Supersedes:	Research Ethics Review Unit Operational Manual
Prepared by:	San Lazaro Hospital – Research Ethics And Review Unit (SLH-RERU) *(Based on 2017 DOH-REC SOP Team)*
Reviewed by:	ELIZABETH FREDA O TELAN, MD, PhD
Approved by:	EDMUNDO B. LOPEZ, MD, MPH, MHA
Approval Date:	

2. Initial Review Procedures

2.1 Management of Protocol Submissions
2.2 Use of Study Assessment Forms
2.3 Exempt from Review
2.4 Expedited Review
2.5 Full Board Review of Submitted Protocols
2.6 Review of Resubmission

See Appendix B

Form 2.1 List of Requirements for Non-Clinical, Clinical and Experimental Research

Form 2.2 Application for Initial Review
Form 2.3 Application for Exemption
Form 2.4 Participating Investigators Form
Form 2.5 Confidentiality and Non-Disclosure Agreement (Primary Investigator)
Form 2.6 Presenter Confirmation Form
Form 2.7 Protocol Assessment Form
Form 2.8 Informed Consent Assessment Form
Form 2.9 Protocol Summary Sheet
Form 2.10 SLH-RERU Notice for Protocol Modification (for initial and continuing review)
Form 2.11 Certificate of Approval
Form 2.12 Certificate of Exemption from Ethics Review
Form 2.13 Protocol Resubmission Form
Form 2.14 Protocol Timetable
Form 2.15 Protocol File Index

2.1. Management of Initial Protocol Submission

2.1.1. Purpose

To describe the SLH-RERU procedure for managing the submission of the initial protocol package for review – from the time of receipt to filing of the initial protocol package in the Active File storage cabinet.

2.1.2. Scope

This procedure applies to all protocols submitted to the SLH-RERU for ethical review.

The **SLH-RERU** accepts the following protocols for review: 1) **San Lazaro Hospital** funded researches, 2) researches done in **San Lazaro Hospital,** 3) researches referred from the PNHRS, PCHRD, DOST, PHIC, PHREB, DOH, FDA, CHED, industry organizations, etc. on the condition that the host hospital/institution where the proposal will be done accepts the review of SLH-RERU and agrees to abide by the rules and regulations that the **San Lazaro Hospital** follows. The other research sites also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the Committee may deem necessary. These conditions should be written in a document and signed by other hospitals/ institutions that accept **SLH-RERU** review.

2.1.3. Responsibility

The SLH-RERU Secretariat manages all protocol submissions to the RERU. It covers the actions to be done from the time of submission to the filing of the initial protocol package in the Active Study File cabinet.

2.1.4. Process Flow/Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Receive the initial protocol package for review and check the completeness of the documents submitted and issue a charge slip to the researcher for the settlement of the review fees	SLH-RERU Staff	To be done within 7 days
2	Assign a permanent code to the protocol package	SLH-RERU Staff	
3	Give a duplicate copy of the review application form to the person submitting the package.	SLH-RERU Staff	
4	Determine the type of review and the primary reviewers	Chair/Member Secretary	
5	Prepare the protocol review package for distribution to the primary reviewers	SLH-RERU Staff	
6	Log the received protocol package in the Protocol Database	SLH-RERU Staff	
7	File the initial protocol package in a properly labeled Protocol File folder and place it in the Active Study File cabinet	SLH-RERU Staff	

