants or any other person
- Non-compliance or failure to submit required documents i.e. progress reports/annual reports
- Any other cause as decided by the SL-IERC

4.5.4.3. Monitoring Visit Activities (both for internal/off-site; scheduled/"for-cause") irrespective of the reason for conducting the monitoring visit

4.5.4.3.1. Before the study site monitoring visit

4.5.4.3.1.1. The SL-IERC Representative(s) or CRM(s) shall coordinate with the SL- IERC Secretariat for the clinical research (Sponsored and Investigator-initiated) that will be monitored, either for routine or "for-cause" monitoring.

4.5.4.3.1.2. The SL-IERC Secretariat shall provide the SL-IERC Representative(s) or CRM(s) the reference materials/documents pertinent to the clinical research to be monitored. The SL-IERC Representative(s) or Clinical Research Monitor(s) may photocopy some parts of the files for comparison with the study site files.

4.5.4.3.1.3. The SL-IERC Representative(s) or CRM(s) shall notify the study site Principal Investigator/Project Leader using the "Clinical Research/Site Monitoring Notice Form" about the scheduled site visit (*SL-IERC Template # 16*).

4.5.4.3.2. During the study site monitoring visit

4.5.4.3.2.1. The SL-IERC Representative(s) or CRM(s) shall check the compliance of the Study Team on the following using the Clinical Research/Site Monitoring Form (*SL-IERC Form # 18*):

a) The following source documents/investigational files are filed properly:
   - Approved protocol
   - Revised protocol approved by the IERC
   - Approved Informed Consent Form (ICF)
   - Revised ICF approved by the IERC
   - Investigational Brochure
   - Ethical Clearance
   - Clinical Trial Agreement
   - Other communication letters with IERC and Sponsor
   - Approved flyer or advertisement materials

b) All the study files are filed in a locked cabinet

c) All informed consent/assent forms (latest IERC approved version) are properly signed and dated by the patient/LAR, Principal Investigator/Project Leader, and/or witness (*SL-IERC Form # 19*)

d) All enrolled subjects have hard of the signed ICFs

e) Persons who obtained the ICFs are all stated in the Delegation Log

f) All eligibility criteria are met

g) No subject is enrolled pending IERC approval of the revised ICF

h) All subjects are asked to re-consent using the revised IERC-approved ICF, when necessary

i) All Case Report Forms (CRF) are accomplished within two (2) weeks of the subjects' visit (Check CRFs of 10% of enrolled subjects)
j) Data in CRFs are valid when checked against the source documents (for primary and secondary outcomes)
k) All protocol deviations/violations are reported to the IERC
l) All ADRs, SAEs and SUSARs are reported to the IERC within 24 hours to 7 days upon discovery
m) All progress reports are submitted to the IERC on time.
n) Ethical Clearance is renewed one year from date of issuance
o) Terminal report is submitted to the IERC
p) Final report is submitted to the IERC
q) All GCP certificates of the study team are up-to-date
r) All CVs of the study team are filed properly
s) All members of the study team are included in the Delegation of Responsibility
t) All members of the study team are trained before the start of the study

4.5.4.3.2.2. The IERC Representative(s) or CRM(s) shall discuss with the Principal Investigator/Project Leader the issue(s) that need to be addressed immediately after the monitoring visit.

4.5.4.3.2.3. The IERC Representative(s) or CRM(s) shall calculate the overall performance of the PI, Project Leader, or Project Coordinator's in the conduct of the research. Overall performance shall be calculated as total compliance score divided by the number of applicable items x 2 x 100%.

4.5.4.3.2.4. The IERC Representative(s) or CRM(s) and the Principal Investigator/Project Leader or Project Coordinator shall sign the CRMF.

4.5.4.3.3. After the study site monitoring visit

4.5.4.3.3.1. The SL-IERC Representative(s) or CRM(s) shall submit the accomplished CRMF to the SL-IERC Member-Secretary and to CHRP Head after the monitoring visit.

4.5.4.3.3.2. The SL-IERC Member-Secretary shall review the accomplished CRMF.

4.5.4.4. Evaluation of the site monitoring visit findings

4.5.4.4.1. If the SL-IERC Member-Secretary judges that the issues of the study site monitoring visit have significant impact on the safety of study participants, he/she shall inform SL-IERC Chair and recommends full board review of the findings.

4.5.4.4.1.1. The SL-IERC Member-Secretary or CHRP Head shall present the findings to the Committee.

4.5.4.4.1.2. The SL-IERC Members shall discuss the findings of the monitoring visit and take appropriate specific action by voting for any of the following:

- Restrictions on enrollment

- Recommendations for additional training
- Recruiting additional members in the study team
- Revising/providing qualifications/experience criteria for members of the study team
- Suspension/termination of the study

4.5.4.4.2. If the SL-IERC Member-Secretary judges that the issues of the study site monitoring visit involve minimal or no risk to the study participants, he/she shall submit the accomplished CRMF with his/her recommendations and signature to the SL-IERC Chair.

4.5.4.5. Notice of Action

4.5.4.5.1. The SL-IERC Secretariat shall prepare and send a Notice of Action (if there are queries) or Notice of Approval (if approved) signed by the SL-IERC Chair to the concerned Principal Investigator/Project Leader.

4.5.4.5.2. The SL-IERC Secretariat shall keep the accomplished and signed CRMF and a copy of all correspondences in the SL-IERC files of the study.

4.5.4.5.3. The CHRP Head shall send a copy of the accomplished and signed CRMF to the Head of Medical Practice Group and to the Heads of Units of the Principal Investigator/Project Leader or Project Coordinator (e.g., Medical Practice Group, Nursing Care Group, Supply Chain Management, Ancillary Services, Support Services, etc.)

4.5.5. REFERENCES

4.5.5.1. Forum for Ethics Review Committees in India. (2014). FERCI MODEL SOP 16/V1: Site Monitoring and Post-Monitoring Activities. Mumbai: Forum for Ethics Review Committees in India.

4.5.5.2. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

4.5.5.3. Karlberg JPE and Tam SYM. (2011). Study Site SOP Standardization - 4S - Project. Hong Kong: Clinical Trials Centre. The University of Hong Kong, Li Ka Shing Faculty of Medicine.

—Nothing Follows—

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
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SOP Title: Site Monitoring Visit	SL-IERC SOP No.: SOP # 4.5

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
0	07-2018		0	New SOP	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
1	08-2019		1	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
2	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
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Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Preparation of Notice of Meeting and Agenda	SL-IERC SOP No.: SOP # 5.1

SOP 5. SOPs on Documentation and Archiving

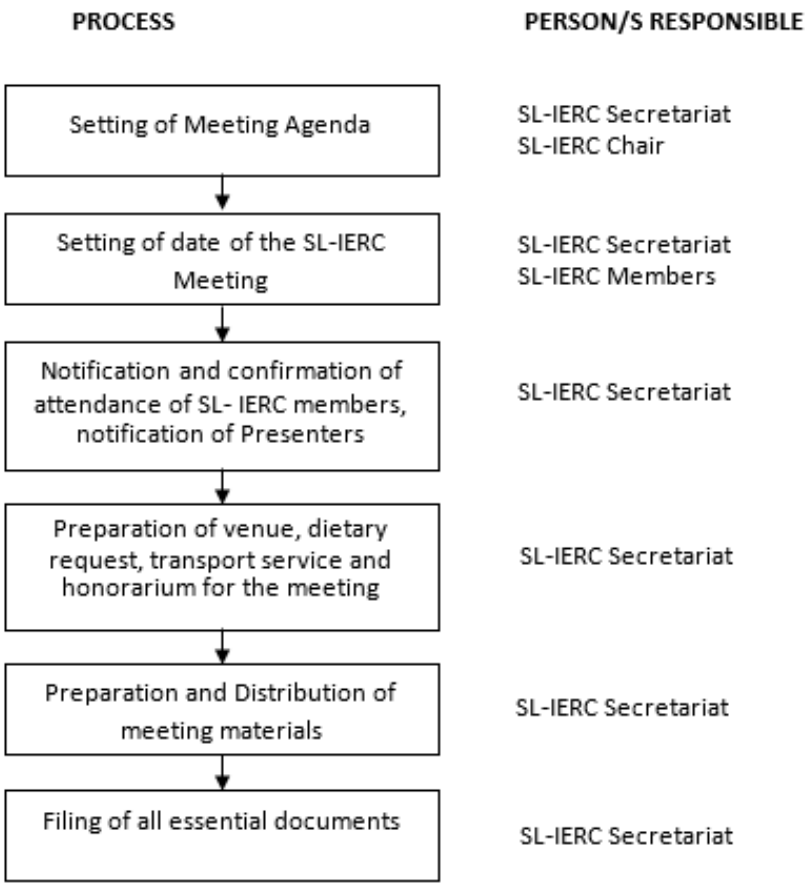
5.1.1. PURPOSE

The purpose of this SOP is to describe the procedures for the preparation of the Agenda and Notice of a regular SL-IERC meeting

5.1.2. SCOPE

This SOP covers the procedures from setting the Meeting Agenda to Scheduling of SL-IERC Meeting, preparation of shall guide the SL- IERC Chair, notification of SL-IERC Members and External/Independent Consultant, preparation and distribution of meeting materials and filing of meeting materials.

5.1.3. FLOWCHART



5.1.4. PROCEDURE

5.1.4.1. Setting of Agenda of Meeting

5.1.4.1.1. The SL-IERC Secretariat, in consultation with the SL- IERC Chair, shall prepare the Tentative Agenda *(SL-IERC Template # 12 Agenda)* for the regular meeting of the SL-IERC.

5.1.4.1.2. The standard Agenda for a regular IERC meeting shall include the following:

a) Approval of the Agenda
b) Reading and Approval of Minutes of the previous meeting
c) Matters arising from Minutes of the previous meeting
d) For full board review
   - Sponsor-initiated Clinical Trials
   - Investigator-initiated Clinical Research studies
   - Response to Notice of Action
   - Reports of SL-IERC Members-in-Charge on:
     i. Protocol Amendments
     ii. Continuing Review/Progress Report/Final Report
     iii. Protocol Deviations/Violations
     iv. SAEs
     v. Study Site Monitoring Visit
e) Matters for Information and Acknowledgement
   - Updates on protocols reviewed
   - Protocol Amendments
   - Response to Notice of Action
   - Study updates
   - Safety reports
   - Materials for information and acknowledgement
f) Announcements
g) Other matters
h) Schedule of next meeting
i) Adjournment

5.1.4.2. Schedule and Date of SL-IERC meetings

5.1.4.2.1. Regular meetings of the SL-IERC shall be held on the 2nd Wednesday of each month or as agreed upon by the IERC at 8:00 in the morning, R&B Conference Room, 6th East, SLMC Quezon City.

5.1.4.3. Notification of SL-IERC Members and Notification of Presenters

5.1.4.3.1. The SL-IERC Secretariat shall send a "Notice of Meeting" *(SL-IERC Template # 04 Notice of Meeting)* to all Members of the SL-IERC signed by the SL-IERC Chair two (2)

weeks prior to the scheduled meeting. The SL-IERC Secretariat shall send the Tentative Agenda of the next meeting and Minutes of the previous meeting via e-mail two (2) days before the meeting

5.1.4.3.2. The SL-IERC Secretariat shall send an invitation to the External/Independent Consultant to be present during the full-board meeting two (2) weeks before the scheduled Full board meeting.

5.1.4.4. Preparation of venue and requests from other concerned Groups

5.1.4.4.1. The SL-IERC Secretariat shall reserve the use of the R&B Conference Room for the SL-IERC meeting.

5.1.4.4.2. The SL-IERC Secretariat shall prepare the following requests:

- Dietary Request Form to Food and Nutrition Department
- Transport Request Form to Transport Services Department

5.1.4.5. Distribution of meeting materials

5.1.4.5.1. The SL-IERC Secretariat shall distribute to each SL-IERC Member and External/Independent Consultant two (2) weeks before the scheduled meeting the protocol binder which includes the following:

- Ethics Review Form for Protocol *(SL-IERC Form # 05A)*
- Ethics Review Form for Informed Consent *(SL-IERC Form # 05B)*
- Ethics Review Form (for External/Independent Consultant) *(SL-IERC Form # 06)*
- Protocols for review

—Nothing Follows—

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Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Preparation of Notice of Meeting and Agenda	SL-IERC SOP No.: SOP # 5.1

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
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4	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
5	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

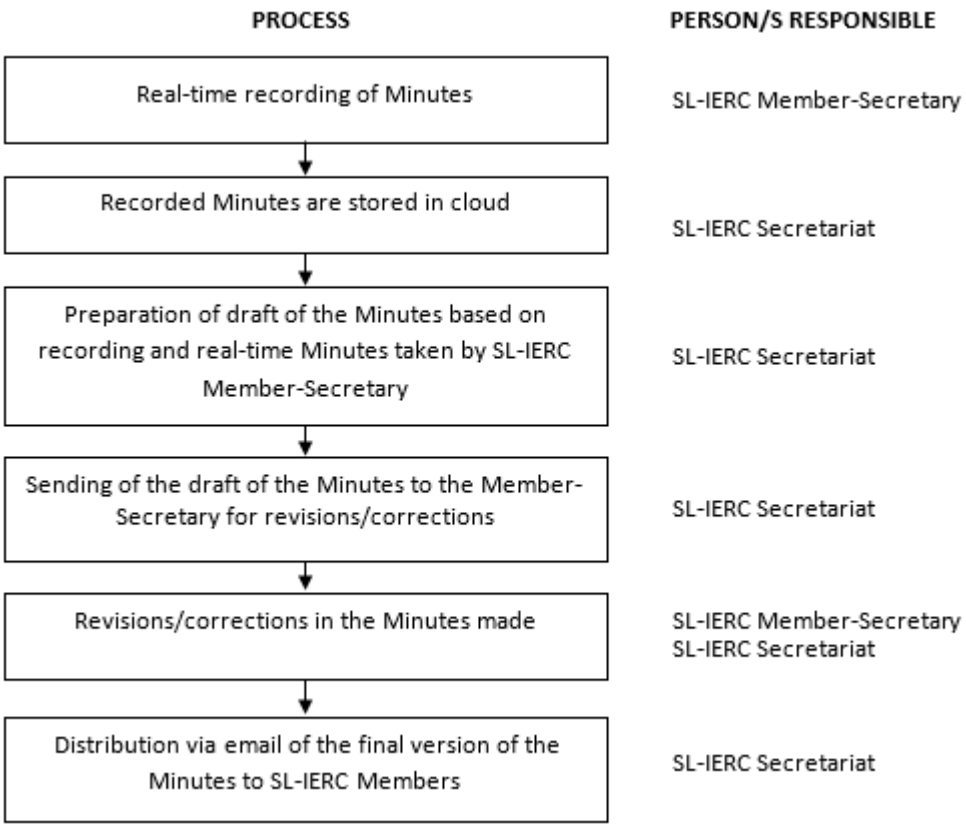
5.2.1. PURPOSE

The purpose of this SOP is to describe the procedures for the preparation of the draft of the Minutes of the SL-IERC Meeting and its final approval.

5.2.2. SCOPE

This SOP covers the process from real-time recording of the Minutes to the preparation of the draft of the Minutes, approval of the Minutes and distribution of the Minutes to the SL-IERC Members.

5.2.3. FLOWCHART



5.2.4. PROCEDURE

5.2.4.1. Recording of Minutes of Meeting

5.2.4.1.1. The SL-IERC Member-Secretary shall record the proceedings of an SL-IERC meeting in real-time.

5.2.4.1.2. The Minutes of the SL-IERC meeting shall be recorded simultaneously in an MP3 recorder.

5.2.4.1.3. The SL-IERC Secretariat shall copy the MP3 record to a record to a cloud (IERC Google drive and server) and shall label the file indicating the date (year, month, and day).

5.2.4.2. Preparation of draft copy of the Minutes *(SL-IERC Template # 13 Minutes of Meeting).*

5.2.4.2.1. The SL-IERC Secretariat shall prepare the draft copy of the Minutes using the following format:

- Date and venue of the meeting
- Attendance/Absences
- Call to order by person presiding
- Invocation
- Declaration of quorum and presence of non-institutional members
- Approval of the Agenda
- Disclosure of Conflict of interest
- Reading and approval of the Minutes of the previous meeting
- Time when the meeting started
- Items discussed in the approved agenda
- Decision on matters discussed i.e. approval/disapproval of clinical research studies
- Schedule of the next SL-IERC Meeting

5.2.4.2.2. The SL-IERC Secretariat shall send the draft of the Minutes of Meeting to the SL-IERC Member Secretary for revisions/corrections.

5.2.4.2.3. The SL-IERC Member-Secretary shall make corrections in the draft of the Minutes of Meeting.

5.2.4.2.4. The SL- IERC Secretariat shall incorporate the corrections in the version of the Minutes of the Meeting that will be sent via email to SL-IERC members.

5.2.4.2.5. The SL-IERC Secretariat shall send via email the final version of the Minutes to individual SL-IERC Members together with the Tentative Agenda two days (2) before the regular meeting.

—Nothing Follows—

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Preparation of Distribution of Meetings of Meeting	SL-IERC SOP No.: SOP # 5.2

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022		6	Saving of Minutes Mp3 recording to cloud instead of CD	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022
SOP Title: Preparation and Conduct of an SL-IERC Meetings	SL-IERC SOP No.: SOP # 5.3

5.3.1. PURPOSE

The purpose of this SOP is to describe the procedures in the preparation and conduct of an SL-IERC meeting.

5.3.2. SCOPE

This SOP covers the process from the preparation of the meeting materials to the distribution of the materials to SL-IERC Members and External/Independent Consultants, calling the meeting to order, real-time documentation of the Minutes of the Meeting, adjournment, and collection of meeting materials from the SL-IERC Members and External/Independent Consultants.

5.3.3. FLOWCHART

PROCESS	PERSON/S RESPONSIBLE
Preparation of meeting materials (Agenda, Minutes of previous meetings, protocols for review) and consolidation in a binder	SL-IERC Secretariat
Distribution of binders/soft copies to SL-IERC Members and/or External/Independent Consultant two (2) weeks before the meeting	SL-IERC Secretariat
Calling of the meeting to order	SL-IERC Chair
Real-time documentation of the Minutes	SL-IERC Member-Secretary
Adjournment of the meeting after all matters have been taken up	SL-IERC Chair
Collection of evaluations and all binders from the SL-IERC Members and External/Independent Consultant	SL-IERC Secretariat

5.3.4. PROCEDURE

5.3.4.1. Preparation and distribution of meeting materials

5.3.4.1.1. The SL-IERC Secretariat shall prepare a binder containing the following documents for the meeting for each SL-IERC Member and/or External/Independent Consultant:

a) Ethics Review Form for Protocol (SL-IERC Form # 05A)
b) Ethics Review Form for Informed Consent (SL-IERC Form # 05B)
c) Ethics Review Form (for External/Independent Consultant) (SL-IERC Form # 06)
d) All study protocols for review

5.3.4.1.2. The SL-IERC Secretariat shall distribute the binders (or soft copies of the study protocols and ethics review forms) to each SL-IERC Member and/or External/Independent Consultant two (2) weeks prior to the scheduled meeting.

5.3.4.2. Conduct of the SL-IERC meeting

5.3.4.2.1. The SL-IERC meeting shall be conducted in accordance with the sequence as prepared in the Agenda. The sequence of the meeting would be:

a) Approval of the Agenda
b) Reading and Approval of Minutes of the previous Meeting
c) Matters arising from Minutes of previous meeting
d) For full board review
   - Sponsor-initiated Clinical Trials
   - Investigator-initiated Clinical Research studies
   - Response to Notice of Action
   - Reports of Members-in-Charge on
     i. Protocol Amendments
     ii. Continuing Review/Progress Report/Final Report
     iii. Protocol Deviations/Violations
     iv. SAEs
     v. Study Site Monitoring Visit
e) Matters for Information and Acknowledgement
   - Updates on protocols reviewed
   - Protocol Amendments
   - Response to Notice of Action
   - Study updates
   - Safety reports
   - Materials for information and acknowledgement
f) Announcements
g) Other matters
h) Schedule of next meeting
i) Adjournment

5.3.4.2.2. The SL-IERC Secretariat shall request the SL-IERC Members, External/Independent Consultant, Head of CHRP, and Secretariat to sign the IERC Meeting Attendance Sheet prior to start of the SL-IERC Meeting. *(SL-IERC Template # 06 Meeting Attendance Sheet)*

5.3.4.2.3. The SL-IERC Chair shall call the meeting to order.

5.3.4.2.4. The invocation shall be delivered by a designated SL-IERC Member.

5.3.4.2.5. The SL-IERC Chair shall ask the SL-IERC Member-Secretary if there is a quorum. Quorum shall be declared if more than half of the SL-IERC Members are present (but not less than five), which should include the community representative (lay person) and one member who is independent of the institution or research site (PHREB National Ethical Guidelines for Health and Health-Related Research 2017).

a) If there is a quorum, the Chair shall proceed with the meeting. Quorum during the full board meeting shall be maintained at all times.
b) If no quorum exists, the Chair shall declare adjournment.

