Chapter IV : Documentation and Archiving	Document Code: **IRB-SOP-1120-DAA-004-06**	
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Approved by:	**D. DARWIN A. DASIG, M.D., Chair, MMC IRB**
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***Review: This Standard Operating Procedure is reviewed every three (3) years or earlier as indicated.**

4.1 Preparation and Distribution of Meeting Agenda

4.1.1 Purpose

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

4.1.2 Scope

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

4.1.3 Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Secretary-Member, to compile all documents/ information submitted to the IRB within a given period to include them in the next full board meeting agenda **(Form 4.1)** for discussion or information of the IRB members.

4.1.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Collect all documents submitted to the IRB within a given period to prepare the full board meeting agenda ⬇	Secretariat/Member -Secretary
2	Have agenda approved by the Chair **(Form 4.1)** ⬇	Secretariat, Chair
3	Distribute notice of meeting and agenda to IRB members and interested parties ⬇	Secretariat
4	Communicate with the members to check if they can attend the meeting to ensure quorum ⬇	Secretariat
5	File the notice of meeting and agenda	Secretariat

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Detailed Instructions

4.1.4.1 Collect all documents submitted to the IRB within a given period and put them in the full board meeting agenda for discussion or information of the IRB members.

4.1.4.2 The Member-secretary reviews the prepared agenda while the Chair approves the notice of meeting or agenda.

Standard notice of meeting or agenda **(Form 4.1)** contains the following:

A. Date of preparation
B. Date, time and venue of meeting
C. Agenda items
    1) Protocol Review
        a. Initial review
        b. Resubmission review
    2) Approved protocols
    3) Post approval monitoring
        a. Amended protocols
        b. Safety reports
        c. Protocol deviations
        d. Site visit reports
        e. Progress reports
        f. Final reports
        g. Early study termination
        h. Queries or complaints
    4) Other matters
        a. Communications
        b. Financial report

4.1.4.3 Recommendations on protocols requiring clarifications from the Principal Investigator during an IRB full board meeting are made by Makati Medical Center IRB primary reviewers, who request the Secretariat to inform the investigators about the meeting schedule. The time slot for their appearance at the IRB meeting is communicated to them. The Secretariat informs and consults the Chair about the agenda items **(Form 4.1)**. The Secretariat arranges the venue and other logistics for the meeting at least one (1) week before the scheduled meeting prior to preparation of the notice of meeting.

The Secretariat makes copies of the notice of meeting containing the approved agenda to the Makati Medical Center-IRB members, at least one (1) week before the meeting.

4.1.4.4 Secretariat communicates with the IRB members to confirm their attendance and ensure quorum during the next board meeting.

4.1.4.5 Secretariat files a copy of the agenda in the Agenda and Minutes folder. Agenda document is a permanent file.

4.2 Preparation of Meeting Minutes

4.2.1 Purpose

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

4.2.2 Scope

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

4.2.3 Responsibility

It is the responsibility of IRB Secretariat, 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 IRB meeting agenda.

4.2.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Organize and document the meeting procedures and the items taken up based on the meeting agenda **(Form 4.1)** ↓	Secretariat
2	Prepare draft of Minutes **(Form 4.2)** ↓	Secretariat, Member-Secretary
3	Approve the Minutes ↓	Member-Secretary, Chair
4	File the approved Minutes	Secretariat

Detailed Instructions

4.2.4.1 Secretariat uses **Form 4.1** as a template to organize the meeting discussion in preparation to writing the minutes ahead of the meeting date.
The Secretariat documents the proceedings of the meeting as the meeting progresses by writing directly into the template prepared.

Secretariat reviews the proceedings prepared during the meeting and verifies that it contains the following sections **(Form 4.2)**:

A. Date and venue of meeting
B. Member attendance (members present and absent) to determine quorum
C. Guests and observer attendance
D. Time when the meeting was called to order
E. Presiding officer
F. Conflict of interest declaration by IRB members
G. Discussion of items based on the Meeting Agenda
H. Decisions, summary of points and recommendations arrived at during the meeting
I. Name and signature of person who prepared the Minutes
J. Name and signature of the Chair with the date of approval
K. Time when the meeting was adjourned

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.

4.2.4.2 The Secretariat submits a complete draft of the minutes to the Member-Secretary within one (1) week after the meeting for corrections, and submits the corrected draft to the Chair for approval.

4.2.4.3 The Member-Secretary and Chair approve the minutes of the meeting (**Form 4.2)**

The Secretariat uses the information in the minutes to communicate full board IRB decisions to the respective Principal Investigators.