2.1.5. Detailed Instructions

2.1.5.1 Receive the initial protocol package for review and check the completeness of the documents submitted

- Ensure that the following forms are completely filled up, signed and dated by the researcher:
    - Application for Initial Review (Form 2.2)
    - Application for Exemption from SLH-RERU Review (Form 2.3) (If Applicable)
    - Participating Investigators Form (Form 2.4)
    - Confidentiality and Non-Disclosure Agreement (Primary Investigator) (Form 2.5)
    - Presenter Confirmation Form (Form 2.6)
    - Protocol Assessment Form (Form 2.7)
    - Informed Consent Assessment Form (Form 2.8)
- For research protocol of resident physicians (on training), and fellows, require submission of the endorsement from the department head and the technical review committee.
- For doctoral or masteral thesis of employees of San Lazaro Hospital or other researchers (not connected with the hospital), check for approval and endorsement from the institutional review board (IRB) or REC of the institution.
- All San Lazaro Hospital- funded protocols need technical review. The Technical Review Committee should have addressed the technical issues in the study protocol.
- For non-San Lazaro Hospital funded protocols, a document stating that the research protocol has undergone and passed technical review should be attached to the study protocol submitted for ethical review.
- Upon submission of the initial protocol for San Lazaro Hospital RERU review, the principal investigator or his/her representative should ensure that the protocol follows the standard protocol format and contains a Protocol Summary Sheet.

2.1.5.2 Assign a permanent code to the protocol package

- For efficient file management, it is necessary to use a unique identifier to refer to this file, the Protocol Code Number. This code number is given as follows: SLH-RERU - yyyy (year) – xx (chronological number based on order of receipt) – I/E (to indicate whether the researcher is internal or external.
- For example, if the study entitled "Clinical Drug Trial of XYZ on Pediatric Patients" by an external researcher is the first protocol received in 2017, the code **SLH-RERU 2017-01-E** should be used to identify this protocol. The code will be communicated to the researcher/principal investigator in all communications regarding the protocol.

2.1.5.3 Give a duplicate copy of the review application form to the person submitting the package.

- Instruct the person submitting the package to inform the researcher/PI to use the Protocol Code Number to identify the protocol in all submissions and in all his/her communications to the SLH-RERU.

  Note: After the submission of the complete protocol documents, the researcher shall settle the review fees and it is based on DOH Department Order 2017-0265. After which, it will be scheduled for review.

2.1.5.4 Determine the type of review and assign primary reviewers

There are three (3) types of review:

a) Exempt from review – for negligible risk protocols
b) Expedited review – for low-risk protocols
c) Full-Board review – for medium to high-risk protocols.

The following are some types of documents/researches that may be exempt from review:

a) Exempt from review
   - Research about public behavior (voting trends, opinion surveys, etc)
   - Evaluation of public programs by the agency itself
   - Quality control studies by the agency itself
   - Standard educational tests and curriculum development
   - Surveillance functions of DOH
   - Historical and cultural events
   - Research involving large statistical data without identifiers
   - Research not involving humans or human data
b) Expedited review - Minimal/low risk health research that requires personal information:
   - About a topic that should not result in causing social stigma
   - Does not involve vulnerable populations
   - Retrospective studies using anonymized data from medical records
   - Studies using simple questionnaires without identifiers
   - Laboratory research that uses anonymized human tissue/specimen

c) Full-Board review may be about the following:
   - Human health research involving medium to high risks to human participants
   - Intervention studies involving experimental treatments like clinical trials
   - May involve vulnerable populations who should be protected
   - Involves private information that may cause stigma

- The Chair/Member-Secretary designates at least two SLH-RERU members to be the primary reviewers of the protocol regardless of whether the type of review is expedited or full board.
  - Primary reviewers are selected on the basis of expertise related to the protocol.
  - The medical/scientific reviewer analyzes the scientific and ethical aspects of the protocol using the Protocol Assessment Form while the non-medical member focuses on the ICF and informed consent procedure using the Informed Consent Assessment Form.
- If the SLH-RERU membership does not have the needed expertise, the Chair/Member Secretary chooses from the roster of Independent Consultants. If none is available, a consultant with the needed expertise is recruited as per SOP on Selection of Independent Consultant (SOP No. 1.2).

2.1.5.5 Prepare the protocol review package for distribution to the primary reviewers

- The timeline from receipt of complete package to distribution to primary reviewers is within 7 calendar days.
- The initial protocol review package consists of all the documents in the initial protocol package plus blank copies of the Protocol Assessment Form**,** with the transmittal letter to the primary reviewers.