5.3.4.2.6. The SL-IERC Chair shall present the Tentative Agenda for approval/revision.

5.3.4.2.7. The SL-IERC Chair shall ask if any SL-IERC Member has a conflict of interest in any of the study protocols for review.

a) Conflict of Interest is present when an SL-IERC Member has affiliation with a Principal Investigator/Project Leader or Sponsor/CRO which will undermine his/her ability to make a free and independent evaluation.
b) If any member of the SL-IERC declares a conflict of interest in any of the protocols for review, the SL-IERC Chair/SL-IERC shall request the concerned Member not to participate in the decision-making of the specified protocol. Members with COI will be required to leave the room during deliberations and decision-making of the protocol.
c) If there is no declaration of any conflict of interest, the SL-IERC Chair shall proceed with the next item in the Agenda.

5.3.4.2.8. The SL-IERC Chair shall

a) present the Minutes of the previous meeting for reading and approval.
b) discuss matters arising from the Minutes.

5.3.4.3. Presentation of clinical research protocols for full board review by the Primary Reviewers *(Refer to SOP 2.1 Full Board Review)*

5.3.4.3.1. The SL-IERC Chair shall request concerned SL-IERC Members-in-Charge to present for review and discussion the following:

a) Protocol Amendments
b) Continuing Review/Progress Report/Final Report
c) Protocol Deviations and Violations
d) Serious Adverse Events
e) Study Site Monitoring Visit
f) Posters/Advertisement

g) Continuing education, ECHO/lectures
h) Other administrative matters

5.3.4.4. Adjournment

5.3.4.4.1. The SL-IERC Chair shall adjourn the meeting after confirmation of the date of the next regular meeting.

5.3.4.4.2. The SL-IERC Secretariat shall ensure completion of entries, including signature and dates on the evaluation forms. It shall collect all binders and keep these on file at the SL-IERC Office.

5.3.5. REFERENCES

5.3.5.1. World Health Organization. (2000). Operational Guidelines for Ethics Committees that Review Biomedical Research. Geneva: World Health Organization.

———*Nothing Follows*———

DOCUMENT HISTORY

REVIEW NO.	REVIEW DATE	REVISION NONE	REVISION NO.	REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2018		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

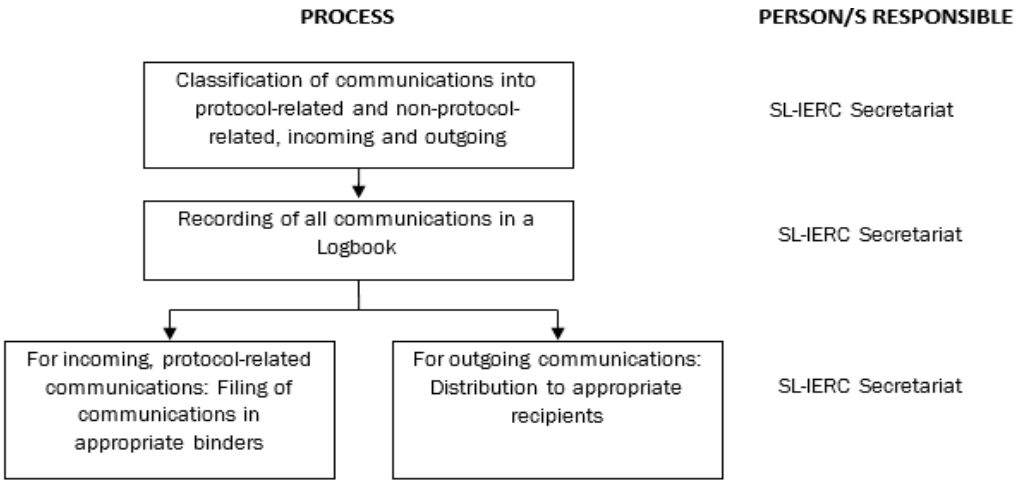
5.4.1. PURPOSE

The purpose of this SOP is to describe the process of managing SL-IERC communications that will ensure proper logging, distribution and documentation of all communications to and from the SL-IERC.

5.4.2. SCOPE

This SOP covers the process from classification of the all communications, to recording of the communications in a logbook, distribution of the communications appropriate recipients, and filing of the communications in the appropriate protocol binders.

5.4.3. FLOWCHART



5.4.4. PROCEDURE

5.4.4.1. SL-IERC Secretariat shall classify all communications as follows:
- a) Incoming or outgoing
- b) Protocol-related or non-protocol-related

5.4.4.2. Incoming/Outgoing Communications

5.4.4.2.1. The SL-IERC Secretariat shall record all incoming communications in a Logbook chronologically.

5.4.4.2.2. The SL-IERC Secretariat shall distribute outgoing communications to appropriate recipients.

5.4.4.2.3. The SL-IERC Secretariat shall file all incoming communications in appropriate protocol binders.

—Nothing Follows—

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Management of Communications	SL-IERC SOP No.: SOP # 5.4

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

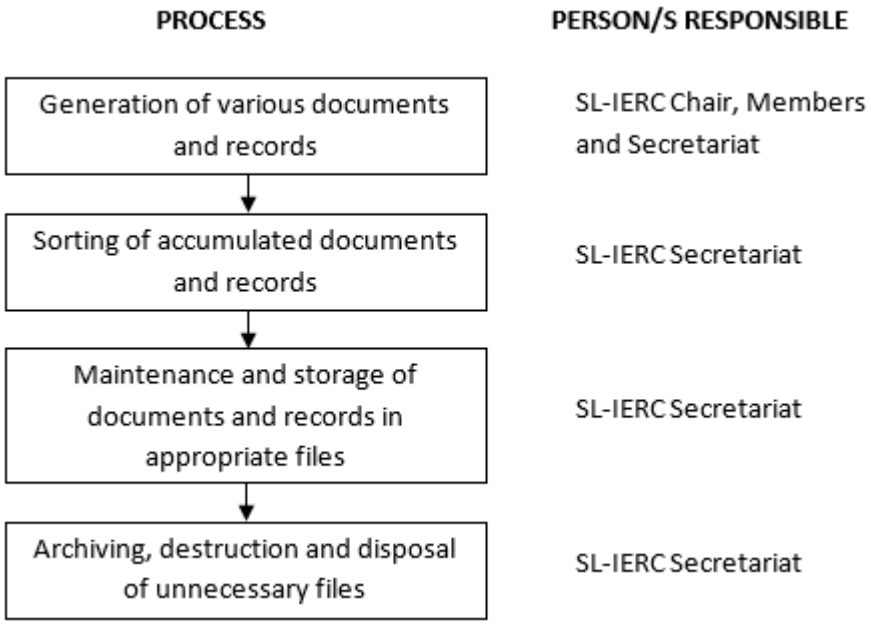
5.5.1. PURPOSE

The purpose of this SOP is to describe the procedures in the management of administrative files, logbooks and forms of the SL-IERC. The files include manuals, references, Tracking Forms and other administrative files.

5.5.2. SCOPE

This SOP covers the process from generation of various documents and records to sorting, maintenance, storage, archiving, destruction and disposal of administrative files, logbooks and forms.

5.5.3. FLOWCHART



5.5.4. PROCEDURE

5.5.4.1. The SL-IERC Secretariat shall receive documents that are not Protocol-related such as:

- reference materials
- letters to SL-IERC Chair
- members and investigator profiles
- logbooks and files
- forms

5.5.4.2. The SL-IERC Secretariat shall sort out documents to protocol-related, non-protocol-related and administrative in nature.

5.5.4.3. The SL-IERC Secretariat shall maintain the following files:

a) Active Study Files which include files of on-going clinical research studies shall contain:

i. Clinical Research Tracking Form

ii. Correspondences

- Submission Letter
- Notice of Action (NOA)
- Response to NOA
- Ethical Clearance (EC)
- Principal Investigator's Responsibilities signed Conforme
- SL-IERC Members' composition
- Notice of EC Renewal

iii. Submissions

- Protocol
- Investigator's Brochure
- Informed Consent Forms
- Case Report Forms or Data Collection Forms
- Patient Recruitment materials/Ads/Posters
- Principal Investigator's CV
- GCP Certificate
- Disclosure of Conflict of Interest
- Insurance
- PFDA approval
- Amendments
- ADR/SAE/SUSAR Reports
- Line Listing of CIOMS/Safety Reports/SUSARS
- Protocol Deviations/Violations reports
- Continuing Review Reports/Progress Reports

**The active study files from time to time shall be updated as documents for specific clinical research studies are submitted by the Principal Investigator/Project Leader. All the active study files shall be stored in a locked cabinet and the key shall be kept by the SL-IERC Secretariat.*

b) Archived Study Files, which include clinical research protocols that are completed, terminated, withdrawn or closed out, shall contain:

i. Files of SAEs, SUSARs and CIOMS

ii. Meeting Agenda, Attendance, and Minutes of SL-IERC meetings

iii. Progress Report Files

**The archived files are stored in the Archive Room accessible only to the SL-IERC Secretariat*

5.5.4.4. The Secretariat shall shred and dispose:

a) unused clinical research protocols and related documents

b) archived documents beyond the retention period (five years).

5.5.4.5. After shredding, all dry waste shall be collected in a black bag. *(Refer to Waste Management Policy)*

—Nothing Follows—

DOCUMENT HISTORY

REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

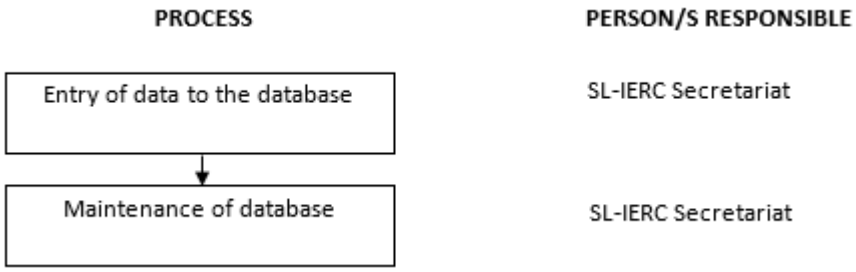
5.6.1. PURPOSE

The purpose of this SOP is to describe the procedures in the management of the SL-IERC database.

5.6.2. SCOPE

This SOP covers the process from data entry in the SL-IERC database to maintenance of the database.

5.6.3. FLOWCHART



5.6.4. PROCEDURE

5.6.4.1. The SL-IERC Secretariat shall encode data into the database such as:

- EC Reference Number
- Protocol number (given by the Sponsor/CRO)
- Study classification
- Name of Principal Investigator/Contact Number/email address/ Department
- Name of Study Coordinator/Contact Number/email address/ Department
- Sponsor/CRO
- Date Received/Reviewed/Approved
- Release date of Notice of Action
- Type of Review i.e. expedited or full-board
- Close-out date/Termination date/Withdrawal date
- Schedule of Continuing Review Submission i.e. progress report *(annually, semi-annually or quarterly)*
- Ethical Clearance Renewal date
- Remarks

5.6.4.2. The SL-IERC Secretariat shall update the database as needed.

–Nothing Follows–

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Management of Database	SL-IERC SOP No.: SOP # 5.6

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022		6	Omission of web portal	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

5.7.1. PURPOSE

The purpose of this SOP is to describe the procedures for electronic submissions, efficient reviews, and documentation.

5.7.2. SCOPE

This SOP covers the process from receipt of electronic clinical research protocol documents, to determination of type of review, designation of reviewers, conduct of electronic expedited reviews and virtual full board meetings, issuance of electronic Notice of Action or Approval, issuance of electronic Ethical Clearance, and documentation and archiving of all electronic protocol documents and reports; protocol and ICF evaluation forms; meeting agenda and minutes; notices of action, approval and ethical clearances; correspondences; and other related documents.

5.7.3. PROCEDURE

5.7.3.1. Initial protocol submission

5.7.3.1.1. The SL-IERC Secretariat shall receive the soft copies of the clinical research protocol documents from the Center for Clinical Trials (CCT) for sponsored-initiated clinical trials or from the Institutional Scientific Review Committee (ISRC) for investigator-initiated studies via email.

5.7.3.1.2. Upon receipt of the clinical research protocol documents, the SL-IERC Secretariat shall log the protocol submission using the electronic Clinical Research Tracking Form. (*Refer to SOP# 3.1 Initial Protocol Submission)*

5.7.3.1.3. The SL-IERC Secretariat shall assign an EC Reference Number to the protocol. (*Refer to SOP# 3.1.4.2.2 for the EC Reference Number*).

5.7.3.1.4. The SL-IERC Secretariat shall send the soft copies of the clinical research protocol documents to the SL-IERC Chair via email for determination of type of review.

5.7.3.1.5. The SL-IERC Chair shall determine the type of review and designate Reviewers in accordance with SOP # 3.1 Initial Protocol Submission.

5.7.3.1.6. The SL-IERC Secretariat shall send the soft copies of the clinical research protocol documents and Evaluation Forms (*SL-IERC Forms # 05A and 05B*) to the designated Reviewers via email in accordance with SOP # 3.1.

5.7.3.2. Review of clinical trial protocols

5.7.3.2.1. For expedited reviews:

5.7.3.2.1.1. The designated Reviewers shall conduct expedited review in accordance with SOP# 2.2 Expedited Review of Protocols.

5.7.3.2.1.2. The designated Reviewers shall submit the soft copies of the accomplished Evaluation Forms to the SL-IERC Secretariat within 14 working days.

5.7.3.2.2. For full board reviews:

5.7.3.2.2.1. SL-IERC shall conduct full board reviews virtually using the platform approved by SLMC (e.g. Google Meet, Zoom, or Microsoft Teams).

5.7.3.2.2.1.1. Face-to-face or hybrid meetings may be conducted as necessary.

5.7.3.2.2.2. The SL-IERC Secretariat shall send the virtual meeting link or code to the SL-IERC Members via email and Viber at least three (3) calendar days before the scheduled meeting.

5.7.3.2.2.3. The SL-IERC Members and Secretariat may use their desktop computer, laptop, tablet, or mobile phone in joining the virtual meeting.

5.7.3.2.2.4. The SL-IERC Secretariat shall start recording of the virtual meeting once the SL-IERC Chair calls the meeting to order.

5.7.3.2.2.5. SL-IERC Members shall open their desktop/tablet/phone cameras for the attendance and quorum.

5.7.3.2.2.6. The meetings shall be conducted in accordance with SOP# 2.1 Full Board Review of Protocols.

5.7.3.2.2.6.1. The designated Primary Reviewers shall share their screen when they present their evaluations.

5.7.3.2.2.6.2. The SL-IERC Member-Secretary shall share the real-time minutes during discussion of the merits of the clinical research protocol and ICF.

5.7.3.2.2.7. SL-IERC Members shall open their desktop/tablet/phone cameras and raise their hands during votation for the decision on the protocol and/or ICF.

5.7.3.2.2.8. The designated Reviewers shall submit the soft copies of the accomplished Evaluation Forms to the SL-IERC Secretariat within seven (7) working days from the virtual meeting.

5.7.3.3. Notice of Action or Approval

5.7.3.3.1. Issuance of electronic Notice of Action or Approval shall be in accordance with the following SOPs:

- SOP 2.1 Full Board Review of Protocols
- SOP 2.2 Expedited Review of Protocols
- SOP 2.4 Review of Protocols that Require Revisions after Initial Review

5.7.3.3.2. The SL-IERC secretariat shall the electronic Notice of Action or Approval to the proponents via email.

5.7.3.4. Continuing and post-approval reviews

5.7.3.4.1. For continuing and post-approval reviews, the SL-IERC Secretariat shall require the Principal Investigator/Project Leader to submit electronic progress reports and post-approval documents via email.

5.7.3.4.2. The SL-IERC shall conduct reviews of electronic progress reports and post-approval submissions in accordance with the following SOPs:

- SOP 4.1 Continuing Review (Progress/Final/Termination Report)
- SOP 4.2 Handling and Monitoring of Safety Reports
- SOP 4.3 Reporting and Handling of Protocol Deviations and Violations
- SOP 4.4 Review of Protocol Amendments

5.7.3.4.3. For site monitoring, the Clinical Research Monitor shall conduct either onsite or remote monitoring via SLMC approved platform (e.g. google Meet, Zoom, or Microsoft Teams) depending on the health situation.

2.6.3.4.3.1. Site monitoring shall be conducted in accordance with SOP# 4.5 Site Monitoring Visit.

5.7.3.5. Electronic Documentation and Archiving

5.7.3.5.1. Upon approval of the clinical research protocol, the PI/Project Leader shall submit soft copies of the all pertinent documents to the SL-IERC Secretariat.

5.7.3.5.2. The SL-IERC Secretariat shall digitally stamp every page the words “IERC Approved” and the date of approval in the following documents: research protocol, informed consent forms, case report forms or data collection forms, patient materials, and other study related documents.

5.7.3.5.3. The SL-IERC Secretariat shall store all electronic protocol documents and reports; protocol and ICF evaluation forms; meeting agenda and minutes; notices of action, approval and ethical clearances; correspondences; GCP Certificates; CVs; COIs; and other related documents in the clinical research protocol folder in the Google Drive cloud and server.

—Nothing Follows—

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
				New SOP			
1	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

SOP 6. Preparation of Standard Operating Procedures (SOPS) and Guidelines For The SL-IERC

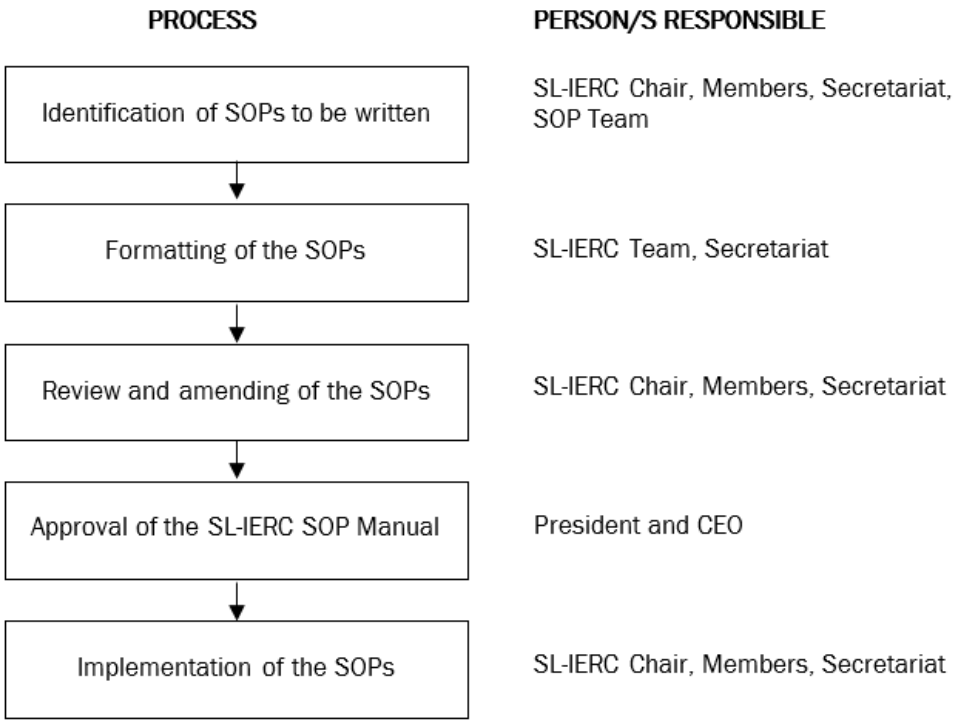
6.1.1. PURPOSE

The purpose of this SOP is to describe the manner in which an SOP shall be formulated, reviewed, approved, distributed, and amended.

6.1.2. SCOPE

This SOP covers the process from identifying SOPs to be formulated to formulation of the SOPs, formatting, reviewing, and amending the SOPs, approval of the SL-IERC SOP Manual and implementation of the SOPs.

6.1.3. FLOW CHART



6.1.4. PROCEDURE

6.1.4.1. Identification of the SOP to be formulated or amended

6.1.4.1.1. The SL-IERC Chair and/or Members of the committee shall propose the formulation of a new SOP or the amendment of an existing SOP.

6.1.4.1.2. The proposal shall include the rationale for the new SOP or for the amendment and shall be discussed as part of the Agenda of an SL-IERC regular meeting.

