MAKATI MEDICAL CENTER

Departmental General Operating Procedures

Chapter III: IRB Post-Approval Review and Monitoring Procedures	Document Code: IRB-SOP-PAM-003	Rev. Code : 09
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The Makati Medical Center Institutional Review Board (MMC IRB) upholds the ongoing protection of research participants by implementing robust post-approval review and monitoring processes. These procedures ensure that all approved studies continue to meet ethical, scientific, and regulatory standards throughout the research lifecycle. This chapter outlines the IRB's framework for post-approval oversight, including continuing review, safety monitoring, handling of protocol deviations and violations, site visits, management of serious adverse events (SAEs), and renewal or termination of approval. It further details the responsibilities of investigators and IRB subcommittees in maintaining research compliance and integrity after the initial approval.

I. Objectives:

The purpose of this chapter is to guide the IRB, investigators, and staff on how to monitor and manage approved research studies after they have received initial approval. Specifically, this section aims to:

1.1. Explain how the IRB reviews and acts on reports of serious adverse events (SAEs) and other safety concerns.
1.2. Clarify how the IRB handles reports of protocol violations and deviations.
1.3. Describe how the IRB conducts site visits to ensure studies are following approved protocols and ethical standards.
1.4. Outline how amendments to study protocols and documents are reviewed and approved before implementation.
1.5. Define how the IRB reviews progress and annual reports to ensure continued protection of participants and compliance with ethical standards.
1.6. Explain how final reports are reviewed when a study is completed.
1.7. Provide a process for handling questions or concerns raised by research participants.

1.8. Describe how the IRB manages studies that are terminated early or withdrawn before completion.

1.9. Identify steps the IRB takes when investigators do not follow approved procedures or fail to comply with ethical guidelines.

1.10. Ensure that the IRB continues to protect the rights and welfare of participants in all approved studies.

II. Scope:

This chapter applies to all post-approval activities related to research studies reviewed by the MMC IRB. It includes the following areas:

2.1. Reviewing safety reports such as SAEs and SUSARs, in compliance with local and international guidelines (e.g., CIOMS, ICH-GCP, FDA Philippines).

2.2. Overseeing research conducted by all MMC-affiliated investigators, both within and outside the institution.

2.3. Conducting site visits to monitor compliance with ethical standards and approved protocols.

2.4. Reviewing and approving any changes (amendments) to the study protocol or documents before they are implemented.

2.5. Evaluating progress and annual reports to ensure the study remains safe and ethically sound.

2.6. Reviewing final study reports after the completion of data collection and participant involvement.

2.7. Managing and documenting studies that are ended early, whether by the investigator, sponsor, or IRB.

2.8. Enforcing rules and corrective actions when investigators do not follow approved procedures or ethical standards.

III. Responsibility

This section outlines the key responsibilities of the MMC IRB, IRB Secretariat, and investigators in ensuring compliance with post-approval requirements and ethical standards throughout the lifecycle of approved research protocols.

A. *General Oversight and Monitoring Functions*

3.1. The **MMC IRB** is responsible for reviewing and acting on all post-approval submissions, including serious adverse event reports, protocol amendments, progress reports, final reports, and cases of non-compliance.

3.2. The **IRB Chair** provides final approval on decisions related to expedited reviews, amendments, and post-approval reports, and leads the full board in making decisions on major protocol concerns.

3.3. The **IRB Member-Secretary** assigns primary reviewers, provides recommendations on type of review, and ensures proper documentation of decisions.

3.4. The **SAE Subcommittee** reviews serious adverse events (SAEs) and prepares summary reports and recommendations for full board consideration when required.

3.5. The **IRB Secretariat** receives and screens post-approval submissions, verifies completeness, manages communication with investigators, updates databases, and maintains documentation in the protocol files.

3.6. The **Principal Investigator** is responsible for submitting post-approval requirements on time, ensuring participant safety, reporting adverse events, and implementing only IRB-approved changes to the protocol.

3.7. The **Clinical Research Center** assists with Clinical Trial Agreements and ensures alignment with institutional and sponsor requirements, when applicable.

B. *Serious Adverse Event (SAE) Subcommittee Responsibilities*

3.8. The SAE Subcommittee is tasked with the timely evaluation and trending of both onsite and offsite SAEs.

- 3.8.1. Conducts monthly SAE meetings and presents onsite SAE cases to the IRB Full Board and Medication Safety Subcommittee (MSS).
- 3.8.2. Analyzes previous SAE history for each protocol to recommend appropriate actions (e.g., protocol amendments or site visits).
- 3.8.3. Provides contextual recommendations based on the Investigator's Brochure, DSMB reports, and SAE history.
- 3.8.4. Summarizes SAE trends biannually per protocol.
- 3.8.5. Conducts quarterly meetings to assess trends in both onsite and offsite SAE reports and makes appropriate board recommendations.

3.9. IRB Secretariat supports the SAE Subcommittee in the following ways:

3.9.1. Maintains and files complete minutes of all SAE meetings.

3.9.2. Ensures completeness of SAE submission forms.

3.9.3. Presents SAE data to the Full Board and MSS in coordination with the SAE Subcommittee Chair.

C. *Protocol Violation and Deviation Reporting*

3.10. The following responsibilities pertain to protocol deviations and violations:

3.10.1. The IRB Secretariat receives all protocol violation/deviation reports.

3.10.2. Designated board members or reviewers assess violations and make recommendations to the Board.

3.10.3. The IRB ensures compliance with ICH-GCP and other applicable standards.

D. *Site Visits and Compliance Monitoring*

3.11. The IRB or its designee shall conduct site visits for approved studies when indicated.

3.12. The IRB Secretariat monitors investigator compliance with MMC IRB SOPs and protocols.

3.13. Board members or their designees are responsible for responding to any confirmed non-compliance findings.

E. Amendments and Post-Approval Submissions

3.14. The IRB Secretariat manages the amendment submission packages from investigators.

3.15. Primary reviewers evaluate all protocol amendments and determine necessary action.

3.16. The IRB Chair determines if an amendment qualifies for expedited or full board review

3.17. The IRB votes to approve or reject submitted amendments, as recommended by the reviewers.

F. Progress, Continuing, and Final Reports

3.18. Investigators are responsible for submitting annual progress reports before the expiration of IRB approval. A 12-working-day grace period is granted. Failure to comply results in the study's automatic inactivation.