2.1.5.6 Log the received protocol package in the Protocol Database

- After ensuring the completeness of the initial protocol package, log the pertinent data in the electronic protocol database/ Logbook.
- As soon as subsequent data is available, complete the required protocol details in the protocol database.

2.1.5.7 File the initial protocol package in a properly labeled Protocol File folder and place it in the Active Study File cabinet

- Write the SLH-RERU Protocol Code Number of the protocol on the side of the file binder. On the front cover of the protocol binder, write the following:
  - SLH-RERU Protocol Code Number
  - Full title of the research
  - Name of the Principal Investigator and Co-Investigator/s
  - Sponsor Protocol Code Number
  - Name of the Sponsor
- Attach a **protocol file index that should serve as a Table of Contents of each protocol file**. (require PI-include in checklist of requirements)
- File the properly-labeled protocol file folders in the appropriate shelf of the storage cabinet for active study files taking note of the sequence of protocol code numbers on the file binders.
- On the side of the folder/ file, a protocol timetable (Form 2.14) is attached to monitor the progress of the study and the documents submitted.

2.2. Use of Study Assessment Forms

2.2.1. Purpose

To describe the SLH-RERU procedures related to the use of study assessment forms in ethics review

2.2.2. Scope

This SOP applies to the use of the Study Assessment Forms in the review and assessment of protocols and related documents submitted to SLH-RERU for its initial review and approval.

The SLH-RERU uses two Study Assessment Forms that are accomplished by individual primary reviewers. All comments, evaluation, recommendations and the initial decision of each reviewer regarding a protocol are all noted in these two Forms.

The two Study Assessment Forms are designed to standardize the review process and to facilitate reporting of recommendation and comments given to each individual protocol and related documents. These are:

a. Protocol Assessment Form (Form 2.7)
b. Informed Consent Assessment Form (Form 2.8)

2.2.3. Responsibility

It is the responsibility of the SLH-RERU reviewers to fill-in the assessment forms after reviewing each study protocol and submit to the Secretariat within 7 days.

The Secretariat is responsible for reminding the primary reviewers to submit the accomplished assessment forms and update the protocol folders.

2.2.4. Process Flow/Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE
1	Fill up the Study Assessment Forms when reviewing the study protocol and related documents.	Primary Reviewers
2	Submit accomplished Study Assessment Forms to the Secretariat within 7 days after receipt of documents	Primary Reviewers

3	Compile accomplished assessment forms for review by the Chair/Member-Secretary	SLH-RERU Staff
NO.	**ACTIVITY**	**PERSON(S) RESPONSIBLE**
4	File copies of accomplished assessment forms and other review documents in the protocol binder	SLH-RERU Staff

2.2.5 Detailed Instructions

2.2.5.1 Fill up the Study Assessment Forms when reviewing the study protocol and related documents.

- The Primary Reviewers read the protocol and related documents, and complete the assessment forms.
- Primary Reviewers should also do literature review to ensure updated knowledge about the protocol.
- The SLH-RERU primary medical reviewer accomplishes the Protocol Assessment and the Informed Consent Assessment Form (ICF) while the primary non-medical reviewer focuses on the ICF only.
- The Protocol Assessment Form allows review of the technical and ethical issues as follows:
  - Rationale and significance of the study
  - Objectives of the study
  - Review of literature
  - Sample size
  - Methodology and data management
  - Inclusion/exclusion criteria
  - Control arms (placebo, if any)
  - Withdrawal or discontinuation criteria
  - Vulnerability determination
  - Risk/ benefit assessment
- The Informed Consent Assessment Form enables review of the following:
  - Full disclosure of information, including risks
  - Benefits that may be derived from the study
  - Use of understandable language, with appropriate translation
  - Voluntary participation
  - Confidentiality
  - Appropriate person to sign the consent form
- If an Assent Form is required, it should be reviewed to ensure that the proper form is available, the appropriate signature is required.

- Review the qualifications of the PI and the research team to include the following:
  - Education and specialty
  - GCP training (if necessary)
- Review the sites where the study will be conducted.

