**V. Documentation and Management of Files and Archiving**

**5.1 Objective/Scope/Responsibilities**

**5.2 Preparation of the Minutes of the Meetings**

**5.3 Communicating the MMMC-RERC Decisions**

**5.4 Administrative Record**

**5.5 Management of Active Files**

**5.6 Archiving of Terminated, Inactive and Completed Study Files**

**5.7 Maintenance of Confidentiality of Study Files**

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| --- | --- |
| Supersedes | Standard Operating Procedure Version 4 |
| Version  | 5 |
| Authored By | Dr. Narcisa Sonia ComiaDr. Mary Warren IlagaDr. Von Andre Medina |
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| Approved By | **Dr. Robert Magsino**President |
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**5.1. OBJECTIVES/SCOPE/RESPONSIBILITIES**

**5.1.1 Objectives**

This SOP describes how the MMMC-RERC manages documentation and communication of review, such as:

1. how the minutes of the meetings are to be prepared, used, distributed, and filed;
2. how to ensure proper completion, distribution, and filing of written study protocol or review-process-related communication;
3. how administrative records and MMMC-RERC administrative documents (exclusive of study protocol files) are processed, stored, or disposed of;
4. how active and inactive or archived study protocol files are maintained, including their amendments and/or modifications; and,
5. how to handle original documents and copies of documents in order to protect confidentiality of documents.

**5.1.2. Scope**

This SOP applies to MMMC-RERC documentation and management of active files to archiving. Handling of all communication records related to study protocols with MMMC-RERC approval or undergoing MMMC-RERC review to administrative documents, active study protocol files, and inactive study protocol files- are described in this chapter. Archiving of all documents including communications, study files and administrative documents are discussed in this chapter so that the records are accessible for auditors and inspectors. This SOP applies to all kinds of handling, distribution, and storage of submitted study protocols, MMMC-RERC documents, and correspondences.

**5.1.3. Responsibilities**

The Administrative Staff, under the supervision of the RERC Member-Secretary, has the primary responsibility for filing study protocol documents and administrative documentation and archiving. The Chair is responsible for final approval of documents.

**5.2 PREPARATION OF THE MINUTES OF THE MEETING**

**5.2.1 Minutes of the Meeting Workflow**

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| **ACTIVITY** | **RESPONSIBILITY** |
| Prepares the template of the Minutes of the Meeting | Administrative Staff |
| Prepares draft of Minutes | Administrative Staff, Member-Secretary |
| Approve the Minutes | Members |
| Stores the approved Minutes | Administrative Staff |

**5.2.2 Detailed Instruction**

**5.2.2.1 Preparation of the Template of the Minutes of the Meeting**

**a.** The RERC Member-Secretary and Administrative Staff use the formatof the Minutes of the meeting, ***MMMC-RERC F-5-A: MINUTES OF THE MEETING*** to organize the template of the minutes ahead of the meeting date.

**b.** In case of a special review RERC meeting, the format of the minutes is adjustedto the actual content of the meeting.

**c.** All the relevant identifying information should be filled out such as standard text in the regular sections and relevant study protocol information.

**d.** The draft of the minutes of the meeting is generated as the meeting progresses. The Administrative Staff, who is in charge of documentation, notes all committee opinions and actions in all specific sections of the agenda, as the agenda is developed and discussed, with respective reasons in the case of study protocol-related actions.

**5.2.2.2 Preparation of the Draft of the Minutes**

**a.** 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.

**b.** The Administrative Staff in charge of documentation submits a complete draft of the minutes to the RERC Member-Secretary within **seven (7) days** after the meeting for form and content corrections and finalization. The finalized draft is sent to the RERC Chair immediately for approval.

**c**.The following information must be indicated in the minutes:

* Date and venue of meeting
* Members’ attendance (members present and absent)
* Guests and observers attendance
* Prayer
* Presiding officer
* Time when the meeting was called to order
* Determination of Quorum
* Disclosure of Conflict of Interest
* Reading and approval of the minutes of the last meeting
* Business arising from the minutes of the last meeting
* Approval of meeting agenda
* Items discussed per meeting Agenda
* Name and signature of person who prepared the minutes
* Date of completion
* Name and signature of the RERC Member-Secretary to indicate that the contents have been verified and corrected
* Name and signature of the RERC Chair to indicate approval
* Date of approval by the RERC Chair