The minutes of the IRB full board meeting, once they are finalized, are sent to the members for comments or correction. The minutes are formally approved during the next full board meeting. The minutes for the Subcommittee PAnels for investigator-initiated REsearch ProtocolS (SPARES) meeting are not required to be approved by the full board.

4.2.4.4 The Secretariat files the signed minutes in the Minutes of the Meeting folder of the IRB. Minutes of the meeting are a permanent file.

4.3 Preparation of Communication Records

4.3.1 Purpose

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

4.3.2 Scope

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

4.3.3 Responsibility

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

4.3.4 Process Flow/Steps

No.	Activity	Responsibility
1	Organize all communications received and issued by the IRB	Secretariat
2	Record the details of the communication	Secretariat
3	Update protocol document tracker	Secretariat
4	File communication documents	Secretariat

Detailed Instructions

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

IRB 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.

4.3.4.2 Log of protocol submissions should have at least the following elements:

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

4.3.4.3 Protocol document tracker **(Form 4.4A and 4.4B)** is updated accordingly.

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

A. Protocol file folder
B. IRB Communications folder
C. Others, as appropriate

4.4 Management of Active Study Files, Documents and Records

4.4.1 Purpose

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

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

4.4.3 Responsibility

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

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

4.4.4 Process Flow/Steps

No.	Activity	Responsibility
1	Collect all protocol files submitted for review ⬇	Secretariat
2	Design a standard coding system for all protocols submitted to the IRB for review ⬇	MMC IRB
3	File all submitted documents in a protocol folder and chronologically organize the contents of the active study files according to time of receipt ⬇	Secretariat
4	Check study file folder for completeness ⬇	Secretariat
5	Update the active protocol files regularly and keep the files in the office ⬇	Secretariat
6	Ensure that all actions are recorded in the database	Secretariat

Detailed Instructions

4.4.4.1 Makati Medical Center IRB-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.

Protocol Classification

Active				
Classification	**Description**	**Criteria for qualification**	**Label color code**	**Label coding**
Ongoing review	Protocols submitted for review and approval by IRB	Application form (Form 2.1)	yellow	Standard coding
Ongoing study	Protocols that have been approved by IRB	Approval letter (Form 2.10)	green	Standard coding

4.4.4.2 Protocol Label Code Format

A. 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: MMCIRB (year)-number (chronological number based on order of receipt). For example, if Protocol entitled "First Clinical Drug Trial on Pediatric Patients" is the first protocol received in 2012, the code MMCIRB 2012-001 is the code that should be used to identify this protocol.
B. Coding of protocol numbering YYYY – XXX
   1) YYYY – year the protocol was submitted
   2) XXX – chronological number for the year

4.4.4.3 Protocol Folders

A. Protocol documents are filed in sturdy file folders, using one (1) folder per study protocol title.
B. The folders are kept in secured well-identified locked cabinets.
   - Keys to locked cabinets are kept by assigned staff.
C. File folders are labeled using the code of the study file.

4.4.4.4 Protocol Folder Contents

Study file folder contains the following documents and should have protocol index:

A. All versions of study protocol
B. Related documents that came with the study protocol
C. Principal investigator and co-investigators' CVs and other similar documents
D. Reviewers' assessment forms
E. Amendment reports
F. Continuing review applications
G. Serious Adverse Event Reports or Safety Notifications
H. Non-compliance (Deviation or Violation) reports
I. Participant Queries
J. Site Visit Reports
K. Approval letters
L. Notifications of IRB Decision
M. Miscellaneous communication
N. Final report

4.4.4.5 Active Protocol File Management

A. Active files, records and documents should be properly maintained and updated.
    1) Secretariat updates the study file folder and the database every week.
    2) Protocol index and document tracker is updated whenever a new document is added.
    3) Secretariat ensures completeness of filling out of forms before filing.
B. Keep all active study files in a secure file cabinet, with access limited only to (personnel allowed) who will be entrusted to keep the lock and key.
C. Actives files can be accessed outside of regular protocol review in accordance with the SOP on Maintaining Confidentiality of Study Files and IRB Documents.
D. The retention period of files is mandated by the national ethical guidelines on clinical trials. The files are retained for three (3) years after completion of the research. After which, the files are disposed.

