



**SAN LAZARO HOSPITAL**  
**CHAPTER 4**  
**DOCUMENTATION AND ARCHIVING**

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
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Approval Date:	

**4. Meeting Conduct, Documentation and Archiving**

- 4.1. Preparation of Meeting Agenda**
- 4.2. Conduct of a Full Board Meeting**
- 4.3. Preparation of Meeting Minutes**
- 4.4. Communicating SLH-RERU Decision to PI**
- 4.5. Management of Active Study Files**
- 4.6. Archiving of Inactive Study Files**
- 4.7. Maintenance of Confidentiality of Study Files and SLH-RERU Documents**

***See Appendix D***

- Form 4.1 Meeting Agenda Template**
- Form 4.2 Meeting Minutes Template**
- Form 4.3 Meeting Attendance Form**
- Form 4.4 Request to Access SLH-RERU Files**



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**4.1 Preparing the SLH-RERU Meeting Agenda**

**4.1.1 Purpose**

To describe the procedures involved in agenda preparation before the conduct of the full board meeting of the San Lazaro Hospital – Research Ethics and Review Unit (SLH-RERU).

**4.1.2 Scope**

This SOP provides instructions related the preparation of meeting agenda before a full board meeting.

**4.1.3 Responsibility**

It is the responsibility of SLH-RERU Secretariat, composed of the SLH-RERU Staff under the supervision of the Member-Secretary to prepare the meeting agenda before an SLH-RERU full board meeting.

**4.1.4 Process Flow/Steps**

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Prepare and finalize the Meeting Agenda	SLH-RERU Staff/Secretariat, Member-Secretary, SLH-RERU Chair	7 days
2	Make arrangements for the meeting	SLH-RERU Staff/Secretariat	
3	Distribute Notice of Meeting	SLH-RERU Staff/Secretariat	
4	File a copy of the agenda after the meeting	SLH-RERU Staff/Secretariat	

**4.1.2 Detailed Instructions**

**4.1.2.1 Prepare and Finalize the Meeting Agenda**

- One week before the scheduled meeting date, the SLH-RERU Staff/Secretariat checks the submissions since the last full board meeting and prepares a list of items for review during the next full board meeting.
- The SLH-RERU Staff/Secretariat uses the Meeting Agenda template (**Form 4.1**) to classify the items for review.
- The SLH-RERU Staff/Secretariat forwards the draft meeting agenda to the SLH-RERU Member-Secretary and SLH-RERU Chair to review and finalize.



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- The SLH-RERU -Member Secretary reviews the draft meeting agenda and makes changes, if needed, then it will be presented to the SLH-RERU Chair for final approval and comments and it becomes the provisional meeting agenda. The provisional meeting agenda is presented at beginning of the full board meeting and SLH-RERU members are given the chance to suggest additional items to finalize the meeting agenda.

**4.1.2.2 Make arrangements for the meeting**

- SLH-RERU Staff/Secretariat contacts SLH-RERU members to check who will be available to attend the meeting to ensure quorum.
- The SLH-RERU Staff/Secretariat makes the necessary arrangements:
  - for reservation of meeting room on the scheduled meeting date and time
  - for snacks of meeting attendees
- Prepares relevant documents to be distributed to SLH-RERU Members who confirmed to attend the meeting.

**4.1.2.3 Distribute Notice of Meeting**

- SLH-RERU Staff/Secretariat distributes the Notice of Meeting (with the provisional meeting agenda) together with the relevant documents, including Protocol Summary Sheet (**Form 2.9**) for review during the meeting to SLH-RERU Members within 7 days prior to meeting date.

**4.1.2.4 File the meeting agenda**

- SLH-RERU Staff/Secretariat takes note of changes in the provisional meeting agenda after this is presented for approval to the SLH-RERU. If there are no changes, the provisional meeting agenda becomes the final meeting agenda.
- SLH-RERU Staff/Secretariat files a copy of the provisional meeting agenda in a folder of Meeting Agenda for the year.



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**4.2 Conduct of a Full Board Meeting**

**4.2.1 Purpose**

To describe the procedures of SLH-RERU when it conducts a full board meeting to review protocol submissions.

