	<p>SAN LAZARO HOSPITAL CHAPTER 5 WRITING AND REVISING STANDARD OPERATING PROCEDURES</p>	<p>VERSION NO. 1</p> <p>EFFECTIVITY DATE: MAY 28, 2018</p>
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Supersedes:	Research Ethics Review Unit Operational Manual
Prepared by:	San Lazaro Hospital – Research Ethics And Review Unit (SLH-RERU) <i>(Based on 2017 DOH-REC SOP Team)</i>
Reviewed by:	ELIZABETH FREDA O TELAN, MD, PhD
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Approval Date:	

5. Writing and Revising Standard Operating Procedures (SOPs)

- 5.1 Writing SOPs**
- 5.2 Revising SOPs**

5.1 Writing SOPs

5.1.1. Purpose

To describe the procedure for writing and SOPs used by the San Lazaro Hospital-Research Ethics and Review Unit (SLH-RERU).

5.1.2. Scope

This SOP provides instructions on how the SLH-RERU SOPs are prepared.

5.1.3. Responsibility

It is the responsibility of the SLH-RERU Chair to organize an SOP Team to formulate the SOPs.

The SOP Team is an ad hoc committee composed of designated SLH-RERU members and invited resource persons. The team is responsible for drafting new SOPs and revising existing SOPs when necessary. The team must follow existing institutional procedures when drafting SOPs in consultation with the SLH-RERU Chair and Staff/Secretariat. The team submits the draft SOPs to the SLH-RERU Chair.

The SLH-RERU Chair convenes in a meeting to review and finalize draft SOPs and submit the final draft to the Medical Center Chief for final approval.

The SLH-RERU Staff/Secretariat is responsible for keeping all versions of SOPs and ensures that all SLH-RERU members and have access to current versions of SOPs to guide them in the performance of their functions.

5.1.4. Process Flow

NO	ACTIVITY	PERSON/S RESPONSIBLE
1	Organize an SOP Team	SLH-RERU Chair
2	Identify reference templates with corresponding layout	SOP Team
3	Draft new SOPs and submit to Chair	SOP Team
4	Review and finalize new SOP in an REC meeting and submit to the Hospital Director/Chief	SLH-RERU Chair and Members
5	Approve and sign new SOPs	SLH Medical Center Chief
6	Distribute approved SOPs and keep copies in the SLH-RERU files	SLH-RERU Staff/Secretariat



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5.1.5 Detailed Instructions

5.1.5.1 Organize an SOP Team.

- The SLH-RERU Chair assigns members to be part of the SOP Team and invites resource person as needed.
- The SOP Team receives an orientation from the SLH-RERU Chair regarding its duties and responsibilities.
- The SLH-RERU Chair may organize SOP Team workshops to facilitate the drafting of SOPs.

5.1.5.2 Identify reference templates with corresponding layout.

- Identify reference templates with corresponding layout from SOPs of other RECs to guide the SOP team in drafting new SOPs.
- A SLH-RERU SOP have the following format:
 - SOP Number
 - Title
 - Purpose of the SOP
 - Scope which defines the extent of coverage of the SOP and its limitations
 - Responsibility identifies the persons assigned to perform specific tasks during SOP implementation
 - Process Flow/Steps
 - Detailed Instructions which elaborates the steps outlined in the process flow
 - Standard forms and checklists to be used
 - Glossary
 - References
 - List of Acronyms
- An SLH-RERU SOP has the following format:
 - Each SOP should be given a number and a title that is self-explanatory and is easily understood.
 - The SOP Document History describes the different versions of the document by version no., version date, and description of main changes. This is attached with the SOP Masterfile.
- The typical SOP uses a header with the following elements:
 - Institutional seal or logo
 - Name of institution
 - SOP identifier
 - SOP title
 - Effectivity date
 - Page number

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5.1.5.3 Draft new SOPs and submit to the SLH-RERU Chair.

- The SLH-RERU SOPs should contain details under the following main topics:
 - Introduction – contains a statement of ethical principles that will guide the SLH-RERU
 - Structure and Composition of the SLH-RERU – describes the composition of SLH-RERU membership with specific review functions
 - Initial Review Procedures – describe types of review and initial review procedures
 - Monitoring Procedures – describe how the SLH-RERU monitors implementation of approved protocols
 - Management of Meetings, Documentation and archiving – describe administrative procedures that support the review functions
 - Writing and Revising SOPs – describes how to draft and revise SOPs
- The SOP Team submits completed SOP draft to the SLH-RERU Chair.