 **5.2.2.3 Approval of the Minutes**

**a.** The RERC Chair approves the draft minutes by affixing his/her signature and the date the minutes was signed.

b. Upon approval of the minutes, the Administrative Staff transfer the content of the Conclusion and Recommendations section (per study protocol discussed into the forms as applicable)

* **MMMC-RERC F-5-B: APPROVAL LETTER**
* **MMMC-RERC F-5-C: ACTION LETTER TO STUDY PROTOCOL SUBMISSIONS/ RESUBMISSIONS/AMENDMENTS** *(as the case maybe)*
* **MMMC-RERC F-5-D: APPROVAL LETTER FOR STUDY PROTOCOL AMENDMENT**
* **MMMC-RERC F-5-E: ACTION LETTER FOR PROGRESS REPORT/ CONTINUING REVIEW APPLICATION/ FINAL REPORT/ DEVIATION/ AE/ SITE VISIT** *(as the case maybe)*
* **MMMC-REC-F-5-F: ARCHIVING NOTIFICATION**
* **MMMC-REC-F-5-G: CERTIFICATION OF MMMC-RERC APPROVAL**

**5.2.2.4. Storage and Distribution of the Minutes**

a. The Administrative Staff files the original copy of the minutes in the Minutes Folder.

b. The minutes approved by the RERC Chair is distributed to the members within fifteen (15) calendar days before the next meeting.

c. The approved minutes will be presented in the next full board meeting for approval.

**5.3 COMMUNICATING THE MMMC-RERC DECISIONS**

**5.3.1 Communicating the MMMC-RERC DECISIONS Workflow**

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| **ACTIVITY** | **RESPONSIBILITY** |
| Sorts all communications received and issued by the MMMC-RERC | Administrative Staff |
| Records the details of the communication | Administrative Staff |
| Stores communication files | Administrative Staff |

**5.3.2 Detailed Instruction**

**5.3.2.1 Sorting of all communications received and issued by the MMMC-RERC**

**a.** Communications can come in the form of letters, official memoranda, or emails.

**b.** The Administrative Staff sorts all communications received and prepares them for recording.

**c.** Unclaimed action letters will be filed in the respective protocol folders.

**5.3.2.2 Recording of the details of the communication**

**a.** Study protocol-related communications received by the MMMC-RERC are recorded in the ***MMMC-RERC F-5-H: SUBMISSIONS* LOG**. This form is updated as each submission is received. The record should contain, but is not limited to, the following:

* Date Received
* Study Code
* Principal Investigator
* Submitting Person
* Receiving Person
* Type of Submission
* Content of Submission
* Mode of Delivery
* Staff Action
* Further Action Required

**5.3.2.3 Storage of communication records**

**a.** Upon completion of the ***MMMC-RERC F-5-H: SUBMISSIONS LOG***the Administrative Staff files a copy of the communication in the study file.

**b.** For SAE Files, the Administrative Staff stores the signed serious adverse event/s report in the study protocol file folder.

**c.** The Administrative Staff then writes in the protocol folder submissions log as each communication is filed. ***[MMMC-RERC F-5-H: SUBMISSIONS LOG]***

**5.4 ADMINISTRATIVE RECORD**

**5.4.1 Administrative Record Workflow**

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| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Compiles administrative documents and/or records | Administrative Staff / Members/ Chair |
| Sorts and stores documents | Administrative Staff |
| Disposes unnecessary copies | Administrative Staff |

**5.4.2 Detailed Instruction**

**5.4.2.1 Compilation of Administrative Records**

**a.** The Administrative Staff maintains administrative documents not related to specific study protocols, but used in daily operations of the MMMC-RERC such as:

* Reference materials and guidelines
* Standard Operating Procedures
* Communications issued to and received from persons other than principal investigators, on matters that are not related to any study protocols, MMMC-RERC members and staff files (CVs, Appointment letters, Signed ***MMMC-RERC F-1-D: TRAINING RECORD, MMMC-RERC F-1-F (A, B & C): CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE***
* Logs of copies of documents requested by non-members ***MMMC-RERC F-5-J: BORROWERS LOG***
* These documents are maintained separately from study protocol-related documents.