2.2.5.2 Submit accomplished Study Assessment Forms to the Secretariat within 7 days after receipt of documents

- The Primary Reviewers sign, date the assessment forms and submit to the Secretariat within 7 days from date of receipt of the protocol review package.

2.2.5.3 Compile accomplished assessment forms for review by the Chair/Member Secretary

- The Secretariat checks whether the forms are complete, compiles the completed assessment forms and submits these to the Member-Secretary/Chair.

- The Member-Secretary/Chair reviews the compiled checklists. If the protocol is for expedited review, the Member-Secretary/Chair determines if there are no conflicting recommendations and if there is an agreement in the review/decision. If there are conflicting recommendations and/or disagreements in the review decision, the Member-Secretary/Chair forwards the protocol for Full-Board review.

2.2.5.4 File copies of accomplished assessment forms and other review documents in the protocol binder

- File accomplished assessment forms in the protocol binder and update the protocol file index by adding the Protocol Assessment Form and the Informed Consent Assessment Form with the date of submission.

2.3 Exempt from Review

2.3.1 Purpose

To describe the SLH-RERU procedures for the review of protocols that qualify for exemption from review.

2.3.2 Scope

This SOP applies to the review of a study protocol submitted to the SLH-RERU that qualifies for exemption from review.

2.3.3 Responsibility

The Chair or an SLH-RERU Member designated by the Chair is responsible for the assessment whether the submitted protocol qualifies for exemption from review.

2.3.4 Process Flow/ Steps (to be done within 7 days)

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Review a study protocol applying for exemption from review	Chair/Designated Member	To be done within 7 days
2	Issue Certificate of Exemption or recommend expedited or full-board review	Chair	
3	Prepare a report of protocols that are exempt from review to full-board	Secretariat	
4	Communicate the SLH-RERU decision to the PI	SLH-RERU Staff	
5	File copy of the documents in the protocol binder and update protocol database for exemption from review	SLH-RERU Staff	

2.3.5 Detailed instructions

2.3.5.1 Review a study protocol applying for exemption from review

- The SLH-RERU Chair or a designated SLH-RERU member who do not have any conflict of interest should review the study protocol applying for review exemption.
- The SLH-RERU Chair or a designated SLH-RERU member shall then evaluate the study protocol using the Exemption Criteria.

2.3.5.2 Issue Certificate of Exemption or recommend expedited or full-board review

- If the protocol qualifies for exemption from review, the reviewer submits the results of the assessment to Secretariat for the SLH-RERU staff to prepare a Certificate of Exemption from Review.
- If the protocol does not meet the Exemption Criteria, the Chair reclassifies the protocol for expedited or full-board review.

2.3.5.3 Prepare a report of protocols that are exempt from review to full-board

- The SLH-RERU Staff prepares a report to the next full board meeting to include details of all protocols exempted from review.

2.3.5.4 Communicate the SLH-RERU decision to the PI

- The SLH-RERU Staff prepares Certificate of Exemption from Review and forwards to the Chair for signature.
- The SLH-RERU Staff issues the Certificate of Exemption to the Principal investigator.

2.3.5.5 File copy of the documents in the protocol binder and update protocol database for exemption from review

- Prepare a binder to contain all protocols exempt from review.
- File the properly-labeled binder in the appropriate shelf of the storage cabinet.
- Update protocol database for exemption from review.

2.4 Expedited Review

2.4.1 Purpose

To describe the SLH-RERU procedures for the review of protocols that qualify for expedited review.

2.4.2 Scope

This SOP applies to the initial and continuing review and approval of study protocols with minimal risks to study participants. In general, Expedited Review is done

- in minimal/low risk health research that requires personal information (ex. review of medical records)
- about a topic that should not result in causing social stigma
- in retrospective studies using anonymized data
- in health studies using simple questionnaires without identifiers
- in laboratory research that uses anonymized human tissue/specimen

2.4.3 Responsibility

Expedited review is the responsibility of assigned primary reviewers appointed to assess a protocol that qualifies for the expedited procedure. The same assessment forms used for full board review should be used to evaluate the scientific and ethical merits of the protocol.

