



**SAN LAZARO HOSPITAL**  
**CHAPTER 1**  
**SLH-RERU STRUCTURE AND COMPOSITION**

VERSION NO. 1  
 EFFECTIVITY DATE:  
**MAY 28, 2018**

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
Approved by:	EDMUNDO B. LOPEZ, MD, MPH, MHA
Approval Date:	

**1. SLH-RERU Structure and Composition**

- 1.1 Appointment of SLH-RERU Members**
- 1.2 Appointment of Independent Consultants**
- 1.3 Training of SLH-RERU Members and Staff**

***See Appendix A***

- 1.1 Statement of Responsibilities of SLH-RERU Member**
- 1.2 Curriculum Vitae Form**
- 1.3 Confidentiality and Conflict of Interest Agreement**
- 1.4 Training Record of an SLH-RERU Member**
- 1.5 Invitation to Independent Consultants**
- 1.6 Nomination Form**



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**1.1 Appointment of San Lazaro Hospital- Research Ethics and Review Unit (SLH-RERU) Members**

**1.1.1 Purpose**

To describe the appointment procedures of the members of the SLH-RERU and to identify the roles and responsibilities of SLH-RERU officers and members.

**1.1.2 Scope**

While the SLH-RERU remains under the authority of the Medical Center Chief, it has to maintain its independence and develop its competence related to decision making as defined in international and national guidelines. The membership SOPs cover the nomination and appointment procedures of SLH-RERU members and officers.

**1.1.3 Responsibility**

It is the responsibility of the Medical Center Chief to formally appoint the members and officers of the SLH-RERU after due consultation with the current members of the SLH-RERU.

**1.1.4 Process Flow/Steps**

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Define the composition of the membership of the SLH-RERU	SLH-RERU Chair, Member-Secretary, SLH-RERU members	<b>To be done 60 days before expiry of appointment</b>
2	Open the nomination of new SLH-RERU members from SLH-RERU itself, hospital management, department chairs, section heads and submit names of potential members to the SLH-RERU members for screening	SLH-RERU Members, hospital management, department chairs, section heads	
3	Recommend and submit the list of potential members to the Hospital Medical Center Chief	SLH-RERU Chair	
4	Obtain approval of appointment of SLH-RERU members and officers	Medical Center Chief	
5	Ensure completion of membership documents	New Member, SLH-RERU Secretariat	

6	Organize and complete the documents in the Membership Files	Administrative Staff	
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**1.1.5 Detailed Instructions**

**1.1.5.1 Define the composition of the membership of the SLH-RERU**

- The Chair discusses the qualifications of additional/new members with the existing members of the SLH-RERU.
- The SLH-RERU shall be composed of at least **9** members.
- Its membership shall be multidisciplinary. The SLH-RERU members should have diverse background and experience to foster a comprehensive and efficient review of research activities commonly conducted by its own affiliated and non-affiliated researchers.
  - The membership shall include persons whose primary concerns are in medical science and/or public health, with at least one member who is in a non-medical/non-scientific area, and at least one member who is not affiliated with San Lazaro Hospital.
  - Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the SLH-RERU should include a person who will represent the interest and concerns of the community.
  - The SLH-RERU shall aim for adequate representation of men and women members in order to promote gender sensitivity in its review procedures.
  - The SLH-RERU shall have representatives from both the older and younger generations.
  - During review meetings, the SLH-RERU shall adhere to quorum requirements as defined in international and national guidelines for SLH-RERUs that review health research. When reviewing clinical trials involving children or pediatric patients, a pediatrician or child development specialist shall be present during its board meeting. **(Refer to Chapter 4 on Conduct of Review Meeting)**

**1.1.5.2 Open the nomination of new members from SLH-RERU itself, hospital management, department chairs, section heads and submit names of potential members to the RERU (using Form 1.6 Nomination Form) for screening**

- Announce the open nomination process for the SLH-RERU to hospital management, department chairs, and section heads.
- Any hospital staff may submit the name of their nominees to the Chair for deliberation, with their corresponding Curriculum Vitae.
- Members are selected based on their good moral character and personal capacities, their scientific expertise and knowledge of



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ethical principles, as well as their willingness to volunteer their time and effort to perform their functions in the SLH-RERU.