**4.2.2 Scope**

This SOP describes the various steps the SLH-RERU follows to review various types of protocol submissions, the types of decision and action taken as well as necessary documentation to record its proceedings.

**4.2.3 Responsibility**

It is the responsibility of the SLH-RERU Chair to preside over the meeting and exercise leadership to enable the SLH-RERU members and SLH-RERU Staff/Secretariat to fulfill their designated roles in the review of protocol related documents submitted to the SLH-RERU in an efficient and effective manner. It is the responsibility of the Member-Secretary to ensure that quorum will be met, that the required documents needed are available, to supervise the SLH-RERU Staff/Secretariat taking real time minutes of the proceedings and to report the results of expedited review, while the details of the protocol assessment are reported by the primary reviewers.

It is the responsibility of SLH-RERU Members to prepare and participate in SLH-RERU full board meetings to enable the SLH-RERU to conduct good review and take appropriate action related to documents submitted to the SLH-RERU.

It is the responsibility of the SLH-RERU Staff/Secretary to prepare and make available all documents needed during the meeting and to take down minutes of the proceedings.

**4.2.4 Process Flow/ Steps**

<b>NO.</b>	<b>ACTIVITY</b>	<b>PERSON/S RESPONSIBLE</b>
1	Call the Meeting to order	SLH-RERU Chair
2	Determine Quorum	SLH-RERU Member Secretary
3	Declare Conflict of Interest	SLH-RERU Members
4	Approve the Minutes of the previous Full Board Meeting and discuss business arising from the Minutes	SLH-RERU Members
5	Approve or modify the agenda	SLH-RERU Members



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<b>NO.</b>	<b>ACTIVITY</b>	<b>PERSON/S RESPONSIBLE</b>
6	Discuss and decide on protocols for initial review	Primary Reviewers SLH-RERU Members
7	Decide on protocol document resubmission	Primary Reviewers SLH-RERU Members
8	Discuss and decide on major Protocol Amendments	Primary Reviewers SLH-RERU Members
9	Discuss and decide on Progress Reports for full board review	Primary Reviewers SLH-RERU Members
10	Approve Final Reports	Primary Reviewers SLH-RERU Members
11	Discuss Protocol Deviation/ Violation Reports for appropriate action	Primary Reviewers SLH-RERU Members, Study Site Visit Team
12	Report Onsite SAEs for appropriate action	SLH-RERU SAE Sub-committee, Primary Reviewers
13	Report Expedited Review results	SLH-RERU Member Secretary
14	Report/ Discuss other matters for full board action/ information	SLH-RERU Chair/ SLH-RERU Members
15	Formally close the Full Board Meeting	SLH-RERU Chair

#### **4.2.5 Detailed Instructions**

##### **4.2.5.1 Call the Meeting to order.**

- The SLH-RERU Chair declares the formal opening of the Meeting at the appointed time and place once majority of the members are present.

##### **4.2.5.2 Determine Quorum.**

- The SLH-RERU Member-Secretary checks and reports if the quorum requirements are met to enable the meeting to start. SLH-RERU Quorum requirements should comply with national and international requirements and as defined in these SOPs. Quorum should be checked and declared at the opening of the meeting, before the review of the protocol and before the decision making, by the SLH-RERU Member-Secretary. Quorum is likewise maintained throughout the duration of the meeting when members



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are required to vote to arrive at a decision. The following should be met to constitute quorum in a full board meeting of SLH-RERU:

- 50%+ 1 of panel membership but not less than 5
- presence of medical/ scientific and non-medical/ non-scientific members
- presence of non-affiliated member

**4.2.5.3 Declare Conflict of Interest**

- The SLH-RERU Chair asks the SLH-RERU members to declare their conflict of interest related to any protocols to be discussed.
- The SLH-RERU members check the agenda and declare their COI related to any protocol to be reviewed. They should be asked to leave the room during the discussion of such protocols, unless they are asked to reply to questions for clarification. Quorum should be maintained when conflicted members leave the room. They return to the room after discussion of their protocol.