6.1.4.1.3. The decision on the proposal shall be made through a consensus of the SL-IERC.

6.1.4.2. Writing, Formulation, Formatting and Approval of the SOP

6.1.4.2.1. The SL-IERC Chair shall form an SOP Team which shall be responsible for the writing or amending the SOP.

6.1.4.2.2. The SOP shall be written in a standard format, as described in SOP # 6.2 Preparation Guidelines on SOPs.

6.1.4.2.3. The final draft of the new/amended SOP shall be included in the Agenda of the SL-IERC regular meeting and shall be formally approved by a consensus.

6.1.4.2.4. The Head of R&B and the President and CEO of SLMC shall sign and date the approved SL-IERC SOP Manual upon recommendation of the SL-IERC Chair.

6.1.4.3. Archiving/filing system

6.1.4.3.1. The signed SOP shall be assigned a Control SOP Number and shall be incorporated in the SOP file.

6.1.4.3.2. The SL-IERC Secretariat shall keep the original signed and dated controlled copy as part of the Updated SOP Manual.

6.1.4.3.3. The SL-IERC Secretariat shall maintain the revision history for all amended SOPs, including the Revision Date and Version Number.

6.1.4.4. Effectivity and implementation

6.1.4.4.1. The new or amended SOP shall be effective immediately upon the recommendation of the SL-IERC Chair and R&B Head and approval of the President and CEO.

6.1.4.4.2. The SL-IERC Chair, Members, and Secretariat shall be responsible for the implementation of the approved new or amended SOP.

6.1.4.4.3. The SL-IERC Secretariat shall provide copies to SL-IERC Members and other authorized personnel.

—Nothing Follows—

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Preparation and Amendment of SOPs	SL-IERC SOP No.: SOP # 6.1

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	07-2018		4	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022	✓			SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Preparation Guidelines on SOPs	SL-IERC SOP No.: SOP # 6.2

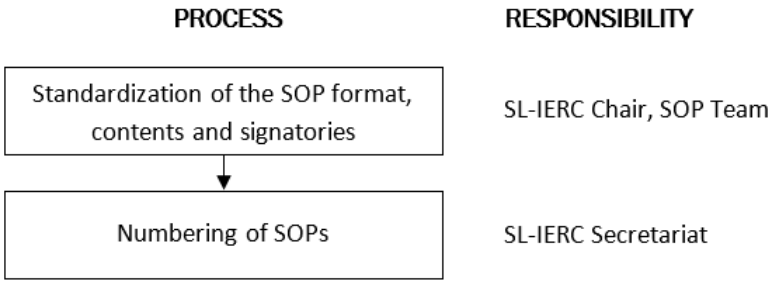
6.2.1. PURPOSE

The purpose of this SOP is to describe the guidelines and procedures in the preparation and writing of the SOP of the SL-IERC.

6.2.2. SCOPE

This SOP covers the process from standardization of the SOP format, contents and numbering of SL-IERC SOPs.

6.2.3. FLOW CHART



6.2.4. PROCEDURE

6.2.4.1. The SL-IERC shall follow a standard format for a written SOP. Each page shall have the following:

a. Header
- Logo of SLMC in the upper middle portion
- INSITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCECURE in bold upper case letters as Title of the Manual
- MANUAL in bold upper case letters as Document Type
- System box ticked as Level of the Manual
- Document Code of the Manual
- Research and Regulatory boxes ticked as Category of the Manual
- Effectivity date of the Manual
- Title of the specific SOP
- SOP number

b. Footer
- Pagination

6.2.4.2. The standard contents of the main text of the SOP shall have the following parts:

- Purpose
- Scope
- Flow Chart
- Procedure

6.2.4.3. Description of contents

6.2.4.3.1. The description of the contents of the SOPs shall be as follows:

- Purpose - This states the aim of the SOP.
- Scope - This refers to the procedures covered in the SOP.
- Flow Chart - This illustrates the chronological order of the various steps involved in the procedure, including the person or groups of persons who are responsible for each step.
- Procedure - This is a detailed description of the various steps outlined in the Flow Chart.
- Optional parts – These are the references and document history. Attachments may be added when necessary.

6.2.4.4. Signatories of SOPs

6.2.4.4.1. The signatories of the SOPs shall include the following:

- Prepared by the Associate Director for R&B Office of Research Integrity
- SL-IERC Chair
- Recommended by the Head of R&B
- Approved by the President and CEO of St. Luke's Medical Center, Head of SLMC One Healthcare System, Head of Hospital Operations

6.2.4.5. Numbering of SOPs

6.2.4.5.1. All SOPs shall be identified by a document code that contains letters and numbers, i.e. SL-IERC SOP #XX.

6.2.4.5.2. Only the final version of an SOP shall be given a document code.

6.2.4.5.3. A revised SOP shall have a new effectivity date.

6.2.5. REFERENCE

6.2.5.1. World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.

—Nothing Follows —

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022

SOP Title: Preparation Guidelines on SOPs	SL-IERC SOP No.: SOP # 6.2

DOCUMENT HISTORY							
REVIEW		REVISION		REASON FOR REVISION	REVIEWED BY	APPROVED BY	REVISED EFFECTIVE DATE
NO.	DATE	NONE	NO.				
1	10-2012		1	Compliance with suggestions of FERCAP surveyors	Filipinas F. Natividad, PhD Executive Secretary	Prospero Ma. Tuaño, MD SL-IERC Chair	April 2013
2	06-2014		2	Compliance with the PHREB suggested SOP Format	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2015
3	10-2015		3	Compliance with suggestions of FERCAP/PHREB surveyors	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	January 2016
4	07-2018		4	Improvement of processes	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	December 2018
5	08-2019		5	Improvement of process	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	September 2019
6	06-2022		6	Integrated the SLMC format for Manuals (Header, signatories)	SL-IERC Members	Prospero Ma. Tuaño, MD SL-IERC Chair	June 2022

5. REFERENCES AND RELATED DOCUMENTS:

- This Manual addresses the Human Subject Research Program (HRP) Standard of the Joint Commission International (JCI).
- Policies on:
  - Institutional Ethics Review Committee, Research 1-06-6 (April 10, 2022)
  - Functional Group Policy (Research and Biotechnology), Leadership 1-13-5 (April 30, 2022)
  - Clinical Trials and Research Projects, Research 1-02-8 (September 30, 2021)
  - Monitoring of Clinical Safety of Investigational Drugs, Research 1-04-2 (October 30, 2021)
  - Clinical Research Monitoring, Research 1-03-4 (October 30, 2021)
  - Clinical Trials and Research Indemnification, Research 1-01-3 (September 23, 2021)
  - Institutional Scientific Review Committee, Research 1-08-5 (April 30, 2022)

  (Refer to SLMC Policies and Procedures page to access the recent versions of the related documents)
- Association for the Accreditation of Human Research Protection Programs, Inc. (2018). Evaluation Instrument for Accreditation. Washington, DC: Association for the Accreditation of Human Research Protection Programs, Inc.
- Cash R, Wikler D, Saxena A, Capron A, eds. (2009). Casebook on Ethical Issues in International Research. Geneva: World Health Organization.
- Council for International Organizations of Medical Sciences. (2016). International Ethical Guidelines for Health-Related Research Involving Humans. Geneva: Council for International Organizations of Medical Sciences.
- Food and Drug Administration. (2012). FDA Circular No. 2012-007 Recognition of Ethical Review Board/ Committee (ERB/ERC) for Purposes of the Conduct of Clinical Trials on Investigational Medicinal Products in the Philippines and Other Purposes. City of Muntinlupa: Department of Health Food and Drug Administration.
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (2016). ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline For Good Clinical Practice ICH E6(R2). Geneva. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).
- Karlberg JPE and Speers MA, eds. (2010). Reviewing Clinical Trials: A Guide for Ethics Committees. Hong Kong: University of Hong Kong Clinical Trial Centre.
- Karlberg JPE and Tam SYM. (2011). Study Site SOP Standardization - 4S - Project. Hong Kong: Clinical Trials Centre. The University of Hong Kong, Li Ka Shing Faculty of Medicine.
- Office of Human Research Protections. (2016). Code of Federal Regulations Title 45, Part 46, Section 46.102 Definitions for the Purposes of this Policy. U.S. Department of Health & Human Services.
- Office of Human Research Protections. (2016). Code of Federal Regulations Title 45, Part 46, Section 46.111 Criteria for Approval of Research. U.S. Department of Health & Human Services.
- Office of Human Research Protections. (2018). Code of Federal Regulations Title 21, Part 312, Section 312.32. U.S. Department of Health & Human Services.
- Philippine Health Research Ethics Board. (2017). National Ethical Guidelines for Health and Health Related Research. Manila: Department of Science and Technology – Philippine Council for Health Research and

Development. Republic of the Philippines (2013). Republic Act No. 10532 - Philippine National Health Research System Act of 2013. Manila: Republic of the Philippines.

- Republic of the Philippines. (2012). Republic Act No. 10173 - Data Privacy Act of 2012. Manila: Republic of the Philippines.
- The Joint Commission (2020). Joint Commission International Accreditation Standards for Hospitals including Standards for Academic Medical Center Hospitals (7th ed.). Joint Commission Resources.
- US Food and Drug Administration (FDA). (2018). Code of Federal Regulations Title 21, Part 56, Section 56.102 Definitions. U.S. Food and Drug Administration.
- World Health Organization. (2000). Operational Guidelines for Ethics Committees that Review Biomedical Research. Geneva: World Health Organization.
- World Health Organization. (2011). Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. Geneva: World Health Organization.
- World Medical Association. (2013). Declaration of Helsinki – Ethical Principles For Medical Research Involving Human Subjects. Journal of the American Medical Association (Special Communication).
- Joint Commission International. (2020). Joint Commission International Accreditation Standards for Hospitals: Including Standards for Academic Medical Center Hospitals (7th Edition). Joint Commission Resources

6. ATTACHMENTS

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

AGREEMENT ON CONFIDENTIALITY AND CONFLICT OF INTEREST

As a Member of the St. Luke's Institutional Ethics Review Committee (SL-IERC), I may be provided with confidential information and documentation *(referred to here as "Confidentiality Information")*. I hereby agree to protect such Confidential Information; not to disclose it to any person nor use it for any purpose that would benefit myself or any third party; and to return all Confidential Information to the Chairperson or Secretariat upon termination of my functions as a Committee member.

Furthermore, whenever there are issues for discussion and decision in which I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

My signature below signifies that I have read and accept the terms and conditions set in this agreement.

_____	_____
Printed Name and Signature of SL-IERC Member	Date
_____	_____
Printed Name and Signature of Head Research and Biotechnology Group	Date

*All members of St. Luke's Institutional Ethics Review Committee are required to sign and date this **Agreement on Confidentiality and Conflict of Interest** before they assume their duties in the committee. The Original signed and dated copy of this Agreement shall be kept on file in the member's binder under the Custody of the IERC Secretariat. A copy will be given to each for his own records.

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

AGREEMENT ON CONFIDENTIALITY AND CONFLICT OF INTEREST

As a Member of the St. Luke's Institutional Ethics Review Committee (IERC), I may be provided with confidential information and documentation *(referred to here as "Confidentiality Information")*. I hereby agree to protect such Confidential Information; not to disclose it to any person nor use it for any purpose that would benefit myself or any third party; and to return all Confidential Information to the Chairperson or Secretariat upon termination of my functions as an Independent Consultant.

Furthermore, I shall immediately inform the Chairperson whenever I have conflict of interest in a study I will evaluate.

My signature below signifies that I have read and accept the terms and conditions set in this agreement.

_____	_____
Printed Name and Signature of Independent Consultant	Date
_____	_____
Printed Name and Signature of Chair St. Luke's Institutional Ethics Review Committee	Date

SL-IERC FORM # 01B (Consultant)

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DISCLOSURE OF CONFLICT OF INTEREST

Please check the appropriate box and print clearly.

☐ Principal Investigator ☐ Sub- or Co-investigator ☐ Study Coordinator or Research Assistant

GIVEN NAME_____ **FAMILY NAME**_____ **MI** _____

Contact No.:_____ **Email**_____

PROTOCOL NO.: _____

PROTOCOL TITLE: _____

*Please answer each of the question below by **CHECKING THE APPROPRIATE BOX.** If you check **YES** to any question you must attach details of the disclosable financial arrangements.*
Please insert and print clearly the name of the Sponsor/CRO (for sponsor-initiated trials) or Collaborator/Supplier (for SLMC investigator-initiated research studies) in the questions.

1. Do you, your spouse, or your dependent children participate in any financial arrangement with the Sponsor/CRO/Collaborator/Supplier _____ relevant to the clinical trial or research study, whereby the value of the compensation could be influenced by the outcome of the study (i.e., could be higher for a favorable outcome than for an unfavorable outcome)?	Yes ☐	No ☐
2. During the time you are conducting the study and for one (1) year following completion of the study, will you, your spouse or dependent children or your institution (to the extent used to support your activities) receive any significant payments of other sorts from the Sponsor/CRO/Collaborator/Supplier _____ relevant to the clinical trial or research study which is exclusive of the costs of conducting the clinical study?	Yes ☐	No ☐
3. Do you, your spouse or dependent children, hold any proprietary interest (property or other financial interest) in the product. Proprietary interest would include, but not limited to, a patent, trademark, copyright or licensing agreement.	Yes ☐	No ☐
4. Do you, your spouse or dependent children, hold any significant interest in the Sponsor/ CRO/Collaborator/Supplier _____ relevant to the clinical trial or research study such as any ownership interest (e.g., stock ≥ PhP 500,000.00), stock options or other financial interest?	Yes ☐	No ☐

I declare that the information provided on this form, is to the best of my knowledge and belief, true, correct and complete.

Furthermore if my financial interests and arrangements, or those of my spouse and dependent children, change from the information provided above during the course of the study or within one year following completion of the study as per site closure letter, I will promptly notify St. Luke's Institutional Ethics Review Committee.

SIGNATURE	DATE (MMM-DD-YYYY)

SL-IERC Form # 01C V2 (Proponent)

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

Initial Submission Reviewer Form for Clinical Trial/Research

Principal Investigator/Project Leader:	Institute/Department:
Type of Research *(Kindly check what applies)*	
☐ **Sponsor-Initiated Trial (SiT)** ***For Pharmaceuticals, CROs, AROs*** ☐ Drug ☐ Phase 1 ☐ Medical device ☐ Phase 2 ☐ Procedure ☐ Phase 3 ☐ Observational ☐ Phase 4 ☐ Others, specify:	☐ **Investigator-Initiated Trial (IiT)** ***For Consultant/Fellow/Resident/Faculty/Personnel/Student*** ☐ Biomedical Study ☐ Systematic review and meta-analysis ☐ Health Operations Research ☐ Public Health Research ☐ Registry/Databank ☐ Social/Behavioral Research ☐ Animal Study ☐ Case study/report ☐ Plant Study ☐ Others, specify:
Email address:	Contact No.s: Office: Mobile:
Sponsor:	CRO:
Protocol Title:	

INSTRUCTIONS:
Please indicate in the columns below whether or not elements stated in the checklist for specific documents (protocol or ICF) have been included (**Y**=Yes; **N**=No; **NA**=Not applicable). If yes, state the page and paragraph where the element can be found.

NOTE:
The following checklist includes the ICH GCP E6 Guideline for Good Clinical Practice recommendations for Protocol content and Informed Consent forms. Supporting documents to use as basis for review may include the Investigator's Brochure (IB), protocol, protocol amendment(s) and other documents, if applicable.

STUDY PROTOCOL	Y	N	NA	Page & Paragraph Nos.
1. General Information				
1.1. Protocol title, protocol identifying number and date. Any amendment(s) should also bear the amendment(s) number and dates.				
1.2. Name and address of the sponsor and CRO (if other than sponsor shall monitor the research)				
2. Background Information				
2.1. Name and description of Investigational product(s)				
2.2. Summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial a. References to literature and data that are relevant to the trial, and that provide background for the trial.				
2.3. Summary of the known and potential risks and benefits, if any, to human subjects.				
2.4. Description of and justification for the route of administration, dosage, dosage regimen, and treatment period(s).				
3. Trial Objectives and Purpose				
3.1. Detailed description of the objectives and the purpose of the trial				
3.2. Specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.				

	Y	N	NA	Page & Paragraph Nos.
4. Trial Design				
4.1. Description of the type/design of trial to be conducted (e.g. double-blind, placebo-controlled, parallel design) and a schematic diagram of trial design, procedures and stages.				
4.2. Description of the measures taken to minimize/avoid bias (e.g. randomization, blinding)				
4.3. Trial treatments a. Drugs, supplements or biologics: description of the trial treatment(s) and the dosage and the dosage regimen of the investigational product(s); If appropriate, description of the dosage form, packaging and labeling of the investigational product(s) b. Devices: description of the trial treatment(s) and the device implantation/ application, removal; description of the device specifications, packaging and labeling of the investigational product(s)				
4.4. Expected duration of subject participation and description of the sequence and duration of all trial periods including follow-up, if any.				
4.5. Description of the "stopping rules" or "discontinuation criteria" for individual subjects, parts of trial, and entire trial.				
4.6. Accountability procedures for the investigational product(s), including the placebo(s)/sham procedures and comparator(s), if any. a. Appropriate monitoring of subjects' compliance				
4.7. Identification of any data to be recorded directly on the CRFs (i.e., no prior written or electronic record of data), and to be considered to be source data				
4.8. Method of collection of biological specimens. Appropriate storage of specimens as well as personal information.				
4.9. Collection of specimens for pharmacogenomics analysis				
4.10. Statement that collected specimens shall be used for future research				
5. Selection and Withdrawal of Subjects				
5.1. Subject identification and recruitment methods				
5.2. Subject Inclusion and Exclusion Criteria. Description of how the eligibility criteria shall be determined: • Information reported by the subject. • Medical record review • Results of screening assessment (e.g. questionnaire diaries, etc.)				
5.3. Subject withdrawal criteria (i.e. terminating investigational product (IP) treatment/trial treatment) and procedures specifying: a. Description of when and how to withdraw subjects from the trial/IP treatment. b. Detailed description of the study withdrawal procedures, including the type and timing of the data to be collected for withdrawn subjects. c. Description of whether and how subjects are to be replaced. d. Description of follow-up for subjects withdrawn from IP treatment and trial				
6. Treatment of Subjects				
6.1. Treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route, mode(s) of administration, and the treatment period(s), including the follow-up period(s) for subjects for each IP treatment/trial treatment group/arm of the trial				

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	Y	N	NA	Page & Paragraph Nos.
6.2. Medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and /or during the trial.				
6.3. Procedures for monitoring subject compliance				
7. Assessment of Efficacy				
7.1. Specification of efficacy parameters.				
7.2. Methods and timing for assessing, recording and analyzing efficacy parameters				
8. Assessment of Safety				
8.1. Specification of safety parameters				
8.2. The methods and timing for assessing, recording, and analyzing safety parameters.				
8.3. Procedures for eliciting reports and for recording and reporting Adverse Events and inter-current illnesses				
8.4. Type and duration of the follow-up of subjects after adverse events.				
9. Statistics				
9.1. Description of the statistical methods to be employed, including timing of any planned interim analysis(ses) a. Sampling design b. Statistical analysis plan c. Level of significance to be used d. criteria for the termination of the trial e. procedure for accounting for missing, unused, and spurious data f. procedures for reporting any deviation(s) from the original statistical plan and justification for deviation				
9.2. Number of subjects planned to be enrolled a. number of subjects to be enrolled in the trial site b. reason for choice of sample size including power of the trial and clinical justification.				
9.3. Selection of subjects to be included in the analyses (e.g. all randomized subjects, all dosed subjects, all eligible subjects, evaluate-able subjects)				
10. Access to Source Data/ Documents, Data Handling and Recordkeeping				
10.1. Statement in the protocol or other written agreement that sponsor shall ensure that investigator(s)/ institution(s) shall permit trial-related monitoring , audits, IERC review and regulatory inspection(s) by providing direct access to source data/documents				
10.2. Description of the data handling and recordkeeping processes and measures to be taken, i.e. provide information about confidentiality protections, sharing of data, storage and archiving of data, and destruction of data after period of storage				
11. Quality Control and Quality Assurance				
11.1. Periodic monitoring visits during study conduct to ensure that the protocol and Good Clinical Practices (GCPs) are being followed				
12. Ethics				
12.1. Ethical issues stated in the protocol and how these issues shall be addressed (e.g. review of management of conflict of interest arising from financial, familial or proprietary considerations of the PI, spouse or the study site; informed consent process)				
12.2. Statement on how, when and where Informed Consent/assent process shall be conducted.				

