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CHAPTER 4

DOCUMENTATION AND MANAGEMENT OF FILES

4.A Preparation and Distribution of Meeting Agenda

4.B Preparation of Meeting Minutes

4.C Preparation of Communication Records


4.D Management of Active Study Files, Documents, and Records

4.E Archiving of Inactive Study Files, Documents, and Records

4.F Maintenance of Confidentiality of Study Files and RERC Documents

4.G Protocol Document Tracker and Protocol Index

Initiated by:  PURA R. CAISIP, MD/ PATRICIA KHU, MD	Reviewed by:  ZENAIDA M. JAVIER-UY, MD	Approved by:  ATTY PILAR YENUCA P. ALMIRA
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4.A Preparation and Distribution of Meeting Agenda

4.A.1 Purpose

To describe the procedures for preparation and distribution of RERC meeting agenda.

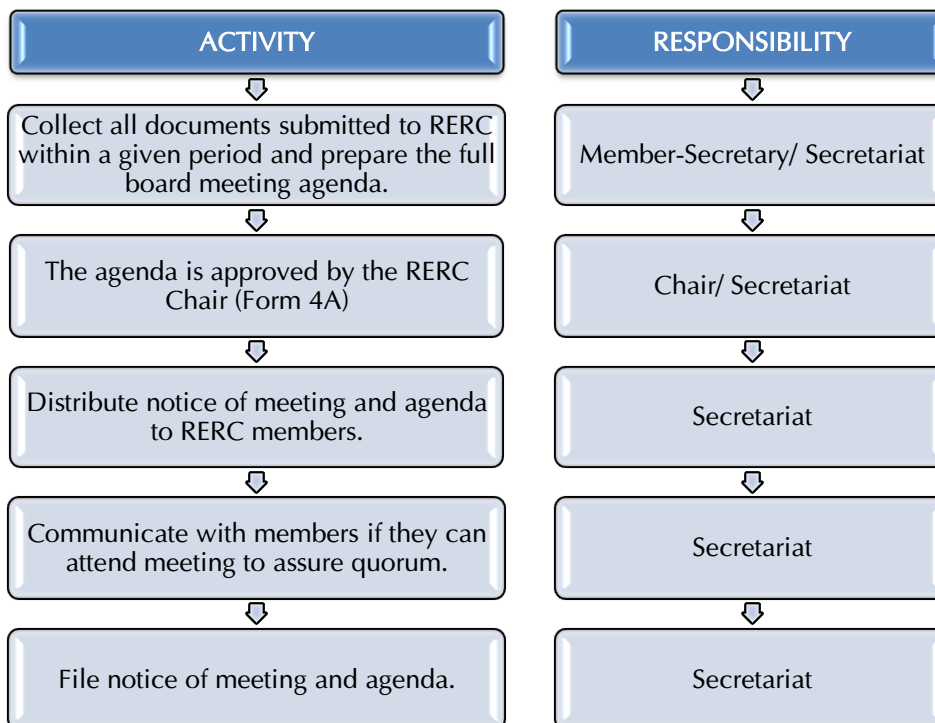
4.A.2 Scope

This SOP provides instructions related to the preparation of the RERC meeting agenda and its distribution to inform RERC members and other interested individuals about the items for discussion during a full-board meeting.


4.A.3 Responsibility

It is the responsibility of RERC Secretariat, under the supervision of the RERC Member-Secretary, to compile all documents/ information submitted to the RERC within a given period and include them in the next full-board meeting agenda (**Form 4A**) for discussion or information of the RERC members.

4.A.4 Process Flow/Steps



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Detailed Instructions

1. Collect all documents submitted to the RERC within a given period and put them on the full board meeting agenda for discussion or information of the RERC members.
2. Standard notice of meeting or agenda (**Form 4A**) contains the following:
 - Date of preparation
 - Date, time and venue of meeting
 - Agenda items
 - Protocol Review
 - Initial review
 - Resubmission review
 - Clarificatory interview
 - Approved protocols
 - Protocol amendments
 - Protocol violations/deviations
 - Progress reports/ continuing review
 - Serious adverse events
 - Site visit
 - Early protocol termination/withdrawal
 - Final reports
 - Participant queries/complaints
 - Other matters
 - Communications
 - Financial report
3. The Secretariat informs and consults the Chair regarding the agenda items (**Form 4A**). The Secretariat arranges the venue and other logistics for the meeting at least 3 days before the scheduled meeting and prior to the preparation of the notice of meeting.