3.18.1. The IRB Secretariat reminds investigators of due dates and manages Forms 3.3A, 3.3B, and 3.4.

3.18.2. Reviewers assess the reports to ensure alignment with the approved protocol. If original reviewers are unavailable, the IRB Chair assumes responsibility

3.18.3. Investigators must submit final reports upon study completion.

G. *Participant Queries and Requests*

3.19. The designated Secretariat member receives, logs, and refers participant concerns to the IRB Chair or relevant board members for appropriate action. All actions are documented accordingly.

H. *Early Termination or Withdrawal of Protocol*

3.20. The IRB is responsible for acting on early termination requests or for withdrawing previously approved protocols due to safety concerns.

3.21. The IRB Admin Staff manages the termination documentation.

3.22. Reviewers assess justifications and recommend whether a full board or expedited review is needed.

3.23. The Principal Investigator must submit timely notifications of early termination.

I. *Notification and Documentation Compliance*

3.24. Primary reviewers shall evaluate all post-approval monitoring submissions according to IRB timelines.

3.25. The IRB Secretariat manages and archives all submissions, ensuring completeness and adherence to documentation standards.

3.26. The IRB ensures all procedures are followed and provisions are interpreted appropriately within the context of this SOP.

IV. Serious Adverse Events

4.1. Upon issuance of the initial protocol approval letter, the MMC IRB informs the Principal Investigator (PI) of the requirement to report all Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) using Form 3.1A or the online submission platform within specified timelines.

4.1.1. For Onsite SAEs:

- The PI must submit a report within seven (7) calendar days from the time the event is first recognized.
- The submission must include a cover letter indicating the vaccination dates (if applicable) and attach a death certificate in case of mortality.
- The report is submitted to irbmmc.admin@makatimed.net.ph.

1.1.1. For Offsite SAEs:

- SUSARs must be submitted with a cover letter via email or included in the progress report (if applicable).
- These are typically reviewed as notification reports unless action is required.

4.2. SAE Reporting Timelines

4.2.1. Fatal or life-threatening unexpected ADRs must be reported to regulatory agencies within seven (7) calendar days of awareness, followed by a full written report within eight (8) calendar days.

4.2.2. All other SAEs or SUSARs must be reported within fifteen (15) calendar days after the sponsor becomes aware.

4.2.3. Other adverse events, including DSURs, are included in the annual progress report.

4.2.4. AEs must also be reported to relevant hospital committees, such as the Therapeutics Committee, Quality Management Division, or Medication Safety Subcommittee, as applicable.

4.3. SAE Initial Processing

4.3.1. The IRB Secretariat checks the completeness and timeliness of the submission.

4.3.2. Late submissions are flagged and a reminder is issued to the investigator.

4.3.3. Acknowledgment of receipt is sent to the PI.

4.3.4. A summary report is created per protocol and distributed to Primary Reviewers and AE Subcommittee members within 24 hours.

4.4. Trending and Classification

4.4.1. Offsite SAEs are stored for trending and analysis.

4.4.2. Onsite SAEs are reviewed for immediate action if necessary.

4.4.3. AE Subcommittee reviews using Form 3.1B and may recommend site visits or protocol modifications.

4.5. Evaluation and Recommendations

4.5.1. Classification of onsite SAE:

6. Unlikely/Unrelated: Forwarded for trend analysis.
7. Definitely, Possibly, Probably Related: Reviewed urgently, recommendations sent to the Chair.

4.5.2. Multicenter studies (local/international) are assessed based on trends, severity, and site-specific occurrence to inform IRB action.

4.6. Full Board Deliberation

4.6.1. All onsite SAEs are discussed during the Full Board meeting**.**

4.6.2. The IRB may:

- Request a protocol or ICF amendment
- Suspend participant enrollment or procedures
- Terminate the study
- Conduct a site visit
- Continue monitoring

4.7. Reviewer comments and decisions are documented and filed.

4.8. The IRB decision is communicated to the investigator via Form 2.9E.

4.9. Secretariat updates the SAE tracker and records.

4.10. PI submits SAE requirements via email.

4.11. IRB Secretariat verifies completeness.

4.12. Secretariat prepares a summary document and disseminates it to the Primary Reviewers and AE Subcommittee**.**

4.13. SAE is reviewed, and necessary recommendations are made.

4.14. On-site SAEs are discussed during the Full Board meeting.

4.15. The Secretariat prepares the Notice of IRB Decision (NOID)**,** and the administrative staff sends it to the PI.

4.16. The following table summarizes the sequential process for managing Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs), including the corresponding responsibilities and expected timelines. This summary ensures consistency and timely handling of all SAE reports in accordance with MMC IRB standards and international regulatory guidelines.

No.	Action	Responsibility	Timeline
1	Acknowledge receipt of onsite Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs).	Secretariat	Within 1 working day

2	Summarize and distribute SAE/SUSAR reports to the Primary Reviewers and Adverse Event (AE) Subcommittee for initial evaluation.	Secretariat	Within 1 working day
3	Review SAE and SUSAR and provide recommendations. **Offsite:** Reviewed as a notification report, if applicable. **Onsite:** Immediate action if required, and report to the Full Board.	Primary Reviewers and AE Subcommittee Chair	Within 1 working day
4	Discuss and deliberate during Full Board Review to decide on appropriate action (e.g., amendment, suspension, or continued monitoring).	IRB Members	Within 1 working day after review
5	File SAE documents in the electronic protocol folder and update the submission tracker for documentation and audit readiness.	Secretariat	Within 1 working day

V. Protocol Violation/Protocol Deviation

The Makati Medical Center Institutional Review Board (MMC IRB) recognizes the importance of strict adherence to approved research protocols to ensure the safety, rights, and well-being of research participants, as well as the scientific integrity of research data. However, deviations from the protocol may occur. These are classified and managed through a structured review and action process by the IRB.

