Chapter IV. Documentation and Archiving	Document Code: IRB-GOP-DAA-004	Rev. Code : 09
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Approved by:	
(original document signed) Dr. Saturnino P. Javier **Division Head** **Date Signed :** December 16, 2025	(original document signed) Dr. Carolyn A. Butler **Physician Head** **Date Signed** : December 18, 2025

I. Objective:

1.1. To outline standardized procedures for the timely preparation and systematic distribution of the Institutional Review Board (IRB) meeting agenda.

1.2. To establish clear guidelines for the accurate documentation, review, and formal approval of minutes from IRB full board meetings.

1.3. To define the processes for preparing, managing, and maintaining records of IRB communications, including proper filing and retrieval protocols.

1.4. To detail the procedures for archiving inactive study files, documents, and records in compliance with regulatory and institutional requirements.

1.5. To describe the policies and practices of the Makati Medical Center Institutional Review Board (MMC IRB) for ensuring the confidentiality and secure handling of study files and all other IRB-related documents.

II. Scope:

2.1. The IRB ensures that all full board meetings are conducted efficiently and transparently by requiring the timely preparation and distribution of a meeting agenda. This agenda informs IRB members and relevant parties of the items scheduled for discussion, facilitating informed and productive deliberations.

2.2. The IRB is committed to maintaining an accurate and official record of its proceedings. Meeting minutes shall be diligently prepared, reviewed, and approved by IRB members to ensure documentation of decisions, discussions, and actions taken during full board meetings.

2.3. The IRB upholds clear and consistent communication with investigators, institutions, and other relevant stakeholders. All IRB-related communications shall be properly

prepared, documented, and securely managed to ensure accountability and traceability.

2.4. The IRB shall maintain comprehensive and organized records of all protocol submissions and related documents. Active study files must accurately reflect all IRB actions prior to study completion, and other IRB documents and records must be properly maintained and stored in accordance with institutional and regulatory standards.

2.5. The IRB requires the Secretariat to archive completed documents upon receipt of final reports or other closing documentation. This ensures proper documentation of research history and supports compliance with regulatory requirements for record retention.

2.6. The IRB is committed to protecting the confidentiality of all research-related documents. The Secretariat shall uphold strict confidentiality measures in the handling, storage, and access of study files and sensitive IRB materials.

2.7. To ensure completeness and accuracy in protocol file management, the IRB requires the use of an index at the front of each protocol folder. A document tracker shall be used to systematically record all protocol submissions and related communications, supporting effective monitoring and retrieval.

III. Responsibility

3.1. It is the responsibility of the 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.

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

3.3. It is the responsibility of the 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.

3.4. It is the responsibility of the 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 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.

3.5. 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.

3.6. The secretariat uses the submissions tracker in OneDrive to record the activities or status of the protocols.

IV. Preparation and Distribution of Meeting Agenda

4.1. Guidelines

4.1.1. 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.

4.1.2. The Member-Secretary and the IRB Chair review the prepared agenda. The IRB Chair shall approve the final agenda for the meeting.

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

4.1.3.1. Date of preparation

4.1.3.2. Date, time and venue of meeting

4.1.3.3. Disclosure of Conflict of Interest

4.1.3.4. No. of Business Arising

4.1.3.5. Agenda items

a. Protocol Review
   - Initial review
   - Resubmission Review

b. Post approval monitoring
   - Amended protocols
   - Safety reports
   - Protocol deviations and violations
   - Site visit reports
   - Progress reports and Renewal of Approval Requests
   - Final reports
   - Early study termination
   - Queries or complaints

c. List of Exempted Protocols
d. Other Matters

4.1.4. 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 before 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.

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

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

4.1.7. The following are the activities and responsibilities:

NO.	ACTIVITY	RESPONSIBILITY
1	Collect all documents submitted to the IRB with 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

V. Preparation of Meeting Minutes

5.1. Guidelines:

5.1.1. 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.

5.1.2. Secretariat uses Form 4.2 as a template to organize the meeting discussion in preparation to writing the minutes ahead of the meeting date. Secretariat documents the proceedings of the meeting as the meeting progresses by writing directly into the template prepared.

5.1.3. 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

5.1.4. If any members declare a conflict of interest, it will be noted in the meeting agenda along with the specific studies related to their disclosures. These members will be asked to leave during the discussions and recommendations regarding those studies. They will also be excluded from voting on the studies and will be advised to return once the discussions, recommendations, and voting are completed.

5.1.5. 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.

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

5.1.7. The Member-Secretary and Chair approve the minutes of the meeting (Form 4.2)

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

5.1.9. 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 Minimal Risk REsearch ProtocolS (SPARES) meeting are not required to be approved by the full board.