	Y	N	NA	Page & Paragraph Nos.
12.3. Name and Title of the investigator(s) who is (are) responsible for conducting the trial and the address and telephone number(s) of the trial site(s).				
12.4. Name and Title of the Study team				
13. Financing and Insurance				
13.1. Financing and insurance if not addressed in a separate agreement				
14. Publication Policy				
14.1. Publication policy if not addressed in a separate agreement.				
15. Involvement of Vulnerable Subjects				
15.1. Statement that vulnerable subjects are part of the clinical trial/study.				
16. Advertisement materials				
16.1. Availability **of** advertisement material(s)				
INFORMED CONSENT FORM	**Y**	**N**	**NA**	**Page & Paragraph Nos.**
1. General Information				
1.1. Protocol Title and Protocol Number 1.2. ICF Footer				
2. Statement that study has been reviewed and approved by SL- IERC				
3. Statement that the trial/study involves research				
4. Explanation of the purpose of the trial/study. 4.1. Statement on the approximate number of participants in the study and whether the study is multi-center				
5. Trial/study–related treatments and the probability for random assignment to each treatment (if applicable				
6. Description of the trial/study procedures to be followed including all invasive procedures				
7. Subject's responsibilities 7.1. Expected duration of the study and length of the individual's commitment during the duration of the study				
8. Aspects of the trial/study that are experimental				
9. Reasonably foreseeable risks/ inconveniences to subject/ embryo/fetus/ nursing infant 9.1. Statement to address the foreseeable risks to the fetus or nursing infant of participant of child-bearing potential 9.2. Risks from allowable use of placebo				
10. Description of any of the benefits to the subject or to others, which may reasonably be expected from the research. If none is expected subject must be informed.				
11. Disclosure of the alternative procedure(s) or course(s) of treatment available, if any and their important potential benefits and risks				
12. Compensation/treatment available in case of trial/study-related injury				
13. Anticipated prorated payment, if any, to the subject for participating in the study				
14. Anticipated expenses, if any, to the subject for participating in the study.				
15. Statement that subject's participation is voluntary and that the subject may refuse to participate or withdraw at any time without penalty or loss of benefits				

	Y	N	NA	Page & Paragraph Nos.
16. Statement that identifying records will be kept confidential and will not be made publicly available. If the results are published the subject's identity will remain confidential.				
17. Statement that the Monitor(s), the auditor(s), the IRB, and the regulatory authority(ies) will be granted direct access to the subject"s original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject"s legally acceptable representative is authorizing such access.				
18. Statement that subject or the legally acceptable representative will be informed in a timely manner if information becomes available that might influence the subject's willingness to stay in the trial/study.				
19. Person(s) to contact for further information regarding the trial/study and the rights of trial/study subjects, and whom to contact in the event of trial/study – related injury				
20. Statement that specimens shall be collected from the subject and that collected specimens shall be for future use.				
21. Statement that foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.				
ACCOMPLISHED BY:				
Printed Name and Signature:	Designation:	Date:		

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INSTITUTIONAL REVIEW COMMITTEE

INITIAL PROTOCOL REVIEW ACKNOWLEDGMENT FORM

EC Reference No.:	SUBMISSION DATE:	☐Phase____ ☐PMS ☐Registry ☐Observational ☐Investigator-Initiated ☐Others:_____	
STUDY TITLE:			
PRINCIPAL INVESTIGATOR:	CONTACT #:	EMAIL:	DIV/DEPT/INST.:
SUB-INVESTIGATOR:	CONTACT #:	EMAIL:	DIV/DEPT/INST.:
RA/SC:	OFFICE TEL./FAX NO.	MOBILE NO.:	EMAIL:

Documents Received *(Pls. check all that applies. Write "NA" if not applicable)*	NO. OF COPIES	VERSION/DATE	REMARKS
☐ Protocol			
☐ Investigator Brochure			
☐ ICF *(English)*			
(Filipino)			
☐ Pharmacokinetics ICF *(English)*			
(Filipino)			
☐ Subject Worksheets *(English)*			
(Filipino)			
☐ Patient Diary/Alert Card *(English)*			
(Filipino)			
☐ Questionnaire *(English)*			
(Filipino)			
☐ Case Report Form (CRF)/ e-CRF			
☐ Project Summary & Flow Chart of the Protocol			
☐ Material to be used for Recruitment of research participants			
☐ PFDA Approval			
☐ Curriculum Vitae of Investigator(s)			
☐ GCP Training Certificate(s)			
☐ Certificate of Insurance			
Others/Remarks:			

SUBMITTED BY:	IERC ACKNOWLEDGEMENT:
_____ Date:_____ *(Signature over Printed Name)*	

SL-IERC FORM # 03

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

CLINICAL RESEARCH TRACKING FORM

EC Reference No.	Type of Protocol:	Sponsor/CRO:
Protocol Title:		
Principal Investigator:	Inst./Dept.	Contact No.:

DATE	PARTICULARS	IN		OUT	REMARKS	Received/Issued by Initial
		FA	FYI			

Legend: ***FA*** *- For Approval*
FYI *- For Information*

SL-IERC FORM #04 V3

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

ETHICS REVIEW FORM FOR PROTOCOL

☐ Expedited ☐ Full Board

EC Reference No.: Enter Study Reference No	**Principal Investigator:** Enter Name of PI/Project Leader
Inst./Dept.: Enter Department/Institute	**Contact Nos.** Enter mobile/landline nos.
Title of Protocol: Enter Title	

Type of Protocol: *(check appropriate boxes)*

☐ **Sponsor-Initiated Trial (SiT)**-*Pharmaceuticals, CROs, AROs*
- ☐ Clinical Trial
  - ☐ Drug
  - ☐ Medical device
  - ☐ Procedure
  - ☐ Phase 1
  - ☐ Phase 2
  - ☐ Phase 3
  - ☐ Phase 4
- ☐ Observational
- ☐ Others_____

☐ **Investigator-Initiated Trial (IiT)**-*Consultant/Fellow/Resident/Faculty/Personnel/Student*
- ☐ Interventional Clinical Research
  - ☐ Drug ☐ Medical device ☐ Procedure
- ☐ Biomedical (observational, epidemiologic)
- ☐ Public Health Research
- ☐ Health Operations Research
- ☐ Social/Behavioral Research
- ☐ Prospective Case Study/Report
- ☐ Registry/Databank
- ☐ Others _____

Name of Sponsor/CRO/ARO: Enter Name of Sponsor/CRO/ARO)

Agreement on Confidentiality and Conflict of interest (COI)

As a member of the St. Luke's Institutional Ethics Review Committee (IERC), I may be provided with confidential information and documentation (referred to here as "Confidential Information"). I hereby agree to protect such Confidential Information; not to disclose it to any person nor use it for any purpose that would benefit myself or any third party; and to return all Confidential Information to the Chairperson or Secretariat upon termination of my functions as a Committee member.

Furthermore, whenever there are issues for discussion and decision in which I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

INSTRUCTIONS for the IERC:

The following is a checklist of ethical issues that need to be addressed by the protocol/Principal Investigator to ensure compliance with GCP standards. Please review the checklist carefully and indicate your assessment by filling up as follows:

- YES, if compliant with ICH-GCP Standards
- NO, if not compliant, and specify the issue to be addressed in the REMARKS/RECOMMENDATIONS column
- N/A if not applicable.

I. CHECKLIST FOR ETHICAL REVIEW OF PROTOCOL

A. Review of the Protocol	Y	N	N/A	REMARKS/RECOMMENDATIONS
1. Qualified Principal Investigator/Proponent and Research Team *(Based on CV, GCP training certificate)*				
2. Disclosure of conflict of interest by the Principal investigator/Project Leader				
3. Social and Scientific Value *(Will it improve health and well-being or increase knowledge?)*				

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	Y	N	N/A	REMARKS/RECOMMENDATIONS
4. **Scientific Validity** - *Use of accepted scientific principles and methods, o produce reliable and valid data* *a. Clear rationale for doing the research* *b. Adequate literature review, gaps identified* *c. Clear objectives (SMART) – are they scientific, ethical, feasible?* *d. Appropriate methodology* • *Research design (descriptive, experimental, etc.)* • *Operational definition of terms* • *Target population and eligibility criteria* • *Indicators of variables to be used* • *Relationships between variables that will be explored* • *Procedures to be performed* • *Equipment to be used* *e. Clear and appropriate outcomes* *f. Adequate and feasible sample size* *g. Appropriate statistical plan* • *Quantitative (use of statistical tools and analysis to arrive at generalizable conclusions)* • *Qualitative (provides in depth insights about specific behavior of social phenomenon)*				
B. Review of Ethical Issues (Required)	**Y**	**N**	**NA**	**REMARKS/RECOMMENDATIONS**
1. **Fair selection of subjects** *(Is selection of subjects not biased so that stigmatized and vulnerable individuals are not targeted for risky research and the rich and socially powerful not favored for potentially beneficial research?)*				
2. **Justification for inclusion of vulnerable population** *such as children, elderly, illiterate, severe physical or mental illness/ condition, prisoners, pregnant women, minority population (migrants, etc.), stigmatized groups (sex workers, drug addicts), deviant behavior, in a dependent relationship with investigator (client or professional relationship, trainees/students/employees)*				
3. **Justifiable use of a placebo**				
4. **Standard of care not compromised**				
5. **Favorable risk-benefit ratio** *(Are potential risks to the subject proportionate to the benefits to the subject and society? How are risks minimized and benefits maximized? Are AEs/SAEs identified? How will they be managed? Withdrawal criteria is appropriate and adequate?)* *Possible risks include physical risks (invasive procedures); psychological risks (psychological discomfort answering questions about private behavior, e.g. sex, etc.); economic risks (possible loss of employment); social risks (research about illegal behavior, possible public disclosure, adverse impact on reputation of communities); political risks (possible political exclusion)* *Possible benefits include direct or indirect benefits to participant (access to drugs, information, etc.), community (access to technology), society (new knowledge and interventions); feedback to participants/community about research findings; provision of medical care; referral to care if not provided in the research*				

SL-IERC FORM # 05A V2 (Protocol)

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

	Y	N	NA	REMARKS/RECOMMENDATIONS
6. Inclusion of a section on ethical considerations *a. Informed consent process, if applicable* *b. Anticipated risks and discomforts to subjects* *c. Expected benefits to the subject and to others* *d. Method/s of dealing with AEs, SAEs, indemnification* *e. Statement of compliance with the Principles of the Declaration of Helsinki (2013) and ICH-GCP guidelines* *f. Statement of review and approval of the SL-IERC* *g. Process of maintaining patient confidentiality and data privacy* *h. Statement on ensuring integrity of the data, i.e. accuracy, completeness, legibility, originality, timeliness and consistency.* *i. Manner of disseminating and communicating study results* *j. Storage, retention and disposal of study-related documents*				
Other Comments				

RISK ASSESSMENT: *(Check the appropriate box to indicate your risk assessment to participants involved in this clinical trial)*

☐ Minimal ☐ Moderate ☐ High

NOTE:
- *A study presents **minimal risk** if "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*
- *A study has **moderate risk** if as a result of research participation, the subjects would be exposed to more than a remote possibility of "substantial or prolonged pain, discomfort, or distress" or "clinically significant deterioration of a medical condition"; subject participant to substantial pain discomfort that is reversible.*
- A study with **high risk** to participants is disapproved unless there is a strong justification for the study to be conducted, in which case additional safeguards are recommended.

RECOMMENDED ACTION:

☐ **EXPEDITED REVIEW** *(Check the appropriate box to indicate your recommended action on the following):*

☐ Approved ☐ Deferment ☐ For Full Board Review
- ☐ With minor revisions
- ☐ With major revisions

☐ **FULL BOARD REVIEW** *(Check the appropriate box to indicate your recommended action on the following):*

☐ Approved ☐ Deferment ☐ Disapproved
- ☐ With minor revisions
- ☐ With major revisions

Reviewed by:

_____ _____
(Name & Signature of Reviewer) *(Date)*

SL-IERC FORM # 05A V2 (Protocol)

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

ETHICS REVIEW FORM FOR INFORMED CONSENT

☐ Expedited ☐ Full Board

EC Reference No.: Enter Study Reference No	**Principal Investigator:** Enter Name of PI/Project Leader
Inst./Dept.: Enter Department/Institute	**Contact Nos.** Enter mobile/landline nos.
Title of Protocol: Enter Title	

Type of Protocol: *(check appropriate boxes)*

☐ **Sponsor-Initiated Trial (SiT)**-*Pharmaceuticals, CROs, AROs*
- ☐ Clinical Trial
  - ☐ Drug
  - ☐ Medical device
  - ☐ Procedure
  - ☐ Phase 1
  - ☐ Phase 2
  - ☐ Phase 3
  - ☐ Phase 4
- ☐ Observational
- ☐ Others_____

☐ **Investigator-Initiated Trial (IiT)**-*Consultant/Fellow/Resident/Faculty/Personnel/Student*
- ☐ Interventional Clinical Study
  - ☐ Drug ☐ Medical device ☐ Procedure
- ☐ Biomedical (observational, epidemiologic)
- ☐ Public Health Research
- ☐ Health Operations Research
- ☐ Social/Behavioral Research
- ☐ Prospective Case Study/Report
- ☐ Registry/Databank
- ☐ Others _____

Name of Sponsor/CRO/ARO: Enter Name of Sponsor/CRO/ARO)

Agreement on Confidentiality and Conflict of interest (COI)

As a member of the St. Luke's Institutional Ethics Review Committee (IERC), I may be provided with confidential information and documentation (referred to here as "Confidential Information"). I hereby agree to protect such Confidential Information; not to disclose it to any person nor use it for any purpose that would benefit myself or any third party; and to return all Confidential Information to the Chairperson or Secretariat upon termination of my functions as a Committee member.

Furthermore, whenever there are issues for discussion and decision in which I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

INSTRUCTIONS for the IERC:
The following is a checklist of ethical issues that need to be addressed by the protocol/Principal Investigator to ensure compliance with GCP standards. Please review the checklist carefully and indicate your assessment by filling up as follows:

- YES, if compliant with ICH-GCP Standards
- NO, if not compliant, and specify the issue to be addressed in the REMARKS/RECOMMENDATIONS column
- N/A if not applicable.

PARTICULARS	Y	N	NA	REMARKS/RECOMMENDATIONS
1. **Appropriate Type of Consent Form** (*i.e. ICF for Clinical Studies/Assent/ Legally Acceptable Representative*)				
2. **Following items are included in the Informed Consent Form:**	Y	N	NA	REMARKS/RECOMMENDATIONS
a. Name of Principal Investigator, Site of Study, Sponsor				
b. An explanation that the study involves research				
c. Title of the study				
d. Purpose of the study				

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	Y	N	NA	REMARKS/RECOMMENDATIONS
e. Type of research intervention				
f. Nature of participation (treatment or control)				
g. Possibility for random allocation				
h. Information on the trial drug				
i. Expected duration of participation				
j. Responsibilities of the participant				
3. The consent form is written in a language that a layman can understand.				
4. The procedure written in the ICF is consistent with the protocol.				
5. The participant is informed of the following:	**Y**	**N**	**NA**	**REMARKS/RECOMMENDATIONS**
a. Informed Consent will be obtained				
b. Explanation of anticipated risks and discomforts of each procedure/drug				
c. Possible benefits of each procedure/drug				
d. Possible adverse effects of each procedure and/or drug				
6. There is a statement about reimbursement for study/ trial-related expenses.				
7. There is a statement about responsibility for medical treatments in case of injury during the study.				
8. There is a provision for free choice of contraception.				

SL-IERC FORM # 05B (ICF) V2

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	Y	N	NA	REMARKS/RECOMMENDATIONS
9. Time is given for participant to consider whether to participate in the study or not.				
10. There is consideration of the following ethical issues:	**Y**	**N**	**NA**	**REMARKS/RECOMMENDATIONS**
a. Confidentiality and data privacy				
b. Alternative treatments				
c. Voluntary participation				
d. Right to withdraw anytime without prejudice to the appropriate medical care				
e. Right to know results of tests				
f. Timely release of new information that may affect his willingness to continue his participation in the trial				
g. Statement about what will be done with left-over specimens				
11. The name and signature of the following are included:	**Y**	**N**	**NA**	**REMARKS/RECOMMENDATIONS**
a. Person getting informed consent				
b. Participant				
c. Witnesses				
d. Representative of participants who are incapacitated				
e. Parent or Guardian (for minors)				
12. The following information are included in the ICF:	**Y**	**N**	**NA**	**REMARKS/RECOMMENDATIONS**
a. Name and contact number of the PI/Study Coordinator				
b. Name and contact number of the Ethics Review Committee (ERC) Chair				
13. Translation (not necessarily literal) of the ICF from English to Filipino (or other language) is accurate and acceptable.				
14. Indemnity insurance is adequate.				

SL-IERC FORM # 05B (ICF) V2

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	Y	N	NA	REMARKS/RECOMMENDATIONS
15. Study advertisements, brochures and patient recruitment materials are appropriate.				
Other comments				

RISK ASSESSMENT: *(Check the appropriate box to indicate your risk assessment to participants involved in this clinical trial)*

☐ Minimal ☐ Moderate ☐ High

NOTE:
- *A study presents **minimal risk** if "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."*
- *A study has **moderate risk** if as a result of research participation, the subjects would be exposed to more than a remote possibility of "substantial or prolonged pain, discomfort, or distress" or "clinically significant deterioration of a medical condition"; subject participant to substantial pain discomfort that is reversible*
- A study with **high risk** to participants is disapproved unless there is a strong justification for the study to be conducted, in which case additional safeguards are recommended.

RECOMMENDED ACTION:

☐ **EXPEDITED REVIEW** *(Check the appropriate box to indicate your recommended action on the following):*

☐ Approved ☐ Deferment
- ☐ With minor revisions
- ☐ With major revisions

☐ **FULL BOARD REVIEW** *(Check the appropriate box to indicate your recommended action on the following):*

☐ Approved ☐ Deferment ☐ Disapproved
- ☐ With minor revisions
- ☐ With major revisions

Reviewed by:

_____ _____
(Name & Signature of Reviewer) *(Date)*

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

ETHICS REVIEW FORM
(FOR EXTERNAL/INDEPENDENT CONSULTANT)

EC Reference No.: Enter Study Reference No	**Principal Investigator:** Enter Name of PI/Project Leader
Inst./Dept.: Enter Department/Institute	**Contact Nos.** Enter mobile/landline nos.
Title of Protocol: Enter Title	
Type of Protocol: ☐ **Sponsor-Initiated Trial** - *Pharmaceuticals, CROs, AROs*	☐ **Investigator-Initiated Trial** - *Consultant/Fellow/Resident/Faculty/Personnel/Student*
Name of Sponsor/CRO/ARO: Enter Name of Sponsor/CRO/ARO)	

INSTRUCTIONS: The following is a list of questions/issues that need to be addressed by the protocol/Principal Investigator to ensure compliance with ICH-GCP standards. Please review the checklist carefully and indicate your assessment by filling up as follows:

- YES, if appropriate, adequate, and compliant with ICH-GCP Standards
- NO, if neither appropriate, adequate nor compliant, and specify the issue(s) to be addressed in the REMARKS/RECOMMENDATIONS column.

Methodology *(Are the following clearly stated/described and appropriate?*	Y	N	REMARKS/RECOMMENDATIONS
1. **Qualified Principal Investigator/Proponent and Research Team** *(Based on CV, GCP training certificate)*			
2. **Social and Scientific Value** *(Will it improve health and well-being or increase knowledge?)*			
3. **Scientific Validity** - *Use of accepted scientific principles and methods, o produce reliable and valid data* *a. Clear rationale for doing the research* *b. Adequate literature review, gaps identified* *c. Clear objectives (SMART) – are they scientific, ethical, feasible?* *d. Appropriate methodology* • *Research design (descriptive, experimental, etc.)* • *Operational definition of terms* • *Target population and eligibility criteria* • *Indicators of variables to be used* • *Relationships between variables that will be explored* • *Procedures to be performed* • *Equipment to be used* *e. Clear and appropriate outcomes* *f. Adequate and feasible sample size* *g. Appropriate statistical plan* • *Quantitative (use of statistical tools and analysis to arrive at generalizable conclusions)* • *Qualitative (provides in depth insights about specific behavior of social phenomenon)*			

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

Methodology *(Are the following clearly stated/described and appropriate?*	Y	N	REMARKS/RECOMMENDATIONS
4. **Vulnerability of Patient Population** *(e.g. children, elderly, illiterate, severe physical or mental illness/ condition, prisoners, pregnant women, minority population (migrants, etc.), stigmatized groups (sex workers, drug addicts), deviant behavior, in a dependent relationship with investigator (client or professional relationship, trainees/students/employees)*			
5. **Risks and Benefits** *(Are risks minimized and benefits maximized?*			
6. **Medical Care** *(Is standard of care compromised?)*			
7. Other Comments			
Reviewed by: Printed Name and Signature			**Date:**

SL-IERC FORM #06 V2

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

PROTOCOL AMENDMENT FORM

*EC Reference #: SL-*_____ *Protocol No.* _____
Principal Investigator: _____ *Inst./Dept.:* _____
Protocol Title: _____
_____

Note: Kindly check below the document(s) for review: Submit 2 copies of the new version and supporting documents *(if applicable)*, completed Protocol Amendment form and Summary of the revisions. One copy of the new version must indicate the track changes, new text is shown in **bold** type; deleted text is shown with a ~~strikethrough.~~ The other copy of the new version must be the clean copy of the document amended.