**5.4.2.2 Sorting and storage of documents**

**a.** The Administrative Staff labels and files administrative documents sequentially.

**b.** Guidelines are filed numerically and alphabetically by subject.

**c.** SOP Manuals are filed chronologically.

**d.** Important communications are chronologically filed in the communications folder.

**e.** Members and staffs’ files are filed alphabetically by last name.

**f.** Only the most recently updated ***MMMC-RERC F-1-C: CURRICULUM VITAE*** are filed in the individual member’s folder.

**g.** Signed ***MMMC-RERC F-1-F (A, B & C): CONFIDENTIALITY AGREEMENT AND CONFLICT DISCLOSURE***and training certificates are filed chronologically under every member’s or staff’s file.

**h.** ***MMMC-RERC F-1-D: TRAINING RECORD*** must be updated as each training certificate is submitted by the member or staff for filing.

**i.** Active MMMC-RERC blank forms are kept in individually labeled folders or envelopes. The folders or envelopes are filed numerically with a list or index of forms written as:

1. Form number
2. Subject of form

**5.4.2.3. Disposal of unnecessary copies**

a. Guidelines and references that have been superseded or outdated for three **(3) years** are removed from the files and disposed properly.

b. Removed document files are shredded and permanently deleted from electronic and physical files.

**5.5 MANAGEMENT OF ACTIVE FILES**

**5.5.1 Management of Active Files Workflow**

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| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
|

|  |
| --- |
| Creates a coding system for active files |
|  |

 | Chair |
| Organizes the contents of the active study files | Administrative Staff |
| Maintains the active study files | Administrative Staff |

**5.5.2 Detailed Instruction**

**5.5.2.1 Creation of coding system for active study files**

**a.** Active files are study protocols that have been received by the MMMC-RERC Administrative Staff and are either undergoing review (full board or expedited) or approved by the RERC members.

**b.** Active study files are coded as **MMMC-RERC NNNN-DD-YYYY** where the **NNNN** represent sequential study protocol number as received by the MMMC-RERC Administrative Staff, **DD** represent month received and **YYYY** represent the year received by the Administrative Staff.

c.The assigned MMMC-RERC code should appear permanently on the study protocol folder.

**5.5.2.2 Organization of Contents of Active Study Files**

**a.** Study files are encoded into the Study Protocol Database, which contains the following information:

* MMMC-RERC Code
* Study Title
* Protocol Number
* Principal Investigator
* Sponsor
* Primary Reviewers
* Date Submitted
* Date Reviewed
* Date Approved
* Type of Review
* Study Protocol/ Informed Consent Amendment/s
* Progress Report
* SAEs/ SUSARs
* Continuing Review Application
* Final Report
* Reviewers’ Fee
* Institutional Fee
* Filing Status
* Status of the Study (reviewed but pending, approved & on-going, disapproved, terminated (give reason), withdrawn (give reason), completed, archived)
* Date of Inactivation
* Shredding Date

b. The elements included in the Study Protocol Database are linked to the following sub-databases, with respective contents:

3. Principal Investigators Database

1. Name
2. Sex
3. Birthday
4. Department
5. Telephone
6. Mobile
7. Facsimile
8. Email Address
9. Educational Attainment
10. Specialization
11. Sponsors
12. Declaration of Conflict of Interest of PI
13. GCP Training

4. Co-PI Database

1. Name
2. Sex
3. Birthday
4. Department
5. Telephone
6. Mobile
7. Facsimile
8. Email Address
9. Educational Attainment
10. Specialization
11. Sponsors
12. Declaration of Conflict of Interest of PI
13. GCP Training

5. Reviewers’ Database

1. Name
2. Home Address
3. Mailing Address
4. Contact Number
5. Birthday
6. Department
7. Area of Expertise
8. Classification
9. Date of Appointment
10. Ethics or GCP Trainings Attended

6. Meeting Database

1. Date of Meeting
2. Place
3. Time
4. Name of Meeting
5. Presided by
6. Attendees
7. Agenda
8. Minutes

7. Serious Adverse Events Database

1. MMMC-RERC Code
2. Patients’ No.
3. Date of Submission of AE
4. Date of AE
5. Type of Report
6. Reporter’s Name
7. Patient Initials
8. Country
9. Date of Birth
10. Age
11. Sex
12. Narrative of the AE
13. Suspected drug
14. Dose of drug
15. Route of administration of drug
16. Concomitant Drugs
17. Dose of Concomitant Drugs
18. Comorbidities
19. Foreseeability
20. Causality
21. Classification
22. Action
23. Outcome

c. The Administrative Staff puts study protocol files in file folders upon processing of the submission of the study protocol, ensuring that one folder contains documents for one study protocol and labeled with the title and code of the study protocol.