5.1. Definitions

5.1.1. **Protocol Violation** refers to a significant departure from the approved protocol that may compromise participant safety, data integrity, or regulatory compliance. It often involves willful or negligent non-compliance.

5.1.2. **Protocol Deviation** refers to a less serious or unintentional departure from the protocol that does not significantly impact participant safety or study validity.

5.2. Reporting Requirements

5.2.1. All **protocol violations** must be reported immediately (within 24–72 hours) to the MMC IRB using **Form 3.2A** and must include a **Corrective and Preventive Action Plan (CAPA)**.

5.2.2. **Protocol deviations** must be reported within **seven (7) calendar days** after the investigator becomes aware of the event. These may be submitted via Form 3.2A or as part of the **Annual Progress Report**.

5.2.3. All submitted violations or deviations are reviewed and logged by the IRB Secretariat, and assigned to primary reviewers for further assessment and recommendation.

5.3. Review and Deliberation

5.3.1. Protocol violations and significant deviations are evaluated either through **Full Board Review** or **Expedited Review**, depending on their nature and severity.

5.3.2. All reports must clearly describe:

- The nature and cause of the deviation/violation.
- The number of participants affected.
- Actions taken to address the issue.
- Preventive measures to avoid recurrence.

5.4. Classification of Protocol Deviations for Full Board Review (PDFB)

Protocol deviations submitted for Full Board review are categorized using the following classification scheme:

PDFB Code	Category	Description
1	Major Protocol Deviation	Non-emergent or planned deviations that represent a significant change from the approved protocol. These may impact subject safety, data integrity, or regulatory compliance.
1.1	Exceptions to Eligibility Criteria	Enrollment of participants who do not meet the defined inclusion/exclusion criteria.
1.2	Informed Consent Process Exceptions	Deviations in the form or process of obtaining informed consent, such as using outdated versions or failing to obtain consent before procedures.

1.3	Dosing or Schedule Exceptions	Deviations in the schedule or administration of the investigational product from what was approved.
1.4	Planned, Non-Emergent Deviations	Intentional changes not pre-approved by the IRB but implemented during the study.
2	Minor Protocol Deviation	Deviations that do not compromise scientific validity or participant safety.
2.1	Administrative Deviations	Clerical errors, missing signatures, or delayed form submissions that do not affect participant rights or safety.
2.2	Logistical/Schedule Changes	Rescheduling of visits, out-of-window appointments, re-screening, or procedural adjustments due to logistical issues.

5.5. Summary of Actions, Responsibilities, and Timelines

No.	Action	Responsibility	Timeline
1	Receive and acknowledge protocol violation/deviation report.	IRB Secretariat	1 working day
2	Assign to primary reviewers and assess impact on participant safety and data integrity.	IRB Secretariat / Chair	1 working day
3	Review and classify the protocol deviation or violation (Major/Minor) and determine appropriate course of action.	Primary Reviewers	2–5 working days
4	Escalate to Full Board if classified as major protocol deviation or if warranted by the situation.	IRB Chair	Prior to next scheduled meeting
5	Provide feedback to the investigator, including recommendations or required CAPA.	Secretariat / Admin Staff	3 working days

6	Document and file decision in protocol records and update tracker.	IRB Secretariat	1 working day

VI. Site Visits

Site visits form part of the MMC IRB's post-approval monitoring program to ensure that research is conducted ethically, in compliance with approved protocols, and with full protection of participant rights and welfare. Visits may be routine or for-cause and are performed by designated members of the IRB.

6.1. **Preparations Before the Visit**

6.1.1. The IRB Secretariat prepares all necessary documentation and forms and distributes these to the designated Site Visit Team.

6.1.2. The Secretariat formally communicates the schedule and purpose of the visit to the Principal Investigator (PI).

6.1.3. The MMC IRB Site Visit Team shall:

1 Review IRB-approved protocol files and investigator documentation.

2 Contact the study site to coordinate the visit schedule.

3 Make necessary logistical or travel arrangements.

4 Prepare notes or copies of key files for comparison with onsite records.

6.2. **Procedures During the Visit**

6.2.1. The Site Visit Team uses the Site Visit Checklist (Form 3.7) to ensure consistency.

6.2.2. The team may perform the following activities:

1. Verify use of the latest IRB-approved informed-consent form.
2. Randomly review subject files for accuracy and completeness of consent.
3. Observe the informed-consent process, if feasible.
4. Assess organization of study documents and confidentiality safeguards.
5. Interview members of the research team.
6. Debrief the PI on initial findings.

6.3. **After the Visit**

6.3.1. The Site Visit Team shall:

1. Complete a written site-visit report using Form 3.7 within five (5) working days.
2. Submit the report to the Secretariat for inclusion in the next Full Board agenda.
3. Send a copy to the study site and file the report in IRB records.

6.4. Presentation of the Site Visit Report

6.4.1. The Site Visit Report is presented to the Full Board for deliberation.

6.4.2. The Board determines the appropriate actions based on findings.

6.5. Possible Board Actions - Depending on the outcome of the visit, the IRB may:

1. Continue the study with ongoing monitoring.
2. Require amendments to the protocol or consent form.
3. Suspend participant recruitment.
4. Suspend study procedures pending review.
5. Terminate the study.
6. Blacklist the PI and/or sponsor.
7. Recommend other corrective or preventive actions as appropriate.