☐ **Protocol**
- ☐ **Major** *(e.g. Study design, objective of study, procedure)* **Does this have significant impact on:**
  - ☐ the safety or physical or mental integrity of the subjects, or
  - ☐ the scientific value of the trial, or
  - ☐ the conduct or management of the trial, or
  - ☐ the quality or safety of any IND used in the trial.
- ☐ **Minor** *(e.g. administrative changes, change of address, grammatical corrections)*

  New version no. & date: _____
  _____

☐ **Informed Consent Form**
- ☐ **Major** *(additional risks to the subjects e.g. updates on side effects of study drug)*
- ☐ **Minor** *(administrative changes, change of address, grammatical corrections)*

  New version no. & date: _____
  _____

☐ **Change in Investigator/Co-investigator/ member of Study team** *(PIs. complete information below)*

a) **Addition** *(Kindly provide copy of individual's Curriculum vitae. New members of the study team must be ICH-GCP certified)*

Name	Position
_____	_____
_____	_____

b) **Deletion**

Name	Position
_____	_____
_____	_____

☐ **Other Study Related Materials: Please Specify** *(Kindly indicate type of document with version date and no.)*

_____ _____
_____ _____
_____ _____

Submitted by:	**Received by:** *(IERC use only)*
_____ *(Name and signature of Principal Investigator)*	_____ *(Name and signature)*
_____ *Date*	_____ *Date*

SL-IERC Form # 07 V2 12/2018

For IERC use only SL-_____

1. Comments/Suggestions of SL-IERC Member:

Does this have significant impact on: *(Pls. check all that apply)*

☐ the safety or physical or mental integrity of the subjects, or
☐ the scientific value of the trial, or
☐ the conduct or management of the trial, or
☐ the quality or safety of any IND used in the trial.

COMMENTS:

Does the proposed changes/amendments affect the risk-benefit ratio of the study? ***(If yes, please explain)***

Recommendation:

Protocol:	☐ Approved	☐ For further Clarification	☐ For Full Board
Informed Consent Forms:	☐ Approved	☐ For further Clarification	☐ For Full Board
Study Related Materials :	☐ Approved	☐ For further Clarification	☐ For Full Board

Name & Signature of SL-IERC Member:	**Date:**

SL-IERC Form # 07 V2 12/2018

2. Comments/Suggestions of the Member-in-Charge on Protocol Amendments:

Does this have significant impact on: *(Pls. check all that apply)*

- ☐ the safety or physical or mental integrity of the subjects, or
- ☐ the scientific value of the trial, or
- ☐ the conduct or management of the trial, or
- ☐ the quality or safety of any IND used in the trial.

Does the proposed changes/amendments affect the risk-benefit ratio of the study? ***(Explain)***

Recommendation:

Protocol:	☐ Approved	☐ For further Clarification	☐ For Full Board
Informed Consent Forms:	☐ Approved	☐ For further Clarification	☐ For Full Board
Study Related Materials :	☐ Approved	☐ For further Clarification	☐ For Full Board

Name & Signature of Member-in-Charge on Protocol Amendments :	**Date:**

SL-IERC Action: ☐ **Approved** ☐ **For further Clarification** ☐ **For Acknowledgment**

Noted by:

_____ _____

SL-IERC Chair Name & Signature *Date*

(If applicable)

NOA release date: _____

Response to NOA receive date: _____

SL-IERC Form # 07 V2 12/2018

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

ETHICAL CLEARANCE

EC Reference No.:	Protocol Title/No:	
Principal Investigator/Institute:	**Address:**	**Date of Approval:**
Email Address & Contact No.:	**Sponsor/CRO:**	**Valid until:**

This clinical trial has been approved by the SL-IERC to be of <Enter Risk Level> risk. The frequency of Continuing Review Reporting shall be <Enter Frequency>:

- ***<Enter Due Date of Submissions>***

Note: Submit Continuing Review Report one (1) month before the due date above. No submission means cancellation of ethical clearance.

The following documents were reviewed and approved for use in this study:

- ☑ **Protocol** <Write title, version no., date>
- ☑ **Informed Consent Forms** <Write version no., date>
- ☑ **Case Report Forms or Data Collection Forms (if applicable)** <Write version no.>
- ☑ **Advertisement materials (if applicable)** <Write date>
- ☑ **Patient's diary (if applicable)**
- ☑ **Other Study Materials** <Write version no., date>

Below are additional study documents included in the review as basis for the approval of the study.

- ☑ **Investigator's Brochure** (Write version no., date)
- ☑ **CV and GCP of Study Team**

---------- *Nothing follows* ----------

<Enter Name>
Chair, Institutional Ethics Review Committee

(Note: This Ethical Clearance carries with it Principal Investigator's commitment to comply with international and national guidelines on Good Clinical Practice. Please see attached for strict compliance.)

- ✦ *(This Committee is recognized by SIDCER Strategic Initiative for Developing Capacity in Ethical Review) and FERCAP (Forum for Ethical Review Committees in Asia and the Western Pacific) and accredited by PHREB (Philippine Health Research Ethics Board).*
- ✦ *The Committee is fully compliant with the regulations as they relate to ethics committee and the conditions and principles of Good Clinical Practice.*

SL-IERC FORM # 13A

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

RENEWAL OF ETHICAL CLEARANCE

EC Reference No.:	Protocol Title/No:	
Principal Investigator/Institute:	Address:	Date of Approval:
Email Address & Contact No.:	Sponsor/CRO:	Valid until:

The following documents were reviewed and approved for use in this study:

- ☑ **Protocol** <Write title, version no., date>
- ☑ **Informed Consent Forms** <Write version no., date>
- ☑ **Case Report Forms or Data Collection Forms (if applicable)** <Write version no.>
- ☑ **Advertisement materials (if applicable)** <Write date>
- ☑ **Patient's diary (if applicable)**
- ☑ **Other Study Materials** <Write version no., date>

Below are additional study documents included in the review as basis for the approval of the study.

- ☑ **Investigator's Brochure** (Write version no., date)
- ☑ **CV and GCP of Study Team**

---------- *Nothing follows* ----------

<Enter Name>
Chair, Institutional Ethics Review Committee

(Note: This Ethical Clearance carries with it Principal Investigator's commitment to comply with international and national guidelines on Good Clinical Practice. Please see attached for strict compliance.)

+ *(This Committee is recognized by SIDCER Strategic Initiative for Developing Capacity in Ethical Review) and FERCAP (Forum for Ethical Review Committees in Asia and the Western Pacific) and accredited by PHREB (Philippine Health Research Ethics Board).*
+ *The Committee is fully compliant with the regulations as they relate to ethics committee and the conditions and principles of Good Clinical Practice.*

SL-IERC FORM # 13B (Renewal)

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INSTITUTIONAL ETHICS REVIEW COMMITTEE
ADR/SAE/SUSAR REPORT FORM

CLINICAL RESEARCH PROFILE

EC Reference #: SL-_____ Principal Investigator. :_____ Contact No.:_____

Protocol Title:_____

_____

_____ Protocol No.:_____

SUBJECT INFO

Subject #/Initial: _____/_____ Date of Birth: __ __/__ __/__ __ __ (Day Month Year) Gender: _____ Date enrolled: __ __/__ __/__ __ __ (Day Month Year)

ADR/SAE/SUSAR DESCRIPTION

SAE Diagnosis: _____

_____

Date of Experience:__ __/__ __/__ __ __ __ (Day Month Year)

End of Experience:__ __/__ __/__ __ __ __ (Day Month Year)

Date of Awareness: __ __/__ __/__ __ __ __ (Day Month Year)

(Kindly check (✓) all that apply)

Category:
[ ] death
[ ] disability/incapacity
[ ] life-threatening
[ ] congenital anomaly/birth defect
[ ] important medical event
[ ] hospitalization-initial or prolonged
[ ] required intervention to prevent permanent impairment
[ ] other _____

Severity:
[ ] Mild
[ ] Moderate
[ ] Severe

Relationship to Study
[ ] Unrelated
[ ] Unlikely
[ ] Possibly
[ ] Definitely

Expectedness:
[ ] Expected
[ ] Unexpected

Investigator's Narrative Report: *(Pls. write legibly and provide attachments if necessary)*

_____

_____

_____

_____

_____

_____

_____

_____

REPORTING

Type of Report: ☐ Initial Report ☐ Follow-up Report #: _____ ☐ Final Report ☐ Response to NOA

Outcome:
☐ Ongoing
☐ Complete Recovery
☐ Fatal/Death
Cause of Death:_____

_____

☐ Recovered w/ sequelae

_____

_____

Reported by:_____
(Printed Name & Signature of PI)
Date:_____

(For IERC only)
Received by: _____
(Signature over printed name/Date)

SL-IERC Form # 14 v3 2019

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022
Form Title: ADR/SAE/SUSAR Report Form	SL-IERC FORM # 14

For IERC use only

ADR/SAE/SUSAR ASSESSMENT FORM

SL-IERC Member-in-Charge (Comments/Recommendations):

SL-IERC Member-in-Charge Action: ☐ No further action ☐ Request further information ☐ For full board review

Reviewed by:_____ **Date:**_____
(Signature over Printed Name)

SL-IERC ACTION:

☐ **No further action**

☐ **Request further information**
NOA sent out date: _____
Response to NOA receipt:_____

☐ **For full board review**
Date of Review:_____

Remarks:

Noted by SL-IERC Chair: _____
(Signature over Printed Name)
Date:_____

SL-IERC Form # 14 v3 2019

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

PROTOCOL DEVIATION/VIOLATION FORM

EC Reference No.: SL-_____ Protocol No:_____

Principal Investigator:_____ Inst./Dept.: _____

Protocol Title:_____

_____

_____

Protocol Violation: means an accidental or unintentional change to, or non-compliance with the SL-IERC approved procedures (e.g. the protocol, informed consent document, recruitment process or study materials) without prior sponsor and SL-IERC approval. Protocol violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the research data.

Examples of protocol violations:

i. Failure to obtain valid informed consent (e.g., obtained informed consent on a non-date stamped form)
ii. Loss of laptop computer that contained identifiable, private information about subjects
iii. Accidental distribution of incorrect study medication or dose
iv. Not following inclusion/exclusion criteria

Protocol Deviation: means a minor or administrative departure from the SL-IERC-approved protocol procedures (e.g. the protocol, informed consent document, recruitment process or study materials) that was made without prior Sponsor and SL-IERC approval. It is an accidental or unintentional change to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. A deviation may be due to the research subject's non-adherence, or an unintentional change to or non-compliance with the research protocol on the part of the Principal Investigator or the Clinical Trial staff.

Examples of a deviation include:

i. A rescheduled study visit
ii. Failure to collect an ancillary self-report questionnaire
iii. Subject's refusal to complete scheduled research activities

Note: * as described in IERC SOP 4.3: If there is lapse in IRB approval this report should also be submitted.

I. Date of occurrence:	Date of awareness:	Date of Report:

II. Characterization:

The deviation/violation involves:

☐ Enrollment process *(inclusion/exclusion criteria etc.)*
☐ Consent Process *(oral/written)*
☐ Drug/Device Administration *(dosage, schedule, route of administration, formulation, etc.)*
☐ Other protocol activities (research activities, data analysis, reporting, etc.)
☐ Complaint from research subject
☐ Audit finding that requires corrective action
☐ Other:_____

III. Description

1) **Participant ID** *(if applicable; if more than one participant is involved list all the IDs)*

2) If the purpose of this deviation report is a lapse in IRB approval, please describe all study activities, including enrollment, interventions, data analysis, that have occurred during the lapse **(use additional sheet of paper(s); if not proceed to no.2)**

SL-IERC Form #15

3) Describe in detail specific violation/deviation: (use additional sheet of paper(s) if needed)

4) Explain how/why the deviation occurred. (use additional sheet of paper(s) if needed

5) Describe how the deviation/violation affected the following:

a. Risk/benefit ratio for the subject: Was there a change? ☐ Yes, why? ☐ No, why?

b. Integrity of the research data: Was it compromised? ☐ Yes, why? ☐ No, why?

c. Is the subject willing to continue study participation? ☐ Yes ☐ No, why?

6) Does this protocol deviation/violation require revision of the protocol and/or consent form?

☐ Yes *(If YES, please submit a completed amemndment form and revised documents with changes marked)*

☐ No

7) Please describe: (i) corrective actions, if applicable, for the deviation/violation; and (ii) a plan for preventing the recurrence of the deviation/violation:

By signing below, I declare that the above is an accurate and complete description of the protocol deviation/violation and that, upon receipt of the SL-IERC's review, I will fully and immediately implement any corrective actions required by the SL-IERC.

Signature of PI _____ Date _____

Signature of co-PI (if applicable) _____ Date _____

SL-IERC Form #15

For IERC use only

PROTOCOL DEVIATION/VIOLATION ASSESSMENT FORM

EC Reference No.: SL-_____ Protocol No: _____ Principal Investigator: _____

Report Date: _____

1. SL-IERC Reviewer

I have reviewed this reported protocol deviation/violation and determined that: *(check all that apply)*

☐ No further action is required.
☐ The corrective action described in this form is acceptable and must be implemented. PI must issue a statement to the IRB that he/she has implemented the corrective action plan as described.
☐ PI must submit an interim report to the IRB on _____ describing his/her progress in implementing the corrective action described below.
☐ The deviation/violation reported appears to represent serious or continuing non-compliance. Review according to that policy is required.
☐ Other: _____

COMMENTS:

_____
_____
_____
_____
_____

_____ _____
(Signature above printed name) Date

2. SL-IERC Member-in-Charge

I have reviewed this reported protocol deviation/violation and determined that: *(check all that apply)*

☐ No further action is required.
☐ The corrective action described in this form is acceptable and must be implemented. PI must issue a statement to the IRB that he/she has implemented the corrective action plan as described.
☐ PI must submit an interim report to the IRB on _____ describing his/her progress in implementing the corrective action described below.
☐ The deviation/violation reported appears to represent serious or continuing non-compliance. Review according to that policy is required.
☐ Other: _____

COMMENTS:

_____
_____
_____
_____
_____

_____ _____
(Signature above printed name) Date

SL-IERC Form #15

SL-IERC Action on Protocol deviation/violation

☐ No Further action required
☐ Requires further information
NOA Release Date : _____
Response to NOA Receipt Date : _____
☐ To submit reports that corrective actions have been implemented
NOA Release Date : _____
Response to NOA Receipt Date : _____
☐ For review according to policy required
☐ Other: _____

Comments:

Noted by SL-IERC Chair:

_____ _____
(Signature above printed name) Date

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

CONTINUING REVIEW/ PROGRESS REPORT FORM

EC Reference No.:**SL-**_____ Protocol No.: _____
Principal Investigator: _____
Institute/Department: _____
Sponsor/CRO: _____
Protocol Title:
_____
_____
_____
_____

☐ Sponsor-initiated Trial
CT Phase/Type: _____
☐ Investigator-initiated Trial
IERC Approval Date: _____
Continuing Review Interval:
☐Annual ☐Semi-Annual ☐Quarterly
Continuing Review Date: _____
Type of Initial Review: ☐Full Board ☐Expedited

Use this form if you are requesting approval for continuation of this study, i.e. if you are still actively recruiting participants or continuing visits; collecting data and analysis; or writing manuscripts for publications. If all data collection and participant follow-up has ended and the study is either completed or cancelled, attach an accomplished Final Report Form.

RESEARCH TEAM

Name	Role (PI, Co-I, Research Nurse etc.)	Responsibilities* (indicate numbers from the study tasks listed below)	Date of GCP Training

*Study Tasks
1 – Protocol Development
2 – Study protocol assessments/procedures
3 – Participant recruitment
4 – Obtain Informed Consent
5 – Chart Review
6 – Data Collection
7 – Data Entry
8 – Data Analysis
9 – Protocol Amendments

DETAILS OF THE STUDY

Section 1: STATUS OF STUDY *(What is the current status of this study? Check all that apply)*

1. ☐ Study not started (proceed to Sections: 5, 6 and 9)
   Explain* _____
2. ☐ Open Study
   - ☐ Recruiting (*The study is currently recruiting participants*)
   - ☐ Not yet recruiting (*The study has not started recruiting participants*)
3. ☐ Closed Study
   - ☐ Active, Not recruiting (*The study is ongoing, that is participants are receiving an intervention or being examined, but potential participants are not currently being recruited or enrolled*)
   - ☐ Completed (*The study has ended normally and participants are no longer being examined or treated, that is, the "last subject, last visit" has occurred).*
   - ☐ Terminated (*the study has stopped recruiting or enrolling participants early and will not start again. Participants are no longer being examined or treated).*
   - ☐ Suspended (*The study has stopped recruiting or enrolling participants early, but may start again).*
   - ☐ Withdrawn (*The study stopped recruiting or enrolling its first participant).*

SL-IERC Form # 16

☐ Enrolling by invitation *(A study that selects its participants from a population, or group of people, decided on in advance by the researchers. These studies are not open to everyone who meets the eligibility criteria, but only to people in that particular population, who are specifically invited to participate).*

4. ☐ Data Analysis
5. ☐ Manuscript/Publication Phase
6. ☐ For study close-out Expected Date:_____

* If necessary, use additional sheets

Section 2: STUDY PARTICPANTS

1. ☐ Number of particpants required for this site
2. ☐ No enrollment to date (proceed to Sections 3no.1, 5,6 and 9)
3. ☐ Number of participants in the screening stage
4. ☐ Number of consented participants enrolled
5. ☐ Number of participants still on study drug/undergoing study procedures (i.e. lab tests,questionnaires)
6. ☐ Number of participants completed taking study drug/study procedure but currently in follow-up
7. ☐ Number of participants who have been withdrawn/terminated from the study (due to withdrawal of consent,loss to follow-up,death)
8. ☐ Number of participants who have completed the study
9. ☐ Number of biological samples utilized for a retrospective study data

Note: For chart review/registry research state number of charts under enrolled field.

State reason if difficulty is encountered in recruiting participants._____

Section 3: INFORMED CONSENT PROCESS

1. ☐ Number of participants who signed Informed Consent Form (ICF) but failed screening.
2. ☐ Number of consented participants who discontinued before treatment/study procedures began.
3. ☐ Number of consented subjects who discontinued due to occurrence of SAE or AE
4. ☐ Number of consented participants who discontinued before trial completion.

   Reasons: _____

5. ☐ Number of subjects enrolled but failed to sign consent prior to performance of any procedures

   Reasons: _____

6. List the consent form(s) currently in use (e.g. main, genomics, etc.)

Consent Form	Version / Date	Date approved by IERC

Section 4: SAFETY REPORTING

1. Serious Adverse Event(SAE)/Suspected Unexpected Serious Adverse Reaction (SUSAR) Information Summary (site only) N/A ☐
   Number of site SAEs ☐
   Number of site SUSARs ☐

2. Summary of all ON SITE SAEs/SUSARs since initial approval*

Participant Study Number	Date of Onset	Description of SAE/SUSAR	Date reported to IERC	Study Drug Relationship (Yes, No, N/A)	Outcome

* If necessary use additional sheets

3. Has the study been stopped, put on hold or recruitment put on hold at any site for any reason ?*
Yes ☐ No ☐ N/A ☐

*If YES, in additional sheet, provide details including dates.

Section 5: PROTOCOL AMENDMENTS N/A ☐

Detail all protocol amendments since initial approval, version number and date and date of IERC approval.

Date amendment submitted to IERC	Amendment Version Number (or description)	Amendment version date	Date approved by IERC

Section 6: NEW INFORMATION

Is there any new information in the literature, interim findings or preliminary results that would change the rationale, procedures, study design and/or risk benefit profile of this study since the last review ? ☐ Yes ☐ No
If YES, in additional sheet, please describe.