**4.2.5.4 Approve the Minutes of the previous Full Board Meeting and discuss business arising from the Minutes**

- The Minutes of the previous meeting should have been sent to all members before the meeting for comments. The SLH-RERU Chair asks the members to approve the Minutes of the last meeting and ask the members to voice out their comments, if any.
- The SLH-RERU Chair also ask the members to comment about issues arising from the Minutes and the discussions are recorded in the current Minutes by the SLH-RERU Staff/Secretariat.

**4.2.5.5 Approve or modify the agenda**

- The SLH-RERU Chair asks the SLH-RERU Members to examine and approve the items in the Meeting Agenda.
- SLH-RERU members may suggest additional items for discussion and the meeting agenda may be modified to include additional items for discussion.

**4.2.5.6 Discuss and decide on protocols for initial review**

The list of protocols for initial review are discussed according to the following procedures:

- The primary medical reviewer summarizes the protocol to enable the members to understand it.
- He/she uses the protocol assessment form (**Form 2.7**) to comment on the technical and ethical issues in the protocol and makes recommendations about clarification, modification or approval. He/she also comments on the qualifications of the researchers and the sites.
- The SLH-RERU Chair opens the protocol for discussion of SLH-RERU members taking note of additional and contradictory comments.
- The PI is called to enter the room to answer questions and clarify certain protocol related matters, after which, he/she is asked to leave the room.
- The SLH-RERU Chair summarizes the points raised and notes different views among members that should be resolved. The SLH-RERU Chair asks the SLH-RERU members to vote based on the decision points in the SOPs



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- Approval (no further revision of the documents is required)
- Minor Modification
- Major Modification,
- Disapproval

**Note:** The SLH-RERU Chair ensures that all issues are resolved prior to REC decision.

- The Non Medical/ Non Scientific Reviewer presents his/her assessment of the Patient Information Sheet and Informed Consent Form making use of the ICF Assessment Form (**Form 2.8**). The comments should note the discrepancies between the protocol and the information sheet, the correct consent or assent is enclosed, and provisions for proper signatures in the form.
- The SLH-RERU Member-Secretary takes note of voting results, records them and includes them in the Minutes of the meeting.
- Once the protocol documents are approved, the SLH-RERU should agree on the frequency of continuing review.

**4.2.5.7 Decide on protocol document resubmission for Major Modification**

- The SLH-RERU Staff/Secretariat includes in the Meeting Agenda resubmissions required for Major Modification for full board discussion.
- The Primary Reviewers check if the researchers complied with the SLH-RERU requirements and recommends appropriate decision. The SLH-RERU members vote to approve the resubmission.

**4.2.5.8 Discuss and decide on Major Protocol Amendments**

- The SLH-RERU Member-Secretary screens amendments to determine Major Protocol Amendments that require full board review and to ensure inclusion in the Meeting Agenda.
- The Primary Reviewers review the amendment and presents their assessment to full board.
- The SLH-RERU members vote to approve the Major Amendment.

**4.2.5.9 Discuss and decide on Progress Reports for full board review**

- The SLH-RERU Staff/Member-Secretary screens Progress Reports that require full board review to ensure inclusion in the Meeting Agenda.
- The Primary Reviewers review Progress Reports and present their assessment to full board.
- The SLH-RERU members vote to approve the Progress Reports.

**4.2.5.10 Approve Final Reports**

- The SLH-RERU Staff/Secretariat submits a list of Final Reports to full board review and includes them in the Meeting Agenda.
- The Primary Reviewers review Final Reports and presents their assessment to full board.
- The SLH-RERU members vote to approve the Final Reports



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**4.2.5.11 Discuss Protocol Deviation/ Violation Reports for appropriate action**

- The SLH-RERU Staff/Secretariat includes all Protocol Deviation/ Violation Reports in the Meeting Agenda.
- The Primary Reviewers/Study Site Visit team (as appropriate) review the Reports and present their assessment and recommendation for appropriate action to full board.
- The SLH-RERU members vote to take corresponding action on the Protocol Deviation/ Violation Reports.

**4.2.5.12 Report Onsite SAEs for appropriate action**

- The SLH-RERU Staff/Secretariat prepares a list of Onsite SAEs/ SUSARs and submits them to full board for appropriate action.
- The SAE Sub-committee/Primary Reviewers review the Onsite SAE/SUSAR Reports and present their assessment and recommendation for appropriate action to full board.
- The SLH-RERU members vote to take corresponding action on the Onsite SAE/ SUSAR Reports.