4.4.4.6 Protocol Database

A. Study file information is entered into the IRB database using its unique code.
B. Create a secure protocol database to facilitate protocol monitoring including due dates of reports and determining active protocol status.
C. 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:
    1) Date Submitted
    2) IRB Code
    3) URL Address
    4) Nickname
    5) Protocol No.
    6) Title
    7) Principal Investigator(s)
    8) Sponsor
    9) Sites
    10) Type of Research
    11) Reviewers
    12) Type of Review
    13) Department
    14) Review decision
    15) Date of Review
    16) Date of Submission of Revised Protocol
    17) Approval/ Disapproval Date
    18) Submission of Amendments
    19) Date of Review of Amended Protocol
    20) Approval/ Disapproval Date of Amended Protocol
    21) Status
    22) Submission Date of Updated Annual Report
    23) No. of Patients Enrolled/ No. of Patients Required (Single Site)
    24) No. of Patients Enrolled/ No. of Total Population Required for all Sites (Multi-center)
    25) SAE Reported
    26) SUSARs Reported
    27) No. of Drop-outs
    28) No. of Patients who completed the Trial
    29) Date of Closure/ Termination of the Study

30) Reason for Closure/ Termination of Study
31) Date of Submission of Final Report
32) Others

4.5 Archiving of Inactive Study Files, Documents and Records

4.5.1 Purpose

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

4.5.2 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.

4.5.3 Responsibility

It is the responsibility of IRB 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.

4.5.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Classify which protocols are for archiving. ⬇	Secretariat
2	Design a standard coding system for inactive protocols. ⬇	MMC IRB
3	Approve final report or early study termination report. ⬇	Reviewers/ Members
4	Archive studies for three (3) years after submission of final report and update protocol database regularly. ⬇	Secretariat
5	Retrieve protocol documents when needed and record protocol documents retrieval	Secretariat

Detailed Instructions

4.5.4.1 Inactive study files are classified as follows:

Inactive				
Classification	**Description**	**Criteria for qualification**	**Label color code**	**Label coding**
Unfinished review/incomplete review	Protocols for review with no resubmissions for 6 months and remained dormant and inactive	6 months inactive from the last communication form	Orange	Standard coding with YEAR at the end to indicate the year it was rendered inactive
Completed	Studies that were completed and finished and submitted a final report	Final report form 3.4	Pink	Standard coding with YEAR at the end to indicate the year it was rendered inactive
Terminated	Studies that were terminated by IRB	Form 3.8	Red	Standard coding with YEAR at the end to indicate the year it was rendered inactive
Withdrawn	Studies were withdrawn by sponsor/principal investigator	Letter from the sponsor or principal investigator stating the reason for withdrawing study	Blue	Standard coding with YEAR at the end to indicate the year it was rendered inactive

4.5.4.2 Protocol Label Code Format

A. Protocol folders are re-coded indicating the year YYYY – XXX / ZZZZ
   1) YYYY – year the protocol was submitted
   2) XXX – chronological number for the year
   3) ZZZZ – year the protocol was completed, withdrawn or terminated
B. An archive number is assigned to the protocol by adding the / (year the final report is approved) as a suffix to the original protocol code. For example if the Final Report of Protocol MMC IRB 2010-002 is approved in 2012, the archiving code is MMC IRB 2010-002/2012.

4.5.4.3 Inactive Protocol File management

A. Inactive files are identified every last month of the year or earlier for completed or terminated protocols.
B. 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.
C. Secretariat reviews the completeness of contents of the protocol file using the protocol index and transfers it from the active study filing area to the designated archive area.
D. The archiving data should be entered accordingly in the protocol database.

4.5.4.4 Retention Period

Archived study files are retained for at least three (3) years (or more for some particular cases) after completion of the research or deemed inactive.

4.5.4.5 Archived Protocol Retrieval

A. Archived protocols can be retrieved within the five-year archiving period in accordance with the SOP on Maintaining Confidentiality of Study Files and IRB Documents.
B. Documents retrieval is recorded accordingly.

4.6 Maintenance of Confidentiality of Study Files and MMC IRB Documents

4.6.1 Purpose

To describe Makati Medical Center Institutional Review Board (MMC IRB) procedures related to maintaining the confidentiality of the study files and other MMC IRB documents.

4.6.2 Scope

This Standard Operating Procedure (SOP) provides instructions to the Secretariat related to maintaining the confidentiality of all study files and documents.

4.6.3 Responsibility

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

4.6.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Classify which IRB documents are confidential ⬇	Members/ Secretariat
2	Restrict access to confidential documents ⬇	Secretariat
3	Record copies made of confidential documents ⬇	Secretariat
4	File log of copies ⬇	Secretariat
5	Dispose files according to retention period	Secretariat

Detailed Instructions

4.6.4.1 Study files submitted to the MMC IRB and related documents are considered confidential, such as:

A. Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)

B. MMC IRB documents (Meeting minutes, advice, and decisions)
C. Correspondence (experts, auditors, study participants, etc.)