- Members shall have prior training in research ethics, research methodology, and Good Clinical Practice or should be willing to undergo continuing training during their membership.
- During the SLH-RERU meeting the Chair presents the credentials of the person being nominated. SLH-RERU Members discuss and decide by consensus on the final list of nominees to be submitted to the Medical Center Chief. Conflict of interest issues of nominees shall also be discussed.

**1.1.5. 3 Recommend and submit the list of potential members to the Hospital Medical Center Chief**

**a. Selecting Members**

- The Medical Center Chief of Hospital reviews the list of nominees and decides on the appointment to be made.
- The appointment letter should include conditions of appointment, term of office, and honorarium (if any), as follows:
  - Members are appointed for a period of two (2) years and renewable for several consecutive terms depending on their performance.
  - Willingness to make public his/her full name, profession, and affiliation as an SLH-RERU member
  - Members shall disclose all financial accountability related to their work in the SLH-RERU that may record and publicly disclose its financial records upon request
  - Members shall sign the Confidentiality and Conflict of Interest Agreements. The agreement should cover all applications, meeting deliberations, information on research participants and related matters.
- It should contain an attachment about the responsibilities of an SLH-RERU member, as follows:
  - Serve as Primary Reviewers for research protocol documents within their area of expertise, and as General Reviewers for all researches discussed at convened meetings of the SLH-RERU
  - Submit on time (within 7 calendar days) to the Secretariat the completed Protocol and ICF Assessment forms when they are designated as Primary Reviewers
  - Conduct expedited review on behalf of the SLH-RERU of protocols assigned by the SLH-RERU Chair/Member-Secretary and submit the assessment forms on time (within 7 calendar days)
  - Perform post-approval review procedures of protocol-related documents within 7 calendar days



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- Update CV (using Form 1.2) and training record (using Form 1.4) every time appointment is renewed
  - Conform at all times with the legal and ethical principles accepted by the SLH-RERU
  - Attend basic and continuing education on Research Ethics at least once a year
  - Perform other tasks requested by the SLH-RERU Chair.
- Appointment of Non-Medical/Non-Scientific Member of the SLH-RERU should contain an attachment of their responsibilities as follows:
    - The non-medical or non-scientific members of the SLH-RERU shall focus on the human subject/participant concerns and review the informed consent process and the informed consent forms to ensure adequate the proper application of international and national principles and guidelines.
    - An alternate, non-affiliate, non-medical/non-scientific member shall be appointed who will take on the responsibilities of the regular non-affiliate, non-medical/non-scientific member in his/her absence.
  - The SLH-RERU shall adopt some mechanism to enable participation of new members with fresh outlook and approaches, but it shall also strive to ensure continuity, as well as the development and maintenance of expertise.

**b. Selecting Officers**

- The SLH-RERU Chair and Member-Secretary are nominated by the members of the SLH-RERU They should be highly-respected individuals within or outside the institution, fully capable of managing the SLH-RERU and ensuring fairness and impartiality in dealing with matters brought the SLH-RERU. They should have the following qualifications:
  - Good personal characteristics and reputation
  - Have training on Basic Research Ethics, GCP in Research and advanced courses on Research Ethics in the past 2 years
  - Have been a member of an Ethics Review Committee for **at least 2 years.**
  - The members should be guided by the ethical principles and procedures as expressed in the following international guidelines:
    - Declaration of Helsinki (2013 and subsequent revisions)
    - International Conference on the Harmonization of Good Clinical Practice (ICH-GCP)
    - CIOMS 2016



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- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization (WHO)