Section 7: PROTOCOL VIOLATIONS/DEVIATIONS

Is there any protocol violation that ocurred since the last IERC review? Yes ☐ No ☐
If YES, in additional sheet, please attach a copy(s). *(Any protocol violation should have been reported as soon as PI have been notified of its occurrence. If not, please explain why IERC was not informed immediately.)**

Characterization (Refer to PD/Violation Form)	Description	Date of awareness	Corrective Action

*If necessary use additional sheets

Section 8: STUDY MONITORING VISITS

1.Has this study been monitored by the sponsor (CRM/CRA) within the last IERC review? ☐ Yes ☐ No
If yes, state:
Date(s) of Monitoring:_____
Type of Monitoring Visit: _____
2. Have there been any issues/findings during the monitoring visit? ☐ Yes ☐ No
If yes, please attach copy(s) of the Monitoring Report/Follow-up Letter.

Section 9: AUDIT

1.Has this study been audited by any local or foreign regulatory authorities within the last IERC review? Yes ☐ No ☐
If yes, state:
Date of audit: _____
Regulatory authority: _____
2. Have there been any issues/findings during the audit? ☐ Yes ☐ No
If yes, please attach copies of the Established Inspection Report (EIR).

Section 10: ATTACHMENTS

Kindly submit copy of the latest Curriculum Vitae and Disclosure of Conflict of Interest *(signed and dated)* of all the study team members *(applies on anniversary dates only)*.

Submitted by:	IERC Acknowledgment:
_____ *(PI Name and Signature)* _____ *(Date)*	_____ *(Secretariat Name and Signature)* _____ *(Date)*

EC Reference No.:	Name of PI/Project Leader:	Institute/Department:

SL-IERC Member-in-Charge:

☐ **For Approval of Renewal** ☐ **For approval of study continuation**
☐ **Request further information** ☐ **Deferment of Action**

REMARKS *(If any)*:

_____
_____
_____
_____
_____

Reviewed by: *(Signature over printed name)*	Date:

SL-IERC ACTION:

☐ **Approved for Renewal** ☐ **Request further information** ☐ **Deferment of Action** NOA sent out date : _____ Response to NOA receipt date : _____	**Noted by:** _____ *(IERC Chair Name and Signature)* _____ *(Date)*

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

FINAL REPORT FORM

EC Reference No.: CT or SL - / Protocol No.:	☐Sponsor-initiated Trial *CT Phase/CT Type:*
Principal Investigator:	
Institute/Department:	☐Investigator-initiated Trial
Sponsor/CRO:	Type of Initial Review: ☐Full Board ☐Expedited
Protocol Title:	Ethical Clearance Date:
	Study Ended/Close-out Date:

Section 1: STUDY PARTICIPANTS *(Write N/A if not applicable)*

1. _____ Number of particpants required for this site
2. _____ Number of consented participants enrolled
3. _____ Number of participants who have been withdrawn/terminated from the study due to withdrawal of consent, loss to follow-up, death, etc.
4. _____ Number of biological samples utilized for a retrospective study data

Note: For chart review/registry research state number of charts under enrolled field.

Section 2: DEVIATIONS FROM THE PROTOCOL

Were there any deviations from the protocol? ☐ No ☐ Yes. If yes, please specify and provide reason for deviation.

Section 3: ISSUES/PROBLEMS

1. Were there any unanticipated problems involving risks to subjects or others at your site that have not been previously reported to IERC? ☐ N/A ☐ No ☐Yes. If Yes, kindly attach a report to this form.
2. Were there other issues or problems encountered? ☐No ☐Yes. If Yes, kindly described.

Section 4: FINDINGS AND CONCLUSION

Summary of findings:

Conclusion:

Section 5: DISSEMINATION

Actions for dissemination of study results:

Submitted by:	**IERC Acknowledgment:**
_____ _____ *(PI Name and Signature)* *(Date)*	_____ _____ *(Name and Signature of IERC Secretariat)* *(Date)*
SL-IERC Member-in-Charge:	
☐ For closure of file and archiving ☐ Request further information ☐ Recommend further action Remarks:_____	**Reviewed by:** _____ _____ *(Name and Signature of Reviewer)* *(Date)*
SL-IERC ACTION:	
☐ For closure of file and archiving ☐ Request further information ☐ Recommend further action NOA sent out date: _____	**Noted by:** _____ _____ *(Name and Signature of IERC Chair)* *(Date)*

SL-IERC Form # 17 ver.2 1 of 1

St. Luke's Medical Center
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Research and Biotechnology Group
OFFICE OF RESEARCH INTEGRITY

CLINICAL RESEARCH/SITE MONITORING FORM

EC Reference No.		Monitoring Date	
Investigator/Project Leader		Approval Date	
Project Coordinator		Reporting Frequency	
Institute/Department		Project Status	
Protocol Title			

PATIENT RECRUITMENT SUMMARY	NO.	REMARKS
1. Total no. of required subjects		
2. Total no. of screened subjects		
3. Total no. of enrolled subjects		
4. Total no. of screening failure		
5. Total no. of signed ICF		
6. Total no. of drop-outs		
7. Total no. of subjects withdrawn		
8. Total no. of subjects completed		

Performance Evaluation: N/A=Not applicable; 0=Not met; 1=Partially met; 2=met

ITEMS	Rate				RECOMMENDATIONS/REMARKS
	N/A	0	1	2	
I. SOURCE DOCUMENTS/INVESTIGATIONAL FILES					
1. The following files are filed properly:					
a. Approved protocol					
b. Revised protocol approved by the IERC					
c. Approved Informed Consent Form (ICF)					
d. Revised ICF approved by the IERC					
e. Investigational Brochure					
f. Ethical Clearance					
g. Clinical Trial Agreement					
h. Other communication letters with IERC and Sponsor					
i. Approved flyer or advertisement materials					
2. All the study files are filed in a locked cabinet					
II. STUDY CONDUCT					
1. All informed consent/assent forms *(latest IERC approved version)* are properly signed and dated by the patient, Principal Investigator/ Project Leader, LAR, and/or witness					
2. All enrolled subjects have copies of the signed ICFs					
3. Persons who obtained the ICFs are all stated in the Delegation Log					
4. All eligibility criteria are met					
5. No subject is enrolled pending IERC approval of the revised ICF					

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Research and Biotechnology Group
OFFICE OF RESEARCH INTEGRITY

CLINICAL RESEARCH/SITE MONITORING FORM

EC Reference No.		Monitoring Date	
Investigator/Project Leader		Approval Date	
Project Coordinator		Reporting Frequency	
Institute/Department		Project Status	
Protocol Title			

PATIENT RECRUITMENT SUMMARY	NO.	REMARKS
1. Total no. of required subjects		
2. Total no. of screened subjects		
3. Total no. of enrolled subjects		
4. Total no. of screening failure		
5. Total no. of signed ICF		
6. Total no. of drop-outs		
7. Total no. of subjects withdrawn		
8. Total no. of subjects completed		

Performance Evaluation: N/A=Not applicable; 0=Not met; 1=Partially met; 2=met

ITEMS	Rate				RECOMMENDATIONS/REMARKS
	N/A	0	1	2	
I. SOURCE DOCUMENTS/INVESTIGATIONAL FILES					
1. The following files are filed properly:					
a. Approved protocol					
b. Revised protocol approved by the IERC					
c. Approved Informed Consent Form (ICF)					
d. Revised ICF approved by the IERC					
e. Investigational Brochure					
f. Ethical Clearance					
g. Clinical Trial Agreement					
h. Other communication letters with IERC and Sponsor					
i. Approved flyer or advertisement materials					
2. All the study files are filed in a locked cabinet					
II. STUDY CONDUCT					
1. All informed consent/assent forms *(latest IERC approved version)* are properly signed and dated by the patient, Principal Investigator/ Project Leader, LAR, and/or witness					
2. All enrolled subjects have copies of the signed ICFs					
3. Persons who obtained the ICFs are all stated in the Delegation Log					
4. All eligibility criteria are met					
5. No subject is enrolled pending IERC approval of the revised ICF					

EC Reference No.: _____ **Date:** _____

Principal Investigator: _____

ICF CLINICAL MONITORING FORM

Date Enrolled	PATIENT CODE	PATIENT SIGNED	RELATIVE SIGNED	NO RELATION STATED	PERSON WHO OBTAINED THE CONSENT (Initial)	PERSON WHO OBTAINED THE CONSENT (Reconsent)	Date of Reconsent	OTHERS/REMARKS
1.								
2.								
3.								
4.								
5.								

SL-IERC Form #19

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OFFICE OF THE PRESIDENT

<Enter Date>

<Enter Name of IERC Member>
<Enter Position>
<Enter Address>

Dear _____,

I am pleased to inform you that you are hereby appointed as Member of the Institutional Ethics Review Committee (IERC) of St. Luke's Medical Center Quezon City and Global City effective *<Enter start date>* until <Enter end date>.

The primary role of the IERC is to safeguard the rights and well-being of the human participants in research. The committee is responsible for:

1. Evaluating and recommending approval or disapproval of research activities involving human subjects, including Clinical Trials undertaken at SLMC, based on ICH-Good Clinical Practice Guidelines
2. Determining the acceptability and propriety of specific research proposals based on organizational commitments and regulations, local laws, standards of professional conduct and practice, and community mores, values, and needs.
3. Safeguarding the integrity of the research from divided loyalties or conflicts of interest of the people involved in the study

Attached herein are the duties and responsibilities of the IERC and its individual members.

By signing the CONFORME below means acceptance of this important responsibility.

Sincerely yours,

<Enter name of President and CEO>
President and CEO

CONFORME:

_____
Signature of Member

Attachments: *Duties and Responsibilities of the IERC Members*
List of SL-IERC members

SL-IERC Template # 01

St. Luke's Medical Center
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INSTITUTIONAL ETHICS REVIEW COMMITTEE

Institutional Ethics Review Committee Composition
<Enter Inclusive Dates of Appointments>

Designation	Name	Affiliation	Expertise
Chair			
Vice-Chair			
Member-Secretary			
Members			
Alternate Member/s			
Ex-Officio			

Schedule of IERC Meetings: 2nd Wednesday of the month at 9:00AM

Venue of Meetings: R& B Conference Room, 6th East

Contact Numbers: SL-IERC Secretariat
Tel. No. 8727-5562 /8723-0101 loc. 7391
E-mail: ethicsreview@stlukes.com.ph

SL-IERC Template 02

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

I. ROLES AND RESPONSIBILITIES OF THE SL-IERC

1. The SL-IERC shall be the committee which shall determine whether an activity is research and whether the research involves human participants.
2. The SL-IERC shall act as central review committee which can review onsite **clinical researches or researches involving human participants**. The SL-IERC shall review researches (sponsored- and investigator-initiated) that involve human participants including research on identifiable human material or identifiable data.
3. The SL-IERC shall review essential documents of **clinical researches** (i.e. all Phases of Clinical Trials including Investigator-Initiated, Observational, Registry and Post Marketing Surveillance Studies) submitted to IERC to safeguard the rights, dignity and welfare of human participants.
4. The SL-IERC shall ensure that clinical researches shall be conducted in accordance with Philippine laws and National Ethical Guidelines for Health and Health-Related Research (2017) by Philippine Health Research Ethics Board (PHREB), Declaration of Helsinki (2013 ed.), and International Conference on Harmonization (ICH) for Good Clinical Practice E6(R2) (2016).
5. The SL-IERC shall recommend the approval of clinical trial/study, investigator-initiated clinical researches, R&B-funded clinical researches if:
   5.1. all ethical issues have been addressed
   5.2. the protocol is compliant with Good Clinical Practice
   5.3. the protocol has been revised in accordance with the Notice of Action issued by the SL-IERC Secretariat to the Principal Investigator and the IERC has made a Continuing Review of the response.
6. The SL-IERC shall identify an Expert/Independent Consultant to provide additional information about a study when necessary.
7. The SL-IERC shall assemble for meetings on the following occasions:
   7.1. Regularly every 2nd Wednesday of the month or on a date commonly agreed by the SL-IERC Members
   7.2. Emergency meetings convened by the IERC chair
   7.3. Special assignments designated by the Philippine FDA, PHREB, St. Luke's Medical Center President & CEO, and SLMC medical directors
8. The SL-IERC shall issue the Ethical Clearance to indicate approval following review of the Protocol.
   8.1. The Ethical Clearance shall indicate the dates of review, approval, validity and responsibilities of the Principal Investigator.
   8.2. The Ethical Clearance shall be valid for a maximum of one (1) year. Validity may be shorter depending on the level of risk (*Refer to SOP 4.3*).
   8.3. Extension of the validity of the Ethical Clearance shall be granted upon fulfilment of the following requirements:
      - written request of the Principal Investigator
      - submission of progress report
      - favorable evaluation of the progress report
      - payment of extension fee
9. The SL-IERC shall evaluate reports on adverse drug reactions/serious adverse events/suspected unexpected serious adverse reactions and perform continuing review of each ongoing clinical research at intervals appropriate to the of risk to human subjects or at least once a year *(based on the*

SL-IERC Form # 03 V2 12/2018 (For Chair)

IERC review approval date) using the IERC Continuing Review Report Form issued by the IERC Secretariat.

10. The SL-IERC shall have authority to suspend or terminate approval of human research not being conducted in accordance with the SL-IERC's requirements or that has been associated with unexpected serious harm to subjects.
11. The SL-IERC may observe or authorize the CHRP to observe, in certain occasions (e.g. numerous reports of protocol deviations/violations, onsite ADRs, SAEs & SUSARs and complaints) the consent process and the conduct of the human research.
12. The SL-IERC shall evaluate conflict of interest (COI) of investigators and research staff and have the final authority to decide whether the COI and management plan, if any, allow the human research to be approved.

II. RESPONSIBILITIES OF THE IERC MEMBER

Each Member of the SL-IERC shall have the following responsibilities:

1. Reads the Minutes of the Meetings sent by email
2. Attends SL-IERC meetings regularly and participates in the review and evaluation of research protocols and other related requests as part of a full or expedited review
3. Participates in the evaluation of approved protocols through the continuing review process
4. Participates in the review of progress and final reports, amendments, ADR/SAE/SUSAR reports, and protocol deviation/violation reports presented during SL-IERC meetings
5. Makes himself familiar with the SOPs of the SL-IERC
6. Attends seminars, workshops and conferences in research ethics to enhance his competencies as member of the SL-IERC
7. Obtains GCP certificate which shall remain valid for three (3) years
8. Submits an updated CV at the start of each new appointment
9. Declares any conflict of Interest on any of the research protocols submitted for review
10. Maintains confidentiality of the documents and deliberations of the SL-IERC meetings

III. RESPONSIBLITIES OF THE IERC CHAIR

The SL-IERC Chair shall have the following responsibilities:

1. Finalizes the agenda and presides in all SL-IERC meetings
2. Conducts a preliminary review of all clinical research protocols and decides on the nature of review
3. Assigns Members of the SL-IERC for expedited review
4. Ensures that a final decision on all protocols reviewed is made and breaks a tie whenever a deadlock in SL-IERC voting occurs
5. Ensures that appropriate decisions/actions are made by the SL-IERC on issues that include but are not limited to research participants complaints, findings of non-compliance during an FDA audit, loss of records or study drugs, higher than expected occurrences of adverse events, unexpected adverse events that are at least possibly related to the study, drug accountability problems, unanticipated change in Principal Investigator, etc.
6. Signs the following communications: Notice of Meetings, Notice of Action to Principal Investigators and Sponsors
7. Signs the Ethical Clearance Form in behalf of SL-IERC.

8. Communicates decisions of the SL-IERC to Principal Investigators/Project Leaders
9. Designates External/Independent Consultants
10. Represents St. Luke's Medical Center in ethics-related symposia or meetings that require institutional participation
11. Submits annual reports on the accomplishments of the SL-IERC to PHREB

IV. RESIGNATION, DISQUALIFICATION AND REPLACEMENT OF MEMBERS

1. An SL-IERC Member may resign from the committee at any time during his term through an official letter addressed to the President and CEO through the Chair. A copy of the letter shall be furnished to the Head of R&B.
2. An SL-IERC Member may be recommended by the Chair for disqualification for any of the following reasons:
   2.1. Failure to attend three (3) consecutive meetings of the IERC without any valid reason
   2.2. Failure to disclose Conflict of Interest
   2.3. Violation of the Confidentiality Rule
   2.4. Other justifiable causes as determined by the SL-IERC
3. Replacement of the resigned SL-IERC Member shall be made by the President and CEO, upon recommendation of the Head of R&B Group and IERC Chair.

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

I. ROLES AND RESPONSIBILITIES OF THE SL-IERC

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3. The SL-IERC shall review essential documents of **clinical researches** (i.e. all Phases of Clinical Trials including Investigator-Initiated, Observational, Registry and Post Marketing Surveillance Studies) submitted to IERC to safeguard the rights, dignity and welfare of human participants.
4. The SL-IERC shall ensure that clinical researches shall be conducted in accordance with Philippine laws and National Ethical Guidelines for Health and Health-Related Research (2017) by Philippine Health Research Ethics Board (PHREB), Declaration of Helsinki (2013 ed.), and International Conference on Harmonization (ICH) for Good Clinical Practice E6(R2) (2016).
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   - 5.2. the protocol is compliant with Good Clinical Practice
   - 5.3. the protocol has been revised in accordance with the Notice of Action issued by the SL-IERC Secretariat to the Principal Investigator and the IERC has made a Continuing Review of the response.
6. The SL-IERC shall identify an Expert/Independent Consultant to provide additional information about a study when necessary.
7. The SL-IERC shall assemble for meetings on the following occasions:
   - 7.1. Regularly every 2nd Wednesday of the month or on a date commonly agreed by the SL-IERC Members
   - 7.2. Emergency meetings convened by the IERC chair
   - 7.3. Special assignments designated by the Philippine FDA, PHREB, St. Luke's Medical Center President & CEO, and SLMC medical directors
8. The SL-IERC shall issue the Ethical Clearance to indicate approval following review of the Protocol.
   - 8.1. The Ethical Clearance shall indicate the dates of review, approval, validity and responsibilities of the Principal Investigator.
   - 8.2. The Ethical Clearance shall be valid for a maximum of one (1) year. Validity may be shorter depending on the level of risk (*Refer to SOP 4.3*).
   - 8.3. Extension of the validity of the Ethical Clearance shall be granted upon fulfilment of the following requirements:
     - written request of the Principal Investigator
     - submission of progress report
     - favorable evaluation of the progress report
     - payment of extension fee
9. The SL-IERC shall evaluate reports on adverse drug reactions/serious adverse events/suspected unexpected serious adverse reactions and perform continuing review of each ongoing clinical research at intervals appropriate to the of risk to human subjects or at least once a year *(based on the*

IERC review approval date) using the IERC Continuing Review Report Form issued by the IERC Secretariat.

10. The SL-IERC shall have authority to suspend or terminate approval of human research not being conducted in accordance with the SL-IERC's requirements or that has been associated with unexpected serious harm to subjects.
11. The SL-IERC may observe or authorize the CHRP to observe, in certain occasions (e.g. numerous reports of protocol deviations/violations, onsite ADRs, SAEs & SUSARs and complaints) the consent process and the conduct of the human research.
12. The SL-IERC shall evaluate conflict of interest (COI) of investigators and research staff and have the final authority to decide whether the COI and management plan, if any, allow the human research to be approved.

II. RESPONSIBILITIES OF THE IERC MEMBER

Each Member of the SL-IERC shall have the following responsibilities:

1. Reads the Minutes of the Meetings sent by email
2. Attends SL-IERC meetings regularly and participates in the review and evaluation of research protocols and other related requests as part of a full or expedited review
3. Participates in the evaluation of approved protocols through the continuing review process
4. Participates in the review of progress and final reports, amendments, ADR/SAE/SUSAR reports, and protocol deviation/violation reports presented during SL-IERC meetings
5. Makes himself familiar with the SOPs of the SL-IERC
6. Attends seminars, workshops and conferences in research ethics to enhance his competencies as member of the SL-IERC
7. Obtains GCP certificate which shall remain valid for three (3) years
8. Submits an updated CV at the start of each new appointment
9. Declares any conflict of Interest on any of the research protocols submitted for review
10. Maintains confidentiality of the documents and deliberations of the SL-IERC meetings

III. RESIGNATION, DISQUALIFICATION AND REPLACEMENT OF MEMBERS

1. An SL-IERC Member may resign from the committee at any time during his term through an official letter addressed to the President and CEO through the Chair. A copy of the letter shall be furnished to the Head of R&B.
2. An SL-IERC Member may be recommended by the Chair for disqualification for any of the following reasons:
   - 2.1. Failure to attend three (3) consecutive meetings of the IERC without any valid reason
   - 2.2. Failure to disclose Conflict of Interest
   - 2.3. Violation of the Confidentiality Rule
   - 2.4. Other justifiable causes as determined by the SL-IERC
3. Replacement of the resigned SL-IERC Member shall be made by the President and CEO, upon recommendation of the Head of R&B Group and IERC Chair.