4.6.4.2 Access to MMC IRB confidential documents is subject to the following limitations:

A. MMC IRB 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.
B. 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 Makati Medical Center IRB Documents* **(Form 4.3)** to be accomplished by the person making the request, and signed by the Chair.
C. Regulatory authorities have full access to Makati Medical Center IRB 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).

4.6.4.3 Management of Confidential Files

A. Properly handle original documents and copies of IRB documents during the day-to-day operation of the IRB 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 IRB.
B. Secretariat records the retrieval of Makati Medical Center IRB documents. Access to Makati Medical Center IRB documents is generally room use only, but requests to make copies can be accommodated on a case to case basis.
C. All requests for access are recorded by the Secretariat Staff in the log before copies of any documents are released.
D. Secretariat makes only the exact number of copies requested.
E. Recipient signs for the copies requested in the Makati Medical Center IRB upon receipt of the copies.

F. Access to Makati Medical Center IRB documents is generally room use only, but requests to make copies can be accommodated on a case to case basis.

4.6.4.4 Secretariat makes a record every time a document of the Makati Medical Center IRB is accessed as described above **(Form 4.3).**

- A log filed in the protocol folder is dedicated for purposes of recording access as described above, which contains the following fields of information:
  A. Study file code
  B. Date borrowed
  C. Name of borrower
  D. Signature of borrower upon retrieval
  E. Signature of Makati Medical Center IRB Secretariat upon return of document to file box
  F. Document copied
  G. Number of copies made
  H. Number of copies received

4.6.4.5 Maintenance of IRB and Administrative Documents

4.6.4.5.1 The following are the IRB 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	Three (3) years
Database	Protocol data	Update once new data is added	Permanent file
IRB member profile folder	Curriculum vitae, confidentiality of agreement, appointment letter, training record	Depends on years of contract	Depends on years of contract
IRB staff profile folder	Curriculum vitae, confidentiality of agreement, training record, job description	Depends on years of employment	Depends on years of employment
Independent consultant profile folder	Curriculum vitae, confidentiality of	Depends on years of contract	Depends on years of contract

	agreement, appointment letter, training record		
Communications (incoming & 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	Once a year	Permanent file

4.6.4.5.2 Disposal of Obsolete Files

Guidelines on Shredding of Obsolete Documents

A. Shredding is done every last Friday of the month.
B. One (1) staff will be assigned for the shredding.
C. Shredding of documents is properly documented with the following information:
    1) Document
    2) Date
    3) Person responsible
    4) Approval of an authorized person
D. Obsolete documents will be shredded on the last Friday of the month, following its retention period and after verification that it has been scanned and incorporated in the database. The following documents are considered obsolete documents:
    1) Spare documents
    2) Protocols (after 3 years of retention period)
    3) IRB Member's outdated CV
    4) Any document with confidential information
E. During submission, only one copy is kept in file. The rest of the copies are returned to the principal investigator after the review of the protocol.

4.7 Protocol Document Tracker and Protocol Index

4.7.1 Purpose

To describe the tracking procedures of the Makati Medical Center Institutional Review Board using the Document Tracker Forms **(Form 4.4A and 4.4B)**.

4.7.2 Scope

Index is use 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.

4.7.3 Responsibility

The secretariat records the activities or status of the protocols using the Document Tracker Forms **(Form 4.4A and 4.4B).**

4.7.4 Process Flow/Steps

NO.	ACTIVITY	RESPONSIBILITY
1	Receives and records the protocol file and documents submitted on the protocol index ⬇	Secretariat
2	Record the movements and details of communications on protocol tracker until the time when the study is completed, terminated or withdrawn ⬇	Secretariat
3	Check for completeness of protocol files using protocol index	Secretariat

Detailed Instructions

4.7.4.1 Secretariat records all protocol files on the protocol index

4.7.4.2 The Document Tracker Forms **(Form 4.4A and 4.4B)** are used to record the activities or status of a protocol. Document Tracker Forms **(Form 4.4A and 4.4B)** contains:

A. Title of the document
B. Name of Recipient and Date Received
C. Name of the person submitting/ forwarding the document and date.

D. Name of the person who returns the documents and date.

4.7.4.3 Protocol index is updated regularly to ensure completeness of all protocol documents.

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Darwin A. Dasig, M.D.	4	6	November 17, 2020	• Updated the version to Version 6