5.1.5.4 Review and finalize new SOPs in an SLH-RERU meeting and submit to the Medical Center Chief

- The SLH-RERU Chair presents the draft SOPs during a meeting for the members to discuss and finalize the draft.
- The SLH-RERU Chair submits the approved draft to the Medical Center Chief for approval.

5.1.5.5 Approve and sign new SOPs

- The Medical Center Chief reviews and approves the SOPs by signing in the designated section.
- The approved SOPs will be implemented after approval by the Medical Center Chief.

5.1.5.6 Distribute approved SOPs and keep copies in the SLH-RERU files.

- The SLH-RERU Staff/Secretariat distributes the new SOPs to all SLH-RERU Members and Staff and files the original copy in the designated storage cabinet.
- The SOP Manual with downloadable forms are uploaded on the Hospital website for the use of and guidance of researchers.

5.2 Revising SOPs

5.2.1 Purpose

To describe the procedure for revising SOPs used by the San Lazaro Hospital – Research Ethics and Review Unit (SLH-RERU).

5.2.2 Scope

This SOP provides instructions on how to revise existing SOPs.

5.2.3 Responsibility

It is the responsibility of the SLH-RERU members to suggest revisions in existing SOPs

The SLH-RERU Chair appoints an SOP Team, an ad hoc committee composed of designated REC members and invited resource persons. The team is responsible for revising relevant parts of existing SOPs. The team must follow existing institutional procedures when drafting or editing SOPs and consult the SLH-RERU Chair and Staff/Secretariat and about revisions. The team submits the revised sections to the Chair.

The SLH-RERU Chair convenes a full board meeting to review and finalize revised SOPs and submit the final draft to the Medical Center Chief for final approval.

The SLH-RERU Staff/Secretariat is responsible for keeping all versions of SOPs and ensures that all members and have access to current versions of SOPs to guide them in the performance of their functions.

5.2.4 Process Flow/ Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Propose to revise an SOP	SLH-RERU Member/s
2	Revise existing SOPs	SOP Team
3	Review & discuss SOP revision in full board meeting	SLH-RERU Members
3	Approve SOP revision	Medical Center Chief
4	File and distribute revised SOP	SLH-RERU Staff/Secretariat
5	Retrieve and archive copies of superseded SOP	SLH-RERU Staff/Secretariat



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5.2.5 Detailed Instructions

5.2.5.1 Propose to revise an SOP

- SOPs are reviewed at least every three years and may be revised, as necessary by the SLH-RERU members.
- A revision should be substantial enough to warrant major changes. Major changes are those that have a substantial effect on procedures, definitions, requirements, and similar considerations. Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures.
- When an SOP section does not cover what it should, or it does not follow new regulations, a revision may become necessary.
- Any member of the board may propose for the revision of the SOPs.

5.2.5.2 Revise existing SOPs

- The SLH-RERU Chair assigns an SOP team consisting of SLH-RERU Member/s, to draft the revision.
- The SOP team prepares the draft of revisions.
- The SLH-RERU Chair presents the revised SOP to the SLH--RERU for deliberation during a full committee meeting.

5.2.5.3 Review & discuss SOP revision in full board meeting.



- The SLH-RERU Chair convenes a full board meeting to discuss the revisions and finalize the draft.

5.2.5.4 Approve SOP revision

- The SLH-RERU Chair submits the final version of the revised SOP to the Medical Center Chief for final approval.
- The Medical Center Chief approves the revised SOP by signing on the appropriate SOP section.
- The approved version of revised SOPs will be implemented from the date of approval by the Medical Center Chief.

5.2.5.5 File and distribute revised SOP

- Upon approval, the SLH-RERU Staff distributes the printed copy of the revised SOPs to the SLH-RERU members and staff and retrieves the extra copies of superseded SOP for disposal.
- SLH-RERU Staff/Secretariat changes the electronic copy of the SOP published in the SLH's website with the newly revised version.
- The SLH-RERU Staff/Secretariat maintains an updated SOP Manual in the office.
- The SLH-RERU Staff/Secretariat retains the original signed copy of the revised SOP in the SOP Masterfile.

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- The original copy of the superseded copy is transferred to the archive after the updating of the SOP Document History.

5.2.5.6 Retrieve and archive original copy of superseded SOP

- The SLH-RERU Staff/Secretariat archives the superseded version of the SOP as part of the historical file maintained by the SLH-RERU.
- The word "SUPERSEDED" is stamped on the cover page of the superseded SOPs with the date of archiving,
- All printed copies of the superseded SOP in circulation are retrieved and disposed by shredding.