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

5.1.11. The following is the summary of procedures:

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

VI. Preparation of Communication Records

6.1. Guidelines:

6.1.1. 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. IRB Secretariat organizes a log of communications which also function as a log of submissions if the communication comes with a submission.

6.1.2. 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.

6.1.3. As the IRB has transitioned to electronic submissions, hard copies are no longer required. However, if hard copies are submitted, they will be received and stamped for the submitter's personal records only. The IRB administrative staff shall also record the submission in the incoming logbook.

6.1.4. The following is the summary of procedures:

No.	Activity	Responsibility
1	Organize all communications received and issued by the IRB	IRB Administrative Staff

2	Record the details of the communication	IRB Administrative Staff
4	File communication documents	IRB Administrative Staff

VII. Management of Active Study Files, Documents and Records

7.1. 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 2.1A)	Yellow	Standard coding
Ongoing study	Protocols that have been approved by IRB	Approval letter (Form 2.10)	Green	Standard coding

7.2. Protocol Label Code Format

7.2.1. 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)-month-(month submitted) - number (chronological number based on order of receipt). For example, if the protocol entitled "First Clinical Drug Trial on Pediatric Patients" was the first protocol received in the year 2012, with a submission date of January 1, 2012. The protocol shall be identified using the code MMCIRB 2012-01-1.

7.2.2. All research protocols submitted to the IRB shall be assigned a unique protocol number following the format: **YYYY–MM–XXX**. The coding shall be applied as follows:

- **YYYY**: The four-digit year when the protocol was submitted (e.g., 2025).
- **MM**: The two-digit month of submission (e.g., 07 for July).
- **XXX**: A three-digit sequential number assigned in the order protocols are received during the year (e.g., 001, 002, 003, etc.).

7.2.3. This standardized coding ensures accurate tracking, organization, and retrieval of protocol submissions across the review period. The Secretariat is responsible for assigning and documenting the protocol number upon receipt of a complete submission.

7.2.4. Additional Tag:

- Exempted Protocol – Add EXEMPT on the code format and counting is chronological per year. Example: MMCIRB 2021 – 001 EXEMPT
- SJREB Protocols– Add SJREB Code to the MMC-IRB Code; must be reflected on all protocol files. Example: MMCIRB 2021 – 001/SJREB 2021-01

7.2.5. Protocol Folders

7.2.5.1. Protocol documents are filed in electronic folders, with one (1) folder assigned per study protocol title.

7.2.5.2. The electronic folders are systematically organized to enhance clarity and accessibility. Each folder contains the following sections: initial submissions, resubmissions, and post-approval submissions. Within each section, you will find all relevant actions taken by the Research Ethics Committee (REC) along with the necessary documentation corresponding to each submission. This structure ensures that all necessary information is easily retrievable and that the submission process is well-documented, facilitating effective communication and compliance with ethical standards

7.2.5.3. These folders are stored securely on OneDrive with restricted access.

7.2.5.4. Keys to physical locked cabinets, if applicable, are held by designated staff.

7.2.5.5. Electronic folders are labeled using the official study protocol code for easy identification and retrieval.

7.2.5.6. Access to electronic folders is limited to authorized IRB personnel only, and access rights are reviewed periodically to ensure data security and confidentiality.

7.2.6. Active Protocol File Management

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

a. The study files shall include the protocol and current version, informed consent documents, amendments, and all communications regarding the application, decision, follow-up, safety reports, and continuing progress reports.

b. Secretariat updates the submissions trackers and the Masterlist database every week.
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.

7.2.7. Protocol Masterlist Database

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

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

7.2.7.3. The electronic Masterlist Database should have at least the following fields:

- MMCIRB CODE
- PROTOCOL TITLE
- NAMES OF RESEARCHER (s)/INVESTIGATOR (s)
- FUNDING
- DEPARTMENT/SPONSOR OF THE STUDY
- SPONSORS PROTOCOL NUMBER
- REVIEWERS
- STUDY DESIGN
- TYPE OF REVIEW
- TYPE OF REVIEW SENT
- TYPE OF RESEARCH (based on 2.7A form)
- SUBMISSION DATE (SOFT COPY)
- Date Requirements Completed
- (Date sent in IRB Admin Email)
- DATE OF FIRST REVIEW
- DECISION
- DATE OF FIRST DECISION LETTER TO THE PI / RESEARCHER
- DATE OF APPROVAL
- STATUS
- COLOR
- ANNUAL REPORT REMARKS
- ANNUAL REPORT STATUS
- TURNAROUND TIME

- REVIEW FEE PAYMENT
- CTA FEE PAYMENT
- AMENDMENT FEE
- PROGRESS REPORT FEE

7.2.8. **The submissions tracker** should also include the following details for both pre and post -approval submissions.