**1.1.5.4 Obtain approval of appointment of SLH-RERU members and officers**

- The Medical Center Chief of SAN LAZARO HOSPITAL is responsible for appointing the SLH-RERU Officers with due consideration to the SLH-RERU recommendations.
- The Medical Center Chief issues an appointment letter that identifies the SLH-RERU Officers
- The appointment letter should include an attachment of the responsibilities of the SLH-RERU Officers as follows:

**Responsibilities of the SLH-RERU Chair**

The responsibilities of the Chair include the following:

- Ensures that all SLH-RERU members receive orientation and undergo basic Research Ethics Training immediately after their appointment, and continuing education thereafter
- Obtains administrative and logistics support for the sustained operations of the SLH-RERU
- Approves the agenda and presides over SLH-RERU review meetings (If Chair has COI relative to the protocol for deliberation s/he designates the Member Secretary or any Member to preside over the meeting.)
- Selects suitable (somebody with related expertise) member/independent consultant to be the primary reviewer of a protocol whether by full board or expedited review, and ensures that aforementioned member does not have conflict of interest.
- Manages complaints from study participants, authorities or the general public
- Designates a member or group of members to investigate in cases of complaints or report of major non-compliance Ensures that the SLH-RERU is perceived as fair and impartial, and complies with institutional, national and international standards
- Represents the SLH-RERU in various local, national and international meetings and conferences.
- Prepares the Annual Work Financial Plan (WFP) and the Project Procurement Management Plan (PPMP) and approved by the hospital director
- Ensure adherence to quality standards to maintain the accreditation status
- A Vice-Chair, duly appointed by the Medical Center Chief will perform duties and responsibilities above, in



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the absence of the RERU Chair. He/She will also serve as primary reviewer of an assigned protocol.

**Responsibilities of the Member-Secretary**

The responsibilities of the Member-Secretary include the following:

- Supervises the SLH-RERU Staff related to good RERU office management
- Prepares and finalizes the meeting agenda of full-board meeting after consultation with the Chair
- Collects and reviews the assessment forms submitted by the Primary Reviewers before the meeting
- Ensures that the members completely fill out necessary forms used for the review of protocol or protocol related submissions,
- Supervises the SLH-RERU Staff in the preparation of the meeting agenda and minutes
- Supervises the SLH-RERU Staff in the preparation of the annual report of the SLH-RERU to be submitted to the Medical Center Chief, DOH, PHREB and other bodies.
- Ensures good SLH-RERU documentation and archiving.
- Ensures overall SLH-RERU compliance with good clinical practice.
- Ensures good financial management of SLH-RERU resources

**SLH-RERU Secretariat**

The SLH-RERU secretariat is composed of the Member-Secretary and the administrative staff who are employees of the San Lazaro Hospital.

The Secretariat shall have the following functions:

- Organizing an effective and efficient tracking procedure for each proposal received
- Preparation, maintenance and distribution of study files
- Organizing SLH-RERU meetings regularly
- Preparation and maintenance of meeting agenda and minutes
- Maintaining good SLH-RERU documentation and archiving procedures
- Communicating with the SLH-RERU members and Investigators
- Arrangement of training for personnel and SLH-RERU members
- Organizing the preparation, review, revision and distribution of SOPs and guidelines;



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- Providing the necessary administrative support for SLH-RERU -related activities to the Chair
- Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the SLH-RERU members
- Maintaining a library of relevant resource materials and references

**1.1.5.5 Ensure completion of membership documents**

- After the approval of the appointment, newly appointed members/officers should complete all documents in their Membership File.
- Upon the acceptance of their appointment, and before assuming their responsibilities as members/officers, they shall sign and date the TOR of the appointment letter indicating their willingness to assume their responsibilities.
- The Secretariat provides duplicate copies of the Confidentiality and Conflict of Interest Agreement form (**Form 1.3**) to newly appointed members of the SLH-RERU, one copy for the member and the other for the Membership File. For each protocol that they review, they must disclose their COI (any interest or involvement such as financial, professional or otherwise in a research proposal under review).
- The appointee is also required to submit an updated, signed and dated curriculum vitae (using Form 1.2), and the completed Training Record (using Form 1.4) including photocopies of relevant training certificates.