The Secretariat sends a copy of the notice of meeting containing the approved agenda to the CSMC RERC members electronically, at least 3 days before the meeting.
4. Secretariat communicates with the RERC members to confirm their attendance and ensure quorum during the next board meeting.
5. Secretariat files a copy of the agenda in the Agenda and Minutes folder.

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4.B Preparation of Meeting Minutes

4.B.1 Purpose

To describe the procedures for preparation and approval of the minutes of the RERC full board meeting.

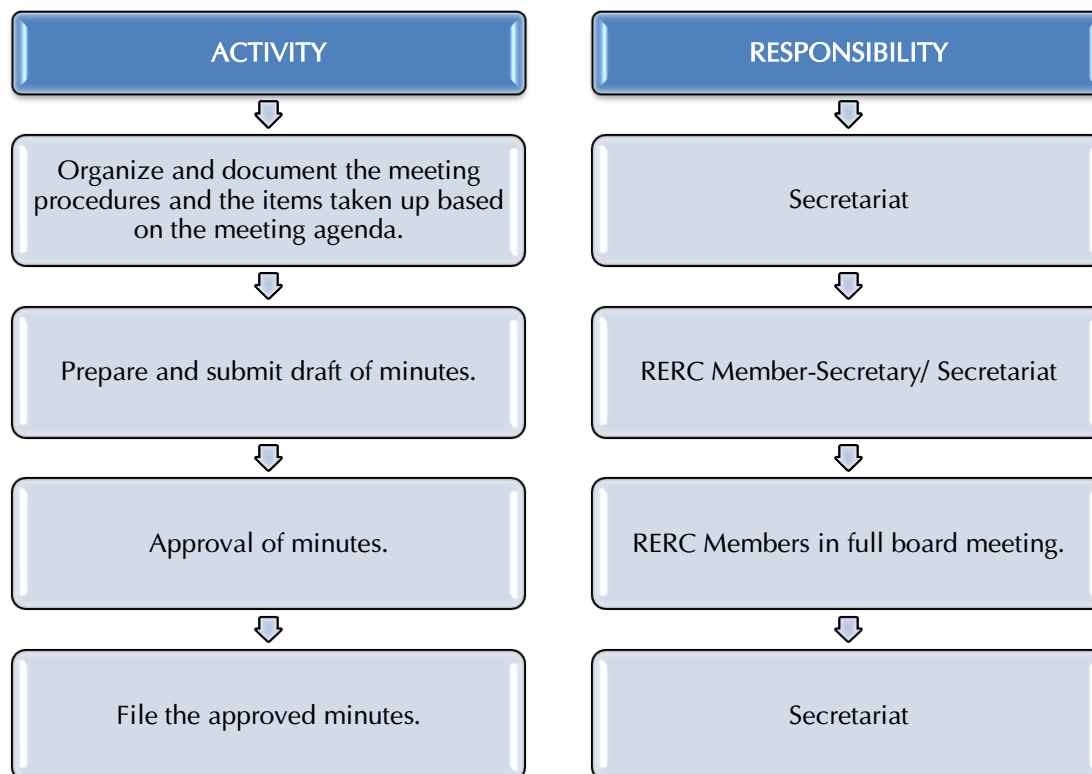
4.B.2 Scope




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


4.B.3 Responsibility

It is the responsibility of RERC Secretariat, under the supervision of the RERC 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 RERC meeting agenda.

4.B.4 Process Flow/Steps



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Detailed Instructions

1. Secretariat uses **Form 4B** as a template to organize the meeting discussion in preparation to writing the minutes.




The Secretariat documents the proceedings of the meeting as the meeting progresses by writing directly onto the template prepared.


Secretariat reviews the proceedings prepared during the meeting and verifies that it contains the following sections (**Form 4B**).