- MMCIRB CODE
- NAMES OF RESEARCHER (s)/INVESTIGATOR (s)
- Date received (Date of cover letter)
- Sponsor
- Details of the submission
- Name of Reviewers
- Decision
- Decision Letter Sent
- Review Fee Status

7.2.9. For Serious Adverse Event: The following information should contain the ff:

- Diagnosis
- Participant number
- Onsite SAE/SUSAR
- Causal Relationship (PI and Sponsor)
- Outcome
- On-Site or Off-Site
- Expected reaction (As seen on the SAE form based on the I.B. As seen on the I.B)
- Reaction Onset
- Date Known by P.I.
- Submission Report
- No. Of days from Date Known to P.I. Until Submission to IRB
- Seriousness
- Vaccination Date/s
- Age
- Date Decked
- NOID sent
- Person In-Charge of who is handling the post-approval submission

7.2.10. The Masterlist Database and Submissions Tracker shall be updated on a weekly basis under the supervision of the Member-Secretary to ensure accuracy and completeness of records.

7.2.11. The following is the summary of procedures:

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

VIII. Archiving of Inactive Study Files, Documents and Records

8.1. Guidelines:

8.1.1. 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

8.1.2. Protocol Label Code Format

8.1.2.1. Protocol folders are re-coded indicating the year YYYY –MM-XXX / ZZZZ

a. YYYY – year the protocol was submitted
b. MM – submission date
c. XXX – chronological number for the year
d. ZZZZ – year the protocol was completed, withdrawn or terminated
e. 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 2010-01-2 is approved in 2012, the archiving code is MMC IRB 2010-01-2/2012.

8.1.3. Inactive Protocol File management

8.1.3.1. Inactive files are identified every last month of the year or earlier for completed or terminated protocols.

8.1.3.2. 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.

8.1.3.3. Secretariat reviews the completeness of contents of the protocol file based on its submission in the electronic folder and transfers it from the active study filing area to the designated archive area.

8.1.3.4. The Secretariat will assign a year to the end of a study code (e.g., MMCIRB-2025-01-02-**2028**). The year "2028" represents when the study will be archived and subsequently transferred to its designated archiving folder.

8.1.3.5. The archiving data should be entered accordingly in the protocol Masterlist Database.

8.1.4. Retention Period

8.1.4.1. 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.

8.1.5. Archived Protocol Retrieval

8.1.5.1. Archived protocols can be retrieved within the three (3)-year archiving period in accordance with the SOP on Maintaining Confidentiality of Study Files and IRB Documents.

8.1.5.2. Documents retrieval is recorded accordingly.

8.1.6. The following is the summary of procedures:

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

IX. Maintenance of Confidentiality of Study Files and MMC IRB Documents

9.1. Guidelines:

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

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

9.1.1.2. MMC IRB documents (Meeting minutes, advice, and decisions)

9.1.1.3. Correspondence (experts, auditors, study participants, etc.)

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

9.1.2.1. 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.

9.1.2.2. 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.

9.1.2.3. 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).

10.1.1.2. Management of Confidential Files

10.1.1.2.1. 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.

10.1.1.2.2. The IRB Secretariat staff and IRB Administrative Staff have exclusive access to a secure master list of electronic files, which is protected by a password to ensure confidentiality and prevent unauthorized access before opening it.

10.1.1.2.3. 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

10.1.1.2.4. All requests for access are recorded by the Secretariat Staff in the log before copies of any documents are released.

10.1.1.2.5. Secretariat makes only the exact number of copies requested.

10.1.1.2.6. Recipient signs for the copies requested in the Makati Medical Center IRB upon receipt of the copies.

10.1.1.2.7. 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.

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

10.1.1.4. A log filed in the protocol folder is dedicated for purposes of recording access as described above, which contains the following fields of information:

- Study file code
- Date borrowed
- Name of borrower
- Signature of borrower upon retrieval

- Signature of Makati Medical Center IRB Secretariat upon return of document to file box
- Document copied
- Number of copies mad
- Number of copies received

10.1.1.5. Maintenance of IRB and Administrative Documents

10.1.1.6. 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	Electronic Protocol folder	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	Depends on years of employment	Depends on years of employment
	agreement, training record, job description		
Independent consultant profile folder	Curriculum vitae, confidentiality of agreement, appointment letter, training record	Depends on years of contract	Depends on years of contract
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

10.1.1.7. 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:
   - Document
   - Date
   - Person responsible
   - 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:
   - Spare documents
   - Protocols (after 3 years of retention period)
   - IRB Member's outdated CV
   - Any document with confidential information

Review: A GOP is reviewed every three years or as deemed necessary.

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