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

<Insert Name>
Chair

<Insert Name>
Vice-Chair

Members:

<Insert Name>

<Insert Name>

<Insert Name>

<Insert Name>

<Insert Name>

<Insert Name>

<Insert Name>

<Insert Name>

<Insert Name>

Alternate Member:
<Insert Name>

NOTICE OF MEETING

<Insert Date>

To All Members:

We will have the Institutional Ethics Review Committee meeting on **<Insert Day, Date>** at **<Insert Time>** to be held at the **R&B Conference Room, Annex 3 East, 6/Floor.**

Materials for the meeting will follow.

Your attendance will be highly appreciated.

Thank you very much.

<Insert Name>
Ethics Chair

SL-IERC FORM # 04

Title: INSTITUTIONAL ETHICS REVIEW COMMITTEE STANDARD OPERATING PROCEDURE	Document Type: MANUAL
Level ☒System ☐Hospital Site Specific ☐Group ☐Department ☐SLMC College	Document Code: Research 1-01-6
Category ☐Clinical ☐Management ☐Academe ☒Research ☐Regulatory	Revision Effective Date: June 1, 2022
Template Title: IERC Meeting Attendance Sheet Template	SL-IERC TEMPLATE # 06

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

IERC MEETING ATTENDANCE SHEET
<Insert Date>
8:00 AM

NAME		SIGNATURE
Chair:	<Enter Name>	_____
Vice Chair:	<Enter Name>	_____
Member:	<Enter Name>	_____
Member:	<Enter Name>	_____
Member:	<Enter Name>	_____
Member:	<Enter Name>	_____
Member:	<Enter Name>	_____
Member:	<Enter Name>	_____
Member:	<Enter Name>	_____
Member:	<Enter Name>	_____
Member:	<Enter Name>	_____
Ex-Officio Member:	<Enter Name>	_____

SL-IERC Form # 06

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

Alternate Member:

<Enter Name> _____

Secretariat: <Enter Name> _____

<Enter Name> _____

<Enter Name> _____

SL-IERC Form # 06

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

INSTITUTIONAL ETHICS REVIEW COMMITTEE

<Enter Name of IERC Chair>
Chair

<Enter Name of IERC Vice-Chair>
Vice-Chair

Members:

<Enter Name of Member>
<Enter Name of Member>
<Enter Name of Member>
<Enter Name of Member>
<Enter Name of Member>
<Enter Name of Member>
<Enter Name of Member>
<Enter Name of Member>
<Enter Name of Member>
<Enter Name of Member>

Alternate Member/s:

<Enter Name of Member>

Cc: <Enter Sponsor/CRO/ARO>

NOTICE OF ACTION

TO: **<Enter Name>**
Principal Investigator/s

FROM: **<Enter Name>**
Chair, Ethics Review

RE: *Clinical Trial Protocol entitled* **SL-_____: *<Enter Title of Clinical Trial or Clinical Research Project>***

DATE: <Enter Date>

This is to inform you that the St. Luke's Institutional Ethics Review Committee (IERC) has done an <full board/expedited> review of your proposal.

I. **Review Elements of the Protocol**

_____
_____

II. **Review Elements of the Informed Consent**

_____
_____

III. **Others**

_____
_____

Please send your response to the above two (2) weeks after receiving the notice to facilitate continuing review of your protocol. Failure to respond within the time frame of 90 days will be considered withdrawal of the application. The submitted protocol files will be placed in the inactive file.

If you have any questions or clarifications, please call <Enter Name> of the Secretariat at 8723-0101 local 7391.

Thank you.

SL-IERC Form # 08

SUMMARY OF THE REVISIONS

IERC Recommendations/Clarifications	Investigator's Response

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

NOTICE OF APPROVAL

TO: **<Enter Name of PIs/Project Leaders>**
<Enter Institute/Department>

FROM: **<Enter Name of IERC Chair>**
Chair, Institutional Ethics Review Committee

RE: ***SL-_____: <Enter Title of Clinical Research>***

DATE: <Enter Date>

This is to inform you that the St. Luke's Institutional Ethics Review Committee (IERC) has done a (full board or expedited review) on your above protocol. (Expedited review is done by the IERC Chair or a designated voting member or subgroup of voting members rather than by the entire Committee.)

The following submitted documents have been reviewed and approved <**Enter Date**> for use in the study:

- Approved protocol <Enter version no., date>
- Approved ICF <Enter version no., date>
- Approved advertisement materials (if applicable) <Enter date>
- Case report form (or data collection form) (if applicable) <Enter version no., date>
- Patient's diary (if applicable)

Pertinent documents shall be included in your original protocol for filing purposes. Please be reminded that the study must be conducted according to the approved proposal, and compliance to the same shall be monitored. Any subsequent amendments to the protocol must be brought to the attention of the Committee for re-approval. Once the study is completed, two (2) copies of the research paper must be submitted for filing.

If you have any questions or clarifications, please call the Secretariat at 8727-5562 or 8723-0101 local 7391.

For your information and guidance.

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

PRINCIPAL INVESTIGATOR'S RESPONSIBILITIES

In the conduct of the clinical study, the Investigator has the following responsibilities:

1. Complies with the policies and procedures of the Medical Center including any applicable financial policies. Principal Investigator will notify Sponsor/CRO promptly of any conflict and/or discrepancy between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation.
2. Ensures that all members of the study team have adequate training on Good Clinical Practice and informed about their obligations in the conduct of the clinical trial or clinical research;
3. Delegates duties and responsibilities to Sub-investigators and/or study team only to the extent permitted by Applicable Law governing the Trial/Study conduct;
4. Explains to the patient/relative how clinical trial or clinical research protocols are reviewed and approved by the Institutional Ethics Review Committee;
5. Obtains the patient's consent after thorough explanation of the Informed Consent elements;
6. Ensures that during Screening, he/she or any member of the study delegated to get Informed consent competent to answer all relevant questions concerning the study, obtains from each subject, or where applicable, the Subject's legal guardian/legally acceptable representative a signed written, informed consent (write version number approved by SL-IERC) to participate in the Study and to the fair and lawful processing of data obtained by CRO and Sponsor;
7. Conducts the clinical trial or clinical research in accordance with the protocol and applicable Institutional/hospital policies;
8. Reviews all Subject Case Report Forms (CRF) to assure accuracy and completeness of data and to provide, in the format and manner agreed upon by the parties, in coded forms, all CRFs and any other Study data or samples;
9. Complies with time schedules and correct errors in CRFs;
10. Maintains adequate and accurate records and source documents and to make those records available for inspection by regulatory authorities;
11. Issues an Identification Card to enrolled participants to identify that patient is a participant of a clinical trial or clinical research;
12. Tags the medical charts of admitted patients enrolled in clinical trials or clinical research projects;
13. Ensures that the study team has adequate insurance for malpractice;
14. Provides reasonable medical care for study subjects for medical problems arising during participation in the study that are, or could be, related to the study intervention;
15. Provides reasonable access to needed medical care, either by the investigator or by another identified, qualified individual (e.g., when the investigator is unavailable, when specialized care is needed);
16. Submits the following documents to the St. Luke's Institutional Ethics Review Committee:
    - 16.1. Progress report using the attached SL-IERC Form #16: Continuing Review Report Form (CRRF) every year from date of approval which includes the following:
        - 16.1.1. Date covered by the report
        - 16.1.2. Protocol summary and status report on the progress of the study
        - 16.1.3. Number of patients enrolled
        - 16.1.4. Discontinued or withdrawal
        - 16.1.5. Any relevant information especially about risks associated with the study
        - 16.1.6. Copy of the informed consent document

EC Reference No. SL-_____
SL-IERC Template # 10 V2 12/2018

16.2. Any changes in the protocol, especially those that may adversely affect the safety of the subjects during the conduct of the trial including changes in personnel, must be submitted or reported;
16.3. Revisions in the informed consent form;
16.4. Reporting for all adverse drug reactions (ADRs), serious adverse events (SAEs), and suspected unexpected serious adverse reactions (SUSARs) which occur in conjunction with clinical trials using the SL-IERC Form #14: ADR/SAE/SUSAR Reporting Form
16.4.1. For SAEs which occur at SLMC, the time frame for reporting shall be as follows:
a. Fatal or Life-threatening SAEs and SUSARs shall be reported upon discovery but not later than 7 calendar days, followed by a complete report within additional 8 calendar days.
b. All other SAEs and SUSARs that are not fatal or life-threatening must be reported no later than 15 calendar days after discovery. Updated or follow-up reports shall be submitted periodically until resolution of the event
16.4.2. For SAEs which occur outside SLMC, local or international:
a. The PI shall submit a line listing or summary report together with the soft copies of the reports in compact disc (CD) on a quarterly basis.
b. The PI shall submit an individual report upon the request of the SL-IERC when deemed necessary. *(ICH-GCP Guidelines as reference)*
16.5. Notice of early termination of the study and reasons for such;
16.6. Any event which may have ethical significance;
16.7. Any information which is needed by the SL-IERC to do ongoing review;
16.8. Notice of time of completion of the study;
16.9. Application for renewal of Ethical clearance 30 days before the expiration date of this approval through submission of SL-IERC Form #13C: Request for Ethical Clearance Renewal Form;
16.10. Copy of the "Follow-up Report or Correspondence to the Principal Investigator" furnished by the Sponsor/CRO after their monitoring visit

(Note: In view of active Ethical Clearance, this report is mandatory even if the study has not started.)

❖ Kindly sign the Conforme below to acknowledge that you have read the above stated responsibilities as Principal Investigator.

Conforme:

_____ _____
Principal Investigator's Signature over Printed name Date

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

NOTICE OF ACTION

INSTITUTIONAL ETHICS REVIEW COMMITTEE COMPOSITION

EC Reference No:
TITLE:

MEMBER (TITLE AND NAME)	OCCUPATION (DESIGNATION)	INSTITUTION	TICK (✓) IF PRESENT WHEN ABOVE ITEMS WERE REVIEWED
<Insert Name> *Chair*			
<Insert Name> *Vice-Chair*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			

Comments:

I hereby confirm that this Independent Ethics Committee was organized and operates according to ICH-GCP applicable laws and regulations.

DATE OF REVIEW:

<Insert Name>
Chair, Institutional Ethics Review Committee

Cc: SL-IERC

SL-IERC Template # 11A (For Notice of Action)

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

NOTICE OF APPROVAL

INSTITUTIONAL ETHICS REVIEW COMMITTEE COMPOSITION

EC Reference No:
TITLE:

MEMBER (TITLE AND NAME)	OCCUPATION (DESIGNATION)	INSTITUTION	TICK (✓) IF PRESENT WHEN ABOVE ITEMS WERE REVIEWED
<Insert Name> *Chair*			
<Insert Name> *Vice-Chair*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			
<Insert Name> *Member*			

Comments:

I hereby confirm that this Independent Ethics Committee was organized and operates according to ICH-GCP applicable laws and regulations.

<Insert Name>
Chair, Institutional Ethics Review Committee

Cc: IERC

SL-IERC Template # 11B (Approval)

St. Luke's Medical Center
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INSTITUTIONAL ETHICS REVIEW COMMITTEE

AGENDA
<Enter Date and Time>
6/Flr. East R&B Conference Room
St. Luke's Medical Center Quezon City

1. Approval of the Agenda
2. Reading and approval of Minutes of previous meeting
3. Matters arising from Minutes of previous meeting
4. For full board review
   - 4.1 Sponsor-Initiated Clinical Trials
   - 4.2 Investigator-initiated Clinical Researches
   - 4.3 Response to Notice of Action
   - 4.4 Protocol Amendment/s:
   - 4.5 Continuing Review/Progress Report:
   - 4.6 Protocol Deviation/Violation
   - 4.7 SAE
   - 4.8 Study Site Monitoring Visit
5. Matters for Information
   - 5.1 Annex 1 - Updates on protocols reviewed
   - 5.2 Annex 2 – Protocol Amendments
   - 5.3 Annex 3 – Response to Notice of Action
   - 5.4 Annex 4 – Study updates
   - 5.5 Annex 5 – Safety reports
   - 5.6 Annex 6 – Materials for information and acknowledgement
6. Announcement/s
7. Other matters
8. Schedule of next meeting
9. Adjournment

St. Luke's Medical Center
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INSTITUTIONAL ETHICS REVIEW COMMITTEE

MINUTES OF THE MEETING
<Insert Date>
R&B Conference Room
6th East St. Luke's Medical Center Quezon City

ATTENDANCE

PRESENT	Position
<Insert Name of IERC Chair>	Chair
<Insert Name of IERC Vice-Chair>	Vice-Chair
<Insert Name of IERC Member-Secretary>	Member-Secretary
<Insert Name of IERC Member>	Member
<Insert Name of IERC Member>	Member
<Insert Name of IERC Member>	Member
<Insert Name of IERC Member>	Member
<Insert Name of IERC Member>	Member
<Insert Name of IERC Member>	Member
<Insert Name of IERC Member>	Member
Absent	
<Insert Name>	Member
<Insert Name>	Member

1. **Call to order**
2. **Invocation**
3. **Determination of quorum and presence of non-institutional members**
4. **Approval of the Agenda**
5. **Disclosure of Conflict of interest**
6. **Reading and approval of the Minutes of the previous meeting**
7. **Matters arising from the Minutes of the previous meeting**
8. **Full Board Review of Clinical Trial Protocols**
   - **8.1. Sponsor-initiated Trial**

EC Reference No.:	
Protocol Title	
Principal Investigator	
Sponsor	
Protocol Type	
Quorum Status	
Conflict of interest	
Primary Reviewer	
REVIEW ELEMENTS	
Qualifications of PI	▪
COI of PI	▪
Social and Scientific Value	▪
Scientific validity/design	▪

Selection of subjects	▪
Inclusion/exclusion Criteria	▪
Vulnerability	▪
Justifiable use of placebo	▪
Standard of Care	▪
Withdrawal criteria	▪
Risks-benefits assessment	▪
Recruitment process	▪
ICF	▪
Insurance	▪
Recommendations	▪
SL-IERC ACTION *(Approved; Disapproved; Deferred: minor revisions; major revisions)*	
Risk Assessment:	<Enter Risk (Low; Moderate; High)>: <Enter no. of members>
Protocol	<Enter Action (Approved; Disapproved; Deferred: minor/major revisions)>: <Enter no. of members>
ICF	<Enter Action (Approved; Disapproved; Deferred: minor/major revisions)>: <Enter no. of members>
IERC Action on <Protocol/ Response to NOA>:	

8.2. Investigator-initiated Clinical Researches
(Copy template used in 8.1 above)

8.3. Response to Notice of Action

EC Reference No.	
Protocol Title	
Principal Investigator	
Sponsor	
Protocol Type	
Quorum Status	
Conflict of interest	
Primary Reviewer	
Other Reviewers	
REVIEW ELEMENTS	
Issues	▪
Comments	▪
Recommendations	▪

8.4. Protocol Amendments

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Document Submitted	▪
Status/Remarks	▪
IERC Action	▪

8.5. Continuing Review/Progress Report/Terminal Report

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Document Submitted	▪
Status/Remarks	▪
IERC Action	▪

8.6. Protocol Deviation/Violation

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Member-in Charge	
Primary Reviewer	
Characterization	▪
Corrective Action	▪
IERC Action	▪

8.7. SAE

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Principal investigator	
Document Submitted	▪
Status/Remarks	▪
IERC Action	▪

8.8. Study Site Monitoring Visit

EC Reference No.	
Protocol Title	
Principal investigator	
Sponsor	
Principal investigator	
Document Submitted	▪
Status/Remarks	▪
IERC Action	▪

9. Matters for Information

9.1 ANNEX 1 Updates on protocols reviewed and discussed

1. Full board review

A. Sponsor-initiated

EC Reference No. and Title:
Principal investigator/s:
Sponsor:
Primary Reviewer:

Sponsored by:
Status/Remarks:

B. Response to Notice of Action
(Copy template as 9.1.1.A above)

2. Expedited review
A. Investigator-initiated
B. Response to Notice of Action

9.2 ANNEX 2 Protocol amendments
9.3 ANNEX 3 Response to Notice of Action
9.4 ANNEX 4 Study updates
9.5 ANNEX 5 Safety reports
9.6 ANNEX 6 Materials for information and acknowledgment

10. Announcements:
11. Other matters:
12. Schedule of Next Meeting: <Enter Date>
13. Adjournment: <Enter Time>

Prepared by:

<Enter Name>
Secretary

Noted by:

<Enter Name>
Chair

<Enter Name>
IERC Member Secretary

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INSTITUTIONAL ETHICS REVIEW COMMITTEE

RESEARCH AND BIOTECHNOLOGY
Institutional Ethics Review Committee

M E M O

TO: **<Enter name of PI/Project Leader>**
<Enter Institute/Department>

FROM: **<Enter name of IERC Chair>**
IERC Chair

RE: **Extension of Ethical Clearance for Clinical Trial entitled:**
<SL-_____: *Enter Title of Clinical Trial Research*>

DATE: **<Enter Date>**

In accordance with the SOP of the Institutional Ethics Review Committee, Ethical Clearance is valid for <one (1) year/six (6) months/three (3) months>. In this regard please be informed that based on the Ethical Clearance issued to you, the Continuing Review/Progress Report Form shall be submitted <annually/semi-annually/quarterly> from date of approval which is **<Enter Date of Approval>**.

Non-receipt of your continuing review/progress report will entail revocation of your Ethical Clearance thus it is understood that all clinical research activities will be suspended.

Please disregard this notice if the Clinical <Trial/Research> Project has been closed-out and inform the SL-IERC on the details of the study closure.

Should you have any questions, please do not hesitate to contact the IERC Secretariat local 5562.

Thank you for your attention.

SL-IERC Template # 15 V2

St. Luke's Medical Center
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Research and Biotechnology Group
Office of Research Integrity

CLINICAL RESEARCH/SITE MONITORING NOTICE FORM

Monitoring Visit No.	:	Monitoring Date	:
Principal Investigator	:	EC Reference no.	:
Project Coordinator	:	Date of Approval	:
Institute/Department	:	CT/Project Status	:
Protocol Title	:		

Date_____

Dear _____,

In compliance with Good Clinical Practice Guidelines, please be informed that our Clinical Research Monitor, _____ is scheduled to review the records of the above-mentioned Clinical Trial.

Please advise Project Coordinator, Fellow, Clinical Research Coordinator, Research Assistant or any person in-charge of the above-mentioned study to make the records available to <Enter Name of Clinical Research Monitor> on <Enter date of monitoring>.

Please confirm schedule of visit at local 8723-0101 local #'s 7391 and 5562.

For your compliance. Thank you.

Sincerely yours,

<Enter Name>
Head, Center for Human Research Protection
Office of Research Integrity
Research and Biotechnology

Noted:

<Enter Name>
Chair, Institutional Ethics Review Committee

SL-IERC Template #16

St. Luke's Medical Center
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INSTITUTIONAL ETHICS REVIEW COMMITTEE

ITEMS TO BE MONITORED

I. PATIENT RECRUITMENT SUMMARY
1. Total no. of required subjects
2. Total no. of screened subjects
3. Total no. of enrolled subjects
4. Total no. of screening failure
5. Total no. of signed ICF
6. Total no. of drop-outs
7. Total no. of subjects withdrawn
8. Total no. of subjects completed

II. SOURCE DOCUMENTS/INVESTIGATIONAL FILES
1. The following files are filed properly:
   a. Approved protocol
   b. Revised protocol approved by the IERC
   c. Approved Informed Consent Form (ICF)
   d. Revised ICF approved by the IERC
   e. Investigational Brochure
   f. Ethical Clearance
   g. Clinical Trial Agreement
   h. Other communication letters with IERC and Sponsor
   i. Approved flyer or advertisement materials
2. All the study files are filed in a locked cabinet

III. STUDY CONDUCT
1. All informed consent/assent forms are properly signed and dated by the patient, Principal Investigator/ Project Leader, LAR, and/or witness
2. All enrolled subjects have copies of the signed ICFs
3. Persons who obtained the ICFs are all stated in the Delegation Log
4. All medical charts of patients enrolled in clinical trials have copies of the signed ICF
5. All eligibility criteria are met
6. No subject is enrolled pending IERC approval of the revised ICF
7. All subjects are asked to re-consent using the revised IERC-approved ICF
8. All Case Report Forms (CRF) are accomplished within 2 weeks of the subjects' visit
9. Data in CRFs are valid when checked against the source documents
10. All protocol deviations/violations are reported to the IERC
11. All ADRs, SAEs and SUSARs are reported to the IERC within 24 hours to 7 days upon discovery

IV. PROGRESS REPORTS
1. All progress reports are submitted to the IERC
2. Ethical Clearance is renewed one year from date of issuance
3. Terminal report is submitted to the IERC
4. Final report is submitted to the IERC

V. GCP CERTIFICATES/CURRICULUM VITAE/DELEGATION OF RESPONSIBILITY
1. All GCP certificates of the study team are up-to-date
2. All CVs of the study team are filed properly
3. All members of the study team are included in the Delegation of Responsibility
4. All members of the study team are trained before the start of the study

NOTE: Kindly prepare a copy of the following:
1. Updated *Curriculum Vitae* of all study team members
2. GCP Certificates of all study team members
3. Latest follow-up report

SL-IERC Template #16

St. Luke's Medical Center
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INSTITUTIONAL ETHICS REVIEW COMMITTEE

<Enter Date>

<Enter Name of Proponent>
<Enter Name of Proponent>
<Enter Institute/Department>

Dear Dr. <Surname> and Dr. <Surname>,

The <case report/case study/systematic review and meta-analysis> entitled "<Enter Title>" from the <Enter Institute/Department> has been received and registered by the SL-IERC. It is exempted from Ethics Review.