- Date and venue of meeting
- Member attendance (members present and absent) to determine quorum
- Guests and observer attendance
- Time when the meeting was called to order
- Presiding officer
- Conflict of interest declaration by RERC members
- Discussion of items based on the Meeting Agenda
- Decisions, summary of points and recommendations arrived at during the meeting
- Time when the meeting was adjourned
- Name and signature of person who prepared the Minutes
- Name and signature of the Chair with the date of approval

Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members, unless in the case of administrative or operational queries from members who require follow-up information or action.

2. The Secretariat submits draft of the minutes to the Member-Secretary within one (1) week after the meeting for corrections.
3. The Secretariat uses the information in the minutes to communicate the full-board decisions to the respective Principal Investigators.
4. The minutes are sent to the members 3days before scheduled board meeting for comments or correction. The minutes are formally approved during the full-board meeting.
5. The Secretariat files the signed minutes in the Minutes of the Meeting.

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4.C Preparation of Communication Records

4.C.1 Purpose

To describe the preparation of RERC communication records and the filing of such records.

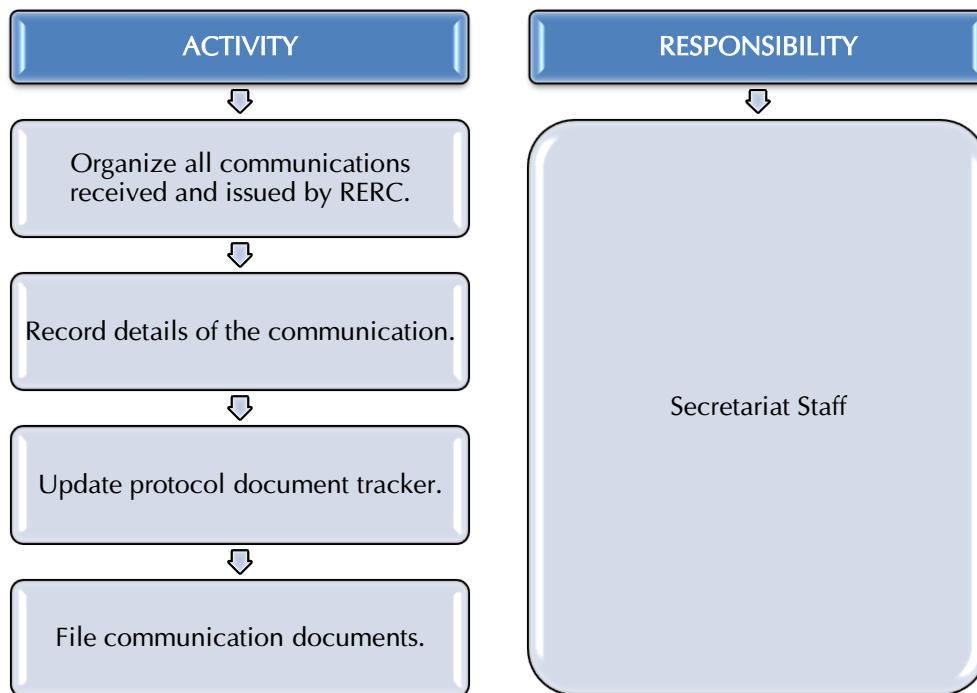
4.C.2 Scope





This SOP provides instructions related to the preparation of RERC communication to various parties and the management of such files.


4.C.3 Responsibility

It is the responsibility of RERC Secretariat, under the supervision of the Member-Secretary, to document all communication made by the RERC secretariat to different parties that deal with the RERC.

4.C.4 Process Flow/Steps



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Detailed Instructions

1. RERC communications refer to documented communications and can be in the form of hard copy letters or emails. It is encouraged that all RERC communications, received and issued, are in this form to facilitate documentation of all actions, instructions, and even responses to queries. The RERC Secretariat organizes a log of communications which also function as a log of submissions if the communication comes with a submission.




The RERC communication folder is organized into two (2) sections – outgoing and incoming communications, filed per year. All communication documents are permanent and must be kept confidential.