6.6. Criteria for Conducting Site Visits: Site visits are initiated when one or more of the following apply:

1. Newly approved study sites or new PIs.
2. Reports of serious or unexpected adverse events.
3. High study volume or frequent protocol deviations.
4. Frequent receipt of complaints from research participants.
5. Need to ensure compliance with Single Joint Research Ethics Board (SJREB) or other regulatory-body recommendations.
6. Non-compliance or suspected misconduct (e.g., data falsification, violation of participant rights).
7. Repeated failure to submit required progress or final reports.
8. Frequent protocol violations affecting participant safety or scientific integrity.

6.7. Composition of the Site Visit Team: The Site Visit Team is appointed by the IRB Chair during a Full Board meeting and generally includes:

15 A primary reviewer of the study.

16 A member of the Adverse Event Subcommittee; and

17 One additional IRB member.

6.8. Post-Visit Communications and Follow-up

6.8.1. The IRB Admin Staff issues a Notification of IRB Decision (Form 2.9D) to the PI.

6.8.2. The Secretariat tracks the PI's responses and presents follow-up actions at the next Full Board meeting.

6.8.3. All related documents are filed, and the IRB database is updated.

6.9. Summary of Actions, Responsibilities, and Timelines

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Select the study sites and the site visit team.	IRB Members/ Chair	1 working day
2	Inform the principal investigator.	Secretariat	1 working day
3	Prepare the documents and other relevant information prior to site visit.	Secretariat	1 working day
4	Distribute to site visit team	Secretariat	1 working day
5	Site visit proper: check the onsite documents and compare with the current documents in the protocol file; interview the principal investigator and/or research staff	Site Visit Team	1 working day
6	Write a report and make a recommendation utilizing the Site Visit Report (Form 3.7); Present the findings and recommend appropriate action for the Full Board to decide	Site Visit Team	5 working day
7	Communicate the decision to the Principal Investigator and give Notice of Decision	Admin	1 working day
8	File the documents and update the database	Secretariat	1 working day

VII. Amendments

Amendments refer to any change made to an approved research protocol, study site, study personnel, or any related document (e.g., Informed Consent Form, study instruments). All proposed changes must be submitted to the MMC IRB for review prior to implementation, except where changes are necessary to eliminate immediate hazards to participants.

7.1. **Submission and Screening of Amendments**

7.1.1. Investigators must submit an Amendment Application files, including **Form** 2.1C, Form 3.2, and supporting documents, whenever changes are made to the

study site, study team composition, or protocol-related content previously approved by the MMC IRB.

7.1.2. The IRB Secretariat screens the submission using the Requirement Checklist – Amendment (Form 2.4) to ensure completeness.

7.1.3. Once deemed complete, the amendment package is logged, and the turnaround time for IRB review and approval officially begins.

7.1.4. The amendment package is distributed to the original primary reviewers for evaluation. If the original reviewer is no longer active, the IRB Chair assigns a new reviewer.

7.2. **Review Process**

7.2.1. Primary reviewers compare the amended documents with the latest IRB-approved versions to evaluate the impact of changes.

7.2.2. Any amendment that significantly alters the risk/benefit ratio of the study is escalated for Full Board Review.

7.2.3. Minor changes may qualify for Expedited Review under existing IRB review categories.

7.2.4. The IRB may also require re-consenting of already-enrolled participants when appropriate.

7.2.5. The following IRB decision points may be rendered for both full board and expedited review:

a. Request for clarification or additional information
b. Approval
c. Recommendation for minor or major revision
d. Disapproval
e. Pending decision

7.3. **Amendment Review Fee**

7.3.1. Sponsor-initiated and external protocols are subject to a non-refundable amendment review fee of PHP 5,600.00 (net of withholding tax), payable to Makati Medical Center.

7.3.2. Investigators may request a Statement of Account from the IRB Admin Staff to facilitate processing.

7.3.3. If payment cannot be made before approval, a Promissory Note may be submitted, with the understanding that payment must be settled within four (4) weeks after the release of the approval letter.

7.3.4. Approval letters will be withheld until payment or a valid promissory note is received.

7.4. Notification and Documentation

7.4.1. Following review and decision, the IRB Secretariat prepares the Notification of IRB Decision (NOID) using Form 2.9, and the Administrative Staff sends this to the Investigator.

7.4.2. The Secretariat ensures that all amendment-related documents are filed in the protocol file and updates the IRB's amendment tracker and database.

7.5. Step-by-step Procedure and Timeline

No.	Activity	Responsibility	Timeline
1	Receive and acknowledge the amendment package (Form 2.1C and attachments); update document tracker	Secretariat	1 working day
2	Distribute amendment to original primary reviewers or designated IRB members	Secretariat	1 working day
3	Review amendment and issue recommendation using Form 3.2	Primary Reviewers / IRB Members	1 working day
4	Include in full board meeting if major changes; expedited reviews proceed without meeting discussion	IRB Members	1 working day
5	Prepare and issue Statement of Account; manage Promissory Note if applicable	Administrative Staff	1 working day
6	Prepare Notification of IRB Decision (NOID) and send to investigator	Secretariat / Admin Staff	1 working day

7	File amendment documents in the protocol folder	Secretariat	1 working day
8	Update submissions tracker and master database	Secretariat	1 working day

VIII. Annual/Progress Report

The Annual/Progress Report serves as a formal mechanism for the IRB to ensure continued ethical oversight of approved research protocols. It allows the IRB to monitor study conduct, verify compliance with approved procedures, and safeguard participant welfare through periodic reassessment of risk-benefit balance.

8.1. Policy Statement and Applicability

8.1.1. All IRB-approved protocols must undergo continuing review at least once every 12 months unless otherwise specified by the IRB based on risk level, study complexity, or participant vulnerability.

8.1.2. This SOP covers all annual and progress report submissions, including studies requiring full board or expedited review for renewal of IRB approval.

8.2. Monitoring and Notification

8.2.1. The IRB Secretariat shall maintain an updated master list of all active protocols and their corresponding approval expiration dates.