2.4.4 Process Flow/ Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Determine that the submission qualifies for expedited review.	Member Secretary/ Chair	7 days
2	Assign primary reviewers (medical/scientific and a non medical/non scientific members).	Member-Secretary / Chair	
3	Send the protocol package to the primary reviewers	SLH-RERU Staff	
4	Review the documents with the use of the assessment forms.	Primary Reviewers	7 days

5	Return the accomplished assessment forms to the Secretariat.	Primary Reviewers	
6	Collate and reviews the assessment forms to take appropriate action.	Member Secretary	7 days
7	Communicate the SLH-RERU decision to the PI	SLH-RERU Staff	
8	Prepare a list of all expedited review results and report to full board	Secretariat	7 days
9	File copies of the documents in the protocol file folder and update the protocol database	SLH-RERU Staff	

2.4.5 Detailed instructions

2.4.5.1 Determine that the submission qualifies for expedited review.

- For initial review: The Chair/ Member Secretary checks if the submitted protocol qualifies for expedited review. The following are types of protocols that can be subjected to expedited review after initial submission:
  - Protocols of a non-confidential nature (not of a private character, e.g. relate to sexual preference etc., or not about a sensitive issue that may cause social stigma), not likely to harm the status or interests of the study participants and not likely to offend the sensibilities or cause psychological stress to the people involved.
  - Protocols **not** involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in case of refusal to retaliate, 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).
  - Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
  - Research involving data, documents or specimens that have been previously collected

- Proposed continuing review of previously expedited protocols, minor protocol amendments and end of study reports.

- For resubmitted documents: SLH-RERU decision for minor modification qualifies for expedited review by the Primary Reviewers or Chair/ Member Secretary.
- Submissions after initial approval may qualify for expedited review as follows:
  - Administrative revisions, such as correction of typing errors
  - Addition or deletion of non-procedural items, such as the addition/change in study personnel or changes in their address or contact number, change in laboratories, and the like.
  - The research activity includes only minor changes from previously approved protocol.
  - Minor protocol amendments that do not change the risk/ benefit assessment
  - Progress/Final reports that were initially reviewed by expedited review and that do not deviate from approval given by the SLH-RERU.
  - SAEs that are off-site provided these are not SUSARs.

2.4.5.2 Assign primary reviewers (medical/scientific and a non-medical/non-scientific members) to review the submitted documents.

- Assign a Medical/ Scientific Reviewer (SLH-RERU member or Independent Consultant) to review the scientific and ethical merits of the protocol related documents.
- Assign a non-medical/ non-scientific member to review the ICF.

2.4.5.3 Send the protocol package to the primary reviewers

- The SLH-RERU Staff contacts the designated Primary Reviewers to determine if they can review the protocol documents within the 7 day deadline. If not, other primary reviewers are identified.
- The Staff prepares the notice to the Primary Reviewers, the protocol package and the corresponding assessment forms and forwards them to the designated reviewers.

2.4.5.4 Review the documents with the use of the assessment forms.

- The Primary Reviewers read the protocol and related documents, and complete the assessment forms. The SLH-RERU primary medical reviewer accomplishes both the protocol and ICF assessment forms while the primary non-medical reviewer evaluates informed consent documents by using the Informed Consent Assessment Form.
- The Primary Reviewers decide whether the protocol can be approved, modified or disapproved.

- When the modification is required, the protocol documents are returned for the researchers to revise the documents and resubmit to the SLH-RERU for approval.
- Disapproved protocols are automatically forwarded to full board for discussion and decision. Disapproval cannot be done at the expedited level.

2.4.5.5 Return the accomplished assessment forms to the Secretariat

- The Primary Reviewers signs, dates the assessment form/s and return them to the Secretariat within 7 days from receipt of the protocol review package.
- The Secretariat checks completeness of the assessment forms and forwards them to the Member-Secretary to recommend appropriate SLH-RERU follow up action.