2. The log of submissions should have at least the following elements.
 - Date of communication/ submission
 - Name of RERC party contacted
 - Study information, i.e. sponsor, protocol number, principal investigator, etc.
 - Content of submission or resubmission
 - Notation of any follow up needed
 - Type of submission (if communication refers to a submission)
 - Contact information (address, telephone number, and email) of sending party
 - Name and signature of individual who received the communication and completed the record
3. Protocol document tracker is updated accordingly.
4. A copy of the communication/ submission is filed in the:
 - Protocol file folder
 - RERC communications folder
 - Others, as appropriate

4.D Management of Active Study Files, Documents, and Records

4.D.1 Purpose

To describe the RERC procedures related to the management of active study files, documents and records.

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4.D.2 Scope

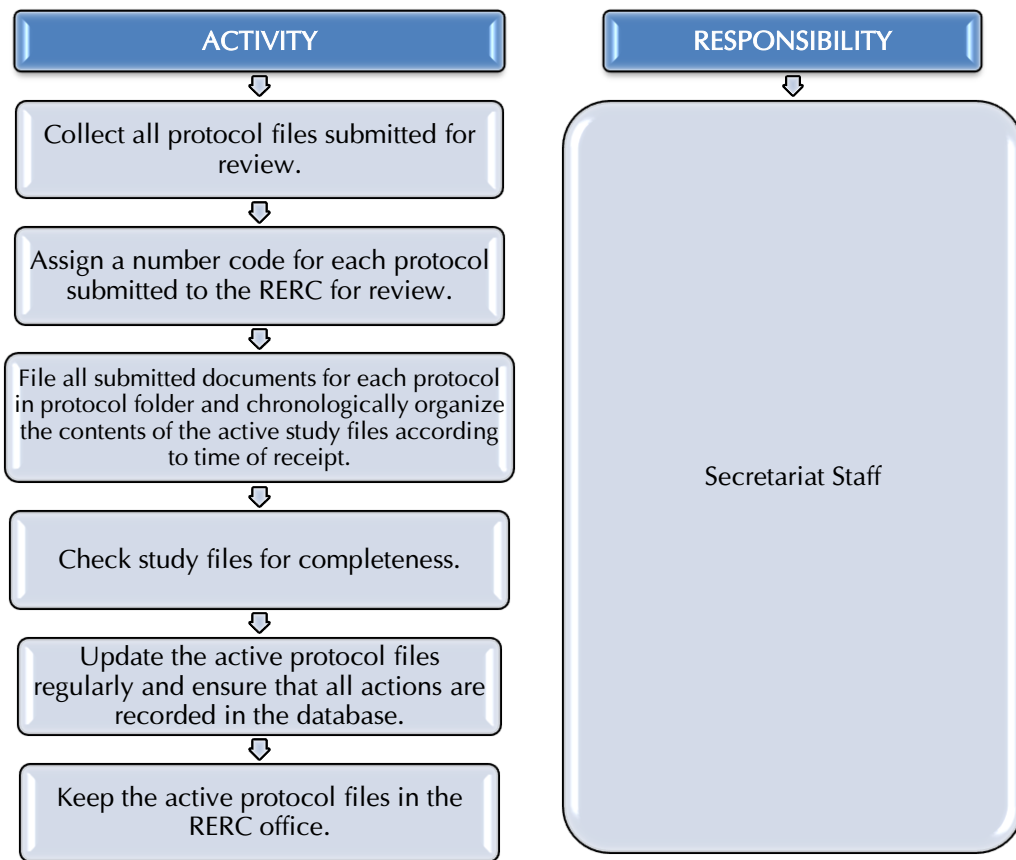
This SOP provides instructions related to the management of active study files originating from protocol submissions and includes all documents that reflect all actions taken by the RERC before completion of the study. It also provides instructions for the maintenance and storage of other RERC documents and records.





4.D.3 Responsibility


It is the responsibility of RERC Secretariat, under the supervision of the Secretary-Member, to manage all protocol submissions and all documents that reflect all RERC actions, and organize them into orderly files that are kept at the RERC office.

The Secretariat also manages the maintenance and storage of all relevant RERC documents and records.

4.D.4 Process Flow/Steps



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Detailed Instructions

1. Protocol files of CSMC RERC approved protocols are considered active from the moment the protocol files are received for review until such time they are inactivated (completed, withdrawn or terminated). Active files are either ongoing review or ongoing study.

2. Protocol Label Code Format




It is necessary to use a unique identifier or code to refer to this file for efficient file management. Labelling shall follow the standard format implemented by the hospital.


CSMC RERC LABEL CODE	EXAMPLE
Year submitted – Chronological number the protocol is received	CSMC RERC 2014 – 001

3. Protocol Folders

Documents are filed and divided into three (3) folders that contain the following documents in each folder.

FOLDER	CONTENTS
Folder 1 (Initial Protocol Evaluation)	A. Initial protocol submission package B. Investigator's Brochure C. Requirement checklist – RERC Forms 2A.1/ 2A.2 D. Application for Protocol Review – RERC Forms 2B.1/ B.2 E. Protocol Assessment – RERC Forms 2D.1/ 2D.2 F. Informed Consent Assessment – RERC Form 2E G. Minutes – RERC Form 4B H. Action letter – RERC Form 2G I. Resubmission – RERC Form 2C J. Certificates of Approval – RERC Form 2H.1/ 2H.2
Folder 2 (Post Approval)	A. Requirement checklist for protocol amendment - RERC Form 3A B. Amendments to the protocol and ICF C. Protocol Amendment Review – RERC Form 3B D. Approval letter for Protocol Amendment – RERC Form 3C E. Action/ Acknowledgement letters – RERC Form 3G F. Letters of communication to PI and Sponsors G. Protocol deviations – RERC Form 3D H. On site SAE's – RERC Form 3F I. Progress reports – RERC Form 3E J. Site visit reports – RERC Form 3H K. Early termination report – RERC Form 3G L. Final report – RERC Form 3I M. Queries and complaints – RERC Form 3K

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Folder 3 (Administrative Files)	A. Clinical Trial Agreement (CTA) and CTA amendments B. Clinical trial synopsis C. Statement of Account (SOA) and Official receipts – Review and Institutional Fee D. Off site SAE's and SUSARS
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4. Active Protocol File Management

Active files, records, and documents should be properly maintained and updated.

- Secretariat updates the study file folder and the database every week.
- Protocol index and document tracker is updated whenever a new document is added.
- Secretariat ensures completeness of filling out of forms before filing.

Keep all active study files in a secure file cabinet, with access limited only to authorized personnel who will be entrusted with the key.

Active files can be accessed outside of regular protocol review in accordance with the SOP on Maintaining Confidentiality of Study Files and RERC Documents.

Keys to locked cabinets are kept by assigned staff.

File folders are labelled using the code of the study file.

The retention period of files is mandated by the national regulations on clinical trials. The files are archived for five (5) years after completion of the research. After which, the files are disposed.




5. Protocol Database


Study file information is entered into the RERC database using its unique code.

Create a secure protocol database to facilitate protocol monitoring including due dates of reports and determining active protocol status.

The database is electronic (password protected) and should have at least the following fields.



- RERC Code
- CSMC RC Code – For physician-initiated researches
- Short description title
- Study design
- Clinical drug trial
- Protocol title
- Category of Investigator
- Principal Investigator


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- Department
- Mobile Numbers
- Email address
- Description of study
- Sponsor
- Email address of sponsor
- Mobile number of sponsor
- Contract research organization (CRO)
- Type of research
- Review type
- Purpose of study
- Type of funding agency
- Funding agency (if applicable)
- Total amount paid
- Lay members
- Time Line
 - Status
 - Entry date
 - Modified date
 - Last user
 - Date received
 - ERC approval date
 - Expected end date
 - Meeting discussed
 - Action letter to PI
 - Actual end date
- Archived
- Payment
- Amendment and submitted reports
- Primary reviewers

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4.E Archiving of Inactive Study Files, Documents and Records

4.E.1 Purpose

To describe the RERC procedures related to archiving of inactive study files, documents, and records.

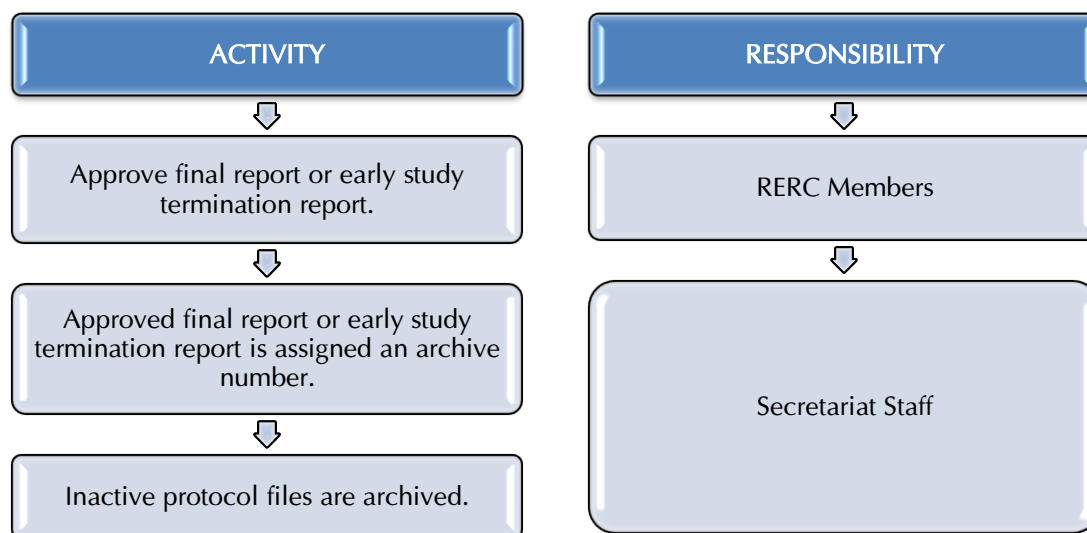
4.E.2 Scope




This SOP provides instructions to the Secretariat related to requirements for archiving completed documents after the final report or other relevant documents that have been received.


4.E.3 Responsibility

It is the responsibility of RERC Secretariat, under the supervision of the Member-Secretary, to archive in an orderly manner all protocol files that have been terminated, completed, withdrawn, or is 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.E.4 Process Flow/Steps



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Detailed Instructions

- Inactive study files are classified as follows:

INACTIVE			
CLASSIFICATION	DESCRIPTION	CRITERIA FOR QUALIFICATION	LABEL CODING
Unfinished review/ incomplete review	Protocols for review with no resubmissions for 3 years and remained dormant and inactive	3 years inactive from the last communication	Standard coding with YEAR at the end to indicate the year it was rendered inactive
Completed	Studies completed and finished and submitted a final report	Final report Form 3I	Standard coding with YEAR at the end to indicate the year it was rendered inactive
Terminated	Studies terminated by RERC	Form 3G	Standard coding with YEAR at the end to indicate the year it was rendered inactive
Withdrawn	Studies withdrawn by sponsor/principal investigator	Letter from the sponsor or principal investigator stating the reason for withdrawing study	Standard coding with YEAR at the end to indicate the year it was rendered inactive

- Protocol Label Code Format of inactive study files

An archive number is assigned to the protocol by adding the year the final report of a particular study protocol is approved by RERC. The year is suffix to the original protocol code. For example if the Final Report of Protocol is approved in 2012, the archiving code is CSMC RERC 2012-01/2014.

- Inactive Protocol File management


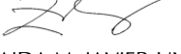

Upon approval of the Final Report or Early Study Termination or withdrawal, the protocol is reclassified as inactive study files and the Secretariat initiates archiving procedure.


Secretariat reviews the completeness of contents of the protocol file using the protocol index as a guide and transfers it from the active study filing area to the designated archive area.

The archiving data should be entered in the protocol database.

- Retention Period

Archived study files are retained for five (5) years after completion of the research or deemed inactive after which they are disposed of by shredding.

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5. Archived Protocol Retrieval

Archived protocols can be retrieved within the five-year archiving period in accordance with the SOP on Maintaining Confidentiality of Study Files and RERC Documents.

Documents retrieval is recorded accordingly.

4.F Maintenance of Confidentiality of Study Files and CSMC RERC Documents

4.F.1 Purpose

To describe CSMC RERC procedures related to maintaining the confidentiality of the study files and other RERC documents.

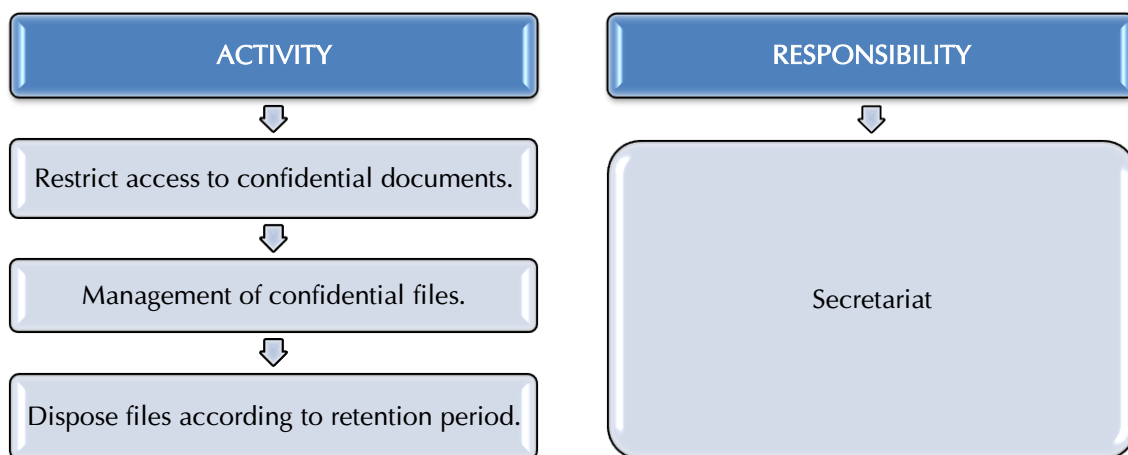
4.F.2 Scope

This SOP provides instructions to the Secretariat related to maintaining the confidentiality of all study files and documents.

4.F.3 Responsibility

It is the responsibility of CSMC RERC Secretariat, under the supervision of the Member-Secretary, to ensure that confidentiality is maintained in the management of all study files and records.




4.F.4 Process Flow/Steps




Detailed Instructions

- Study files submitted to the CSMC RERC 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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CSMC RERC documents (Meeting minutes, advice, and decisions) and correspondence (experts, auditors, study participants, etc.)

2. Access to CSMC RERC confidential documents is subject to the following limitations:
 - CSMC RERC members and staff with a signed Confidentiality Agreement and Conflict of Interest Disclosure (**Form 1D**) can access confidential documents outside of regular protocol review access, upon request.
 - Non-members can access specific documents by submitting a formal request. The Secretariat will provide a copy of the Confidentiality Agreement Form for Non-members requesting for Copies of Cardinal Santos Medical Center RERC Documents (**Form 4C**) to be accomplished by the person making the request, and signed by the Chair.
 - Regulatory authorities, as represented by the recognized officials of the regulatory authority, can have (e.g. FDA Director) full access to Cardinal Santos Medical Center RERC documents provided it is within their mandate (e.g. FDA), and upon reasonable notice to make the files available.

3. Management of Confidential Files

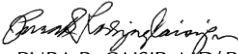


The secretariat carefully handles original documents and copies of RERC documents during the day-to-day operation of the RERC to protect the confidentiality of study files and related documents. Proper handling also involves proper control and care in the distribution and storage of confidential documents of the RERC.


Secretariat records the retrieval of RERC documents. Access to RERC documents is room use only.

4. Maintenance of RERC and Administrative Documents

The following are the RERC and administrative files and records, frequency of updating and retention period.

NAME OF RECORD	DESCRIPTION	FREQUENCY OF UPDATING	RETENTION PERIOD
Protocols	Protocol folder, document tracker, index	Update once a new document is added	Five (5) years
Database	Protocol data	Update once a new data is added	Permanent file
RERC Member profile folder	Curriculum vitae, Confidentiality Agreement, Appointment Letter, Training Record	Depends on years of contract	Depends on years of contract
RERC Staff profile folder	Curriculum Vitae, Confidentiality Agreement, Training	Depends on years of employment	Depends on years of employment

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	Record, Job Description		
Independent Consultant profile folder	Curriculum vitae, Confidentiality Agreement, Appointment Letter, Training Record	Depends on years of contract	Depends on years of contract
Communications (incoming and outgoing letters)	Approval letters, correspondence, queries	Updated immediately	Permanent file
Financial records	Review fee, honorarium, miscellaneous, receipts	Updated immediately	Permanent file
Standard operating procedures (SOP)	Policies and forms	When needed	Permanent file

5. Disposal of Obsolete Files

Guidelines on Shredding of Obsolete Documents

- Shredding is done every month. One (1) member of the RERC secretariat staff will be assigned to do the shredding.
- Shredding of documents is documented with the following information.
 - Document
 - Date
 - Person responsible
 - Approval of an authorized person
- Obsolete documents will be shredded every month, on completion of their retention period and after verification that these have been scanned and incorporated in the database. The following documents are considered obsolete documents.
 - Spare documents
 - Protocols (after 5 years retention period)
 - RERC Member's outdated CV
 - Any document with confidential information

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4.G Protocol Document Tracker and Protocol Index

4.G.1 Purpose

To describe the tracking procedures of the Cardinal Santos Medical Center RERC using the Document Tracker Forms (**Form 4D.1 and 4D.2**).

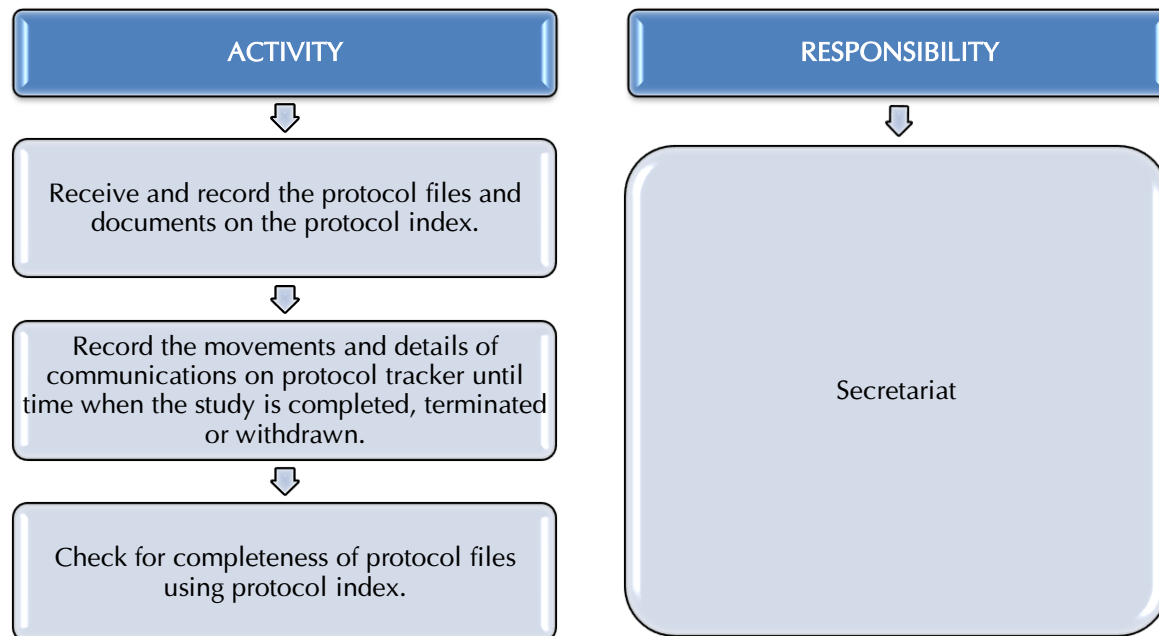
4.G.2 Scope

Index is used to check the completeness of the protocol files and is placed in front of the protocol folder. Document tracker is **used** to record all protocol submissions and communication details.

4.G.3 Responsibility

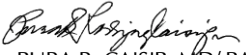


The secretariat records the activities or status of the protocols using the Document Tracker Forms (**Form 4D.1 and 4D.2**)

4.G.4 Process Flow/Steps



Detailed Instructions

1. Secretariat records all protocol files on the protocol index.
2. The Document Tracker Forms (**Form 4D.1 and 4D.2**) are used to record the activities or status of a protocol. Document Tracker Forms (**Form 4D.1 and 4D.2**) contain:
 - Title of the document

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- Name of Recipient and Date Received
 - Name of the person submitting/ forwarding the document and date. Name of the person who returns the documents and date.
3. Protocol index is updated regularly to ensure completeness of all protocol documents.

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