8.2.2. Two (2) months prior to expiration, the Secretariat shall issue a formal reminder to the Principal Investigator (PI) requesting submission of the annual/progress report.

8.2.3. The report must be submitted at least one (1) month before expiration to allow sufficient time for review and deliberation.

8.2.4. Failure to submit by the due date results in inactivation of the protocol, and the IRB shall withhold further study activities unless safety concerns justify continuation.

8.3. The PI must submit the following documents (via email to irbmmc.admin@makatimed.net.ph):

8.3.1 Completed Form 3.3A (Progress Report Form) and Form 3.3B (Reviewer Evaluation Form)

8.3.2 Current GCP training certificates (dated within the last 3 years) for PI and all key study personnel

8.3.3 Most recent Informed Consent Form, with tracked changes and revision highlights

8.3.4 Summary of:

- Approved amendments since last review
- Protocol deviations/violations and corrective actions
- Serious Adverse Events (SAEs) and causality assessment
- Site visit findings (if applicable)
- Previously submitted progress reports

8.3.5. Letter of Intent explaining rationale for approval renewal

8.4. Secretariat and Review Process

8.4.5. Upon submission, the Secretariat verifies completeness and sends an acknowledgment receipt to the PI.

8.4.6. Complete reports are forwarded to the original Primary Reviewers for evaluation using Form 3.3B.

8.4.7. Key areas for review include:

- Risk Assessment: continued minimization and justification of risks
- Consent Adequacy: use of most current forms; incorporation of new findings
- Local Context: investigator qualifications, complaints, institutional compliance
- Trial Progress: enrollment, withdrawals, deviations, SAE trends

8.5. Board Deliberation and Decision

8.5.5. The Chairperson presents a summary of the progress report and the Primary Reviewer's recommendations to the Full Board.

8.5.6. The Full Board may render any of the following decisions (recorded in Form 2.9C and meeting minutes Form 4.2):

- Renew approval as submitted
- Approval pending clarification or minor revisions
- Recommend major changes, suspension, or termination
- Initiate corrective actions or investigation of compliance issues

8.5.7. Upon approval, the PI receives a Notification of IRB Decision (NOID) indicating:

- Start and end dates of renewed approval
- Any conditions attached
- Next required submission date

8.6. Lapses in Approval

8.6.5. If the IRB has not received a complete progress report within 12 working days after the expiration date, the protocol is marked inactive.

8.6.6. Study-related procedures may only continue if required for participant safety.

8.6.7. The PI must request in writing (Form 3.9) for continued intervention if necessary.

8.6.8. Repeated lapses are subject to IRB investigation and may warrant suspension, sponsor notification, or additional oversight (Form 3.10).

8.7. Annual/Progress Report Review Fee

8.7.5. A Php 22,400.00 (net of tax) fee is required for sponsor-initiated or externally funded protocols.

8.7.6. Payment must be completed prior to the release of approval. A promissory note may be accepted, with a deadline of 4 weeks post-approval.

8.7.7. The Statement of Account is prepared by the Admin Staff upon request.

8.8. Responsibilities and Timelines

No.	Activity	Responsible Unit	Timeline
1	Monitor study expiration dates; issue reminder letters	Secretariat / Admin Staff	2 months before expiry
2	Receive submission; screen for completeness; issue acknowledgment	Secretariat	1 working day
3	Forward complete report to Primary Reviewers	Secretariat	1 working day
4	Prepare Statement of Account or accept Promissory Note	Admin Staff	1 working day

5	Review report using Form 3.3B and recommend action	Primary Reviewers	1 working day
6	Collate comments; prepare full board meeting agenda	Secretariat	1 working day
7	Present to Full Board; deliberate and finalize IRB decision	Chair / IRB Members	During next full board meeting
8	Prepare and send NOID; inform PI of board decision	Secretariat / Admin Staff	1 working day
9	Update master list; file signed reports and decision letters	Secretariat	1 working day

IX. Final Report

The Final Report signifies the formal conclusion of a research study approved by the Makati Medical Center Institutional Review Board (MMC IRB). Submission and evaluation of the Final Report ensure that all protocol activities have been completed, study-related obligations have been fulfilled, and any final outcomes, ethical considerations, or data responsibilities have been addressed.

8.9. Submission Requirements - The Principal Investigator must submit the Final Report Package via email to irbmmc.admin@makatimed.net.ph The package must include the following:

- Letter of Intent addressed to the IRB Chair, indicating: *Start and completion dates of the study*
- Letter of Endorsement, if applicable (e.g., from department/unit heads)
- Final Report Form (Form 3.4)
- Final Paper, for investigator-initiated protocols only

8.10. Initial Processing by the Secretariat

8.10.5. The Secretariat receives and **screens the final report for completeness**.

8.10.6. An **acknowledgment receipt** is sent to the investigator once all required documents are verified.

8.10.7. The complete final report is **forwarded to the original primary reviewers**. If the original reviewers are unavailable, the IRB Chair or a designated reviewer shall assume responsibility.

8.11. Review and IRB Decision

8.11.5. The final report undergoes expedited review, unless otherwise determined by the Chair.

8.11.6. Primary Reviewers evaluate the final report using Form 3.4 and submit recommendations using Form 2.9B.

8.11.7. The IRB Chair reviews and co-signs the decision.

8.11.8. Possible IRB decisions (via Form 2.9B):

- Acknowledged
- Request for further information
- Recommend further action (e.g., reporting of results, ethical follow-up, etc.)
- Others (as applicable)

8.11.9. Once acknowledged, the study is considered officially completed by the MMC IRB.

8.12. Communication and Compliance Tracking

9.6.1. The Secretariat prepares the IRB Decision Letter based on the reviewer's recommendation.

9.6.2. The Administrative Staff forwards the decision to the Clinical Research Center (CRC).

9.6.3. The CRC issues the Final Notification of IRB Decision to the Principal Investigator via email.

9.6.4. A copy of the signed final decision letter is archived in the E-Protocol system by the Secretariat.

9.6.5. The protocol folder is marked as completed and archived for a minimum of three (3) years in accordance with MMC IRB data retention policy.