**Resignation, Disqualification, and Replacement of Members**

- Members may resign their positions by submitting a letter of resignation to the Chair and endorsed to the Medical Center Chief.
- Members may be separated from the committee by disqualification for valid reasons as determined by majority vote of the committee members.
- Members who have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.
- The terms of replacement shall be limited to the remaining term of the member that he/she has replaced.

**1.1.5.6 Organize and complete the documents in the Membership Files**

- The Membership Files shall contain the following:
  - Appointment letter signed and dated by the appointee
  - Updated curriculum vitae that is signed and dated by the member





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- The CV is updated every time the appointment is renewed.
- Training Record and photocopy of Training Certificates of relevant trainings
- Confidentiality and Disclosure of Conflict of Interest Agreement signed and dated by the member.
- The SLH-RERU Staff creates one membership file for each member, and files the following documents in each member's file.
  - Letter of Appointment
  - Curriculum Vitae
  - Training Records
  - Confidentiality and Disclosure of Conflict of Interest Agreement

**1.1.5.7 Honoraria of Members and Staff**

- All SLH-RERU members and staff shall be compensated on their attendance to meetings.
- The rate of the honoraria shall be based on Department Order No. 2017-0265
- RERU members and staff who are regular employees of the institution may receive honorarium provided that the meetings are undertaken after office hours.
- If the signatures of the member in the attendance form are incomplete then he/she is not entitled for the honorarium.  
**Note:** Attendance should be complete with signatures from the start of the meeting until decision is made and declared adjourned by the presiding officer.
- Non-attendees shall not receive honoraria.
- The processing of honoraria shall follow the institution's standard operating procedures.



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## 1.2 Appointment of Independent Consultants

### 1.2.1 Purpose

To describe the procedures for the appointment of SLH-RERU consultants

### 1.2.2 Scope

This SOP describes the procedures for engaging the services of a professional/expert as a consultant to the SLH-RERU. If the Chair of SLH-RERU determines that a study involves procedure(s) that are not within the area of competence or expertise of any of the SLH-RERU members, the Chair may invite individuals with expertise in special areas to assist in the review of protocols that require such expertise in addition to those available within the SLH-RERU.

### 1.2.3 Responsibility

Upon the advice or recommendation of the Secretariat or any SLH-RERU member, the SLH-RERU chair may appoint the name of the independent consultants.

### 1.2.4 Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Assess the need for Independent Consultants and seek approval for contracting their services	Chair, Member-Secretary, Members	To be done every quarter
2	Recruit and appoint an Independent Consultant	Chair, Secretariat	To be completed within 30 days
3	Organize and complete the documents in the Independent Consultant Files	Secretariat	

### 1.2.5 Detailed Instructions

#### 1.2.5.1 Assess the need for independent consultants and seek approval for contracting their services

- Considering the nature of the protocol for review, the Chair with the Members identify the expertise needed that the SLH-RERU membership may not have.
- The Chair submits the names of independent consultants to the Medical Center Chief to request for corresponding honorarium (rates are based on Department Order No. 2017-0265).



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**1.2.5.2 Recruit and appoint an independent consultant**

- Once the Chair decides to invite an Independent Consultant, the SLH-RERU Secretariat prepares the letter of invitation that includes the following:
  - Terms of Reference (TOR) - duration of consultancy, general overview of deliverables
  - Honorarium
  - Request for a copy of the consultant's curriculum vitae (CV) using Form 1.2
- The SLH-RERU Staff sends the letter to the independent consultant after it is signed by the Chair together with the duplicate copies of the Confidentiality and Conflict of Interest Agreement form (Form 1.3) for the consultant's signature.
- The SLH-RERU Staff asks the independent consultant to sign and date his acceptance of the TOR of the appointment.
- The SLH-RERU Staff collects the signed and dated Confidentiality and Conflict of Interest Agreement (Form 1.3), and the signed and dated updated CV using the prescribed format.