**4.2.5.13 Report Expedited Review results**

- The SLH-RERU Staff/Secretariat prepares a list of all Expedited Review results. The SLH-RERU Member-Secretary reports the results to full board to inform the SLH-RERU members. The details of the technical/ethical assessment of the protocol are presented by the primary reviewers.
- SLH-RERU Members may comment on the Report

**4.2.5.14 Report/ Discuss other matters for full board action/ information**

- The SLH-RERU Chair or any of the SLH-RERU Members may suggest items or other matters for the information or discussion by full board.
- The SLH-RERU Chair or any SLH-RERU Members may report queries and complaints that may need board discussion for appropriate action.

**4.2.5.15 Formally close the Full Board Meeting**

- The SLH-RERU Chair formally closes the full board meeting after determination that all the Meeting Agenda items have been discussed.





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### 4.3 Preparation of Meeting Minutes

#### 4.3.1 Purpose

To describe procedures for the preparation and approval of the minutes of the SLH-RERU full board meeting

#### 4.3.2 Scope

This SOP provides instructions related to the preparation of the SLH-RERU full board meeting minutes and its approval by the SLH-RERU members.

#### 4.3.3 Responsibility

It is the responsibility of the Secretariat, composed of the SLH-RERU Staff under the supervision of the Member-Secretary, to document the conduct of the full board meeting, including the issues discussed, the decisions and recommendations made in accordance with the items in the SLH-RERU meeting agenda.

#### 4.3.4 Process Flow/Steps

<b>N O.</b>	<b>ACTIVITY</b>	<b>PERSON/S RESPONSIBLE</b>	<b>TIMELINE</b>
1	Prepare template of Minutes of Meeting	SLH-RERU Staff/Secretariat	7 days
2	Preparation/Correction/Finalization of minutes of the meeting	SLH-RERU Staff/Secretariat	
3	Approve minutes of the meeting	SLH-RERU Members	
4	File minutes of the meeting	SLH-RERU Staff/Secretariat	

#### 4.3.5 Detailed Instructions

##### 4.3.5.1 Prepare template of Minutes of Meeting

- The SLH-RERU Staff/Secretariat fills up the basic information about each protocol submission for review of the SLH-RERU Meeting Minutes template (**Form 4.2**), with identifying information (Protocol number, title, PI, sponsor, etc.) before the meeting date.
- SLH-RERU Staff/Secretariat uses this prepared template to document the proceedings during the full board meeting.



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#### **4.3.5.2 Prepare minutes of the meeting**

- As the SLH-RERU meeting proceeds, the SLH-RERU Staff/Secretariat takes minutes of the meeting on real time according to the prescribed format and projects this on the multimedia screen to enable the SLH-RERU Members to closely follow the proceedings, and to facilitate the recapitulation of discussion points by the SLH-RERU Chair/Presiding Officer.
- The SLH-RERU decisions and recommendations are collective in nature. No attribution to specific SLH-RERU member is stated in the minutes.
- The meeting minutes should include the following items
  - Date and venue of the meeting
  - Member attendance
  - Attendance of Researchers/PI, Independent Consultant and guest or observer, if any
  - Presiding Officer
  - Time when the meeting was called to order
  - Status of quorum at the opening of the meeting, before the review of the protocol and before the decision making, as reflected on the Meeting Attendance (**Form 4.3**)
  - Members who declared COI and the protocol concerned
  - Discussion of items based on the order in meeting agenda
  - Summary of technical and ethical discussion points and recommendations
  - SLH-RERU decision and voting results according to decision categories, abstention and votes for disapproval with reasons given.
    - If the review decision (for initial and continuing reviews) is “approved”, the frequency of submission of progress report are determined.
    - If the review decision is disapproved, the reasons for the disapproval are stated.
    - If the review decision (for initial and continuing reviews) is “for modification”, the items to be revised are identified and the type of review for the resubmission is defined.
  - Attach the list of submission approved through expedited review for the information of SLH-RERU members.
  - Name and signature of the person who prepared the minutes
  - Name and signature of the SLH-RERU Member-Secretary to indicate the contents have been verified and corrected
  - Name and signature of the SLH-RERU Chair who approved the minutes with the date of approval
- The SLH-RERU Staff/Secretariat who prepared the draft of the Meeting Minutes submits it to the SLH-RERU Member-Secretary for correction within 3 days from



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the date of the meeting. The same is then submitted for final review and approval of the SLH-RERU Chair.