9.7. Protocol Closure and Database Update

9.7.1. The study status is updated to "Completed" in the master list and submissions tracker.

9.7.2. The Final Report and supporting documents are securely filed in the protocol folder and tagged as inactive.

9.8. Final Report Procedure and Responsibilities

No.	Activity	Responsible Unit	Timeline
1	Receive final report (Form 3.4); check completeness; issue acknowledgment	Secretariat	1 working day
2	Forward complete report to Primary Reviewers	Secretariat	1 working day
3	Review final report and submit evaluation (Form 2.9B)	Primary Reviewers	1 working day
4	Acknowledge final report for expedited review	Primary Reviewers / IRB Chair	1 working day
5	Prepare and sign IRB decision letter (Form 2.9B)	Secretariat	1 working day
6	Send decision letter to CRC; CRC releases official decision to PI	Admin Staff / Clinical Research Center	1 working day
7	File signed decision letter and report in E-Protocol	Secretariat	1 working day
8	Update tracker and master list; mark protocol as archived	Secretariat	1. working day

X. Early Study Termination or Withdrawal

This section outlines standard procedures when a study is terminated or withdrawn before its scheduled completion, whether initiated by the investigator, sponsor, regulatory bodies, or the IRB. Early termination must be appropriately documented, justified, and reviewed to ensure the ethical management of enrolled participants and compliance with regulatory requirements.

10.1. The IRB Secretariat receives a request or recommendation for early study termination or withdrawal from the Principal Investigator, Sponsor, Data Safety

Monitoring Board (DSMB), Scientific Director, IRB members, or other authorized bodies.

10.2. The Secretariat acknowledges receipt and instructs the Principal Investigator to submit a Study Termination Package, which includes:

10.2.1. Study Termination Form (Form 3.8)

10.2.2. A memorandum detailing:

- Brief summary of the protocol
- Results and accrual data
- Management plan for participants still enrolled at the time of termination
- Justification and reasons for study termination

10.3. The Secretariat checks the completeness of the termination package and retrieves the IRB-approved protocol documents for cross-reference.

10.4. The complete termination package is forwarded to the original Primary Reviewers for evaluation. The protocol is included in the next Full Board Meeting Agenda if the termination requires full board discussion.

10.5. Primary Reviewers assess the safety data, reasons for termination, and management of ongoing participant care. A recommendation is submitted using the Evaluation Form (Form 3.8).

10.6. Depending on the nature of the termination, the following decision points are considered:

- Acknowledged
- Request for additional information
- Request for a meeting with the Principal Investigator
- Other appropriate actions

10.7. The IRB decision is documented using the Notification of IRB Decision (Form 2.9) and communicated to the Principal Investigator.

10.8. The Secretariat files the final documents in the e-Protocol system, archives the study in the inactive files, and updates the IRB master list and tracker

10.9. Termination Workflow Summary

No.	Activity	Responsibility	Timeline

1	Receive termination request or recommendation and acknowledge receipt (Form 3.8)	Secretariat	1 working day
2	Instruct PI to submit the Termination Package	Secretariat	1 working day
3	Review completeness of the package and retrieve protocol files	Secretariat	1 working day
4	Forward to Primary Reviewers and include in Full Board Agenda (if applicable)	Secretariat	1 working day
5	Evaluate termination package and submit recommendation (Form 3.8)	Primary Reviewers	1 working day
6	Deliberate (Full Board) or approve via Expedited Review, and finalize decision	IRB Chair / Members	1 working day
7	Prepare and issue Notification of IRB Decision (Form 2.9)	Secretariat / Admin Staff	1 working day
8	Archive protocol, update e-files, tracker, and master list	Secretariat	1 working day

XI. Requests and Queries

This section outlines the standard procedures for receiving, documenting, responding to, and tracking requests or queries from research participants, patients, or community members addressed to the MMC IRB.

11.1. The MMC IRB Secretariat may receive inquiries or requests through various communication channels including email, telephone, official letter, walk-in, or through the IRB website.

11.2. For verbal or telephone queries, the requestor will be asked to submit a formal written request via email, letter, or the official IRB platform.

11.3. The Secretariat acknowledges and records the request or query using Request Record Form (Form 3.6).

11.4. The nature of the request is assessed and referred to the Member-Secretary for evaluation.

11.5. If within scope, the Secretariat may respond directly; otherwise, the matter is referred to the IRB Chair or designated member for appropriate action.

11.6. The IRB member investigates the concern, determines appropriate follow-up, and documents the action taken using Form 3.6.

11.7. The signed and dated form is submitted to the Secretariat for documentation and filing.

11.8. The outcome and any action taken are reported during the next IRB board meeting, if required.

11.9. The Admin Staff communicates the official response to the requestor using Form 2.9G.

11.10. The Secretariat files a copy of the completed form in both the protocol folder (if applicable) and the "response" file, ensuring secure and appropriate storage.

11.11. The master list and tracker are updated accordingly.

11.12. Request Management Responsibilities:

No.	Activity	Responsible Unit	Timeline
1	Receive and document the request (Form 3.6); acknowledge receipt	Secretariat	1 working day
2	Refer to the Member-Secretary for review	Secretariat	1 working day
3	Evaluate the request and escalate if needed	Member-Secretary	1 working day
4	Take action or refer to the Full Board if warranted	Chair/ Vice Chair	1 working day
5	Communicate the response to the requestor (Form 2.9G)	Admin Staff	1 working day
6	File documentation, update tracker and master list	Secretariat	1. working day

XII. Early Study Termination or Withdrawal

12.1. Initiation or implementation of any study protocol without prior MMC IRB approval is considered a violation of the IRB's Standard Operating Procedures.