2.4.5.6 Collate and review the assessment forms to take appropriate action.

- The Member-Secretary reviews the completed assessment forms to determine if there is agreement in the review/ decision. The comments and decision are consolidated and communicated to the PI.
- If there are conflicting recommendations and/ or disagreement in the review decision or when the protocol is disapproved, the Member-Secretary includes the protocol in the next full board meeting for discussion and decision of full board.

2.4.5.7 Communicate the SLH-RERU decision to the PI.

- The SLH-RERU Staff communicates approval to the PI and uses the Certificate of Approval Form (Form 2.6).
- In case revision is required, the comments are sent to the PI to comply with the required modifications and resubmits the documents to the SLH-RERU using the notification form (Form 2.5) and resubmits the documents to the SLH-RERU.

2.4.5.8 Prepare a report on results of expedited review to full board.

- The SLH-RERU Staff prepares a list of protocols approved through expedited review and the Member Secretary reports them during the full board meeting.
- The report is included in the Minutes of the meeting.

2.4.5.9 File a copy of the documents in the protocol file folder and update the protocol database.

- The SLH-RERU Staff files copies of the approved documents in the protocol file folder.
- Update the protocol file index of the protocol file folder.
- The SLH-RERU Staff updates the protocol database.

2.5 Full Board Review of Submitted Protocols

2.5.1 Purpose

To describe the SLH-RERU procedures when the protocol submissions are classified for full board review

2.5.2 Scope

This SOP applies to the SLH-RERU full board review and approval of study protocols during initial and continuing review.

2.5.3 Responsibility

Full board review is the joint responsibility of all SLH-RERU members who review and make decisions on the protocol related documents during a convened full board meeting.

In general, full board review is done for protocols that involve medium to high risk interventions to human like experimental treatments in clinical trials that may involve vulnerable human subjects.

2.5.4 Process Flow/ Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Determine if the submission should undergo full board	Member Secretary/ Chair	7 days
2	Assign primary reviewers (medical/scientific and a non-medical/non-scientific members).	Member-Secretary / Chair	
3	Send the protocol package to the primary reviewers	SLH-RERU Staff	
4	Review the documents with the use of the assessment forms.	Primary Reviewers	7 days

5	Return the accomplished assessment forms to the Secretariat.	Primary Reviewers	
6	Discuss and decide on the protocol and related documents during a convened full board meeting	SLH-RERU Members	7 days
7	Communicate the SLH-RERU decision to the PI and allocate 15 days for the PI to comply	SLH-RERU Staff	7 days
8	File copies of the documents in the protocol file folder and update the protocol database	SLH-RERU Staff	7 days

2.5.5 Detailed Instructions

2.5.5.1 Determine if the submitted protocol documents should undergo full board review.

- The Chair/ Member Secretary screens the protocol to identify those that should be discussed at full board.
- For initial review: The Chair/ Member Secretary goes over the submitted protocol and decides if it should undergo full board review based on assessment of risks.
- The following are types of protocols that should be reviewed at a convened full board meeting:
    - Clinical trials about investigational new drugs, biologics or device in various phases (Phase 1, 2, 3)
    - Phase 4 intervention research involving drugs, biologics or device
    - Protocols including questionnaires and social interventions that are confidential in nature (about private behavior, e.g. related to sexual preferences etc.; or about sensitive issues that may cause social stigma, psychological, legal, economic and other forms of social harm
    - Intervention protocols involving vulnerable subjects (patients with incurable diseases, persons in nursing homes, patients in emergency situations, ethnic minority groups, homeless persons, refugees, minors

and those incapable of giving consent) that require additional protection from the SLH-RERU during review
        - Protocols that involve collection of identifiable biological specimens from vulnerable groups, etc.
    - For resubmitted documents: SLH-RERU decision for major modification of documents (protocol, ICF, etc.) requires full board review of revisions.
    - The following continuing review submissions should undergo full board review as follows:
        - Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, etc.)
        - Major amendments that change the risk/ benefit ratio
        - Major protocol violations
        - Progress reports of ongoing studies that involve medium to high risks to human subjects/ participants
        - Onsite SAEs or SUSARs that involve safety issues.