- The SLH-RERU Staff/Secretariat send thru a group e-mail, the copy of the provisional meeting minutes to the SLH-RERU Members for their review and comments within 7 days from the meeting date. The SLH-RERU Members are expected to e-mail their corrections to the group.
- The SLH-RERU Staff/Secretariat finalizes minutes of the meeting incorporating corrections from the SLH-RERU Members.
- The SLH-RERU Staff/Secretariat distributes the final version of the minutes of the meeting together with the Notice of Meeting for the next SLH-RERU meeting.

**4.3.5.3 Approve minutes of the meeting**

- During the next full board meeting, the SLH-RERU Chair asks the members to approve the Minutes.
- The SLH-RERU members may suggest further corrections.
- The SLH-RERU members approve the Minutes.
- The SLH-RERU Chair signs approval after the meeting.

**4.3.5.4 File minutes of the meeting**

- The SLH-RERU Staff/Secretariat files approved meeting minutes in the folder for Meeting Minutes.
- Excerpts of meeting minutes may be extracted and filed in specific protocol file folder, and the protocol file index is updated.



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**4.4 Communicating SLH-RERU Decision to the PI**

**4.4.1 Purpose**

To describe the procedure for communicating SLH-RERU decision to the PI.

**4.4.2 Scope**

This SOP provides instructions related to the preparation of SLH-RERU communication to the PI and the management of such documents.

**4.4.3 Responsibility**

It is the responsibility of the SLH-RERU Staff/Secretariat to prepare the Approval or Notification Letter to the PI to be signed by the SLH-RERU Chair.

**4.4.4 Process Flow/Steps**

NO	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Prepare Notification/ Approval Letter to PI	SLH-RERU Staff/ Secretariat, Chair	7 days
2	Send Notification/ Approval Letter to PI	SLH-RERU Staff/Secretariat	
3	File Notification/ Approval Letter to PI	SLH-RERU Staff/Secretariat	
4	Update protocol database	SLH-RERU Staff/Secretariat	

**4.4.5 Detailed Instructions**

**4.4.5.1 Prepare Notification/Certificate of Approval to PI**

- Based on the final version of the Meeting Minutes, the SLH-RERU Staff/Secretariat prepares the communication to the PI in duplicate copies using the standard SOP template.
- For the Notification Letter, the SLH-RERU Staff/Secretariat copies the list of recommendations from the meeting minutes to communicate them to the PI.
- The SLH-RERU Chair signs and dates the Notification/ Certificate of Approval.
- All Notification/ Certificate of Approvals should be ready within 7 calendar days after the meeting date for full board or 7 calendar days after receipt of expedited review results.



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**4.4.5.2 Send Notification/Certificate of Approval to PI**

- The SLH-RERU Staff/Secretariat informs the PI/Research Assistant that the original copy of the Notification or Certificate of Approval is ready for pick-up.
- The SLH-RERU Staff/Secretariat emails a scanned copy of the Notification/ Certificate of Approval to the PI.
- SLH-RERU Staff/Secretariat logs the Notification/ Approval in the Log of Outgoing Document when the original copies are released.

**4.4.5.3 File Notification/Approval Letter to PI**

- The SLH-RERU Staff/Secretariat files a duplicate copy of the Notification/ Approval Certificate in the protocol file folder and updates the Protocol File Index.

**4.4.5.4 Update protocol data base**

- The SLH-RERU Staff/Secretariat updates the protocol data base



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**4.5 Management of Active Study Files, Documents and Records**

**4.5.1 Purpose**

To describe the SLH-RERU procedures related to the management of active study files.