12.2. Any ongoing, unregistered, or non-approved study shall be suspended until the study proponents fully comply with IRB requirements.

12.3. The IRB Secretariat regularly monitors protocol compliance. Any IRB member or affiliated personnel may also receive and report incidents of non-compliance using Form 3.5 (Non-Compliance Report).

12.4. Verified reports of non-compliance shall be included in the agenda of the next Full Board meeting for review and appropriate Board action.

12.5. If a non-registered or unapproved study has already been completed, the following sanctions shall apply:

12.5.1. For the first offense:

a. The investigator is prohibited from citing Makati Medical Center (MMC) as the study location or IRB of record.

b. The study will be excluded from the investigator's official references or publication list.

12.5.2. For the next offense(s), the investigator will be prohibited from participating in any institutional research conducted within MMC.

12.6. MMC IRB may withdraw approval of an already-approved study if any of the following apply:

a. There is a breach in the previously approved research conduct.

b. The investigator fails to respond to IRB requests for additional information or corrective action.

c. There is unauthorized implementation of amendments affecting participant safety or research integrity.

12.7. Based on its evaluation, the Full Board may decide on the following actions:

- Continue the study and monitor compliance.
- Request further information.
- Schedule a site visit.
- Suspend the study
- Suspend enrollment of new participants

- Terminate approval of the study

12.8. Suspension shall remain in effect until the following are satisfied:

a. The required additional information has been submitted by the investigator.

b. The IRB recommendations have been implemented and deemed satisfactory.

12.9. Termination of IRB approval may be warranted under any of the following conditions:

a. SAE reports reveal significant and study-related harm to participants.

b. There is confirmed data falsification or serious protocol violation.

c. Major amendments affecting safety or scientific validity were implemented without prior IRB approval.

d. Repeated failure to respond to IRB communication or corrective action requests.

e. The Chair may also place future studies from the Principal Investigator on hold pending further review.

12.10. The Principal Investigator may be invited to attend the Full Board meeting to clarify the incident or provide explanation as needed.

12.11. The IRB Chair may convene a special meeting to urgently deliberate on major non-compliance issues.

12.12. The Full Board discusses the incident and recommends the appropriate sanction. The final decision is confirmed and signed by the Chair.

12.13. The IRB Secretariat prepares the Notification of IRB Decision (Form 2.9) and the Chair signs the letter electronically.

12.14. The decision letter is sent to the Principal Investigator.

12.15. The Secretariat files the non-compliance record in the e-protocol folder and updates the IRB tracker and database accordingly.

12.16. A follow-up shall be conducted by the Secretariat within the period stated in the decision letter to ensure that corrective actions have been taken by the Principal Investigator.

12.17. Procedure and Responsibilities for Early Study Termination or Withdrawal Due to Non-Compliance:

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Monitor or receive report of non-compliance with the MMC IRB SOP (Form 3.5).	Secretariat	1 working day

2	Forward the non-compliance concern to the Member-Secretary and Chair.	Secretariat	1 working day
3	Review the non-compliance report and determine urgency and necessary action.	Member-Secretary / Chair	1 working day
4	Include the issue in the agenda, discuss during the Full Board meeting, and make a decision.	Members / Chair	1 working day
5	Notify the Principal Investigator of the IRB decision (Form 2.9).	Admin	1 working day
6	File the decision and related documents in the e-protocol folder and update the IRB tracker.	Secretariat	1 working day
7	Follow up on the implementation of recommended actions within the timeline specified in the letter.	Secretariat	As stated in letter

XIII. Notifications

Notification submissions refer to post-approval updates that must be reported to the IRB even if they do not require prior IRB approval. These submissions ensure continuous oversight of study safety, compliance with regulatory requirements, and alignment with institutional policies. Notifications must be submitted within the prescribed timelines set by the IRB, regulatory agencies, and applicable international guidelines.

13.1. The following items typically qualify as notification-only submissions:

- CIOMS or SUSAR reports
- Updated Investigator's Brochure (IB)
- Development Safety Update Report (DSUR)
- Site closure report (for notification only)
- End-of-trial report (for notification only)
- Pregnancy reports without any adverse outcome or safety concern

13.2. The Principal Investigator must submit the Notification package to the IRB with:

- A cover letter
- Notification Evaluation Form (Section 4.6)
- Supporting documents applicable to the type of notification

13.3. The IRB Secretariat screens submissions to ensure completeness before initiating the review process

13.4. Once complete, the Notification Submission is scheduled for review during the next Full Board meeting and forwarded to the assigned Primary Reviewers.

13.5. Primary Reviewers evaluate the submission and select one of the following decision points:

- Acknowledged
- Request for further information
- Recommend further action
- Others (specify)

13.6. Primary Reviewers complete the Notification Evaluation Form and return it to the Secretariat.

13.7. The Secretariat records the reviewer recommendations and includes the item in the Full Board deliberation for a final decision.

13.8. The Secretariat updates the submission tracker and securely stores all documents in the electronic protocol folder.

13.9. If reviewers request additional information, the Principal Investigator must submit the required documents via email.

13.10. The Secretariat screens the additional documents for completeness and lists the item under Business Arising for discussion at the next Full Board meeting.