 9. Folders are then kept in secured cabinets labeled as “Active Files”.

 10. Cabinets labeled as “Active Files” should only contain study file folders classified as “active.”

 11. A study file folder contains the following documents, as applicable:

* 1. Index
	2. Submissions Log
	3. Review Checklist
	4. Registration and Application Form
	5. All Version of Study Protocol
	6. Study
	7. Informed Consent
	8. Investigator Brochure
	9. Other Related Documents
	10. Principal Investigator CV and co-Investigator
	11. Reviewer’s Assessment Form
	12. Approval Letters
	13. Serious Adverse Event Report
* Onsite
* Offsite
	1. Non-compliance or Deviation or Violation
	2. Participant Queries
	3. Site Visit Report
	4. Progress Report
	5. Continuing Review Applications
	6. Final Report
	7. DSMC/ DSMB/ IDMC Report
	8. Miscellaneous Communication
	9. Borrowers’ Log

**5.5.2.3 Maintenance of active study protocol files**

* + - * 1. The Administrative Staff files all the aforementioned documents in the study folder as they come.
				2. The Administrative Staff stamps the receiving date on all documents before putting them in the folders.
				3. All Active File folders are maintained in the “Active Files” cabinet until the ***MMMC-RERC F-3-C: FINAL REPORT FORM*** is approved by the MMMC-RERC.
				4. The Administrative Staff maintains MMMC-RERC Active Files cabinets under the supervision of the RERC Member-Secretary.

**5.6 ARCHIVING OF TERMINATED, INACTIVE AND COMPLETED FILES**

**5.6.1 Archiving of Terminated, Inactive, and Completed Files Workflow**

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| **ACTIVITY** | **RESPONSIBILITY** |
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| --- |
| Manages completed/inactive/terminated study files |

 | Administrative Staff |
| Sorts administrative documents to be archived | Administrative Staff |
| Establishes archived documents retrieval process | Administrative Staff |
|  |  |

**5.6.2 Detailed Instruction**

**5.6.2.1 Management of Archived (inactive/completed/terminated) study files**

 1. Archived (Inactive/Completed/Terminated) study files are either:

* 1. Study protocols with approved (by the MMMC-REC) final reports;
	2. Approved study protocols declared *Inactive* by the committee if no communication is received from study team for a period of twelve months;
	3. Study protocols for initial review with resubmissions beyond 90 days from date of action letter

d) Study protocols that were accepted for initial review, was assigned an MMMC-RERC code but withdrawn prior to initial review.

2. Upon receipt of ***MMMC-RERC F-4-C: FINAL REPORT FORM,*** the MMMC-RERC reviews it in accordance with ***SOP 3.4: REVIEW OF FINAL REPORTS****.*

**3.** Upon RERC approval of the ***MMMC-RERC F-3-C: FINAL REPORT FORM***, the Secretariat Staff removes the contents of the entire file from the active study filing area and verifies that all documents are present in an organized manner.

**4.** An archive number is assigned to the document by adding the year of archiving to the original code of the study file, **<MMMC-RERC NNNN-DD-YYYY-YYYY>**.

**5.** Correspondingly, the data about the study and the year when archived should be entered on the Study Protocol Database.

**5.6.2.2 Sorting of Archived Administrative Documents**

* + - * 1. The Administrative Staff should perform inventories of miscellaneous administrative documents yearly.
				2. Administrative documents that are related to any fund released by MMMC are required to be archived in a manner that allows easy retrieval for audit purposes. These include documents that specify appointment of personnel, issuance of honorarium, approved annual budget, financial reports, as well as financial/funding policies. One set of such documents are stored in the appropriate storage container/cabinet for archived administrative files.
				3. Unnecessary copies are disposed of accordingly

**5.6.2.3 Retrieval of Documents**

* + - * 1. Only authorized RERC Secretariat Staff can retrieve documents either from active study files or from the archived study files.
				2. Active or inactive study files can be borrowed, upon written request by the PI or the RERC personnel, and only for room use.
				3. ***A MMMC-RERC F-5-J: BORROWER’S LOG*** is placed in a pocket on the study file folder cover, and contains the following information:
1. Study file code
2. Date borrowed
3. Borrower’s Name
4. Signature of borrower
5. Type of Documents (New)
6. (Purpose New)
7. Received by (Signature of Secretariat Staff upon return of document to file box)
8. Date Returned ( with Signed and Dated)

**5.6.2.4 Disposal of Archived Documents**

* + - * 1. Archived documents are kept in ARCHIVED FILES Cabinet for at least **three (3) years**.
				2. At the end of **three (3) years,** archived documentscan be shredded.
				3. The date of shredding will be indicated in the logbook for shredded document and will also be encoded in the protocol database.