**4.5.2 Scope**

This SOP provides instructions related to the management of active study files that include protocol submissions, all documents that reflect all actions taken by the SLH-RERU before completion of the study. It also provides instructions for the maintenance and storage of other SLH-RERU documents that include SOPs, SLH-RERU membership files, agenda and meeting minutes, relevant international and national regulations and guidelines, etc.

**4.5.3 Responsibility**

It is the responsibility of SLH-RERU Staff/Secretariat to manage all protocol submissions and documents that reflect all SLH-RERU actions and organize them in an orderly manner. The SLH-RERU Staff/Secretariat also manages the maintenance and storage of all SLH-RERU documents and records.

**4.5.4 Process Flow/Steps**

NO	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	File protocol and other protocol related documents in an organized manner	SLH-RERU Staff/Secretariat	7 days
2	Update protocol file folder regularly as documents come or are produced	SLH-RERU Staff/Secretariat	
3	Store properly labeled protocol file folder in the appropriately labeled file storage cabinet	SLH-RERU Staff/Secretariat	
4	Create an electronic protocol database and update it regularly with PI submissions and SLH-RERU decisions/ actions	SLH-RERU Staff/Secretariat	
5	Keep other SLH-RERU files in storage cabinets	SLH-RERU Staff/Secretariat	



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#### **4.5.5 Detailed Instructions**

##### **4.5.5.1 File protocol and other protocol related documents in an organized manner**

- Protocol files are considered active from the moment the protocols are received for initial review until such time they are inactivated either by its completion or termination or its withdrawal from the review process. Active protocol files are either those undergoing SLH-RERU review process or SLH-RERU -approved ongoing studies. It is necessary to use a unique identifier or code to refer to protocol file for efficient file management and retrieval.
- Study Protocols are identified using a unique identification number known as Protocol Code No. given by the SLH-RERU as described in SOP 2.1 on Management of Initial Submission.
- The protocol file folder contains the following documents arranged chronologically in an organized manner according to the Protocol File Index per type of submission (e.g. initial submission, protocol amendment, progress report, SAE Reports, Protocol Violation/Deviation, etc.):
  - All versions of study protocol
  - Protocol related documents (ICF, CRF, recruitment materials, patient diary, IB, etc.)
  - Principal investigator and co-investigators' CVs and valid GCP Training Certificate, if required
  - Reviewers' assessment forms
  - Decision letters (notification letters or approval letter/s – initial and renewal)
  - Post-Approval submissions (protocol amendment, progress report, SAE report, protocol deviation/violation report, early termination report) and corresponding reviewers' assessment and SLH-RERU decision letters
  - Participant queries/complaints, if any
  - Site Visit Reports, if any
  - Miscellaneous communication related to the protocol
  - Final report
- File in a durable binder all protocol related documents in chronological sequence with the most recent file/document at the top, Update the Protocol File Index whenever a new document is filed.
- Stick a protocol file label (Protocol code no., title of the protocol, name of PI, sponsor on the front cover of the file binder.
- Stick a label with the Protocol No. on the side of the file binder.

##### **4.5.5.2 Update protocol file folder regularly as documents come or are produced**

- The SLH-RERU Staff/Secretariat logs every protocol-related document received. This log should contain at least the following items:
  - Date/Time received



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- Protocol Code No.
- Study Title
- Principal Investigator
- Initial of Person who received the document
- Type of Submission (e.g. Protocol for Initial Review, Resubmitted Protocol, Application for Protocol Amendment, Protocol Violation/Deviation Report, SAE Report, etc.)
- SLH-RERU Action Required.
- The SLH-RERU Staff/Secretariat also logs protocol and protocol-related documents when they are forwarded to SLH-RERU members for review. This log should contain the following items:
  - Date/Time Sent
  - Sending Person
  - Mode (e.g. e-mail, courier, etc.)
  - Receiving Person
  - Content of Document
  - Remarks
- Protocol-related paper files/documents are added to the protocol file folder on the day that they are submitted or accomplished (assessment forms, SLH-RERU decision letters).
- The binders are kept in locked cabinets.

**4.5.5.3 Store properly labeled protocol file folder in the appropriately labeled file storage cabinet**

- Place the protocol file binders in the shelf in vertical position and sequentially arranged according to their Protocol Code No.
- Label the storage cabinet with the year when the protocols were submitted.
- Keep all active study files in a secure filing cabinet, with access limited only to SLH-RERU Chair and Secretariat. The SLH-RERU Staff/Secretariat keeps the keys of file storage cabinets.
- Active files can be accessed outside of regular protocol review in accordance with the SOP 4.6 on Maintaining Confidentiality of Study Files and SLH-RERU Documents.

**4.5.5.4 Create an electronic protocol database and update it regularly with PI submissions and SLH-RERU decisions/ actions**

- Create an electronic database to contain a list of all protocols received by the SLH-RERU with sufficient columns to contain all protocol related information, PI submissions and action taken by the SLH-RERU from initial review to final report approval.
- The Study Protocol or related document is first entered into the SLH-RERU protocol database using its protocol code number, title, names of PI and sponsor, etc.
- Create a secure protocol database to facilitate protocol monitoring including due dates of reports and determining active protocol status. The database should use





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an electronic format and password protected. It should have at least the following fields:

- Protocol Code
  - Protocol title
  - Department
  - PI and details
  - Submission date
  - Full board or Expedited Review date
  - Primary Reviewers
  - Review decision
  - Full Committee review meeting date
  - Approval date and expiration date
  - Due date for progress report
  - Date of approval
  - Date of final report
- The SLH-RERU Staff/Secretariat should also maintain a back-up copy of the protocol database in an external drive that is updated every 1<sup>st</sup> day of the month, or the following day if the day falls on a non-working day.
  - 4.4.5.5 Keep other SLH-RERU files that include the SOPs, Membership Files, international and national guidelines and regulations, etc. in the office cabinets and regularly update them for reference of the SLH-RERU members.



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**4.6 Archiving of Inactive Study Files**

**4.6.1 Purpose**

To describe SLH-RERU procedures related to archiving of terminated, inactive and completed studies

**4.6.2 Scope**

This SOP provides instructions to the SLH-RERU Secretariat/Secretariat related to requirements for archiving completed study protocols after the final report or other relevant documents have been received.

**4.6.3 Responsibility**

It is the responsibility of SLH-RERU Staff/Secretariat, under the supervision of the SLH-RERU Member-Secretary, to archive in an orderly manner all protocol files that have been terminated, completed or are no longer active. They are kept together in a designated place in the hospital where confidentiality and security of the documents can be maintained.

**4.6.4 Process Flow/Steps**

<b>NO</b>	<b>ACTIVITY</b>	<b>PERSON/S RESPONSIBLE</b>	<b>TIMELINE</b>
1	Identify inactive protocol files	SLH-RERU Staff/Secretariat	7 days
2	Affix appropriate label to files for archiving & record in Database of Archived Documents	SLH-RERU/Staff Secretariat	
3	Transfer files to the archiving room	SLH-RERU Staff/Secretariat	
4	Update protocol database	SLH-RERU Staff/Secretariat	

**4.6.5 Detailed Instructions**

**4.6.5.1 Identify inactive protocol files**

- Studies are considered to be completed and inactive when the closure/final report of the study has been reviewed and approved by the SLH-RERU
- Studies are also classified as inactive when no further communication has been received by the SLH-RERU after two years.
- Studies that underwent early termination are subsequently categorized as inactive upon receipt of relevant information about termination.

- The SLH-RERU Staff/Secretariat removes the protocol file folders from the storage file cabinet for active studies, checks its contents and updates the protocol file index.
- SLH-RERU Staff /Secretariat shreds extra copies that are not needed.

**4.6.5.2 Affix appropriate label to files for archiving & record in Database of Archived Documents**

- The SLH-RERU Staff/Secretariat labels protocol file as inactive by attaching a red sticker and adding the year the study is declared inactive.
- The year of approval of the final report will be added to original submission code of the protocol file as its archiving code.
- The SLH-RERU Staff/Secretariat logs the protocol number and other protocol identifiers in the Database of Archived Documents.