13.11. Primary Reviewers reassess the revised submission and resubmit their completed evaluation form.

13.12. The Secretariat prepares the Notification of IRB Decision (NOID).

13.13. The IRB Chair electronically signs the decision.

13.14. The Administrative Staff emails the signed decision letter to the Principal Investigator.

13.15. Below is the procedure summary:

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receive Notification Submission and check for completeness	Secretariat	1 working day
2	Forward complete Notification package to Primary Reviewers	Secretariat	1 working day
3	Evaluate the submission and complete the Notification Evaluation Form	Reviewers	1 working day

4	Discuss during Full Board meeting and finalize IRB decision	Reviewers / Chair	1 working day
5	Communicate the IRB decision to the Principal Investigator	Admin	1 working day
6	File documents in the e-protocol folder and update tracker	Secretariat	1 working day
7	Follow up on any required action from the Principal Investigator	Secretariat	As required

XIV. Single Joint Ethics Review (SJREB) of Post Approval Submissions

The Single Joint Ethics Review (SJREB) process enables streamlined oversight of multi-site studies, particularly those with shared ethics approval responsibilities. This section outlines the procedures for receiving, reviewing, coordinating, and responding to post-approval submissions from the SJREB, including amendments, SAEs, deviations, terminations, final reports, and site visit requests.

14.1. *General Procedure*

14.1.1. The MMC IRB Secretariat shall receive post-approval submissions from the SJREB Secretariat. These may include amendments, SAEs, protocol deviations, final reports, early terminations, and notifications.

14.1.2. The Secretariat shall confirm if there are any site-specific submissions included and request the SJREB meeting agenda and minutes for reference.

14.1.3. Upon receipt of the agenda and minutes, the IRB Chair will be informed of the scheduled SJREB meeting. All related documents shall be forwarded accordingly.

14.1.4. If the Chair is unavailable, a designated representative will attend on their behalf to address any site-specific concerns.

14.1.5. The Secretariat shall verify and forward site-specific submissions to the assigned Primary Reviewers via email, including the Google Drive link with required SJREB documents, such as:

- SJREB Form 10: Protocol Amendment Application
- SJREB Form 9A / 12A: Progress/Annual Report for Philippine Sites
- SJREB Form 11: Consolidated SAE Report
- SJREB Form 13: Early Study Termination Report

- SJREB Form 14: Final Report Form

14.1.6. Primary Reviewers shall conduct the review promptly and return the completed evaluation forms to the Secretariat.

14.1.7. The Secretariat records the decision points in the tracker and stores documents in a secure electronic folder.

14.1.8. Completed evaluation forms shall be submitted to the SJREB Secretariat, and the MMC IRB shall join the meeting in an administrative support role.

14.1.9. The Secretariat shall notify the IRB Chair and Primary Reviewers of their required attendance, including the meeting link provided by SJREB.

14.1.10. During the SJREB meeting, the IRB Chair or designated Primary Reviewer shall present and discuss site-specific issues. MMC IRB shall adopt the SJREB's final decision.

14.1.11. The SJREB Secretariat shall issue the decision letter via email. The IRB Secretariat will forward this to the Chair and Primary Reviewers for reference.

14.1.12. Decision letters are stored by the Secretariat in secure electronic folders.

14.1.13. All SJREB decisions are presented at the next Full Board Meeting of the MMC IRB for transparency and record-keeping, especially for site-specific matters.

14.1.14. The Secretariat shall prepare a corresponding MMC IRB Notification of Decision aligned with the SJREB's resolution, to be signed electronically by the IRB Chair and sent to the Principal Investigator by the Administrative Staff.

14.2. *Site Visit (as recommended by SJREB)*

14.2.1. The SJREB may recommend that the MMC IRB conduct a site visit to monitor specific research sites.

14.2.2. MMC IRB shall follow internal site visit procedures as outlined in Chapter 3, Section 7 (Pages 17–20).

14.2.3. Upon finalization, the site visit report shall be forwarded to the SJREB Secretariat.

14.2.4. The MMC IRB Secretariat shall coordinate with SJREB for inclusion of the report in the upcoming meeting agenda.

14.2.5. The Chair or a designated representative shall present and discuss the report during the SJREB meeting.

14.2.6. The representative shall participate in voting and adhere to the decision of the SJREB.

14.2.7. The final decision letter from SJREB will be forwarded to the MMC IRB Secretariat, which in turn will share it with the Chair and Primary Reviewers.

14.2.8. The Secretariat shall prepare and release a notification to the Principal Investigator, signed by the Chair.

14.2.9. All site visit documents and decisions will be securely stored in the designated electronic folder by the Secretariat.

14.3. The following is the summary of the procedure

NO.	ACTIVITY	RESPONSIBILITY	TIMELINE
1	The SJREB will recommend a site visit to the MMC-IRB as part of its oversight responsibilities. The MMC-IRB's site visit procedures will be reviewed.	SJREB Members/MMC-IRB	1 working day
2	The MMC site visit report will be consolidated and submitted to the SJREB Secretariat for discussion and presentation during the SJREB meeting.	Secretariat	6 working days
3	The SJREB Secretariat will send the agenda to the MMC-IRB. Upon receipt, the IRB Secretariat will notify the Chair and the designated representative.	Secretariat	1 working day
3	The IRB Chair or a designated representative shall attend the SJREB meeting to participate in discussions and voting. The MMC-IRB will comply with the final recommendations issued by the SJREB.	IRB Chair/Primary Reviewers	1 working day
4	The SJREB Secretariat will notify the MMC-IRB of its decision via the decision letter. Upon receipt of the decision, the IRB Secretariat will promptly inform the IRB Chair and the primary reviewers to ensure that all relevant parties are updated and	SJREB Secretariat/ IRB Secretariat	1 working day

	prepared for further actions or discussions.		
5	The IRB Chair and primary reviewers will deliberate and discuss the decisions brought up by the SJREB. This process ensures a thorough review and alignment with ethical and regulatory standards before finalizing any actions or recommendations.	IRB Chair/Primary Reviewers	1 working day
6	The IRB Secretariat will prepare the decision letter and the Admin Staff will communicate it to the Principal Investigator.	IRB Secretariat/Admin Staff	1 working day
7	All pertinent documents about the site visit will be kept in a secured electronic folder.	IRB Secretariat/Admin Staff	1 working day

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

Signatories:

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	IRB Assistant Institutional Review Board
Reviewers	Full name: Department/ Division: ***(may add additional reviewer as necessary)*** Full name: Department/ Division: