

	<b>Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB)</b>	<b>CGHMC RERB SOP Version No. 6</b>
	<b>Chapter 5</b>  <b>DOCUMENTATION and ARCHIVING</b>	<b>Date of Approval: 01 December 2019</b> <b>Effective Date: 01 Jan 2020</b>

- 5.1 Communicating RERB Decisions
- 5.2 Management of Active Study Files
- 5.3 Archiving of Terminated, Inactive, or Completed Studies
- 5.4 Maintenance of Confidentiality of Study Files and RERB Documents

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REVISION NO.	REVIEW DATE	AUTHORS	MAIN CHANGE
6	Sep 26, 2018	RERB Members	Coding system of the protocol identifiers indicated (CT, R, F)
6	Sep 26, 2018	RERB Members	Clarified that the specific personnel who will be entrusted with the lock and key – Chair and secretariat
6	Sep 26, 2018	RERB Members	Process for requesting to make copies of RERB documents were added; making copies of documents was added in the flowchart

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## 5.1. Preparation of Communication Records

### 5.1.1. Purpose

To describe the preparation of RERB communication records and the filing of such records

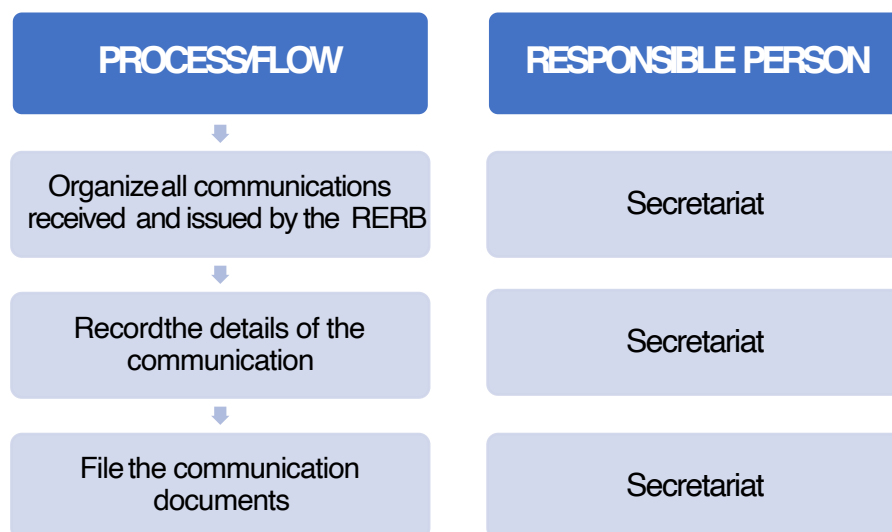
### 5.1.2. Scope

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

### 5.1.3. Responsibility

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

### 5.1.4. Process Flow/Steps



### 5.1.5. Detailed Instructions

5.1.5.1. Organize all communications received and issued by the RERB

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RERB communications refer to documented communications and can be in the form of hard copy letters or emails. It is encouraged that all RERB communications, received and issued, are in this form to facilitate documentation of all actions, instructions, and even responses to queries.

The RERB Secretariat organizes a log of communication which also functions as a log of submissions if the communication comes with a submission. This log should have at least the following elements:

- Date of communication/submission
- Name of RERB party contacted
- Study information, i.e., sponsor, protocol number, principal investigator, etc.
- Content of communication or submission
- Notation of any follow-up necessary
- Type of submission (if communication refers to a submission)
- Contact information (address, telephone number, and e-mail) of sending party
- Name and signature of individual who received the communication and completed the record

#### 5.1.5.2. Record the details of the communication

Store the communication records upon completion of the log of submission

- The Secretariat files a copy of the communication in the study file
- The Secretariat then writes in the protocol folder index as each communication is filed.

#### 5.1.5.3. File communication documents

A copy of the communication/submission is filed in the:

- Protocol file folder
- RERB Communications folder
- Others, as appropriate

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## 5.2. Management of Active Study Files, Documents, and Records

### 5.2.1. Purpose

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

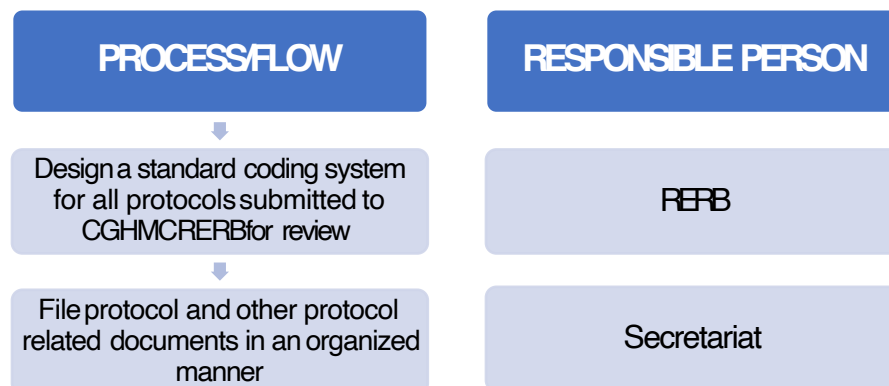
### 5.2.2. Scope

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 RERB before completion of the study. It also provides instructions for the maintenance and storage of other RERB documents and records.

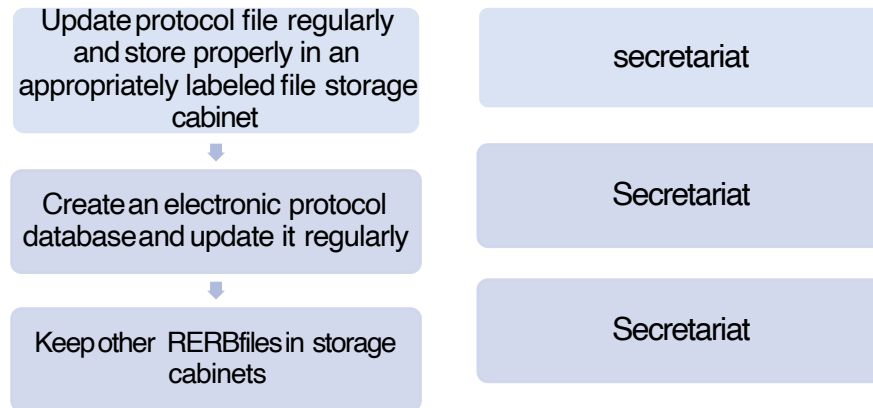
### 5.2.3. Responsibility

It is the responsibility of RERB Secretariat, under the supervision of the Secretary-Member, to manage all protocol submissions and all documents that reflect all RERB actions and organize them into orderly files that are kept at the RERB office. The Secretariat also manages the maintenance and storage of all relevant RERB documents and records.

### 5.4.4. Process Flow/ Steps



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### 5.2.5. Detailed Instructions

5.2.5.1. Protocol files of CGHMCRERB–approved protocols are considered active from the moment the protocol files are received for review until such time they are inactivated either by completion or termination. It is necessary to use a unique identifier or code to refer to this file for efficient file management.

Code active study files as follows:

CGHMC RERB									
	Year				-		-	Series No	

Classification: R - resident; F – fellows; CT- clinical trials/ sponsor-initiated protocol

For example, the code CGHMCRERB2018-F-03 shall mean “Third (03) protocol received in 2018 is a fellow submitted protocol”

5.2.5.2. File protocol and other protocol related documents in an organized manner

File protocol documents in sturdy file folders, using one folder per sturdy protocol title.

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

The folders are kept in secured well-identified locked cabinets.

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The study file folder contains the following documents and should have an index:

- All versions of study protocol
- Related documents that came with the study protocol
- Principal investigator and co-investigator's CVs and other similar documents
- Reviewers' assessment forms
- Amendment reports
- Continuing review applications
- Serious Adverse Event Reports or Safety Notifications
- Non-compliance (Deviation or Violation) reports
- Participant Queries
- Site Visit Reports
- Approval letters
- Notifications of RERB Decision
- Miscellaneous communication
- Final report

5.2.5.3. Update protocol file folders regularly and store properly in an appropriately labeled file storage cabinet

5.2.5.3.1 The active files, records, and documents should be properly maintained and updated

5.2.5.3.2. All active protocol file folders are maintained in the "Active Files" cabinet until the Final Report Form is approved by the CGHMC RERB. All active study files are kept in a secured file cabinet, with access limited only to the Secretariat and the Chair who will be entrusted to keep the lock and key.

5.2.5.3.3. Active files can be accessed outside of regular protocol review in accordance with the SOP on Maintaining Confidentiality of Study Files and RERB Documents. (Form 32)

5.2.5.4. Create an electronic protocol database and update it regularly with PI submissions and RERB decisions/actions

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

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protocol status. The database can be paper-based (logbook locked in the active files cabinet) or electronic (password protected) and should have at least the following fields:

- Protocol Code
- Protocol title
- Department
- PI and details
- Submission date
- Full board or Expedited Review date
- Reviewers
- Review decision
- Board meeting date
- Approval date
- Date for progress report

#### 5.2.5.5. Keep other RERB files in storage cabinets

5.2.5.5.1. The secretariat files other RERB documents that include the SOPs, membership files, international and national guidelines and regulations in the office cabinets and regularly update them for reference of the RERB members



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### 5.3. Archiving of Terminated, Inactive, or Completed Studies

#### 5.3.1. Purpose

To describe RERB procedures related to archiving of terminated, inactive and completed studies

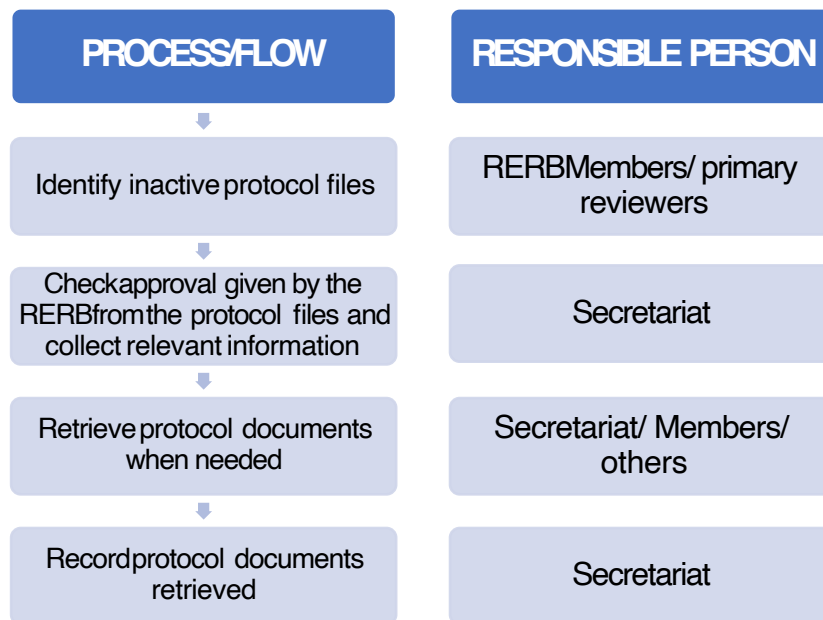
#### 5.3.2. Scope

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

#### 5.3.3. Responsibility

It is the responsibility of RERB Secretariat, under the supervision of the 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.

#### 5.3.4. Process Flow/Steps



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### 5.3.5. Detailed Instructions

#### 5.3.5.1. Identify inactive (Completed/ Inactive/ Terminated) protocol files

The following protocols shall be considered inactive:

- the closure/final report of the study has been reviewed and approved by the RERB.
- no further communication has been received by the RERB after two (2) years.
- If protocol related revisions are not received within twelve (12) months
- Protocols that underwent early termination are subsequently classified as inactive upon receipt of relevant information about termination.

The secretariat staff removes the protocol file folders from the storage file cabinet for active studies, checks its contents and updates the protocol file index.

The secretariat shall shred extra copies that are not needed

#### 5.3.5.2. Archiving Documents

Archived study files refer to protocols that are completed/inactive/terminated (or withdrawn). They are retained for at least three years (or more for some particular cases) after completion of the research so that the records are accessible for auditors and inspectors.

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

An archive number is assigned to the protocol by adding the (year of archiving) as a suffix to the original protocol code. For example, if the Final Report of Protocol (CGHMC)RERB2010-002 is approved in 2012, the archiving code is CGHMCRERB 2010-002/2012.

#### 5.3.5.3. The Secretariat reviews the contents of the protocol file and transfers it from the active study filing area to the designated archive room

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5.3.5.3.1. Secretariat staff transfers the protocol files to the designated secure archive room.

5.3.5.3.2. As in active study files, protocol files in the secure storage cabinet for inactive protocols are arranged sequentially. The storage cabinet is properly labeled with the year in the original protocol code.

5.3.5.3.3. Completed study files are archived for a minimum of three (3) years (National Guidance for Health Research, Philippine Health Research Ethics Board and WHO 2000)

5.3.5.3.4. Archived protocols can be borrowed upon written request by the PI or the CGHMCRERB personnel and only for office use. (See SOP on Maintenance of Confidentiality of Study Protocol Files and RERB Documents).

5.3.5.4. Update protocol database

5.3.5.4.1. The archived data should be entered accordingly in the protocol database.

5.3.5.4.2. The secretariat reviews entries in the protocol database for the protocol for archiving, to check if all fields are completely filled.

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#### 5.4. Maintenance of Confidentiality of Study Files and RERB Documents

##### 5.4.1. Purpose

To describe RERB procedures related to maintaining the confidentiality of the study files and other RERB documents

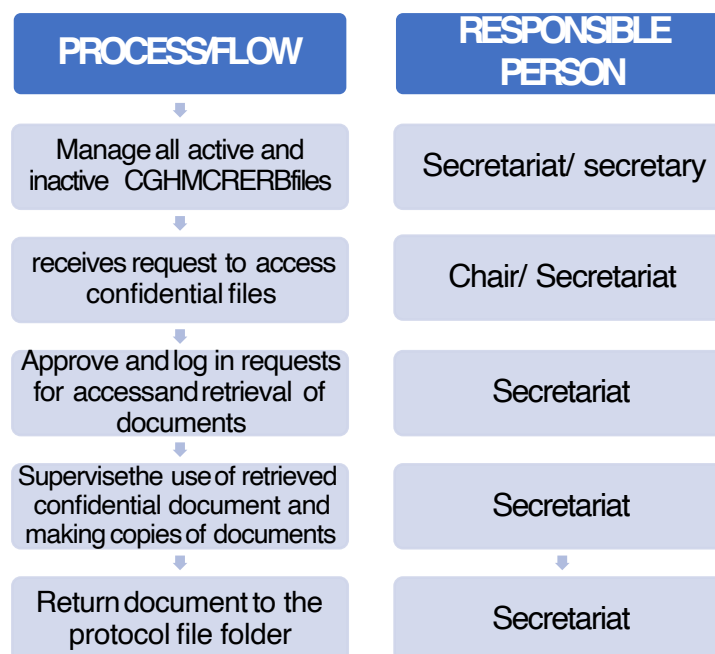
##### 5.4.2. Scope


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

##### 5.4.3. Responsibility

It is the responsibility of RERB Secretariat, under the supervision of the Secretary-Member, 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.

##### 5.4.4. Process Flow/ Steps



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#### 5.4.5. Detailed Instructions

##### 5.4.5.1. Manage all active and inactive CGHMCRERB files

Properly handle original documents and copies of these documents during the day-to-day operation of the RERB 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 ERB.

Study files submitted to the CGHMCRERB 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)
- RERB documents (Meeting minutes, advice, and decisions)
- Correspondence (experts, auditors, study participants, etc.)

##### 5.4.5.2. Receive request to access confidential files

Access to CGHMCRERB confidential documents is subject to the following limitations:

- CGHMC RERB members and staff with a signed CGHMC RERB Letter-Confidentiality Agreement and Conflict of Interest Disclosure can access confidential documents outside of regular protocol review, upon request
- Non-members can request access to specific documents by submitting a formal request (Form 25). The Secretariat will provide a copy of the *Confidentiality Agreement Form for Non-members requesting for Copies of CGHMCRERB Documents (Form 32)* to be accomplished by the person making the request, and signed by the Chair.
- Regulatory authorities have full access to CGHMCRERB documents provided it is within their mandate (e.g. FDA), and upon reasonable notice to make the files available signed by the recognized official of the regulatory authority (e.g. FDA Director).

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5.4.5.3. Approve and log-in requests for access and retrieval of documents.

A separate log is kept in the protocol folder to record access as described above. It contains the following information:

- CGHMCRERB Study Protocol Code
- Date borrowed
- Name of borrower
- Signature of borrower upon retrieval
- Signature of RERB secretariat upon return of document to the protocol file folder
- Document copied
- Number of copies made
- Number of copies received

5.4.5.4. Supervise the use of retrieved confidential document

5.4.5.4.1. Access to RERB documents is generally for room use only, but requests to make copies can be accommodated on a case to case basis.

5.4.5.4.2. The secretariat makes only the exact number of copies requested.

5.4.5.4.3. The recipient signs the RERB Log of Request for Copies of Documents upon receipt of the documents.

5.4.5.4.4. The secretariat shall ensure the diligent recording of all document copies issued in the Log of Request for Copies of Documents. This Log is filed in a separate folder labeled "Log of Copies Issued".

5.4.5.5. Return document to the protocol file folder

5.4.5.5.1. The RERB secretariat shall return the documents in the protocol file folder in the storage cabinet after making sure that all documents are complete as per protocol file index.