2.5.5.2 Assign primary reviewers (medical/scientific and a non-medical/non-scientific members) to review the protocols.

The Chair/ Member Secretary:

- Assign a Medical/ Scientific Reviewer (SLH-RERU member or Independent Consultant) to review the scientific and ethical merits of the protocol related documents.
- Assign a non-medical/ non-scientific member to review the ICF.

2.5.5.3 Send the protocol package to the primary reviewers

- The SLH-RERU Staff contacts the designated Primary Reviewers to determine if they can review the protocol documents within the 7 day deadline. If not, other primary reviewers are identified.
- The Staff prepares the notice to the Primary Reviewers, the protocol package and the corresponding assessment forms and forwards them to the designated reviewers.

2.5.5.4 Review the documents with the use of the assessment forms.

- The Primary Reviewers read the protocol and related documents, and complete the assessment forms. The SLH-RERU primary medical reviewer accomplishes both the protocol and ICF assessment forms while the primary non-medical reviewer evaluates informed consent documents by using the Informed Consent Assessment Form.

- The Primary Reviewers recommend the type of decision for initial review of protocol related documents:
  - Approved
  - Minor modification required
  - Major modification required
  - Disapproved
- Primary reviewers should also check the CV or information about the investigators (including GCP training for clinical trials), the study sites and other protocol related documents, including advertisements:
  - Consider whether study and training background of the principal investigator are related to the study.
  - Look for disclosure or declaration of potential conflict of interest.
- Determine if the facilities and infrastructure at study site are suitable for the study.

2.5.5.5 Return the accomplished assessment forms to the Secretariat

- The Primary Reviewers signs, dates the assessment form/s and return them to the Secretariat within 7 days from receipt of the protocol review package.
- The Secretariat checks completeness of the assessment forms and forwards them to the Member-Secretary who includes it in the agenda of the next full board meeting.

2.5.5.6 Discuss and decide on the protocol and related documents during a convened full board meeting.

- Conduct a full board meeting to discuss and make a decision about the protocol and related documents. (Refer to SOP on Conduct of Review Meeting)
- The members of the SLH-RERU attending the full board meeting have to approve the ff:
  - Principal and Co Investigators and members of the research team
  - Protocol
  - Informed Consent
  - Advertisements or recruitment materials
  - Study sites covered by the application
- The SLH-RERU members vote on specific items to arrive at a decision as follows:
  - Approval (when no further modification is required)
  - Minor modification (requires minor changes in the documents such as typographical errors, administrative issues, additional explanations, etc.)
  - Major modification (requires revision of study design, major sections of the protocol or ICF that affect patient safety or credibility of data)

- Disapproval (due to ethical or legal concerns) Reasons for vote of disapproval should be noted in the minutes and communicated to the PI.

- If the study is approved, the SLH-RERU determines the frequency of continuing review.
- All meeting deliberations and decision regarding a protocol are noted in the meeting minutes. (Refer to SOP on Preparation of Meeting Minutes)

2.5.5.7 Communicate the SLH-RERU decision to the PI and allocate 15 days for the PI to comply.

- All SLH-RERU decisions are communicated to the PI.
  - Approval: The SLH-RERU Staff prepares the Certificate of Approval to be signed by the Chair.
  - Minor modification: The SLH-RERU Staff prepares the Notification Letter to inform the PI of the required revisions in the protocol, ICF or any related document. The resubmitted documents undergo Expedited Review before approval is granted. The Chair/Member-Secretary reviews and checks compliance to recommendations of the resubmitted documents, before granting approval.
  - Major Modification: The SLH-RERU Staff prepares the Notification Letter to inform the PI of a required revisions in the protocol, the ICF or related document. The resubmitted documents are referred to Primary Reviewers and discussed at Full Board Review, once more before approval is granted.
  - Disapproval: The SLH-RERU Staff prepares the Notification Letter to inform the PI of SLH-RERU decision. The reasons should be clearly stated in the notice.
  - (Refer to SOP on Communicating SLH-RERU Decisions to the Researcher/PI)

2.5.5.8 File copies of the documents in the protocol file folder and update the protocol database.

- The SLH-RERU Staff files copies of the approved documents in the protocol file folder.
- Update the protocol file index of the protocol file folder.
- The SLH-RERU Staff updates the protocol database.