**4.6.5.3 Transfer files to the archiving room**

- The SLH-RERU Staff/Secretariat transfers the protocol file to the designated secure archive room.
- As in active study files, protocol files in the secure storage cabinet for inactive studies are arranged sequentially. The storage cabinet is properly labeled with the year in the original protocol code.
- Protocols are archived for 3 years. Archived protocols can be accessed in accordance with the SOP 4.6 on Maintaining Confidentiality of Study Files and SLH-RERU Documents.
- After 3 years in the archive, the protocol files may be transferred to the hospital archive or shredded.

**4.6.5.4 Update protocol database**

- The archiving data should be entered accordingly in the protocol database.
- SLH-RERU Staff/Secretariat reviews entries in the protocol data base for the protocol for archiving, to check if all fields are completely filled.



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**4.7 Maintenance of Confidentiality of Study Files and SLH-RERU Documents**

**4.7.1 Purpose**

To describe SLH-RERU procedures related to maintaining the confidentiality of the study files and other SLH-RERU documents

**4.7.2 Scope**

This SOP provides instructions to the SLH-RERU Staff/Secretariat related to maintaining the confidentiality of all study files and documents.

**4.7.3 Responsibility**

It is the responsibility of the SLH-RERU Staff/Secretariat to ensure that confidentiality is maintained in the management of all study files and records and to follow the confidentiality procedures when requests to access the files are granted. The Data Privacy Act of 2012 also applies to SLH-RERU confidentiality procedures.

**4.7.4 Process Flow/Steps**

No	Activity	Person/s Responsible
1	Properly manage all active and inactive REC files	SLH-RERU Staff/Secretariat, Member-secretary
2	Receive request to access confidential files	SLH-RERU Staff/Secretariat
3	Approve and log in requests for access and retrieval of documents	SLH-RERU Staff/Secretariat
4	Supervise the use of retrieved confidential document	SLH-RERU Staff/Secretariat
5	Return document to the protocol file folder	SLH-RERU Staff/Secretariat

**4.7.5 Detailed Instructions**

**4.7.5.1 Properly manage all active and inactive SLH-RERU files.**

- Properly handle original documents and copies of these documents during the day-to-day operation of the SLH-RERU to protect the confidentiality of study files and related documents. Proper handling also involves proper control and care in the distribution and storage of confidential documents of the SLH-RERU.
- Study files submitted to the SLH-RERU and related documents are considered confidential, such as:
  - Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)



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- SLH-RERU documents (Meeting minutes, advice, and decisions)
- Correspondence (with experts, auditors, study participants, etc.)

**4.7.5.2 Receive request to access SLH-RERU confidential files**

- Access to SLH-RERU confidential documents is subject to the following limitations:
  - SLH-RERU members and staff with a signed *Confidentiality Agreement and Conflict of Interest Disclosure* (**Form 1.3**) can access confidential documents outside of regular protocol review access, upon request.
  - Non-members can access specific documents by submitting a formal request. The SLH-RERU Staff/Secretariat will require a *Confidentiality Agreement Form for Non-Members* (**Form 2.5**) to be signed by the person making the request, and approved by the SLH-RERU Chair or Vice-Chair or designated SLH-RERU Member in the absence of the SLH-RERU Chair.
  - Regulatory authorities can have full access to SLH-RERU documents provided it is within their mandate (e.g. FDA), and within a reasonable notice to make the files available, after due notification (in writing or email) to SLH-RERU.
  - The SLH-RERU Staff/Secretariat records all transactions whenever any document of the SLH-RERU is accessed as described above.

**4.7.5.3 Approve and log in requests for access and retrieval of documents**

- A separate log is kept in the protocol folder is to record access as described above. It contains the following information:
  - Study file code
  - Date borrowed
  - Name of borrower
  - Signature of borrower upon retrieval
  - Signature of SLH-RERU Staff/Secretariat upon return of document to the file folder
  - Document copied
  - Number of copies made
  - Number of copies received
- All requests for access are recorded by the SLH-RERU Staff/Secretariat in the log before copies of any documents are released.

**4.7.5.4 Supervise the use of retrieved confidential document**

- Access to SLH-RERU documents is generally for room use only, but requests to make copies can be accommodated on a case to case basis.
- The SLH-RERU Staff/Secretariat makes only the exact number of copies.