**1.2.5.3 Organize and complete the documents in the Independent Consultant Files**

- The Independent Consultant Files shall contain the following:
  - SLH-RERU Letter of invitation signed and dated by the SLH-RERU Chair
  - Updated curriculum vitae (Form 1.2) that is signed and dated by the Independent Consultant
    - The CV is updated every time the appointment is renewed.
  - Training Record (Form 1.4) and photocopy of Training Certificates of relevant trainings
  - Confidentiality and Disclosure of Conflict of Interest Agreement (Form 1.3) signed and dated by the Independent Consultant.
- The SLH-RERU Staff creates one file for each independent consultant.



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### 1.3 Training of SLH-RERU Members and Staff

#### 1.3.1 Purpose

To describe SLH-RERU procedures to ensure initial and continuing training of SLH-RERU members and staff

#### 1.3.2 Scope

The SLH-RERU recognizes the importance of training and continuing professional development. This SOP describes the training requirements of SLH-RERU members and staff from initial training to continuing education to maintain and update SLH-RERU competence in the review of different types of protocols.

#### 1.3.3 Responsibility

It is the responsibility of the SLH-RERU officers, members and staff to have themselves educated and trained regularly.

It is the responsibility of the SLH-RERU Chair along with the Secretariat to assess the training needs and prepare a training plan for all members, Independent Consultants, and staff.

The Secretariat keeps track of the training records of all members, Independent Consultants, and staff in accordance with the training plan.

#### 1.3.4 Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Require basic research ethics training for all members and staff	Chair	<b>Needs assessment to be done at the beginning of the year</b>
2	Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses	Chair, Secretariat	
3	Track member and staff participation initial and continuing ethics training and file the documents in the Membership File	Members, Secretariat	



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### 1.3.5 Detailed instructions

REC members should maintain competence by ensuring that they have updated knowledge of the following:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- CIOMS
- Ethical Guidelines
- Relevant laws and regulations
- Relevant developments in science, health and safety, etc.
- International meetings and conferences

#### 1.3.5.1 Require Basic Research Ethics Training for all members and staff

- All SLH-RERU members are required to have basic research ethics training that shall consist of research ethics principles, GCP, SOPs, etc. Upon appointment, a new member or staff undergoes orientation, individually or as a group, to cover the following:
  - Member's/Staff's responsibilities;
  - Confidentiality and Conflict of Interest Agreement;
  - REC review process and use of Protocol and ICF Assessment forms; and
  - REC SOPs.
- The REC Chair and Member-Secretary shall ensure that initial research ethics training is provided to all new members.

#### 1.3.5.2 Provide opportunities for continuing education for members and staff through participation in meetings, conferences and training courses

- The SLH-RERU Chair provides training opportunities to members/staff through participation in local and national research ethics seminars, conferences and workshops, and allocating funds for this purpose.
- The SLH-RERU Chair and Secretariat plan the training activities for individual SLH-RERU members based on their training needs.
- The SLH-RERU Chair and Secretariat track and facilitate attendance of SLH-RERU members and staff of specific training activities needed to ensure that each one gets training at least once a year.
- The SLH-RERU Members who participate in research ethics training course or seminar-workshops either through personal or through SLH-RERU efforts/funding are encouraged to:
  - Share information with other members during SLH-RERU meetings; and



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- Distribute photocopies/e-copies of relevant materials to the other members.

**1.3.5.3 Track member and staff participation in initial and continuing ethics training and file the documents in the Membership File**

- For in-house training, the SLH-RERU Staff prepares attendance sheets with relevant information about the topic, duration, date and venue. They ask member-attendees to sign the attendance sheet and keeps a photocopy of the attendance in the membership files, if Training Certificate is not given.
- All SLH-RERU Members and Staff should regularly update their Training Record. They should submit proof of attendance in relevant training or continuing professional education sessions conducted outside of the institution – e.g. certificates of training to the SLH-RERU Staff for filing.
- Administrative Staff should update the Training Record of individual Member and Staff to reflect their attendance in training activities every time a photocopy of Training Certificate is submitted for filing.