Very truly yours,

<Enter Name of SL-IERC Chair>
Chair

SL-IERC Template # 17

St. Luke's Medical Center
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INSTITUTIONAL ETHICS REVIEW COMMITTEE

Elements for Presentation during Full Board Review of Clinical Research Protocols

- Protocol Title
- Principal Investigator/Project Leader
- Sponsor
- Conflict of interest of Principal Investigator/Project Leader
- Social and scientific value
- Scientific validity, study design
- Fair selection of subjects
- Inclusion/exclusion Criteria
- Justification for inclusion of vulnerable subjects
- Justifiable use of placebo, if applicable
- Standard of care
- Withdrawal criteria
- Risks-benefits assessment
- Recruitment process
- Informed Consent form
- Insurance
- Issues on the protocol

SL-IERC Template # 18

7. ACRONYMS AND DEFINITION OF TERMS:

ACRONYMS

ADR	Adverse drug reaction
AE	Adverse event
CCT	Center for Clinical Trials
CFR	Code of Federal Regulations
CHRP	Center for Human Research Protection
CIOMS	Council for International Organizations of Medical Sciences
COI	Conflict of Interest
CRF	Case report form
CRMF	Clinical Research/Site Monitoring Form
CRO	Contract Research Organization
CRRF	Continuing Review/Progress Report Form
CT	Clinical trial
DOH	Department of Health
DOST	Department of Science and Technology
ERC	Ethics Review Committee
FDA	Food and Drug Administration
GCP	Good Clinical Practice
IB	Investigator's Brochure
ICF	Informed consent form
IERC	Institutional Ethics Review Committee
IiT	Investigator-initiated trials
IP	Investigational product
ISRC	Institutional Scientific Review Committee
LAR	Legally Acceptable Representative
MOM	Minutes of meeting
NEGHHRR	National Ethical Guidelines for Health and Health Related Research.
NOA	Notice of Action
ORI	Office of Research Integrity
PCHRD	Philippine Council for Health Research and Development
PD	Protocol deviation
PFDA	Philippine Food and Drug Administration
PHREB	Philippine Health Research Ethics Board
PI	Principal Investigator
PL	Project Leader
PV	Protocol violation
R&B	Research and Biotechnology
REC	Research Ethics Committee
SAE	Serious adverse event
SiT	Sponsor-initiated
SJREB	Single Joint Research Ethics Board
SLEC	St. Luke's Extension Clinic
SLMC	St. Luke's Medical Center
SLMCCM	St. Luke's Medical Center College of Medicine
SOP	Standard Operating Procedure
SUSAR	Suspected unexpected serious adverse reaction
WHO	World Health Organization
WMA	World Medical Association

DEFINITION OF TERMS

Adverse drug reaction (ADR)- In the preapproval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

Regarding marketed medicinal products: A response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function. [ICH-GCP E6(R2), 2016]

Adverse event (AE)- any untoward or unfavorable medical occurrence in a human subject including any abnormal sign (e.g. abnormal physical exam or laboratory finding) symptom or disease, temporarily associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 ICH-GCP E6); encompasses both physical and psychological harms occurring commonly in biomedical research but occasionally can occur in social and behavioral research.

Amendment to the protocol- a written description of a change(s) to, or formal clarification of a protocol and changes on any other supporting documentation made from the originally approved protocol by the research ethics review body after the study has begun. See also protocol amendment.

Approval- a favorable or affirmative decision of the Research Ethics Committee following a review of the protocol and other required documents and thus research may already be started and undertaken as set forth by the ethics committee, CPG, the institution, and relevant regulatory terms; the affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, good clinical practice (GCP), and the applicable regulatory requirements. [ICH-GCP E6(R2), 2016]

Assent - authorization for one's own participation in research given by a minor or another subject who lacks the capability to give informed consent. The assent is a requirement for research in addition to consent given by a parent or legal guardian; it is agreement by an individual not competent to give legally valid informed consent like a child or cognitively impaired person to participate in research. See also child's assent and surrogate assent.

Case Report form (CRF) - 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. [ICH-GCP E6(R2), 2016]

Center for Human Research Protection (CHRP) - a Center of the SLMC Research and Biotechnology Office of Research Integrity responsible for the implementation of the human research protection program. It ensures that the rights, safety, and well-being of human subject participants are protected through the following activities: capacity building for the IERC members, conduct of regular training-workshops on ICH-GCP and research ethics in the Medical Center, symposium on research integrity, lay forum on clinical trials or clinical research studies and the patients' rights and responsibilities as human research participants, site initiation meetings with study team, clinical research monitoring, and ensuring that the St. Luke's IERC complies with

the local applicable laws and regulations by maintaining its accreditation by the Philippine Health Research Ethics Board (PHREB) and recognition by the WHO SIDCER Forum for Ethics Review Committees in Asia and the Western Pacific (FERCAP).

Center for Clinical Trials (CCT) - This is one of the Centers of the Research and Biotechnology Group of St. Luke's Medical Center-Quezon City that provides assistance to individuals or companies who want to conduct investigator-initiated or sponsor-initiated clinical studies/trials. The Department as a "one-stop-shop" is responsible for financial and contract management for the trial, provides assistance for site-feasibility studies, coordinates with Pharmacy Services for the handling, dispensing and storage of investigational drugs, coordinates with different ancillary units and Nursing Care Group for services required, and handles the processing and storage of biological specimens for sponsor-initiated trials.

Clinical research - a study undertaken involving a particular person or group of people with the purpose of increasing knowledge and determining how well treatment or diagnostic test works in a particular patient population. The NIH-USA defines clinical research as: Patient-oriented research involves a particular person or group of people or uses materials from humans. This research can include: studies of mechanisms of human disease; studies of therapies or interventions for disease; clinical trials and studies to develop new technology related to disease. Epidemiological and behavioral studies examine the distribution of disease, the factors that affect health, and how people make health-related decisions. Outcomes and health services research seeks to identify the most effective and most efficient interventions, treatments, and services."

Clinical research monitoring - the act of overseeing the progress of a clinical trials and research studies involving human participants, ensuring that it is conducted in accordance with the protocol, GCP, and local and international guidelines and regulations on research. [Adapted from the ICH-GCP E6(R2) 2018 definition of monitoring]

Clinical trial/study - a planned scientific research or study among human volunteers to determine the effects of treatment or diagnostic test on their safety, efficacy, and its effect on quality of life.

It is also a systematic study on pharmaceutical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reactions to investigational products, and/or to study the absorption, distribution, metabolism, and excretion of the products with the object of ascertaining their efficacy and safety (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products).

It is also defined as investigative work to evaluate new drugs, medical devices, biologics, or other interventions to patients in strictly scientifically controlled settings. Clinical trials may be designed to assess the safety and efficacy of an experimental therapy, to assess whether the new intervention is better than standard therapy, or to compare the efficacy of two standard or marketed interventions. *See also clinical research.*

Conflict of Interest - circumstance that creates a risk that professional judgments or actions concerning a primary interest (e.g., obtaining scientifically valid results, promoting and protecting the integrity of research, safety and well-being of research participants, etc.) will be unduly influenced by a secondary interest (e.g., personal or financial gain, career advancement, etc.) (adapted from Lo & Fields, 2009).

Contract Research Organization (CRO) - a person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions. [ICH-GCP E6(R2), 2016]

Dossier - a file containing detailed records on a particular person or subject. (Merriam-Webster Dictionary)

Ethical clearance - a certification that a research proposal has complied with ethical requirements; action of an ethics review committee on a research protocol that signifies approval and permission to proceed with the research. *See also approval*.

Ethics review - the evaluation of a research protocol by an ethics review committee to promote the safety and protection of the dignity of human participants. This a systematic process by which this independent committee evaluates a study protocol to determine if it follows ethical and scientific standards for carrying out biomedical research on human participants. It checks if the protocol complies with the guidelines to ensure that the dignity, rights, safety and well-being of research participants are promoted.

Ethics review committee (ERC) - also called research ethics committee (REC), institutional ethics review board (IERB), independent ethics committee (IEC) or institutional review board (IRB) - committee constituted to review the ethical aspects of a research proposal and its possible implementation. This is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a trial and to provide public assurance of that protection. *See also research ethics committee, Institutional Ethics Review Committee.*

Expedited review - an ethics review of research protocol by the IRB chair or a designated voting member or subgroup of voting members rather than by the entire IRB. This is done for some research involving no more than minimal risk and maybe for minor changes in approved research, annual renewals of approved projects, approval of protocol amendments, research conducting health record review, and for confirming changes required by the ethics committee for approval of the protocol.

External/Independent Consultant - an expert who gives advice(s), comment(s) and suggestion(s) upon review of the study protocols; with no affiliation to the institute(s) or investigator(s) proposing the research proposal.

Full board review - review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting

Good clinical practice guidelines (GCP) - an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with these standards provide public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the International Declaration of Helsinki, and that the clinical trial data are credible. These are standards and procedures for clinical trials that encompass the design, protocol approval, monitoring, termination, audit, analyses, reporting, and documentation of human studies. It defines the responsibilities and activities of the sponsor, principal investigators and monitor involved in the clinical trials. The GCP ensures that the studies are scientifically and ethically sound, and all the clinical properties of the product

under investigation are properly documented. For complete information, reference is made to the published WHO and International Conference on Harmonization Code of Good Clinical Practice. (Department of Health Administrative Order No. 47-A series of 2001, [August 30, 2001); It is a standard for clinical studies which encompasses the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of the studies and which ensures that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical products (diagnostic, therapeutic or prophylactic) under investigation are properly documented (World Health Organization, Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products).

Guidelines - a set of rules or recommendations intended to effect a course of action.

High Risk - if study can lead to an unexpected/unplanned loss of life, or permanent impairment of quality of life, or may lead to serious legal action against Principal Investigators and/or institution.

The study risk is greater than a moderate risk study due to the increased probability for generating serious adverse events. There is a high probability of an event that is serious and prolonged or permanent occurring as a result of study participation.

Human participant or subject - human participant means a living individual about whom a Researcher conducting research obtains data through intervention or interaction with the individual, or identifiable private information, or an equivalent definition.

Informed consent - the process of obtaining approval to participate in an investigative study or permission to a medical intervention. Consent must be freely given in verbal, video or written form. An important part of the process is the adequacy, appropriateness, and timeliness of the information for decision-making; It is "a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation" (CIOMS, 2002).

Informed Consent Document/Form - a document that describes the rights of the study participants, and includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

Institutional Ethics Review Committee (IERC) - the committee in St. Luke's Medical Center responsible for the review of the protocols of all sponsor-initiated clinical trials (SiT) and IiT involving human subjects to ensure that the studies adhere to the ethical standards of the International Conference of Harmonization Guidelines for Good Clinical Practice (ICH-GCP), the Philippine Health Research Ethics Board (PHREB), and other standards and guidelines on ethics in research (i.e. Declaration of Helsinki, Philippines National Ethical Guidelines for Health Research). *See also ethics review committee, research ethics committee.*

Institutional Scientific Review Committee (ISRC) - the committee in St. Luke's Medical Center responsible for reviewing the technical soundness and scientific validity of the protocols of all investigator-initiated clinical trials and research projects (IiT), whether SLMC-funded or externally-funded.

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. [ICH-GCP E6(R2), 2016]

Investigator - a person responsible for the conduct of the critical trial at a trial site. If trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and be called the principal investigator (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice (E6, R1); It is a person responsible for the trial and for the rights, health and welfare of the subjects in the trial. The investigator should have qualifications and competence in accordance with local laws and regulations as evidenced by an up-to-date curriculum vitae and other credentials. Decisions relating to, and to provisions of, medical or dental care must always be the responsibility of a clinically competent person legally allowed to practice medicine or dentistry (WHO Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products); The investigator must be a qualified scientist who undertakes scientific and ethical responsibility, either on his/her behalf or on behalf of an organization, for the ethical and scientific integrity of a research project at a specific site or group of sites *See also principal investigator.*

Investigator's Brochure - a compilation of the clinical and nonclinical data on the investigational product(s) that is relevant to the study of the investigational product(s) in human subjects. [ICH-GCP E6(R2), 2016]

Legally Acceptable Representative (LAR) - an individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial. [ICH-GCP E6(R2), 2016]

Minimal risk - if the consequences can be dealt with by routine operations the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (45 CFR 46.102)

Moderate Risk - risks are recognized as being greater than minimal, but are not considered high. There is a medium to high probability of a moderate-severity event occurring as a result of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there is adequate surveillance and protections to identify adverse events promptly and to minimize their effects.

Monitor - a person appointed by and responsible to the sponsor or contract research organization for monitoring and reporting progress of the trial and for verification of data (WHO, Guidelines for Good Clinical Practice (GCP) for trials of pharmaceutical products).

Monitoring - the process of checking or scrutinizing research participants' health status during a clinical trial, and/or to oversee the progress of a trial or research and/or to check researcher's compliance with the protocol and regulatory requirements with in which the protocol is given ethical approval. *See also clinical research monitoring.*

Office of Research Integrity (ORI) - an office under the St. Luke's Medical Center Research and Biotechnology tasked with the following responsibilities and functions: (1) establishment and promotion of the code of ethical professional behavior in the conduct of human, animal, and basic science research in SLMC through the development, evaluation and revision of policies, procedures and regulations related to the responsible conduct of

research and the prevention of research misconduct; (2) communication within SLMC, external research partners, collaborators, Sponsors of CTs/research projects, Contract Research Organizations (CROs), Academic Research organizations (AROs) and patients, its commitment to protect human research participants and support the code of ethical professional behavior; (3) maintaining the development of and compliance with all human research policies and procedures; (4) protection of patients enrolled in research irrespective of the sponsor of the research; (5) provision of support to the structure and operational requirements of the research review function to ensure that all research studies conducted in SLMC and SLMCCM-WHQM are epidemiologically valid, correctly conducted and conform to acceptable quality standards and ethics in research; (6) ensuring that the review function complies with applicable laws and regulations; (7) annual review of all research review processes; (8) detection and investigation of research misconduct; (9) recommending administrative action for research misconduct findings; and (10) implementing education and training activities to teach the responsible conduct of research.

Philippine Health Research Ethics Board (PHREB) - the policy-making body for research ethics in the Philippines created on March 1, 2006 through DOST Special Order No. 091 series of 2006.

Principal investigator - the chief or person primarily responsible for the implementation of a research project *See also investigator, project leader*

Privacy - the right or claim or state or ability or condition of an individual or group or institution to conceal or seclude or hide themselves or information about themselves and thus reveal or expose themselves selectively; It is a conceptual space defining the individual's boundary as a person, intrusion of which is limited by human rights and by law. It is right to determine when, how, and to what extent information about someone is communicated to others.

Project Leader - the primary person responsible for the conceptualization and implementation of a research project involving humans.

Protocol - a document that provides the background, rationale, and objective(s) of a biomedical research project and describes its design, methodology, and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol. (WHO, Operational Guidelines for Ethics Committees That Review Biomedical Research, Geneva 2000, TDR/PRD/ETHICS/ 2000, p. 22);

- 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. [ICH-GCP E6(R2), 2016]

Protocol amendment - a written description of a change(s) to, or formal clarification of a protocol. (WHO, Operational Guidelines for Ethics Committees That Review Biomedical Research, Geneva 2000, TDR/PRD/ETHICS/ 2000, p. 22) *See also amendment to the protocol.*

Protocol deviation - a minor or administrative departure from the IRB- approved protocol procedures (e.g. the protocol, informed consent document, recruitment process or study materials) that was made without prior IRB approval. It is an accidental or unintentional change to, or non-compliance with the research protocol that does

not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. A deviation may be due to the research subject's non-adherence, or an unintentional change to or non-compliance with the research protocol on the part of the Principal Investigator or the Clinical Trial staff.

Protocol violation - an accidental or unintentional change to, or non-compliance with the IRB approved procedures (e.g. the protocol, informed consent document, recruitment process or study materials) without prior IRB approval. Protocol violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the research data.

Quorum - at least five people, including at least one lay member and one non-affiliated member, are present to make decisions about the proposed research (WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011).

Regulatory requirements - necessary prerequisites for the approval and conduct of clinical trial by a national regulatory authority. For example, for pharmaceutical and biologic products it means obtaining a "permit for clinical investigational use" which is a "registration document issued by the FDA for the purpose of allowing the conduct of Phase I, Phase II, and Phase III clinical trials of investigational biologic products in the country" DOH Administrative Order No. 47-A series of 2001"Rules and Regulations on the registration including approval and conduct of clinical trials, and lot or batch release certification of vaccines and biologic products." See Permit for clinical investigational use.

Research - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, or an equivalent definition.

Research ethics committee (REC) - an independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favorable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. [ICH-GCP E6(R2), 2016] *See also Institutional Ethics Review Committee, ethics review committee*

Research participant or subject - an individual who participates in a biomedical research project, either as the direct recipient of an intervention (e.g., study product or invasive procedure), as a control, or through observation. The individual may be a healthy person who volunteers to participate in the research, or a person with a condition unrelated to the research carried out who volunteers to participate, or a person (usually a patient) whose condition is relevant to the use of the study product or questions being investigated. (WHO, Operational Guidelines for Ethics Committees That Review Biomedical Research, Geneva 2000, TDR/PRD/ETHICS/ 2000, p. 22)

Research protocol - a document that provides the background rationale and objective(s) of a biomedical research project and describes its design, methodology and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol. *See also protocol.*

Risk - the probability of discomfort or harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Risks to research participants must be justified by the anticipated benefits to the subjects or to society. The investigator(s) and IRB must assess the risks and benefits of proposed research. *See also minimal risk.*

Risk-benefit ratio - the risk to individual participants versus the potential benefits. The risk/benefit ratio may differ depending on the condition being treated. (clinicaltrial.gov/ct2/info/glossary)

Risk factors - variables or conditions that increase the risk or chances of disease or infection; determinants of disease development. *See also risk.*

Serious adverse event (SAE) - any adverse drug experience occurring at any dose that results in any of the following outcomes: Death; Life-threatening drug experience; In-patient hospitalization or prolongation of existing hospitalization; Persistent or significant disability or incapacity; and Congenital anomaly/birth defect. *(21 CFR 312.32)*

Important medical events that may not result in death, be life-threatening or require hospitalization but when based upon appropriate judgment may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes mentioned above.

Sponsor - an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial.

Study document - all records, accounts, notes, report, data and ethics communications (submission, approval and progress reports) collected, generated or used in connection with the Study, whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as CRFs and all other reports and records necessary for the evaluation and construction of the Study.

Suspected unexpected serious adverse reaction (SUSAR) - any adverse drug experience the specificity or severity of which is not consistent with the current Investigator Brochure or with the risk information described in the general investigational plan or elsewhere in the current application. "Unexpected" as used in this definition refers to an adverse drug experience that has not been previously observed or from the perspective of the pharmacological properties of the test product is not anticipated.

Voluntary - free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity. (IRB Guidebook, USDHHS in http://www.hhs.gov/ohrp/irb/irb_glossary.htm downloaded on June 19, 2010)

Vulnerability - a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva 2002, General Ethical Principles)

Vulnerable persons/groups - individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent. [ICH-GCP E6(R2), 2016]

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, Geneva 2002, Commentary on Guideline 9).

These are also classes of individuals who have characteristics that lessen their capacity to protect their own interests or promote their own welfare. These are "persons whose situation or characteristics may make them unable to provide free and informed consent to participate in research. This group includes children, institutionalized persons, those who have cognitive impairments, and those in a position of inferiority" (http://www.pre.ethics.gc.ca.engish/tutorial/glossary.cfm#c down loaded on July 9, 2010)