**5.7 MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES**

**5.7.1 Maintenance of Confidentiality of Study Files Workflow**

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| --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** |
| Classifies documents as confidential | MMMC-RERC |
| Request access to RERC documents | Members, non-members |
| Reproduces confidential documents | Administrative Staff |
| Maintains log of copies issued | Administrative Staff |

**5.7.2 Detailed Instruction**

**5.7.2.1 Classification of Documents as Confidential**

* + - * 1. Access to confidential documents is restricted by the MMMC-RERC to members and staff, but limited access can be provided to non-members who have a legitimate purpose to access the documents.
				2. The MMMC-RERC considers the following as confidential:
1. Study protocols
2. Study protocol-related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
3. Meeting Minutes
4. Decisions, action letters/notification of MMMC-RERC decision, approval letters
5. Study protocol-related communications
6. Database/Submission Logs

**5.7.2.2 Access to confidential MMMC-RERC documents**

1. All MMMC-RERC members and the staff with a signed ***MMMC-RERC F-1-F (A, B & C): CONFIDENTIALITY AGREEMENT AND CONFLICT DISCLOSURE*** can have access to MMMC-RERC confidential documents upon request
2. Non-members can access specific documents upon formal request and completion/signing of **MMMC-RERC F-3-B: CONFIDENTIALITY AGREEMENT FOR GUESTS/OBSERVERS,** the form requires the approval of the MMMC-RERC Chair. Regulatory authorities have full access to MMMC-RERC files provided it is within said authorities’ mandate, and upon reasonable notice to make the files available.
3. All requests for access are recorded by the Administrative Staff in the ***LOG OF REQUEST FOR COPIES OF DOCUMENTS*** before the documents are released.

**5.7.2.3 Reproduction of Confidential Documents**

1. The request to make copies of any confidential documents should have been made in advance and should be approved by the RERC Chair.
2. The Administrative Staff makes only the exact number of copies requested.
3. The recipient signs for the copies requested in the ***LOG OF REQUEST FOR COPIES OF DOCUMENTS*** upon receipt of the copies.

**5.7.2.4 Maintenance of log of copies**

1. The Administrative Staff ensures the diligent recording of all document copies issued in the ***LOG OF REQUEST FOR COPIES OF DOCUMENTS.***
2. This log is filed in a separate logbook labeled **Log of Request for Copies of Documents.**

**RELEVANT FORMS**

 **MMMC-RERC F-5-A: MINUTES OF THE MEETING**

 **MMMC-RERC F-5-B: APPROVAL LETTER**

**MMMC-RERC F-5-C: ACTION LETTER TO STUDY PROTOCOL SUBMISSIONS/RESUBMISSIONS/ AMENDMENTS**

**MMMC-RERC-F-5-D: APPROVAL LETTER FOR STUDY PROTOCOL**

**AMENDMENT**

**MMMC-RERC-F-5-E: ACTION LETTER FOR PROGRESS REPORT/ CONTINUING REVIEW APPLICATION/ FINAL REPORT/ DEVIATION/ AE/ SITE VISIT**

**MMMC-RERC-F-5-E (b): NOTIFICATION LETTER (No further Action) FOR PROGRESS REPORT/ CONTINUING REVIEW APPLICATION/**

 **FINAL REPORT/ DEVIATION/ SAE OR SUSAR REPORT/ SITE VISIT REPORT**

**MMMC-RERC-F-5-F: ARCHIVING NOTIFICATION**

**MMMC-RERC-F-5-G: CERTIFICATION OF MMMC-RERC COMMITTEE**

**APPROVAL**

 **MMMC-RERC F-5-H: SUBMISSIONS LOG**.

**MMMC-RERC F-5-I: BORROWER’S LOG**