2.6 Review of Resubmission

2.6.1 Purpose

To describe the procedures of SLH-RERU when the protocol resubmissions are received.

2.6.2 Scope

This SOP applies to the SLH-RERU review and approval of study protocols recommended for minor or major modifications during initial and continuing review.

2.6.3 Responsibility

It is the responsibility of the SLH-RERU Chair/ Secretariat to classify resubmitted protocols for expedited or full board review.

It is the responsibility of primary reviewers to review the resubmitted documents to determine if they have complied with the required modifications before granting approval during expedited review or to recommend approval of protocols with major modification to full board.

It is the responsibility of SLH-RERU members to approve resubmitted protocols with major modification after discussion.

2.6.4 Process Flow/ Steps

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
1	Receive the resubmitted protocol package from the PI.	SLH-RERU Staff	7 days
2	Send the protocol package to the primary reviewers.	SLH-RERU Staff	
3	Review if the resubmission complied with the required modification	Primary Reviewers	
4	Return the documents with a decision after expedited review or recommended a decision to full board	Primary Reviewers	

NO.	ACTIVITY	PERSON(S) RESPONSIBLE	TIMELINE
5	Discuss and decide on major modifications received during a full board meeting	SLH-RERU Members	7 days
6	Accomplish the Certificate of Approval and communicate the SLH-RERU decision to the PI	SLH-RERU Staff	
7	File copies of the documents in the protocol file folder and update the protocol database	SLH-RERU Staff	

2.6.5 Detailed Instructions

2.6.5.1 Receive the resubmitted protocol package

- The SLH-RERU staff receives the resubmitted protocol documents from the PI
- The Secretariat shall ensure that the Protocol Resubmission Form (Form 2.13) is accomplished properly.

2.6.5.2 Send the protocol package to the primary reviewers

- The SLH-RERU staff sends the package to the primary reviewers during initial review.
- The SLH-RERU staff logs the protocol documents in the Log for Outgoing Documents.

2.6.5.3 Review if the resubmission complied with the required modification

- The Chair/Member-Secretary or designated primary reviewers may review minor protocol modifications.
- The primary reviewers review the resubmitted documents and compares it with the requirements for modification.

2.6.5.4 Return the documents with a decision after expedited review or recommended a decision to full board

- The primary reviewers return the resubmission package indicating their decision.
- In expedited review, the primary reviewers approve the resubmitted documents if the PI has substantially complied with the required modifications.

- Minor modifications recommended by full board should also go to expedited review.
- For major modifications for full board discussion, the primary reviewers recommend approval.

2.6.5.5 Discuss and decide on major modifications received during a full board meeting

- Primary reviewers resend their assessment of major modifications during full board discussion and make a recommendation for approval.
- SLH-RERU members vote to endorse or not to endorse the recommendation for approval.

2.6.5.6 Accomplish the Certificate of Approval and communicate the SLH-RERU decision to the PI

- For approved resubmitted protocols, the SLH-RERU staff prepares the Certificate of Approval that the Chair should sign.
- Only the SLH-RERU Chair is designated as a signatory for the approval of the protocols.
- Once protocol is approved, the primary investigator shall submit a Memorandum of Agreement (MOA) and/ or Material Transfer Agreement (MTA), if applicable, which will be forwarded to the legal office and settle the institutional fee. The rate of the institutional fee is based on the approved Hospital Order No. 19 s. 2017.
- The SLH-RERU decision is communicated to the PI.

2.6.5.7 File copies of the documents in the protocol file folder and update the protocol database.

- The SLH-RERU Staff files copies of the approved documents in the protocol file folder.
- Update the protocol file index of the protocol file folder.
- The SLH-RERU Staff updates the protocol database.

Note: the whole resubmission process should be done within 14 days